Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1076	Arterial Duplex	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1076	Arterial Duplex	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1076	Arterial Duplex	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1077	Arterial PVR and Stress Arterial PVR	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1077	Arterial PVR and Stress Arterial PVR	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1077	Arterial PVR and Stress Arterial PVR	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1078	Ankle Brachial Index	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1078	Ankle Brachial Index	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1078	Ankle Brachial Index	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1079	Duplex Scan of Hemodialysis Access	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1079	Duplex Scan of Hemodialysis Access	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1079	Duplex Scan of Hemodialysis Access	Annual Review	1) Updated timeframe for post-op duplex under Indications 2) References updated	Annual Review
UM CARDIO_1080	Automatic Implantable Cardioverter Defibrillator	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1080	Automatic Implantable Cardioverter Defibrillator	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1080	Automatic Implantable Cardioverter Defibrillator (ICD)		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Added Adult and Pediatric Congenital heart disease indications, Abbreviations listed, References updated	Standardizing the UM program for the shared service between 2 Legacies- NIA and NCH, new indications with supporting literature available.
UM CARDIO_1080	Automatic Implantable Cardioverter Defibrillator	Annual Review	CPT codes corrected from previous policy version, References updated, format changes	Replacement/revisions are within another policy and taken out of this 'initial' implant policy, Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1081	Carotid Duplex	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1081	Carotid Duplex	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1081	Carotid Duplex	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1081	Carotid Duplex		Updated indication "M" to include solid organ transplantation.	Adding additional clarification to the indication.
UM CARDIO_1082	Ambulatory EKG Monitoring	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1082	Ambulatory EKG Monitoring	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1082	Ambulatory EKG Monitoring	Annual Review	1) No clinical changes 2) References updated	Annual Review
UM CARDIO_1083	Vessel Mapping for Hemodialysis Access or CABG PAD Surgery	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1083	Vessel Mapping for Hemodialysis Access or CABG PAD Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1083	Vessel Mapping for Hemodialysis Access or CABG PAD Surgery	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1084 ***Retired and replaced with UM CARDIO_1119-Pharmacological Nuclear Stress Test-Myocardial Perfusion Imaging*	Myocardial Perfusion Imaging-Exercise Nuclear Stress Testing	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1084 ***Retired and replaced with UM CARDIO_1119-Pharmacological Nuclear Stress Test-Myocardial Perfusion Imaging*	Myocardial Perfusion Imaging-Exercise Nuclear Stress Testing	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1085	Patient Activated Event Recorder	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1085	Patient Activated Event Recorder	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1085	Patient Activated Event Recorder		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1093	Venous Duplex	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1093	Venous Duplex	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1093	Venous Duplex	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1094	Percutaneous Coronary Intervention	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1094	Percutaneous Coronary Intervention	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1094	Percutaneous Coronary Intervention	No Clinical Changes	References updated	
UM CARDIO_1095	Aortic Valve Replacement	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1095	Aortic Valve Replacement	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1096	Aorta Coronary Bypass Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1096	Aorta Coronary Bypass Surgery	No Clinical Changes	References updated	
UM CARDIO_1096	Aorta Coronary Bypass Surgery		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1097	Ascending Aortic Graft Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1097	Ascending Aortic Graft Surgery	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1098	Descending Thoracic Aortic Graft Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1098	Descending Thoracic Aortic Graft Surgery	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1099	Mitral Valve Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1099	Mitral Valve Surgery	No Clinical Changes	References updated	
UM CARDIO_1100	Tricuspid Valve Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1101	Cardiac Electrophysiology Study without Arrhythmia Induction	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1101	Cardiac Electrophysiology Study without Arrhythmia Induction	No Clinical Changes	References updated	
UM CARDIO_1112	Cardiac Telemetry	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1112	Cardiac Telemetry	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1113	Cardiac Magnetic Resonance Imaging	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1113	Cardiac Magnetic Resonance Imaging	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1113	Cardiac Magnetic Resonance Imaging		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1114	Cardiovascular Stress Test	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1114	Cardiovascular Stress Test	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1114	Cardiovascular Stress Test	No Clinical Changes	References updated	
UM CARDIO_1115	Coronary Computed Tomographic Angiography	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1115	Coronary Computed Tomographic Angiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1115	Coronary Computed Tomographic Angiography	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1117	Enhanced External Counterpulsation (EECP)	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1117	Enhanced External Counterpulsation (EECP)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1117	Enhanced External Counterpulsation (EECP)	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1119	Pharmacological Nuclear Stress Test-Myocardial Perfusion Imaging	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated. Note, this policy replaces the previous policy of UM CARDIO_1084, Myocardial Perfusion Imaging-Exercise Nuclear Stress Testing
UM CARDIO_1119	Pharmacological Nuclear Stress Test-Myocardial Perfusion Imaging	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB Note, this policy replaces the previous policy of UM CARDIO_1084, Myocardial Perfusion Imaging-Exercise Nuclear Stress Testing

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1119	Pharmacological Nuclear Stress Test-Myocardial Perfusion Imaging	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available. Note, this policy replaces the previous policy of UM CARDIO_1084, Myocardial Perfusion Imaging-Exercise Nuclear Stress Testing
UM CARDIO_1120	Radionuclide Angiogram (MUGA)	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1120	Radionuclide Angiogram (MUGA)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1120	Radionuclide Angiography (MUGA)	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1121	Transthoracic Echocardiography	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1121	Transthoracic Echocardiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1121	Transthoracic Echocardiography		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1122	Transesophageal Echocardiography	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1122	Transesophageal Echocardiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1122	Transesophageal Echocardiography		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1122	Transesophageal Echocardiography	Annual Review	CPT codes corrected from previous policy version, References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1123	Stress Echocardiography	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1123	Stress Echocardiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1123	Stress Echocardiograph	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1124	Positron Emission Tomography PET Myocardial Imaging	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1124	Positron Emission Tomography PET Myocardial Imaging	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1124	Positron Emission Tomography PET Myocardial Imaging	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1124	Positron Emission Tomography PET Myocardial Imaging		Removed inapplicable CPT Codes	Codes unrelated to PET policy
UM CARDIO_1125	Renal Retroperitoneal Vascular Duplex Ultrasound	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1125	Renal Retroperitoneal Vascular Duplex Ultrasound	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1125	Renal_Retroperitoneal Vascular Duplex Ultrasound	Annual Review	1) No clinical changes 2) Updated verbiage to reflect Evolent, 3) References updated	Annual Review
UM CARDIO_1126	Abdominal Aortic Ultrasound	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1126	Abdominal Aortic Ultrasound	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1127	Diagnostic Heart Catheterization	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1127	Diagnostic Heart Catheterization	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1127	Diagnostic Heart Catheterization		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1127	Diagnostic Heart Catheterization	Annual Review	Corrected CPT codes from previous policy version, References updated, format changes - right heart cath only points were taken out and new policy created	As a merged policy with NIA, the legacy groups varied as to coverage of left vs right heart cath guidelines therefore was separated into two individual guidelines.
UM CARDIO_1129	Thoracic Surgical Services Request Process	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1139	Electrophysiology Study with Arrhythmia Induction	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1140	EPS with Transseptal Left Heart Cath with Arrhythmia Induction and VT Ablation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1140	EPS with Transseptal Left Heart Cath with Arrhythmia Induction and VT Ablation	No Clinical Changes	References updated	
UM CARDIO_1141	EPS with AI Pacing after DI and Atrial or SVT and AP Ablation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1141	EPS with AI Pacing after DI and Atrial or SVT and AP Ablation	No Clinical Changes	References updated	
UM CARDIO_1142	EPS with AI and AFib AVN and AP Ablation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1142	EPS with AI and AFib AVN and AP Ablation	No Clinical Changes	References updated	

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1143	Non Invasive Programmed Stimulation of AICD	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1144	Automatic Implantable Cardioverter Defibrillator Battery Replacement	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1145	Pacemaker Battery and Lead(s) Replacement	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1145	Pacemaker Battery and Lead(s) Replacement		Rebranding of the Policy, Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1146	Implantation of Loop Recorder Systems	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1146	Implantation of Loop Recorder Systems	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1147	Pacemaker Implantation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1147	Pacemaker Implantation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1147	Pacemaker Implantation		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1148	Synchronized Electrical Cardioversion	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1148	Synchronized Electrical Cardioversion	No Clinical Changes	References updated	
UM CARDIO_1149	Cardiac Resynchronization Therapy Implantation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1149	Cardiac Resynchronization Therapy Implantation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1149	Cardiac Resynchronization Therapy		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature
UM CARDIO_1149	Cardiac Resynchronization Therapy Implantation	Annual Review	Corrected CPT codes from previous policy version; References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1152	Device Physiologic CV Data Element Interrogation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1158	Microvolt T-Wave Alternans	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1158	Microvolt T-Wave Alternans	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1158	Microvolt T-Wave Alternans	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, indication updated with supporting literature available.
UM CARDIO_1159	Tilt Table Testing	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1162	Endo Vascular Abdominal Aortic and Iliac Artery Aneurysm Repair	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1162	Endo Vascular Abdominal Aortic and Iliac Artery Aneurysm Repair	Annual Review	Removed reference to the descending thoracic aorta and thoracoabdominal aorta, references updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1163	Carotid Endarterectomy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1164	Femoral Popliteal Bypass Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1164	Femoral Popliteal Bypass Surgery	No Clinical Changes	References updated	
UM CARDIO_1165	Hemodialysis Access Creation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business.' Updated access date for reference #1.	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1166	Central Venous Access Procedures	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1166	Central Venous Access Procedures	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1168	Inferior Vena Cava Filter Device	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1168	Inferior Vena Cava Filter Device	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1169	Catheter Based Carotid Artery Digital Angio	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1169	Catheter Based Carotid Artery Digital Angio	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1170	Abd Aortography Plus Bilateral Iliofemoral Extremity Runoff	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1170	Abd Aortography Plus Bilateral Iliofemoral Extremity Runoff	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1171	Carotid Artery Stenting	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1171	Carotid Artery Stenting	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1172	Endovascular Iliac Interventions	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1172	Endovascular Iliac Interventions	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1173	Endovascular Femoropopliteal Interventions	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1173	Endovascular Femoropopliteal Interventions	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1174	Endovascular Tibioperoneal Interventions	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1174	Endovascular Tibioperoneal Interventions	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1175 *** Retired*	Perioperative Cardiovascular Evaluation Before Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1175 *** Retired*	Perioperative Cardiovascular Evaluation Before Surgery		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1252	Endovascular Venous Laser-Radiofrequency Ablation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1252	Endovascular Venous Laser-Radiofrequency Ablation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1253	Lower Extremity Venous Stripping Ligation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1253	Lower Extremity Venous Stripping Ligation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1253	Lower Extremity Venous Stripping Ligation	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1254	Lower Extremity Venous Sclerotherapy	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1254	Lower Extremity Venous Sclerotherapy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1254	Lower Extremity Venous Sclerotherapy	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1255	Lower Extremity Venous Stab Phlebectomy	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1255	Lower Extremity Venous Stab Phlebectomy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1255	Lower Extremity Venous Stab Phlebectomy	Formatting and template changed, clinical content update	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1256	Device Interrogation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1256	Device Interrogation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1256	Device Interrogation		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1257	Device (PPM AICD CRT-D CRT-P Subcut-ICD ILR) Programming	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1257	Device (PPM AICD CRT-D CRT-P Subcut-ICD ILR) Programming		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1268	Aorto-Renal Endarterectomy or Bypass Surgery	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1268	Aorto-Renal Endarterectomy or Bypass Surgery	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1269	Coronary Fractional Flow Reserve	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1269	Coronary Fractional Flow Reserve	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1291	Coronary Atherectomy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1291	Coronary Atherectomy		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1292	Coronary Intra Vascular Arterial Ultrasound	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1292	Coronary Intra Vascular Arterial Ultrasound	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1292	Coronary Intra Vascular Arterial Ultrasound	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1293	Renal Angiography	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1293	Renal Angiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1294	Renal Artery Intervention	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1294	Renal Artery Intervention	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1295	Trans Catheter Aortic Valve Replacement	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1295	Trans Catheter Aortic Valve Replacement	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1295	Transcatheter Aortic Valve Replacement	1. Definition section -Added definitions for abbreviations - Replaced Stages of Aortic Stenosis table with bullet points to make it reader friendly - Reworded Risk Assessment for Surgical Valve Procedure 2. Policy Section - Grammatical correction done by adding 'a' to C,D,E - Limitation- - I: Replaced 'heart assistance ' with 'circulatory support' - U: Replaced New Century Health with Evolent	References updated	
UM CARDIO_1296	Trans Catheter Mitral Valve Repair	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1296	Trans Catheter Mitral Valve Repair	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1296	Transcatheter Mitral Valve Repair	1. Policy section - A: Added 'high' before STS score - Limitations: -Reworded J,K - U: Replaced New Century Health with Evolent	References updated	
UM CARDIO_1318	Peripheral Arterial and Venous Ultrasound	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1318	Peripheral Arterial and Venous Ultrasound	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1319	Venogram Invasive Vein Mapping	No Clinical Changes	Added Medicare to 'Applicable Lines of Business.' Updated access date for reference #1.	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1319	Venogram Invasive Vein Mapping	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1320	Percutaneous Left Atrial Appendage Closure	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1320	Percutaneous Left Atrial Appendage Closure	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1320	Percutaneous Left Atrial Appendage Closure	1. Definitions: - Added ' widely used for evaluating thromboembolic risk in those with nonvalvular AF' 2. Policy: - Limitations- A: Replaced New Century Health with Evolent	References updated	
UM CARDIO_1321	Temporal Artery Biopsy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1321	Temporal Artery Biopsy		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1336	Automated Ambulatory Blood Pressure Monitoring	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1336	Automated Ambulatory Blood Pressure Monitoring	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1337	Abdominal Aortic Aneurysm Open Repair	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1337	Abdominal Aortic Aneurysm Open Repair	Annual Review	Removed reference to the descending thoracic aorta and thoracoabdominal aorta, references updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1339	Hemodialysis Access Maintenance	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1339	Hemodialysis Access Maintenance	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1339	Hemodialysis Access Maintenance	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1358	Intra Cardiac Echocardiography	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1358	Intra Cardiac Echocardiography	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1368	Percutaneous IlioCaval Intervention	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1368	Percutaneous IlioCaval Intervention	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1369	Pericardial Disease Interventions	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1370	Thoracentesis and Pleurodesis	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1388	Endomyocardial Biopsy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1389	Subcutaneous ICD Device Implantation	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1389	Subcutaneous ICD Device Implantation	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1389	Subcutaneous ICD Device Implantation	No Clinical Changes	References updated	
UM CARDIO_1389	Subcutaneous ICD Device Implantation		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1390	Ventricular Assist Device (VAD) Percutaneous and Permanent	No Clinical Changes	Updated CMS reference	Other: CMS reference needed to be updated.
UM CARDIO_1390	Ventricular Assist Device (VAD) Percutaneous and Permanent	No Clinical Changes	Added Medicare to 'Applicable Lines of Business,' Omitted prior access date from Reference #1.	Other: Annual Review, Medicare Needed to be included in LOB
UM CARDIO_1390	Ventricular Assist Device (VAD) Percutaneous and Permanent	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1390	Ventricular Assist Device (VAD) Percutaneous and Permanent	Positive	Non-stigmatizing language was used to revise contraindications regarding active substance use, unstable psychiatric conditions, and medical nonadherence	Remove non-stigmatizing language
UM CARDIO_1402	Wireless Pulmonary Artery Pressure Device Policy	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1402	Wireless Pulmonary Artery Pressure Device Policy	No Clinical Changes	References updated	
UM CARDIO_1417	Percutaneous Closure of PFO	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1417	Percutaneous Closure of PFO	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1418	Intervention on Adults with Congenital Heart Defects	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1428** *Retired and replaced with UM CARDIO_1462-Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)*	Guidelines for Medical Management of Heart Failure	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1430** *** Retired*	Guidelines for Medical Management of Atrial Fibrillation (AF)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1431** *Retired and replaced with UM CARDIO_1462-Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)*	Guidelines for Medical Management of Coronary Artery Disease (CAD)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1432** *** Retired*	Guidelines for Medical Management of Peripheral Artery Disease (PAD)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1435** *** Retired*	Guideline Directed Medical Therapy for Cardiovascular Condition	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1436** *** Retired*	Guidelines for Medical Management of Moderate Severe Mitral Regurgitation (MR)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1437** *** Retired*	Guidelines for Medical Management of Peripheral Venous Disease	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1438** *** Retired*	Guidelines for Medical Management of SVT and VA	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1450** *** Retired*	Guidelines for Medical Management of Aortic Stenosis	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1451** ***Retired*	Guidelines for Medical Management of Arterial Hypertension	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1452** *** Retired*	Guidelines for Medical Management of Stroke and Transient Ischemic Attack (TIA)	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1453	Ultrasound Guided Vascular Access	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Medicare needed to be included in LOB
UM CARDIO_1453	Ultrasound Guided Vascular Access	Formatting and Template changed, Clinical content change	Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1456	Vascular Embolization and Occlusion	No Clinical Changes	Added Medicare to 'Applicable Lines of Business'	Other: Annual Review, Medicare Needed to be included in LOB

Evolent (New Century Health) Cardiology Internal Coverage Criteria Revisions, including New Coverage Criteria				
Policy	**Policy Name**	**Type**	**Brief Description of Policy Change**	**Reason for Change**
UM CARDIO_1456	Vascular Embolization and Occlusion	Annual Review	References updated, format changes	Standardizing the policy template, clarification of prior bullet points with supporting literature
UM CARDIO_1457	Fractional Flow Reserve CT	New policy	New policy	
UM CARDIO_1458	Coronary Artery Calcium Scoring by Electron-Beam Tomography or Non-Contrast Coronary Computed Tomography	New Policy	N/A	N/A
UM CARDIO_1458	Coronary Artery Calcium Scoring by Electron-Beam Tomography or Non-Contrast Coronary Computed Tomography		Rebranding of the Policy,Added Table of contents, General Information, Redefined Clinical Indications with conditions as header, Abbreviations listed, References updated	Standardizing the policy template, new indications with supporting literature available.
UM CARDIO_1459	Heart CT	New Policy	N/A	N/A
UM CARDIO_1460	Right Heart Catheterization Only	New Policy	N/A	N/A
UM CARDIO_1460	Right Heart Catheterization Only	Annual Review	Corrected CPT codes from previous policy version; New policy, separated from Left Heart Catheterization policy, added CPT codes omitted from previous policy version	As a merged policy with NIA, the legacy groups varied as to coverage of left vs right heart cath guidelines therefore was separated into two individual guidelines.
UM CARDIO_1461	Heart PET with CT	New Policy	N/A	N/A
UM CARDIO_1461	Heart PET with CT		Removed inapplicable CPT Codes	Codes unrelated to PET policy
UM CARDIO_1462	Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)	New Policy	N/A	N/A Note, this policy replaces the previous policy of UM CARDIO_1428, Guidelines for Medical Management of Heart Failure AND UM CARDIO_1431, Guidelines for Medical Management of Coronary Artery Disease (CAD)

Cardio Policy

Arterial Duplex

POLICY NUMBER UM CARDIO_1076	SUBJECT Arterial Duplex (upper and lower extremities)		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 03/10/14, 06/16/14, 02/19/15, 08/12/15, 11/23/16, 10/10/17, 02/13/19, 02/21/19, 04/23/19, 12/11/19, 05/13/20, 07/31/20, 03/10/21, 08/11/21, 09/08/21, 09/14/22, 01/11/23, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 04/01/11, 11/07/12, 03/10/14, 06/16/14, 02/19/15, 08/12/15, 11/23/16, 10/10/17, 02/13/19, 02/21/19, 04/23/19, 12/11/19, 05/13/20, 07/31/20, 03/10/21, 08/11/21, 09/08/21, 09/14/22, 01/11/23, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM			COMMITTEE/BOARD APPROVAL Utilization Management Committee	
NCQA STANDARDS UM 2			ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for arterial duplex of the extremities.

II. DEFINITIONS

Duplex ultrasound imaging of the major arteries in the extremities is for assessing any abnormalities in the blood flow.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in the major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

III. POLICY

Indications for approving a request for medical necessity are:

A. Evaluation of patient that has developed sudden pallor, numbness, and coolness of an extremity and vascular obstruction is suspected. **(AUC Score 9)**[1,2,3]

B. Evaluation of a patient with no prior diagnosis of peripheral artery disease (PAD) presenting with leg pain, claudication, and Ankle Brachial Index (ABI) greater than or equal to 1.3. **(AUC Score 9)**[1,2,3]

C. Evaluation of a patient with no prior diagnosis of PAD presenting with leg pain, claudication, and Ankle Brachial Index (ABI) less than or equal to 0.9 done within the last 12 months. **(AUC Score 9)**[1,2,3]

D. Evaluation of a patient with no prior diagnosis of PAD, with and or without Diabetes Mellitus, presenting with leg pain, claudication and decreased infra-popliteal pulses and no prior ABI within the last 12 months. **(AUC Score 9)**[1,2,3]

E. Evaluation of a patient with PAD risk factors presenting with leg pain and/or with clinical presentation suggestive of critical limb ischemia i.e., absent, or markedly diminished infra-popliteal pulses and no prior arterial duplex done within the last 3 months. **(AUC Score 9)**[1,2,3]

F. Evaluation of symptomatic patient with PAD risk factors- age greater than or equal to 65 years or Age 50-64 years with one or more risk factors for atherosclerosis (diabetes mellitus, history of smoking, hyperlipidemia, hypertension, family history of PAD) or with known atherosclerotic disease in another vascular bed (coronary, carotid, subclavian, renal, mesenteric artery stenosis, or AAA), with no prior diagnosis of lower extremity PAD and abnormal quantified volume plethysmography (Quantaflo) result (less than 0.6). No prior arterial duplex done within last 6 months. **(AUC Score 6)**[1,2]

G. Evaluation of a patient with no prior diagnosis of PAD presenting with foot or toe ulcer or gangrene or with infection of leg/foot without palpable pulses and no prior arterial duplex done within the last 3 months. **(AUC Score 9)**[1,2,3]

H. Evaluation of a patient who has undergone lower extremity Percutaneous or Surgical Intervention, presenting with new or worsening lifestyle-limiting claudication or with non-healing ulceration despite being on maximally tolerated GDMT. **(AUC Score 9)**[1,2,3,5,6,7,8,9,10]

I. Evaluation of a patient with PAD and has not undergone lower extremity Percutaneous or Surgical Intervention, presenting with new or worsening lifestyle-limiting claudication or with non-healing ulceration despite being on maximally tolerated GDMT. **(AUC Score 8)**[1,2,3,5,6,7,8,9,10]

J. An initial surveillance duplex in asymptomatic patients on maximally tolerated GDMT after lower extremity Percutaneous or Surgical intervention can be done as a baseline. **(AUC Score 8)**[1,2,3,5,6,7,8,9,10]

K. Surveillance duplex in asymptomatic patients on maximally tolerated GDMT after lower extremity Surgical Intervention can be done at 6 months after baseline study. **(AUC Score 8)**[1,2,3,5,6,7,8,9,10]

L. Surveillance duplex in asymptomatic patients maximally tolerated GDMT after lower extremity Percutaneous or Surgical Intervention is appropriate annually for 3 years, provided there is no change in clinical status, after the baseline study. **(AUC Score 7)**[1,2,3,5,6,7,8,9,10]

M. Evaluation of a patient that has an aneurysm or arteriovenous malformation of a lower extremity with no prior arterial duplex within the last 12 months. **(AUC Score 7)**[1,2,3]

N. Evaluation of a patient after femoral access procedure who has developed or is suspected to have developed groin complications e.g., a pseudo aneurysm or arteriovenous malformation of a lower extremity with no prior duplex since the procedure. **(AUC Score 8)**[1,2,3]

O. Evaluation of a patient that has sustained lower extremity trauma with possible vascular injury with no prior duplex since the injury. **(AUC Score 9)**[1,2,3]

P. Evaluation of upper extremity with duplex is appropriate in presence of claudication, ulcer, suspected thoracic outlet syndrome, trauma, pre-op radial artery harvest for CABG, presence of pulsatile mass or evidence of ischemia or bruit after vascular access with no prior arterial duplex within the last 3 months. **(AUC Score 8)**[1,2,3]

Q. Evaluation of a patient who has undergone upper extremity Percutaneous or Surgical Intervention, presenting with new or worsening lifestyle-limiting claudication despite being on maximally tolerated GDMT. **(AUC Score 8)**[1,2,3,5,6,7,8,9,10]

R. Surveillance of a patient on maximally tolerated GDMT after upper extremity PAD after revascularization is appropriate if done within one month of procedure as baseline. **(AUC Score 8)** [1,2,3,5,6,7,8,9,10]

S. Surveillance duplex in asymptomatic patients on maximally tolerated GDMT after upper extremity surgical intervention can be done at 6 months following baseline study post intervention. **(AUC Score 7)**[1,2,3]

T. Surveillance duplex in asymptomatic patients on maximally tolerated GDMT after upper extremity Percutaneous or Surgical intervention can be done annually for 3 years, provided there is no change in clinical status after baseline study post intervention. **(AUC Score 7)** [1,2,3,5,6,7,8,9,10]

Limitations:

A. It is preferred that the use of non-invasive physiologic and imaging studies for post catheter-based or surgical intervention surveillance as per K-M and S-U above is limited to one modality i.e., either ABI or PVR or duplex ultrasound. It is also preferred that utilization of that chosen modality be consistent throughout the surveillance period. Additional modalities may be utilized only if clinical or symptomatic changes are documented.

B. The use of non-invasive physiologic and imaging studies for screening, or initial workup is limited to one modality i.e., either ABI or PVR or duplex ultrasound.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request,
2. All previous vascular studies performed,
3. Progress note from Vascular Surgeon (if seen previously by a surgeon)

B. Primary codes appropriate for this service:

93925 (Bilateral lower extremity)

93926 (Unilateral lower extremity)

93930 (Bilateral upper extremity)

93931 (Unilateral upper extremity)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Marie D. Gerhard-Herman, et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines; Circulation. 2017;135:e686–e725. DOI: 10.1161
2. Schaefer ME, Long JB, Pollick C, et al. Non-invasive detection of vascular disease in the arteries of the lower extremity: Clinical evaluation of PVS compared to doppler and definitive imaging. Vasc Dis Management March 2016 supplement
3. Emile R. Mohler, III, MD, FACC, et. al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. Journal of the American College of Cardiology. July 2012, Volume 60, Issue 3, Pages 242-276.
4. Hendel RC, et. al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. Gerhard-Herman MD, et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2017 Mar 21;135(12):e726-e779.
6. Whelton PK, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018 Jun;71(6):1269-1324.
7. Bailey SR, et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237.
8. Anderson JL, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Apr 2;127(13):1425-43. 5. CAPRIE Steering Committee. A randomized, blinded, trial of clopidogrel versus aspirin in patients at risk of ischemic events (CAPRIE). CAPRIE Steering Committee. The Lancet. Volume 348, Issue 9038, 16 November 1996, Pages 1329-

1339.

9. Fakhry F, et.al. Long-term clinical effectiveness of supervised exercise therapy versus endovascular revascularization for intermittent claudication from a randomized clinical trial. British Journal of Surgery 2013; 100: 1164–1171.
10. David L Dawson MD et.al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. The American Journal of Medicine. Volume 109, Issue 7, November 2000, Pages 523-530.

Cardio Policy

Arterial PVR and Stress Arterial PVR

POLICY NUMBER UM CARDIO_1077	SUBJECT Arterial Pulse Volume Recording (PVR) and Stress Arterial PVR		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 03/10/14, 06/16/14, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 03/07/18, 02/13/19, 02/21/19, 04/23/19, 12/11/19, 05/13/20, 02/10/21, 03/10/21, 08/11/21, 07/13/22, 01/11/23, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 04/01/11, 11/07/12, 03/10/14, 06/16/14, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 03/07/18, 02/13/19, 02/21/19, 04/23/19, 12/11/19, 05/13/20, 02/10/21, 03/10/21, 08/11/21, 07/13/22, 01/11/23, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Arterial Pulse Volume Recording (PVR) and Stress Arterial PVR.

II. DEFINITIONS

A Pulse volume recording is a non-invasive test that measures the blood volume changes that occur in the legs. During this test, a blood pressure cuff is placed on the arm and multiple cuffs are placed on the legs. The cuffs are inflated slightly while the patient is lying down. As blood pulse s through the arteries, the blood vessels expand, causing an increase or decrease in the volume of air within the cuff. A recording device displays these pulse volume changes as a waveform on a monitor. Blood pressures are measured for the purpose of localizing the area of blockage in the extremities.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in the major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. [2,3,4,5,6,7,8,9]

III. POLICY

Indications for approving a request for medical necessity are:

A. Arterial PVR

1. Patient with claudication with Ankle –Brachial Index (ABI) greater than or equal to 1.3 and no prior PVR done within the last 12 months. **(AUC Score 7)[1]**
2. Patient with DM-2 presenting with claudication and absence of or diminished femoral-popliteal pulses or clinical presentation suggestive of chronic limb ischemia and no prior PVR done within the last 12 months. **(AUC Score 9)[1]**
3. Patient with rest pain associated with absent leg pulses and no prior PVR done within the last 12 months. **(AUC Score 9)[1]**
4. Patient with claudication with Ankle–Brachial Index (ABI) less than or equal to 0.9 no prior PVR done within the last 12 months. **(AUC Score 9)[1]**
5. Patient with no prior diagnosis of PAD but has decreased and/or absence of infra popliteal pulses and/or presence of ulcer(s)/infection in lower extremity. **(AUC Score 9)[1]**
6. Patient with PAD on maximally tolerated GDMT and with/ or without prior lower extremity Percutaneous or Surgical Intervention, now presenting with a new or worsening lifestyle-limiting claudication despite being on pharmacological therapy and no prior PVR done since the onset of new signs and symptoms. **(AUC Score 9)[1,2,3,4,5,6,7,8]**
7. Asymptomatic patients on maximally tolerated GDMT with prior lower extremity Percutaneous or Surgical Intervention who did not have a postintervention baseline vascular surveillance testing done. **(AUC Score 7)[1,2,3,4,5,6,7,8]**
8. An initial surveillance PVR in asymptomatic on maximally tolerated GDMT patients after lower extremity Percutaneous or Surgical intervention can be done preferably within 6 weeks post intervention.as a baseline. **(AUC Score 8)[1,2,3,4,5,6,7,8]**
9. Surveillance PVR in asymptomatic patients on maximally tolerated GDMT after lower extremity surgical intervention can be done at 6 months after baseline study. **(AUC Score 7)[1,2,3,4,5,6,7,8]**
10. Surveillance PVR in asymptomatic patients on maximally tolerated GDMT after lower extremity Percutaneous or Surgical Intervention is appropriate annually, after the baseline study. **(AUC Score 7)[1,2,3,4,5,6,7,8]**
11. Evaluation of upper extremity with PVR is appropriate in presence of claudication, ulcer, suspected thoracic outlet syndrome, trauma, pre-op radial artery harvest for CABG, presence of pulsatile mass or evidence of ischemia or bruit after vascular access with no prior PVR done within the last 12 months. **(AUC Score 8)[1]**
12. Evaluation of a patient who has undergone upper extremity Percutaneous or Surgical Intervention, presenting with new or worsening lifestyle-limiting claudication despite being on pharmacological therapy with no PVR done since onset of symptoms. **(AUC Score 8)[1]**

13. An initial surveillance PVR of upper extremity PAD after revascularization can be done preferably within 6 weeks post intervention as a baseline. **(AUC Score 8)[1]**
14. Surveillance PVR in asymptomatic patients after upper extremity surgical intervention can be done at 6 months following baseline study post intervention. **(AUC Score 7)[1]**
15. Surveillance PVR in asymptomatic patients after upper extremity Percutaneous or Surgical intervention can be done annually for 3 years provided there is no change in clinical status, after baseline study post intervention. **(AUC Score 7)[1]**

B. Stress Arterial PVR

1. Patients with leg pain and/or claudication with border line abnormal ABI (between 0.91-0.99). **(AUC Score 7)[1]**
2. Patients with a resting ABI that is within normal limits, however they continue to describe ambulatory symptoms that are typical for claudication or have physical characteristics that suggest peripheral arterial insufficiency. **(AUC Score 7)[1]**

Limitations:

A. Continuous burning of the feet is considered to be a neurologic and not a vascular symptom.

B. Edema rarely occurs with arterial occlusive disease. The absence of pulses is not an indication to proceed beyond the physical examination unless it is related to other signs and/or symptoms.

C. Arterial PVR is not to be utilized to follow non-invasive medical treatment regimens.

D. Stress arterial PVR is not appropriate once an abnormal resting ABI study or a prior abnormal stress arterial PVR study has been obtained.

E. It is preferred that the use of non-invasive physiologic and imaging studies for post catheter-based or surgical intervention surveillance as per #8-10 and #13-15 above is limited to one modality i.e., either ABI or PVR or duplex ultrasound. It is also preferred that utilization of that chosen modality be consistent throughout the surveillance period. Additional modalities may be utilized only if clinical or symptomatic changes are documented.

F. The use of non-invasive physiologic and imaging studies for screening, or initial workup is limited to one modality i.e., either ABI or PVR or duplex ultrasound.

G. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

H. Before an arterial PVR and Stress Arterial PVR test can be requested for a patient, following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[2,3,4,5,6,7,8]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request,
2. All previous vascular studies performed,
3. Progress notes from Vascular Surgeon (if seen previously by a surgeon)

B. Primary codes appropriate for this service

93923 (Rest)

93924 (Stress)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Heather L. Gornik MD, FACC, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing :A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Inter-societal Commission for the Accreditation of Vascular Laboratories ,Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. Journal of the American College of Cardiology. July 2012, Volume 60, Issue 3, Pages 242-276.
2. Robert C. Hendel MD, FACC, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
3. Gerhard-Herman MD, et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2017 Mar 21;135(12):e726-e779.
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8. Fakhry F, et.al. Long-term clinical effectiveness of supervised exercise therapy versus endovascular revascularization for intermittent claudication from a randomized clinical trial. British Journal of Surgery 2013; 100: 1164–1171.
9. David L Dawson MD et.al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. The American Journal of Medicine. Volume 109, Issue 7, November 2000, Pages

523-530.

Cardio Policy

Ankle Brachial Index

POLICY NUMBER UM CARDIO_1078	**SUBJECT** Ankle Brachial Index		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 06/16/14, 02/19/15, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 02/13/19, 02/21/19, 04/09/19, 05/08/19, 12/11/19, 05/13/20, 07/31/20, 01/13/21, 03/10/21, 08/11/21, 02/09/22, 12/14/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 04/01/11, 11/07/12, 06/16/14, 02/19/15, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 02/13/19, 02/21/19, 04/09/19, 05/08/19, 12/11/19, 05/13/20, 07/31/20, 01/13/21, 03/10/21, 08/11/21, 02/09/22, 12/14/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for ankle brachial index.

II. DEFINITIONS

The Ankle Brachial Pressure Index, known more commonly as an ABI, is the ratio of the blood pressure in the lower legs to the blood pressure in the arms. Compared to the arm, lower blood pressure in the leg is an indication of blocked arteries (peripheral vascular disease). The ABI is calculated by dividing the systolic blood pressure at the ankle by the systolic blood pressures in the arm while a person is at rest.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for medical necessity determinations are:

A. Patients with atypical leg pain and/or claudication with prior established diagnosis of peripheral artery disease (PAD) with no prior ABI within the last 12 months. **(AUC Score 8)**[1,2,3]

B. Asymptomatic/Symptomatic patients with no prior established diagnosis of PAD who have absent or diminished infra-popliteal pulses or femoral bruit by physical examination with no prior ABI done within the last 12 months. **(AUC Score 8)**[1,2,3]

C. Patients with DM-2 in absence of claudication presenting with absence of or diminished femoral-popliteal pulses with no prior ABI done within the last 12 months. **(AUC Score 8)**[1,2,3]

D. Asymptomatic/Symptomatic patients with no prior established diagnosis of PAD who have ulcer(s) or infection on their lower extremity with no prior ABI done within the last 6 months since onset of ulcer/infection. **(AUC Score 9)**[1,2,3]

E. Asymptomatic/Symptomatic patients with no prior established diagnosis of PAD but is at increased risk for PAD (age greater than 50years, presence of Diabetes Mellitus and/or history of smoking) with no prior ABI done within the last 12 months **(AUC Score 6)**[1,2,3]

F. Evaluation of asymptomatic patient with PAD risk factors age greater than or equal to 65 years or Age 50-64 years with one or more risk factors for atherosclerosis (diabetes mellitus, history of smoking, hyperlipidemia, hypertension, family history of PAD) or with known atherosclerotic disease in another vascular bed (coronary, carotid, subclavian, renal, mesenteric artery stenosis, or AAA) and with no prior diagnosis of lower extremity PAD and with moderately abnormal quantified volume plethysmography (Quantaflo) result: less than 0.9. No prior ABI or arterial duplex done within last 6 months. **(AUC Score 6)**[1,4]

G. Rest pain associated with absent pulses with no prior ABI done within the last 6 months. **(AUC Score 9)**[1,2,3]

H. An initial surveillance duplex in asymptomatic patients after lower extremity percutaneous or surgical intervention can be done as a baseline. **(AUC Score 8)**[1,2,3]

I. Surveillance ABI in asymptomatic patients after lower extremity Surgical Intervention can be done at 6 months after baseline study. **(AUC Score 8)**[1,2,3]

J. Surveillance ABI in an asymptomatic patient after lower extremity Percutaneous or Surgical Intervention is appropriate annually, after the baseline study. **(AUC Score 7)**[1,2,3]

K. Evaluation of upper extremity with ABI is appropriate in presence of claudication, ulcer, suspected thoracic outlet syndrome, trauma, pre-op radial artery harvest for CABG, presence of pulsatile mass or evidence of ischemia or bruit after vascular access with no prior ABI done within the last 6 months since onset of new symptoms and signs. **(AUC Score 8)**[1,2,3]

L. Evaluation of a patient who has undergone upper extremity Percutaneous or Surgical Intervention, presenting with new or worsening lifestyle-limiting claudication despite being on pharmacological therapy with no prior ABI performed since onset of new symptoms. **(AUC Score 8)**[1,2,3]

M. Surveillance of upper extremity PAD after revascularization is appropriate if done within one month of procedure as baseline. **(AUC Score 8)**[2]

N. Surveillance duplex in asymptomatic patients after upper extremity surgical intervention can be done at 6 months following baseline study post intervention. **(AUC Score 7)**[1,2,3]

O. Surveillance duplex in asymptomatic patients after upper extremity Percutaneous or Surgical intervention can be done annually for 3 years provided there is no change in clinical status, after baseline study post intervention. **(AUC Score 7)**[1,2,3]

P. ABI is considered appropriate to perform, to screen for peripheral arterial insufficiency as initial work up, prior to any organ transplant, no prior ABI within the last 6 months. **(AUC Score 7)**[5]

Q. Exercise ABI may be an appropriate test in patients with PAD risk factors, with either prior normal resting ABI within the last 6 months or no resting ABI has been done. Performing resting ABI will not give additional information to the physician. **(AUC Score 7)**[6,7]

R. Exercise ABI is helpful in symptomatic patients with prior aortoiliac interventions suggestive for progression of Aorto-iliac arterial disease. **(AUC Score 8)**[8]

S. Exercise ABI can be performed for post Aorto-iliac artery intervention if resting ABI is inconclusive, at 1, 6, and 12 months post intervention. **(AUC Score 7)**[8]

Limitations:

A. Continuous burning of the feet is considered to be a neurologic and not a vascular symptom.

B. Non-specific leg pain in limb with normal pulses is considered too general to warrant vascular testing

C. Edema rarely occurs with arterial occlusive disease.

D. ABI is not to be utilized to follow non-invasive medical treatment regimens.

E. It is preferred that the use of non-invasive physiologic and imaging studies for post catheter-based or surgical intervention surveillance as per H-J and M-O above is limited to one modality i.e., either ABI or PVR or duplex ultrasound. It is also preferred that utilization of that chosen modality be consistent throughout the surveillance period. Additional modalities may be utilized only if clinical or symptomatic changes are documented.

F. The use of non-invasive physiologic and imaging studies for screening, or initial workup as per I-J and N-O above is limited to one modality i.e., either ABI or PVR or duplex ultrasound.

G. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Cardiologist/Vascular Surgeon progress note that prompted request
2. All previous vascular studies preformed

B. Primary code appropriate for this service:

93922 –Rest ABI

93924 – Exercise ABI

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Marie D. Gerhard-Herman, et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines; Circulation. 2017;135: e686–e725. DOI: 10.1161
2. Heather L.Gornik MD, FACC, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing :A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Inter-societal Commission for the Accreditation of Vascular Laboratories ,Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. Journal of the American College of Cardiology. July 2012, Volume 60, Issue 3, Pages 242-276.
3. Robert C.HendelMD, FACC, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
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Cardio Policy

Duplex Scan of Hemodialysis Access

POLICY NUMBER UM CARDIO_1079	**SUBJECT** Duplex Scan of Hemodialysis Access		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 12/17/13, 12/15/14, 05/19/15, 08/12/15, 11/28/16, 12/21/16, 10/23/17, 02/13/19, 02/20/19, 12/11/19, 05/13/20, 05/28/21, 07/14/21, 08/11/21, 07/13/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 04/01/11, 11/07/12, 12/17/13, 12/15/14, 05/19/15, 08/12/15, 11/28/16, 12/21/16, 10/23/17, 02/13/19, 02/20/19, 12/11/19, 05/13/20, 05/28/21, 07/14/21, 08/11/21, 07/13/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for duplex scan of hemodialysis (HD) access.

II. DEFINITIONS

Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow). Combines Doppler and conventional ultrasound, to see the structure of blood vessels, how the blood is flowing through the vessels, and whether there is any obstruction in the vessels. Combining spectral Doppler analysis and color flow doppler images provide anatomic and hemodynamic information.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Duplex scan may be appropriate after access placement, for any signs or symptoms of HD access vascular compromise and complications (e.g. infections, pseudo aneurysm, AVF/Graft stenosis, or fluid collection). The results are necessary to determine the clinical course of treatment. **(AUC Score 8)**[1,2]

B. There is elevated venous pressure greater than 200 mmHg on a 300 cc/min pump during dialysis **(AUC Score 8)**[1,2]

C. There is elevated recirculation of time of 15% or greater and low urea reduction rate less than 60% **(AUC Score 8)**[1,2]

D. HD access demonstrates a palpable “water hammer” pulse or decreased or absent thrill or abnormal bruit over fistula on examination. **(AUC Score 8)**[1,2]

E. Difficult cannulation, thrombus aspiration or prolonged bleeding (greater than 20 minutes) from access needle sites after dialysis despite local pressure. **(AUC Score 8)**[1,2]

F. Patients with prolonged immaturity (greater than 6 weeks) of a surgically created AVF. **(AUC Score 8)**[1,2]

G. A baseline duplex post-op within 6-8 weeks after AVF/AVG creation, is reasonable to perform in order to validate maturation of newly created AVF/AVG. **(AUC Score7)**[1,2]

Limitations:

A. The routine use of Duplex scan following creation of A-V communication is not appropriate in the absence of symptoms, abnormal physical exam findings, or other suspicion of a complication, as documented in the medical notes.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Cardiologist/Vascular Surgeon/Nephrologist progress note that prompted request
2. All previous vascular studies performed

B. Primary codes appropriate for this service:

93990

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Gornik HL, et al. ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 Appropriate

Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part II: Testing for Venous Disease and Evaluation of Hemodialysis Access: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. The American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Inter-Societal Accreditation Commission, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society of Interventional Radiology, Society for Vascular Medicine, Society for Vascular Surgery. Journal of the American College of Cardiology Aug 2013; Volume 62 Issue 7, Pages 649-665.

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Cardio Policy
Automatic Implantable Cardioverter Defibrillator (ICD)

POLICY NUMBER UM CARDIO_1080	**SUBJECT** Automatic Implantable Cardioverter Defibrillator		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 12**
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PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

SPECIAL NOTE

Indications for determining medical necessity for an implantable cardiac defibrillator (ICD). Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. All indications are predicated on a meaningful life expectancy of greater than one year if the ICD is implanted.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care [1, 2, 3, 4, 5].

INDICATIONS FOR ICD INSERTION

ISCHEMIC HEART DISEASE (CAD) [6, 7, 8]

Primary Prevention of SCD/Prophylactic ICD Implantation

- LVEF ≤ 35% due to nonischemic or ischemic heart disease and NYHA class II or III, despite GDMT, and at least 40 days post-MI (AUC 9)
- LVEF ≤ 30% due to ischemic heart disease, NYHA class I, GDMT, and at least 40 days post-MI (AUC 8)
- LVEF ≤ 40% with prior MI, NSVT, and inducible sustained VT or VF at electrophysiological testing

Secondary Prevention of SCD

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes (AUC 9)
- Syncope of undetermined origin, with inducible VF or sustained VT at electrophysiological study (AUC 9)
- Syncope of undetermined origin, with EF ≤ 35% (AUC 8-9)

NONISCHEMIC CARDIOMYOPATHY (NICM) [6]

Primary Prevention of SCD/Prophylactic ICD Implantation

- Lamin A/C gene mutation, with ≥ 2 risk factors from the following: NSVT, LVEF < 45%, male sex, missense mutation
- LVEF ≤ 35% and NYHA functional Class II or III, despite at least 3 months of GDMT

NOTE: LVEF ≤ 35% and NYHA functional Class I despite at least 3 months of GDMT may be considered

Secondary Prevention of SCD

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes
- LVEF ≤ 50% with unexplained syncope presumed to be due to VA who do not meet indications for primary prevention ICD implantation

ADVANCED HEART FAILURE & TRANSPLANTATION [6, 8, 7]

- In non-hospitalized patients with NYHA class IV who are candidates for cardiac transplantation or left ventricular assist device (LVAD)
- In a patient with an LVAD, sustained ventricular arrhythmias
- In NYHA ambulatory class IV, with appropriate indications for CRT

MYOCARDIAL DISEASES

Hypertrophic cardiomyopathy (HCM) [8, 9, 10, 6, 11]

- Previously documented cardiac arrest or sustained VT
- Adult patients with HCM with at least 1 risk factor for SCD as follows:
    - Sudden death attributable to HCM in at least 1 first-degree relative who is ≤ 50 years of age
    - LVH ≥ 30 mm
    - At least 1 recent (within 5 years) episode of syncope suspected by history to be arrhythmic (unlikely neurocardiogenic (vasovagal), especially occurring within 6 months of evaluation
    - LV apical aneurysm
    - LV systolic dysfunction (EF < 50%)
    - Pediatric patients with HCM with at least 1 risk factor for SCD as follows:
        - Unexplained syncope
        - LVH ≥ 30 mm
        - Nonsustained VT
        - Family history of HCM-related SCD

Cardiac Sarcoidosis

With one of the following [6, 8, 9]:

- Cardiac arrest or documented sustained VT
- LVEF ≤ 35% (AUC 8)
- LVEF > 35% with inducible sustained VA at electrophysiological testing
- Syncope and/or scar on CMR or PET
- Requires a permanent pacemaker

Neuromuscular Disorders

Including but not limited to Duchenne, Becker, Limb-girdle type 1B, Limb-girdle type 2C-2F, Limb-girdle type 2I, Myotonic type 1, Myotonic type 2, Emery-Dreifuss, or Facioscapulohumeral Muscular Dystrophy with one of the following [6, 8]:

- Primary and secondary prevention, with same indications as for NICM
- Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement

Arrhythmogenic right ventricular cardiomyopathy

With at least one of the following risk factors for SCD [6, 10, 9]:

- Resuscitated sudden cardiac arrest
- Sustained VT
- Right or left ventricular systolic dysfunction with an EF ≤ 35%
- Syncope with documented or presumed ventricular arrhythmia

CHANNELOPATHIES

Congenital long QT syndrome

With one of the following (AUC 9) [6, 10, 8]

- Sudden cardiac arrest
- Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated
- QTc > 500 ms on a beta blocker
- Strong family history of SCD
- High risk genotype

Brugada syndrome and spontaneous type 1 Brugada electrocardiographic pattern

With one of the following (AUC 9) [6, 10, 8]:

- Cardiac arrest
- Documented sustained VA
- Syncope presumed to be due to VA

Catecholaminergic polymorphic VT

With one of the following (AUC 9) [6, 10, 7]:

- Sudden cardiac arrest
- Syncope or sustained VT
- Inducible VT or VF

Early Repolarization ("J-wave Syndrome") or Short QT Syndrome

With one of the following (AUC 9) [6, 8]:

- Cardiac arrest
- Sustained VA

Idiopathic Polymorphic VT/VF [6]:

- Cardiac arrest due to polymorphic VT or VF

ADULT & PEDIATRIC CONGENITAL HEART DISEASE (CHD) [6, 7, 9, 8, 11]

- Cardiac arrest due to VF or VT, or unstable VT, after exclusion of a reversible etiology
- Systemic LVEF ≤ 35%, biventricular physiology, and NYHA class II or III on GDMT
- Tetralogy of Fallot with one of the following:
    - Spontaneous sustained VT
    - Inducible VF or sustained VT
    - ≥ 1 risk from the following list:
        - Prior palliative systemic to pulmonary shunts
        - Unexplained syncope
        - Frequent PVCs (Premature Ventricular Contractions)
        - Atrial tachycardia

        - Left ventricular dysfunction or diastolic dysfunction
        - NSVT
        - QRS duration ≥ 180 ms
        - Dilated right ventricle
        - Residual pulmonary regurgitation or stenosis
        - RV Hypertension
- Single or systemic RVEF < 35%, in the presence of an additional risk factor such as:
    - NSVT
    - Unexplained syncope
    - NYHA class II or III, despite GDMT
    - QRS duration ≥ 140 ms
    - Severe systemic AV valve regurgitation
- Syncope of unknown origin in the presence of either at least moderate ventricular dysfunction or marked hypertrophy or inducible sustained VT or VF
- Syncope and moderate or severe complexity CHD, with high clinical suspicion of VA
- Non-hospitalized patients with CHD awaiting heart transplant
- Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD

ICD WITH AN APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS [7, 12, 6]

NOTE: With these ICD indications, CRT would sometimes be the appropriate pacing modality. CRT is likely to be the appropriate modality with anticipated requirement for significant (> 40%) ventricular pacing

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction
- ICD criteria met, except for myocardial infarction within 40 days or revascularization within 3 months, but a non-elective permanent pacemaker (new or replacement) is required, and recovery of left ventricular function to LVEF > 35% is uncertain or not expected *
- ICD criteria met, except NICM or ischemic cardiomyopathy has not had 3 months' time for LVEF to improve on medical therapy, a non-elective permanent pacemaker is required, and recovery of LVEF is uncertain or not expected*
- Patient met primary prevention criteria for an ICD prior to coronary revascularization, and it is unlikely that LVEF will recover to > 35% despite a 90-day wait

*** These indications avoid a second implantation procedure within less than 3 months**

CODING and Standards

CPT Codes: 33216, 33217, 33230, 33231, 33240, 33249, 93640, 93641
NCQA Standards: UM 2
Applicable Lines of Business : Commercial, Exchange, Medicaid, Medicare

BACKGROUND

The implantable cardioverter defibrillator (ICD) has become valuable in the management of patients with ventricular arrhythmias (VA) capable of causing syncope, cardiac arrest, and sudden cardiac death (SCD). An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention).

Patient eligibility for an ICD presumes all the following:

- Anticipated reasonable quality of life for ≥ 1-year post implantation
- Patient's ability to live with a shock-delivering device that requires management
- Absence of a completely reversible cause that led to VA for which an ICD is being considered
- Completion of ≥ 3 months of guideline-directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises
- ICD indications are present in most scenarios in which cardiac resynchronization therapy (CRT) is appropriate

Guidelines for the pediatric population are extrapolated from the adult population due to a lack of relevant trials.

NYHA Class Definitions [13, 7]

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Guideline-Directed (or Optimal) Medical Therapy in Heart Failure [14]

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker

Other options/considerations for GDMT

- Addition of loop diuretic for all NYHA class II – IV patients

- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73m2 and K+ < 5.0, NYHA class II-IV
- Normal serum sodium and potassium
- Not required for consideration of ICD: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of Ivabradine.

Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
ARVD/C	Arrhythmogenic right ventricular dysplasia/cardiomyopathy
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
CHD	Congenital heart disease
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy
CRT-D	Cardiac resynchronization therapy ICD system
DCM	Dilated cardiomyopathy
ECG	Electrocardiogram
EF	Ejection fraction
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HCM	Hypertrophic cardiomyopathy
HF	Heart failure
HV	His-ventricle
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle-branch block
LV	Left ventricular/left ventricle
LVAD	Left ventricular assist device, mechanical heart
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
MI	Myocardial infarction
ms	Milliseconds
NICM	Nonischemic cardiomyopathy
NSVT	Nonsustained ventricular tachycardia
NYHA	New York Heart Association
PET	Positron emission tomography
PVC	Premature Ventricular Contraction
RV	Right ventricular/right ventricle
RVEF	Right ventricular ejection fraction
SCD	Sudden Cardiac Death
STEMI	ST-elevation myocardial infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia
VF	Ventricular fibrillation

References

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Cardio Policy

Carotid Duplex

POLICY NUMBER UM CARDIO_1081	SUBJECT Carotid Duplex		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 03/10/14, 11/08/14, 02/17/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 02/21/19, 04/24/19, 07/24/19, 12/11/19, 05/13/20, 07/13/20, 01/13/21, 02/10/21, 03/10/21, 05/12/21, 08/11/21, 01/12/22, 02/09/22, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 04/01/11, 11/07/12, 03/10/14, 11/08/14, 02/17/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 02/21/19, 04/24/19, 07/24/19, 12/11/19, 05/13/20, 07/13/20, 01/13/21, 02/10/21, 03/10/21, 05/12/21, 08/11/21, 01/12/22, 02/09/22, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Carotid Duplex.

II. DEFINITIONS

Non-invasive extra cranial arterial studies involve the use of direct methods of ultrasound. The direct tests examine the anatomy and physiology of the carotid artery.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Evaluation of a patient presenting with an asymptomatic carotid bruit(s) with no prior Carotid duplex done within the last 12 months **(AUC Score 7)**[1,2,3,4,5,6]

B. Monitoring of an asymptomatic patient with known carotid stenosis (greater than 30% narrowing).

30–50% percent stenosis followed on an annual basis **(AUC Score 5)**, greater than 50% stenosis, followed every six months **(AUC Score 8)**[1,2,3,4,5,6]

C. Evaluation of a patient with a recent stroke (less than 6 months) or with focal cerebral or ocular transient ischemic symptoms (does not include blurred vision or dizziness) with no prior Carotid Duplex since recent episode of stroke. **(AUC Score 9)**[1,2,3,4,5,6]

D. Evaluation of a patient with syncope that is strongly suggestive of vertebra-basilar or bilateral carotid artery disease in etiology with no prior carotid duplex within the last 6 months. **(AUC Score 7)**[1,2,3,4,5,6]

E. Evaluation of a patient with retinal arterial emboli or amaurosis fugax with no prior carotid duplex since onset of the symptoms. **(AUC Score 9)**[1,2,3,4,6]

F. Evaluation of a patient with signs/symptoms of subclavian steal syndrome with no prior carotid duplex performed within the last 6 months. **(AUC Score 7)**[1,2,3,4,5,6]

G. Evaluation of a patient with known carotid disease on medical management with recurrent cerebrovascular Symptoms with no prior carotid duplex within the last 3 months or since the last episode of CVA. **(AUC Score 9)**[1,2,3,4,5,6]

H. Evaluation of a patient presenting with an injury to the carotid artery or blunt neck trauma **(AUC Score 8)**[1,2,3,4,5,6]

I. Evaluation of a patient with vasculitis involving the extra cranial carotid arteries **(AUC Score 7)**[1,2,3,4,5,6]

J. Evaluation of a patient with suspected aneurysm of the carotid artery or suspected aortic dissection **(AUC Score 8)**[1,2,3,4,5,6]

K. Evaluation of a patient with pulsatile neck mass with no prior carotid duplex performed within the last 6 months. **(AUC Score 8)**[1,2,3,4,5,6]

L. Monitoring of the post carotid intervention patient is appropriate at 6 weeks, 6 months, 12 months, and 24 months post intervention. **(AUC Score 7)**[1,2,3,4,5,6]

M. Carotid duplex maybe appropriate for preoperative evaluation of patients scheduled for cardiac surgery (e.g., CABG, valve repair/replacement) and solid organ transplantation when there is evidence of systemic atherosclerosis, greater than 65 years, left main coronary stenosis, or history of smoking if no carotid duplex is performed within the last 6 months. **(AUC Score 6)**[2,3,4,5,6]

N. Carotid duplex is indicated in asymptomatic patient with no evidence of carotid bruit but has risk factors for Carotid Artery Disease i.e., atherosclerotic disease in other vascular beds (e.g., lower extremity PAD, coronary artery disease, abdominal aortic aneurysm) No previous carotid duplex performed. Once in a lifetime screening if GDMT for risk factors have been initiated. **(AUC Score 7)**[1,2,3,4,5,6]

O. Carotid Duplex is medically indicated in patients with no prior history of Carotid Artery Disease and is presenting with atypical neurological symptoms with evidence of recent cerebrovascular event on CT/MRI brain. NO previous carotid duplex in the last 12 months **(AUC Score 7)**[1,2,3,4,5,6]

Limitations:

A. Dizziness is not a typical indication unless associated with other localizing signs or symptoms. When reporting syncope as an indication for this service, it is necessary to document that other

more common causes have been ruled out. Carotid duplex studies are reasonable and necessary only if the outcome will potentially impact the clinical course of the patient.

B. The United States Preventative Services Task Forces (USPSTF) recommends against screening for carotid artery stenosis (CAS) among healthy adult patients with no prior history of transient ischemic attack or stroke and no symptoms of a blocked artery in the neck.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Cardiologist/Vascular Surgeon progress note that prompted request
2. All previous vascular studies performed

B. Primary codes appropriate for this service:

93880 – (Complete Bilateral)

93882 – (Unilateral or Limited Study)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy

Ambulatory EKG Monitoring

POLICY NUMBER UM CARDIO_1082	SUBJECT Ambulatory EKG Monitoring		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 09/07/18, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 01/12/22, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 04/01/11, 11/07/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 09/07/18, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 01/12/22, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Ambulatory EKG Monitoring.

II. DEFINITIONS

Ambulatory EKG Monitoring is the continuous monitoring on an outpatient basis of the electrical activity of the heart while the patient undergoes their usual activities. The duration of the monitoring period should be long enough to capture heart rhythm abnormalities based on the patient's description of the frequency of their symptoms.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. The patient complains of palpitations, and physical examination and / or standard EKG have not satisfactorily explained the patient's complaints. **(AUC Score 9)**[2,3]

B. The patient has experienced an unexplained syncopal episode, or the patient has experienced a transient episode of cerebral ischemia or documented CVA, which is felt to possibly be secondary to a cardiac rhythm disturbance. **(AUC Score 9)**[2,3]

C. Holter monitor is appropriate if there is a recent change made in medications or in dosage of medication(s) for controlling the arrhythmia. **(AUC Score 8)**[2,3]

D. The patient has a pacemaker and clinical findings (history or physical examination) suggest possible pacemaker malfunction. **(AUC Score 9)**[2,3]

E. The patient has been found to have a significant cardiac arrhythmia or conduction disorder (see list below) and external cardiac monitoring is necessary as part of the evaluation and management of the patient **(AUC Score 9)**[2,3]

1. Complete Heart Block
2. Second Degree AV Block
3. New Left Bundle Branch Block
4. New Right Bundle Branch Block
5. New Bi-fascicular Block
6. Paroxysmal SVT
7. Paroxysmal VT
8. New Atrial Fib/Flutter
9. Ventricular Fib/Flutter
10. Cardiac Arrest
11. New evidence SA Node Dysfunction
12. Frequent PAC's
13. Frequent PVC's
14. Wandering Atrial Pacemaker

The frequency of the patient's symptoms should be elicited during the patient encounter. It is appropriate to monitor for up to 48 hours if the patient describes symptoms that occur daily. It may be more appropriate to initiate monitoring for periods longer than 48 hours only if the patient indicates that symptoms occur less frequently than 2-3 times per week.

Limitations:

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request
2. Recent EKG (within 10 days) if applicable
3. Most recent holster results if available

B. Primary codes appropriate for this service:

93224- Up to 48 Hours (including recording, scanning analysis with report, review and interpretation)

93225- Recording

93226- Scanning and Analysis with Report

93227- Review and interpretation

93241- Up to 7 days (including recording, scanning analysis with report, review and interpretation)

93242- Recording

93243- Scanning and Analysis with Report

93244- Review and Interpretation

93245- 7-15 Days ((including recording, scanning analysis with report, review and interpretation)

93246- Recording

93247- Scanning and Analysis with Report

93248- Review and Interpretation

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Sana M. Al-Khatib, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death - A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 138: e272–e391
2. Crawford MH, et al. ACC/AHA guidelines for ambulatory electrocardiography: executive summary and recommendations. A report of the American College of Cardiology/American Heart Association task force on practice guidelines. Circulation, Aug 1999, Volume 100, Issue 8, Pages 886-93.
3. Robert C. Hendel MD, FACC, FAHA, FASNC, et. al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.

Cardio Policy

Vessel Mapping for Hemodialysis Access or CABG/PAD Surgery

POLICY NUMBER UM CARDIO_1083	SUBJECT Vessel Mapping for Hemodialysis Access or CABG/PAD Surgery		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 08/22/13, 06/28/14, 02/19/15, 05/05/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 05/12/21, 08/11/21, 11/10/21, 11/09/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 04/01/11, 11/07/12, 08/22/13, 06/28/14, 02/19/15, 05/05/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 05/12/21, 08/11/21, 11/10/21, 11/09/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for vessel mapping for hemodialysis access or CABG surgery.

II. DEFINITIONS

This study consists of the use of Duplex ultrasound to evaluate arterial inflow, venous outflow, and the adequacy of the venous system to support an autogenous access in the extremity.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Anticipated creation of hemodialysis access using autogenous conduit. **(AUC Score 7)**[1,2]

B. Anticipated use of upper or lower extremity veins for CABG and PAD surgery. **(AUC Score 7)**[1,2]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Progress notes from Vascular Surgeon/Nephrologist requesting hemodialysis access creation/Cardiac surgeon.

B. Primary codes appropriate for this service:

93985 - Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study.

93986 - Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study.

Vessel mapping for CABG/PAD graft:

93970 (bilateral extremities) or 93971 (unilateral extremity).

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. American College of Radiology Practice Guidelines. ACR Practice guidelines for the performance of peripheral venous ultrasound examination. Revised 2019 (Resolution 29)
2. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.

Cardio Policy

Patient Activated Event Recorder

POLICY NUMBER UM CARDIO_1085	SUBJECT Patient Activated Event Recorder		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 07/14/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 04/01/11, 11/07/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 07/14/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress notes which prompted the request
    - Recent Electrocardiogram (ECG) (within 10 days) if applicable
    - Most recent Holter monitor results, if available

II. Purpose

Indications for determining medical necessity of patient-activated event recorder.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Patient Activated Event Recorder [6, 7]

- Patient experiencing frequent and/or transient spontaneous symptoms likely to recur within 2–6 weeks, suggestive of cardiac arrhythmia (palpitations, presyncope or syncope etc.) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring. No prior Event monitoring done within the last 3 months.

  Note: When the goal is to correlate the patient's rhythm or ECG pattern with symptoms that are very infrequent (at weekly intervals or more), the patient activated event recorder is the optimal choice, and a service request may be approved in the absence of prior monitoring for a shorter duration. However, if the patient's symptoms are of such brief duration (seconds) or severity (frank syncope) to preclude capture by such a unit, then a loop event recorder is required. It is important to correlate an abnormal rate and rhythm with cardiovascular symptomatology and determine the precise mechanism of the arrhythmia.

V. Potential Exclusions

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

VI. Background

A. Definitions

1. Patient or symptom activated loop recorder (event recorder): is a patient-activated or event-activated ECG device attached to a patient, which records cardiac rhythm at the onset of symptoms. For patient-activated event monitors, the patient initiates recording when symptoms appear or when instructed to do so by a physician (e.g., following exercise).
2. Self-sensing automatically triggered monitors, an ECG is automatically recorded when the device detects an arrhythmia, without patient intervention. Some devices permit a patient to transmit ECG data trans-telephonically (i.e., via telephone) to a receiving center where the data is reviewed.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

ECG	Electrocardiogram

VII. Codings and Standards

- **Primary Codes**
  - 93268: Complete Event Monitor (recording, transmission, analysis, review and interpretation)
  - 93270: Recording (including connection, recording and disconnection)
  - 93271: Transmission and Analysis
  - 93272: Review and interpretation
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VIII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] H. Calkins, G. Hindricks, R. Cappato , Y. Kim , E. Saad, L. Aguinaga and et al, "2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation," *Heart Rhythm,* vol. 14, no. 10, pp. e275-e444, Oct 2017.

[7] F. Kusumoto , M. Schoenfeld, C. Barrett, J. Edgeton, K. Ellenbogen, M. . Gold and et al, "2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay," *J Am Coll Cardiol,* vol. 74, no. 7, pp. e51-e156, Aug 2019.

Cardio Policy

Venous Duplex

POLICY NUMBER UM CARDIO_1093	SUBJECT Venous Duplex		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 03/10/14, 05/21/14, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 05/01/18, 02/13/19, 02/21/19, 04/02/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 04/06/11, 11/07/12, 03/10/14, 05/21/14, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 05/01/18, 02/13/19, 02/21/19, 04/02/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Venous Duplex.

II. DEFINITIONS

Venous Duplex consists of imaging of the veins of the extremities to obtain anatomic and physiologic information.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Evaluation of a patient with deep venous thrombophlebitis or has clinical findings (otherwise unexplained limb pain, swelling) which suggest the possibility of acute deep venous thrombophlebitis with no prior venous duplex within the last 3 months. **(AUC Score 9)**[1,2]

B. Evaluation of a patient presenting signs and symptoms of pulmonary embolism (PE) indicated by dyspnea, chest pain, and/or hemoptysis with no prior venous duplex within the last 3 months. **(AUC Score 8)**[1,2]

C. Evaluation of a patient with symptomatic varicose veins and non-invasive studies are needed to guide management of the patient with no prior venous duplex within the last 6 months. **(AUC Score 7)**[1,2]

D. Evaluation of a patient with known or suspected chronic venous insufficiency, post phlebitic syndrome, or lymphedema with no prior venous duplex within the last 3 months. **(AUC Score 7)**[1,2]

E. Venous duplex is appropriate if there is lower extremity swelling or pain as a complication following the venous intervention. **(AUC Score 8)**[1,2]

F. Venous duplex of the intervened extremity as a baseline follow up is appropriate provided no venous duplex has been performed within the last 2 weeks of venous intervention. **(AUC Score 7)**[1,2]

G. Evaluation of a patient with sustained trauma and injury of the venous system is suspected, making evaluation of the venous system of extremities necessary with no prior venous duplex in the last 6 months. **(AUC Score 7)**[1,2]

Limitations:

A. It is inappropriate to perform non-invasive physiologic testing (93965) and duplex scan (93970, 93971) of the same extremity veins during the same encounter as duplex scan is inclusive of non-invasive physiologic testing.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. All previous vascular studies performed
   3. Progress note from Cardiologist or Vascular Surgeon (if seen previously by a surgeon)

B. Primary codes appropriate for this service:

   93970 (Bilateral, Complete)

   93971 (Unilateral or Limited Study)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Gornik HL, et al. ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 appropriate use criteria for peripheral vascular ultrasound and physiological testing part II: testing for venous disease and evaluation of hemodialysis access: a report of the american college of cardiology foundation appropriate use criteria task force. Journal of the American College of Cardiology. Aug 2013. Volume 62, Issue 7, Pages 649-665.
2. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.

Cardio Policy:

Percutaneous Coronary Interventions

POLICY NUMBER UM CARDIO_1094	SUBJECT Percutaneous Coronary Interventions		DEPT/PROGRAM UM Dept	PAGE 1 OF 6
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/31/14, 05/15/15, 08/12/15, 05/24/16, 11/23/16, 12/21/16, 10/31/17, 02/20/19, 07/30/19, 12/11/19, 08/12/20, 06/09/21, 08/11/21, 09/08/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 04/06/11, 11/07/12, 08/22/13, 06/31/14, 05/15/15, 08/12/15, 05/24/16, 11/23/16, 12/21/16, 10/31/17, 02/20/19, 07/30/19, 12/11/19, 08/12/20, 06/09/21, 08/11/21, 09/08/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for the procedure of Percutaneous Coronary Intervention (PCI).

II. DEFINITIONS

Percutaneous Transluminal Coronary Angioplasty (PTCA) is a procedure used to open clogged heart arteries. Angioplasty involves temporarily inserting and blowing up a tiny balloon where the artery is clogged to help widen the artery.

Percutaneous Coronary Intervention (PCI) with Stent: Angioplasty is often combined with the permanent placement of a stent, a small wire mesh tube, to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

A decision for PCI is made based on the findings on diagnostic cardiac catheterization. The target vessel, except the left main coronary artery, must have a hemodynamically and angiographically significant lesion (greater than or equal to 70%) in one or more vessels. Intermediate coronary lesions are defined as lesions with 50-60% stenosis on cardiac angiography. This may require further workup with Fractional Flow Reserve (FFR) or IVUS depending on patient's symptomatology and nuclear stress test findings. Hemodynamically significant left main stenosis is angiographically defined as having greater than or equal to 50% stenosis.

A single vessel CAD may have single or multiple lesions/stenosis in native coronary artery or single bypass graft. A 2 vessel CAD may have single or multiple lesions/stenosis in 2 different native coronary vessels or in combination with bypass graft(s). Similarly, 3 vessel CAD may have single or

multiple lesions/stenosis in 3 different native coronary vessels/arteries or a combination of native coronary arteries with bypass graft(s).

Risk Stratification[1]

A. High-Risk findings on Stress Test (greater than 3% annual mortality rate or MI) includes:

1. Severe resting or exercise left ventricular dysfunction (LVED less than 35%)
2. High-risk Duke treadmill score (score less than or equal to -11)
3. Stress-induced large perfusion defect (particularly if anterior)
4. Stress-induced multiple perfusion defects of moderate size
5. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201)
6. Stress induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)
7. Echocardiographic wall motion abnormality (involving 2 segments) developing at low dose of Dobutamine (less than or equal to 10 mg/kg/min) or at a low heart rate (less than 120 beats/min).
8. Stress echocardiographic evidence of extensive ischemia

B. Intermediate-Risk findings on Stress Test (1% to 3% annual mortality rate)

1. Mild/moderate resting left ventricular dysfunction (LVEF 35% to 49%)
2. Intermediate-risk Duke treadmill score (score between -11 and -5)
3. Stress induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201)
4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of Dobutamine involving less than or equal to 2 segments

C. Low-Risk findings on Stress Test (less than 1% annual mortality rate)

1. Low-risk treadmill score (Duke score greater than or equal to 5)
2. Normal or small myocardial perfusion defect at rest or with stress
3. Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress.

Grading of Angina Pectoris by the Canadian Cardiovascular Society Classification System:

Class I: Ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: Slight limitation of ordinary activity. Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal condition.

Class III: Marked limitations of ordinary physical activity. Angina occurs on walking 1 or 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace.

Class IV: Inability to carry on any physical activity without discomfort. Angina symptoms may be present at rest.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC

is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[7]

Appropriate Care – Median Score 7-9

May be Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.[2]

III. POLICY

Indications for determining medical necessity are based on the most recent guidance from ACC/AHA guidelines and appropriate use criteria.[1,2,3,4]

A. Patients without prior bypass grafts and on maximally tolerated GDMT

1. Patients should have objective evidence of myocardial ischemia due to lesions amenable to transluminal intervention and/or has not responded to GDMT. **(AUC Score 8)**
2. Patients with Angina Class III or IV and/or evidence of intermediate to high-risk findings on noninvasive testing with 2 vessels CAD with LAD stenosis. **(AUC Score 7)**
3. Patients with Angina Class III or IV and/or evidence of intermediate to high-risk findings on noninvasive testing with 3 vessels CAD with focal stenosis and low SYNTAX score. **(AUC Score 7)**
4. Patients with Angina Class III or IV and/or evidence of intermediate to high-risk findings on noninvasive testing and with isolated left main stenosis. **(AUC Score 6)**
5. Patients with Angina Class III or IV with one or 2 vessel CAD without involvement of proximal LAD and with evidence of high-risk findings on noninvasive testing. **(AUC Score 9)**
6. Patients with Angina Class III or IV with one or 2 vessel CAD without involvement of proximal LAD and with no prior non-invasive testing. **(AUC Score 7)**
7. Patients with Angina Class III or IV with one or 2 vessel CAD with borderline stenosis of 50-60% but with FFR less than or equal to 0.80 and/or IVUS with significant reduction of cross-sectional area of coronary lumen. **(AUC Score 7)**
8. Patients with Angina Class III or IV with Chronic Total Occlusion (CTO) of 1 major coronary artery, and with evidence of intermediate **(AUC Score 7)** or high-risk **(AUC Score 8)** findings on noninvasive testing.
9. Patients with Angina Class III or IV with one vessel CAD involving proximal LAD, and with evidence of low **(AUC Score 8)** or intermediate **(AUC Score 9)** or high **(AUC Score 9)** risk findings on noninvasive testing.
10. Patients with Angina Class I or II with one vessel CAD involving proximal LAD, and with evidence of low **(AUC Score 7)** or intermediate **(AUC Score 8)** or high **(AUC Score 9)** risk findings on noninvasive testing.
11. Asymptomatic Patients with one or 2 vessel CAD without involvement of proximal LAD and with evidence of high-risk findings on noninvasive testing. **(AUC Score 7)**

12. Patients with Angina Class I or II with one or 2 vessel CAD without involvement of proximal LAD and with evidence of high-risk findings on noninvasive testing. **(AUC Score 8)**
13. Asymptomatic patients with 3 vessel CAD with no left main involvement, and with evidence of intermediate **(AUC Score 7)** or high **(AUC Score 8)** risk findings on noninvasive testing.
14. Patients with Angina Class I or II with 3 vessel CAD with no left main involvement, and with evidence of intermediate **(AUC Score 8)** or high-risk findings **(AUC Score 9)** on noninvasive testing.
15. Patients with Angina Class III or IV with 3 vessel CAD with no left main involvement, and with evidence of intermediate **(AUC Score 9)** or high-risk findings **(AUC Score 9)** on noninvasive testing.
16. Asymptomatic patients with 3 vessel CAD with no left main involvement and with abnormal LV systolic function. **(AUC Score 8)**
17. Patients with Angina Class I or II with 3 vessel CAD with no left main involvement and with abnormal LV systolic function. **(AUC Score 9)**
18. Patients with Angina Class III or IV with 3 vessel CAD with no left main involvement and with abnormal LV systolic function. **(AUC Score 9)**
19. Asymptomatic or symptomatic patients with left main stenosis. **(AUC Score9)**
20. Symptomatic patient with Angina Class II-IV with intermediate or high-risk findings on noninvasive testing and hemodynamically/angiographically significant stenosis in one or more native coronary artery. **(AUC Score 8)**
21. Asymptomatic patient with intermediate or high-risk findings on noninvasive testing, and hemodynamically/angiographically significant stenosis in one or more native coronary artery. **(AUC Score 7)**

B. Patients with prior bypass grafts and on maximally tolerated GDMT

1. Asymptomatic patients with one or more stenosis in bypass graft and with high-risk **(AUC Score 7)** findings on noninvasive testing.
2. Patients with Angina Class I or II with one or more stenosis in bypass graft and with low **(AUC Score 6)** intermediate **(AUC Score 7)** or high-risk **(AUC Score 8)** findings on noninvasive testing.
3. Patients with Angina Class I or II with patent bypass grafts but with one or more stenosis in native coronary arteries without bypass graft and have intermediate **(AUC Score 6)** or high-risk **(AUC Score 8)** findings on noninvasive testing.
4. Patients with Angina Class III or IV with one or more stenosis in bypass graft and with low **(AUC Score 7)** intermediate **(AUC Score 8)** or high-risk **(AUC Score)** findings on noninvasive testing.
5. Patients with Angina Class III or IV with patent bypass grafts, but with one or more stenosis in native coronary arteries without bypass graft and have low **(AUC Score 7)** intermediate **(AUC Score 8)** or high-risk **(AUC Score 9)** findings on noninvasive testing.
6. Symptomatic patient with Angina Class II-IV with intermediate or high-risk findings on noninvasive testing and having hemodynamically/angiographically significant stenosis of one or more native coronary artery and/or bypass graft(s). **(AUC Score 8)**
7. Asymptomatic patient with one or more failed bypass graft(s) not amenable for intervention, having intermediate or high-risk findings on noninvasive testing and hemodynamically/angiographically significant stenosis in one or more native coronary artery that is amenable for percutaneous intervention. **(AUC Score 7)**

C. Limitations

A. Avoid intervention in hemodynamically stable patients with:

1. Significant (greater than or equal to 60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
2. Extremely long or angulated infarct-related lesions with Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow.
3. Infarct-related lesions with TIMI grade 3 flow in stable patients with 3 vessel disease.
4. Infarct-related lesions of small or secondary vessels.

B. Before PCI can be performed in a patient with CAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following documents must be submitted for review
   1. Cardiology specialist note that prompted request
   2. Cardiac catheterization that supports PCI request

B. Primary codes appropriate for this service:

   PCI with Stent – 92928 (Single Artery), 92929 (Each Additional Branch),

   PTCA – 92920 (Single Artery), 92921 (Each Additional Branch)

   PCI of CTO – 92943 (Single Artery), 92944 (Each Additional Branch)

   PCI with Atherectomy with Stent – 92933 (Single Artery), 92934 (Each Additional Branch),

   PCI of Bypass Graft with Stent/PTA/Atherectomy – 92937 (Single Artery), 92938 (Each Additional Branch)

   Atherectomy when performed with angioplasty -- 92924 (Single Artery) 92925 (Each Additional Branch)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy

Aortic Valve Replacement

POLICY NUMBER UM CARDIO_1095	**SUBJECT** Aortic Valve Replacement		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 08/01/18, 02/13/19, 03/05/19, 05/01/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** March 29, 2024	**COMMITTEE APPROVAL DATES** 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 08/01/18, 02/13/19, 03/05/19, 05/01/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

- To review for medical determination, the following items must be submitted for review
  - Latest cardiology or cardiothoracic surgeon's progress note
  - Most recent echocardiogram or TEE
  - Cardiac catheterization report

II. Purpose

Indications for determining medical necessity for Aortic Valve Replacement. Aortic valve replacement is a cardiac surgery in which a patient's failing aortic valve is replaced with an alternate healthy valve.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications for Aortic Valve Replacement (AVR)

Asymptomatic (Isselbacher, et al., 2022; Vahanian, et al., 2022; Bonow, et al., 2017)

- AVR is recommended for asymptomatic patients with severe aortic stenosis (AS) and left ventricular ejection fraction (LVEF) < 50% **(AUC Score 8)**
- AVR is reasonable for asymptomatic patients with very severe AS and low surgical risk **(AUC Score 8)**
- AVR is indicated for asymptomatic patients with chronic severe aortic regurgitation (AR) and

LV systolic dysfunction (LVEF < 50%)

- AVR is reasonable for asymptomatic patients with severe AR with normal LV systolic function (LVEF < 50%) but with severe LV dilation (LVESD < 50 mm)

Symptomatic (Isselbacher, et al., 2022; Vahanian, et al., 2022)

- AVR is recommended with severe high-gradient AS who have symptoms by history or on exercise testing
- AVR is reasonable in symptomatic patients with:
  - low-flow/low-gradient severe AS with reduced LVEF
  - AND with a low dose Dobutamine stress study that shows an aortic velocity > 4.0 m/s (or mean pressure gradient > 40 mm Hg)
  - AND with a valve area > 1.0 cm^2 at any Dobutamine dose
- AVR is indicated for symptomatic patients with severe AR regardless of LV systolic function

During Other Interventions (Isselbacher, et al., 2022)

- AVR is indicated for patients with severe AR while undergoing cardiac surgery for other indications
- AVR is indicated for patients with severe AS when undergoing other cardiac surgery

Potential Exclusions

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

V. Background

Definitions

Severe aortic stenosis is defined as an aortic velocity ≥4.0 m/s and/or mean pressure gradient ≥40 mm Hg and/or valve area ≤1.0 cm^2 and/or an indexed valve area ≤0.6 cm^2/m^2 on trans thoracic echocardiogram or Dimensionless index <0.25 on trans thoracic echocardiogram.

Very severe aortic stenosis is defined as an aortic velocity > 5m/s and/or mean pressure gradient ≥60 mmHG and/or valve are <0.6 cm^2 and/or an indexed valve area <o.4cm^2/m^2 or Dimensionless index <0.20.

Severe aortic insufficiency is defined as vena contracta >0.6cm, holodiastolic flow reversal in descending aorta, regurgitation volume ≥60ml/beat, effective orifice area ≥0.3cm^2 on trans thoracic echocardiogram or 34+ grade on angiography with LV dilation.

Dimensionless index or Velocity ratio (DI) is expressed as a simple ratio of velocities (or velocity-time integrals) in left ventricular outflow track and across the valve. It can used to measure the severity of aortic stenosis especially in prosthetic aortic valve and thereby avoiding use of LV outflow

tract diameter which is a common source of error in calculating Aortic Valve area by continuity equation. DI is not influenced by conditions producing high flow across the valve. DI<0.25 is severe aortic stenosis.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. (Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Acronyms

AR: aortic regurgitation
AS: aortic stenosis
AVR: aortic valve replacement
LV: left ventricle
LVEF: left ventricular ejection fraction

VI. Coding and Standards

- **Primary codes**
  - 33405, 33406, 33410-33412
- **Related Codes**
  - 33530 - Reoperation, CABG, or valve surgery, more than 1 month after original operation
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

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Cardio Policy

Coronary Artery Bypass Graft

POLICY NUMBER UM CARDIO_1096	SUBJECT Coronary Artery Bypass Graft		DEPT/PROGRAM UM Dept	PAGE 1 OF 7
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 05/01/18, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 10/14/20, 08/11/21, 10/14/21, 10/12/22, 02/01/23, 01/10/24, 02/14/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 04/06/11, 11/07/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 05/01/18, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 10/14/20, 08/11/21, 10/14/21, 10/12/22, 02/01/23, 01/10/24, 02/14/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review for medical determination, the following items must be submitted for review
    - Cardiothoracic Surgeon and or Cardiologist Progress Note
    - Cardiac Catheterization report

II. Purpose

Indications for determining medical necessity for Coronary Artery Bypass Graft.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for CABG

Stable Ischemic Heart Disease [6, 7]

One-Vessel Disease

- Proximal LAD or LCX involvement
    - With ischemic symptoms on 1 antianginal drug
        - Intermediate or high-risk findings on non-invasive stress imaging (AUC 7)
    - With ischemic symptoms on ≥ 2 antianginal drugs
        - Low-risk findings on non-invasive stress imaging (AUC 7)
        - Intermediate or high-risk findings on non-invasive stress imaging AUC 8)
        - No stress test/indeterminate stress test results and FFR ≤ 0.80 (AUC 7)

Two-Vessel Disease

- No proximal LAD involvement
    - With ischemic symptoms on ≥ 2 antianginal drugs
        - Intermediate or high-risk findings on non-invasive stress imaging (AUC 7)
        - No stress test/indeterminate stress test results and FFR ≤ 0.80 in both vessels (AUC 7)
- Proximal LAD involvement
    - Asymptomatic
        - Intermediate or high-risk findings on non-invasive stress imaging with diabetes (AUC 7)
    - With ischemic symptoms without antianginal drugs
        - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (AUC 7)
        - No stress test/indeterminate stress test results and FFR ≤ 0.80 in both vessels with diabetes (AUC 7)
    - With ischemic symptoms on 1 antianginal drug
        - Low-risk findings on non-invasive stress imaging with diabetes (AUC 7)
        - Intermediate or high-risk findings on non-invasive stress imaging gwithout diabetes (AUC 7) or with diabetes (AUC 8)
        - No stress test/indeterminate stress test results and FFR ≤ 0.80 in both vessels without diabetes (AUC 7) or with diabetes (AUC 8)
    - With ischemic symptoms on ≥ 2 antianginal drugs
        - Low-risk findings on non-invasive stress imaging without diabetes (AUC 7) or with diabetes (AUC 8)
        - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (AUC 8) or with diabetes (AUC 9)
        - No stress test/indeterminate stress test results and FFR ≤ 0.80 in both vessels with or without diabetes (AUC 8)

Three-vessel Disease

- Low disease complexity
    - Asymptomatic with or without antianginal drug
        - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (AUC 7)
    - Symptomatic without antianginal drug
        - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (AUC 7) or with diabetes (AUC 8)
    - Symptomatic on 1 antianginal drug
        - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (AUC 8)

        - Low-risk findings on non-invasive stress imaging with diabetes present (AUC 7)
    - Symptomatic on ≥ 2 antianginal drugs
        - Low-risk findings on non-invasive stress imaging without diabetes present (AUC 7) or with diabetes present (AUC 8)
        - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (AUC 8) or with diabetes present (AUC 9)
- Intermediate or high disease complexity
    - Asymptomatic with or without antianginal drugs
        - Low-risk findings on non-invasive stress imaging with diabetes present (AUC 7)
        - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (AUC 7) or with diabetes (AUC 8)
    - Symptomatic without antianginal drugs
        - Low-risk findings on non-invasive stress imaging with or without diabetes present (AUC 7)
        - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (AUC 7) or with diabetes (AUC 8)
    - Symptomatic on 1 antianginal drug
        - Low-risk findings on non-invasive stress imaging without diabetes present (AUC 7) or with diabetes present (AUC 8)
        - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (AUC 8)
    - Symptomatic on ≥ 2 antianginal drugs
        - Low-risk findings on non-invasive stress imaging without diabetes present (AUC 8) or with diabetes present (AUC 9)
        - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (AUC 9)

Left Main Coronary Artery Stenosis

- Asymptomatic with or without antianginal drugs
    - With or without additional CAD, without multivessel involvement or with low disease burden in other vessels, with ostial, midshaft, or bifurcation involvement (AUC 8)
    - With bifurcation involvement and intermediate or high disease burden in other vessels (AUC 8)
    - With ostial or midshaft stenosis and intermediate or high disease burden in other vessels (AUC 9)
- Symptomatic without antianginal drugs
    - With ostial, midshaft, or bifurcation involvement, without multivessel involvement or with low disease burden in other vessels (AUC 8)
    - With ostial, midshaft or bifurcation involvement, with low disease burden in LMCA and/or intermediate or high disease burden in other vessels (AUC 9)
- Symptomatic on ≥ 1 antianginal drug (AUC 9)

Prior IMA to LAD Graft that is not patent

- Symptomatic without antianginal drugs or with 1 antianginal, stenoses affecting multiple territories, intermediate or high-risk findings (AUC 7)
- Symptomatic on ≥ 2 antianginal drugs, stenoses affecting multiple territories, intermediate or high-risk findings on non-invasive stress imaging (AUC 8) or stenoses affecting ≥ 3 territories and low-risk findings on non-invasive stress imaging (AUC 7)

NOTE: CABG can be considered as a concurrent procedure for patients with SIHD and AUC scores ≥ 7 undergoing other surgical procedures.

Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

Definitions

Coronary Artery Disease (CAD) is narrowing or blockage of the coronary arteries (blood vessels that carry blood and oxygen to the heart). Coronary artery disease is usually caused by atherosclerosis (a buildup of fatty material and plaque inside the coronary arteries) which may cause chest pain, shortness of breath during exercise, and heart attacks.

Ischemic symptoms, aka angina pectoris, include tightness, heaviness, pressure, squeezing, or other discomfort in the chest or adjacent areas. Ischemia may also present with fatigue, faintness, or dyspnea.

Non-invasive testing includes stress testing and imaging modalities with or without contrast.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. [1]

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Abbreviations

CABG: coronary artery bypass graft

FFR: fractional flow reserve

GDMT: guideline directed medical therapy

IMA: Internal Mammary Artery

LAD: left anterior descending coronary artery

LCA: Left coronary artery

LCX: left circumflex coronary artery

LMCA: left main coronary artery

GDMT

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

VI. Coding and Standards

- **Primary codes**
  - 33508, 33510-33514, 33516-33519, 33521-33523, 33533, 33534, 33535, 33536, 33530
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

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[8] M. R. Patel, J. H. Calhoon, G. J. Dehmer, J. A. Grantham, T. M. Maddox, D. J. Maron and P. K. Smith, "ACC/AATS/AHA/ASE/ASNC/SCAISCCT/STS 2016 Appropriate Use Criteria for Coronary Revascularization in Patients With Acute Coronary Syndromes," *Journal of the American College of Cardiology,* 2017.

Cardio Policy
Ascending Aortic Graft Surgery

POLICY NUMBER UM CARDIO_1097	SUBJECT Ascending Aortic Graft Surgery		DEPT/PROGRAM UM Dept	PAGE 1 OF 8
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 10/14/20, 08/11/21, 10/14/21, 10/12/22, 09/13/23, 01/10/24, 03/13/24	APPROVAL DATE March 13, 2024	EFFECTIVE DATE March 29, 2024	COMMITTEE APPROVAL DATES 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 10/14/20, 08/11/21, 10/14/21, 10/12/22, 09/13/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- Request for medical determination (the following items must be submitted for review)
    - Most recent Cardiology or Cardiothoracic surgeon's note
    - Cardiac Catheterization or thoracic vascular imaging report

II. Purpose

Indications for determining medical necessity for Ascending Aortic Graft Surgery.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Ascending Aortic Graft Surgery

Asymptomatic Patients

- Asymptomatic patient with a ≥ 5.5 cm (maximum diameter) ascending aorta. [6] **(AUC Score 7)** [7]

Aortic Aneurysm or Anomaly

- Aortic Syndrome [6]
    - Diagnosed Intramural Hematoma (IMH)

        - Complicated Type A (see Background) – Urgent
        - Uncomplicated Type A (see Background) – Prompt
- Diagnosed thoracic aneurysm
- Diagnosed aortic pseudoaneurysm [8]
- Diagnosed chronic aortic dissection [6]
- Documented aneurysm growing ≥ 0.5 cm in 1 year or ≥ 0.3 cm/y in 2 consecutive years in an aorta that is < 5.5 cm in diameter [6] **(AUC Score 7)** [7]
- Replacement of the entire aortic arch [6]
    - Aneurysms of the entire arch
    - Chronic dissection when the arch is enlarged
    - Distal arch aneurysms that also involve the proximal descending thoracic aorta (usually with the elephant trunk procedure)
- Genetic Aortopathies [6]
    - Syndromic heritable thoracic aortic diseases (HTAD) **(AUC Score 8)** [7]
        - Marfan Syndrome
            - ≥ 5.0 cm (diameter) ascending aorta
            - ≥ 4.5 cm (diameter) and features associated with risk of aortic dissection (see features of increased risk in Marfan Syndrome)
        - Loeys-Dietz Syndrome
            - ≥ 4.5 cm (diameter) may be considered (see features for Loeys-Dietz Syndrome)
        - Ehlers-Danlos Syndrome (Vascular)
            - No diameter thresholds, indications for treatment include rapid arterial aneurysm growth or occurrence of dissection

              NOTE: due to the vascular fragility and bleeding complications there is an increased surgical risk to this population
    - Nonsyndromic heritable thoracic aortic diseases (nsHTAD)
        - Familial **with no high risk** features for adverse events (see features associated with increased risk in Heritable TAA)
            - ≥ 5.0 cm (diameter) ascending aorta
        - Familial **with high risk** features for adverse events (see features associated with increased risk in Heritable TAA)
            - ≥ 4.5 cm (diameter) ascending aorta
- Pregnancy with Aortopathy [6]
    - Before Pregnancy (Women with Aortic Disease)
        - Patients with Marfan Syndrome and > 4.5 cm (aortic root diameter)
        - Patient with Marfan Syndrome and aortic root diameter 4.0 cm to 4.5 cm

is considered especially if there are risk factors for aortic dissection (e.g., aortic rapid growth of ≥ 0.3 cm/y or family history of aortic dissection)

- Patient with Loeys-Dietz Syndrome with Genetic Variants TGFB2 or TGFB3 and aortic diameter ≥ 4.5 cm
- Patient with Loeys-Dietz Syndrome with Genetic Variants TGFBR1, TGFBR2, or SMAD3 and aortic diameter ≥ 4.0 cm
- Patient with nsHTAD and aortic diameter ≥ 4.5 cm
- Patient with nsHTAD and aortic diameter 4.0 cm to 4.5 cm is considered with dependency on the molecular diagnosis, family history, and aortic growth rate
- Patient with Turner Syndrome and ASI of ≥ 2.5 cm/m^2
- Patient with Bicuspid Aortic Valve (BAV) (in absence of Turner Syndrome or an HTAD) and aortic diameter ≥ 5.0 cm
- Patient with sporadic aortic root aneurysms, ascending aortic aneurysms, or both and diameter of ≥ 5.0 cm

Aortic Valve

- Aortic valve replacement is planned in the presence of an ascending aorta ≥ 4.5 cm [6, 9] **(AUC Score 7)** [10]

V. Potential Exclusions

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent

VI. Background

Dilation of the ascending aorta (Thoracic Aortic Aneurysms (TAA)) is often detected during other cardiovascular imaging. Ascending aortic graft surgery is an excision and surgical replacement of the most proximal portion of the diseased thoracic aorta with a graft.

A. Definitions

1. Common Types of Aortic Syndromes [6, 11, 8]

- Aortic dissection – disruption of the medial layer by bleeding, resulting in separation of the aortic wall layers
- IMH – hematoma develops in the aortic wall media (in absence of intimal tear)
- Penetrating Atherosclerotic Ulcer (PAU) – ulceration of aortic atherosclerotic plaque

(penetrated through internal lamina into the media)

2. Aortic Dissection Chronicity [6, 8]

- Hyperacute
  - < 24 hours
- Acute
  - 1-14 days
- Subacute
  - 15-90 days
- Chronic
  - > 90 days

3. Features of IMH [6]

- **Complicated**
  - Malperfusion
  - Periaortic hematoma
  - Pericardial effusion with cardiac tamponade
  - Persistent, refractory, or recurrent pain
  - Rupture
- **Uncomplicated (DO NOT have the following high-risk imaging features)**
  - Maximum aortic diameter > 4.5-5.0 cm
  - Hematoma thickness ≥ 1.0 cm
  - Focal intimal disruption with projection (ulcer like) involving ascending aorta or arch
  - Pericardial effusion (on admission)
  - Progression of aortic dissection
  - Increasing aortic diameter
  - Increasing hematoma thickness

4. Features of Increased Risk in Marfan Syndrome [6]

- Family history of aortic dissection
- ≥ 0.3 cm/y (rapid aortic growth)
- Diffuse aortic root and ascending aortic dilation
- Marked vertebral arterial tortuosity

5. Features for Surgical Threshold for Loeys-Dietz Syndrome [6]

- Family history, age, and aortic growth rate inform surgical thresholds along with the below genetic variants

- Aortic growth rate > 0.3 cm/y
- Genetic variants:
    - TGFBR1: ≥ 4.5 cm w/o high risk features and ≥ 4.0 cm with high risk features
    - TGFBR2: ≥ 4.5 cm w/o high risk features and ≥ 4.0 cm with high risk features
    - SMAD3: ≥ 4.5 cm
    - TGFB2: ≥ 4.5 cm (different pathogenic variants than TGFBR1)
    - TGFB3: ≥ 5.0 cm

NOTE: Aortic surgery may be recommended at smaller aortic diameters to the above genetic variants when there are features for higher risk of aortic dissection (e.g., family history of aortic dissection at young age or smaller aortic diameter, women with TGFBR2 and small body size, or extra-aortic features such as cleft palate, bifid uvula, craniosynostosis)

6. Features Associated with Increased Risk of Aortic Dissection in Patients with Heritable TAA (and no identified Genetic Cause)

- Family history of aortic dissection at an aortic diameter <5.0 cm
- Family history of unexplained sudden death at age < 50 y
- Rapid aortic growth (≥ 0.5 cm in 1 year or ≥ 0.3 cm/y in 2 consecutive years)

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

C. Acronyms/Abbreviations

AAS	Acute Aortic Syndrome
BAV	Bicuspid Aortic Valve
IMH	Intramural Hematoma
nsHTAD	Nonsyndromic Heritable Thoracic Aortic Diseases
PAU	Penetrating Atherosclerotic Ulcers
TAA	Thoracic Aortic Aneurysm

VII. Codings and Standards

- **Primary Codes**
    - 33863, 33864, 33858, 33859
- **Related Codes**
    - 33530 - Reoperation, CABG or Valve surgery, more than 1 month after original operation
    - 33866
- **Place/Site of Service**
    - Inpatient hospital (21)
- **Medicare**
    - If there is a Medicare guideline available use first
- **Review**
    - Utilization Management Department
- **Final Approval**
    - Utilization Management Committee

VIII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for

evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] E. Isselbacher, O. Preventza, J. Hamilton Black 3rd, J. Augoustides, A. Beck, M. Bolen , A. Braverman, B. Bray, M. Brown-Zimmerman, E. Chen, T. Collins, A. DeAnda Jr and et al., "2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines," *Circulation,* vol. 146, no. 2, pp. e334-e482, 13 Dec 2022.

[7] J. U. Doherty, S. Kort, R. Mehran and et al., "ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease," *J Am Coll Cardiol,* vol. 73, no. 4, pp. 488-516, 2019.

[8] R. Erbel, V. Aboyans, C. Boileau, E. Bossone, R. Di Bartolomeo, H. Eggebrecht, A. Evangelista , V. Falk, H. Frank and et al., "2014 ESC Guidelines on the diagnosis and treatment of arotic diseases," *European Heart Jouranl,* vol. 35, pp. 2873-2926, 2014.

[9] N. Swerdlow, W. Wu and M. Schermerhorn, "Open and Endovascular Management of Aortic Aneurysms," *Circulation Research,* vol. 124, pp. 647-661, 14 Feb 2019.

[10] J. Doherty, S. Kort, R. Mehran, P. Schoenhagen, P. Soman and et al., "ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 appropriate use criteria for multimodality imaging in valvular heart disease," *J Am Coll Cardiol,* vol. 70, no. 16, pp. 1647-72, 2017.

[11] V. Vignaraja, A. Thapar and S. Dindyal, "Acute Aortic Syndrome. [Updated 2022 Dec 12]," 12 December 2022. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK576402/. [Accessed 28 February 2024].

Cardio Policy

Descending Thoracic Aortic Graft Surgery

POLICY NUMBER UM CARDIO_1098	SUBJECT Descending Thoracic Aortic Graft Surgery		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 03/13/24	APPROVAL DATE March 13, 2024	EFFECTIVE DATE March 29, 2024	COMMITTEE APPROVAL DATES 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- Request for medical necessity (the following items must be submitted for review)
    - Most recent Cardiology or Cardiothoracic Surgeon's progress note
    - Cardiac Catheterization or vascular imaging report (AAA Duplex/CTA or Aorta/MRA Aorta)

II. Purpose

Indications for determining medical necessity for Descending Thoracic Aortic Graft Surgery.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Descending Thoracic Aortic Graft Surgery

Thoracic Aortic Aneurysm (TAA) [6]

- Patient with intact descending or infra renal or juxtarenal aortic aneurysm (JRA) when the diameter is ≥ 5.5 cm [7] **(AUC Score 7)** [8]
- Patients with intact descending TAA and risk factors for rupture (see Risk Factors for Aortic Rupture) at a diameter of < 5.5 cm **(AUC Score 7)** [8]
- Documented aneurysm growing ≥ 0.5 cm/year in an aorta < 5.5 cm in diameter [9] **(AUC Score 7)** [8]

Thoracoabdominal Aortic Aneurysm (TAAA) [6]

- Intact TAAA or suprarenal ≥ 5.5 cm diameter **(AUC Score 7)** [8]
- Intact degenerative TAAA < 5.5 cm diameter in patients with features associated with increased risk of rupture (see Features associated Risk Factors) **(AUC Score 7)** [8]

V. Potential Exclusions

- Intervention is not recommended for asymptomatic infrarenal or juxtarenal aortic aneurysm ≤ to 5.0 cm in **men** or ≤ 4.5 cm in **women** [9]
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent

VI. Background

Dilation of the descending aorta (TAA) is often detected during other cardiovascular imaging. Descending aortic graft surgery is defined as excision and surgical replacement of the most distal portion of the diseased thoracic aorta with a graft.

A. DEFINITIONS

1. Features Associated with Increased Risk of AAA Rupture [6]

- Rapid growth (confirmed increase in diameter of ≥ 0.5 cm/y
- Symptomatic aneurysm
- Significant change in aneurysm appearance
- Saccular aneurysm or presence of penetrating atherosclerotic ulcers (PAU)

2. Risk Factors for Aortic Rupture with Descending TAA [6]

- Aneurysm growth ≥ 0.5 cm/y
- Symptomatic aneurysm
- Marfan, Loeys-Dietz, or vascular Ehlers-Danlos syndrome, or Heritable Thoracic Aortic Disease
- Saccular aneurysm
- Female sex
- Infectious aneurysm

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health

outcomes in a cost effective manner. [1]

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

JRA	Juxtarenal Aortic Aneurysm
PAU	Penetrating Atherosclerotic Ulcers
TAA	Thoracic Aortic Aneurysm
TAAA	Thoracoabdominal Aortic Aneurysm

VII. Coding and Standards

- **Primary Codes**
  - 33875, 33877, 33880
- **Related Codes**
  - 33530 – Reoperation, CABG, or valve surgery, more than 1 month after original operation
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Medicare**
  - If there is a Medicare guideline available use first
- **Review**
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- **Final Approval**
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[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

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Cardio Policy:

Mitral Valve Surgery

POLICY NUMBER UM CARDIO_1099	**SUBJECT** Mitral Valve Surgery		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Mitral Valve Surgery.

II. DEFINITIONS

Mitral valve replacement or repair is a cardiac surgery procedure in which a patient's failing mitral valve is either repaired or replaced with an alternate healthy valve.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[5]

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,5]

III. POLICY

Patients need to be on maximally tolerated GDMT for MR. Indications for Mitral Valve Surgery (Replacement/Repair) are as follows:

A. Symptomatic patients with chronic severe primary MR and LVEF greater than 30%. **(AUC Score 8)[1,2,3,4]**

B. Asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30% to 60% and/or LVESD greater than or equal to 40 mm. **(AUC Score 8)[1,2,3,4]**

C. Mitral Valve Repair is appropriate in patients with chronic severe primary MR limited to posterior leaflet. **(AUC Score 8)[1,2,3,4]**

D. Mitral Valve Repair is appropriate in patients with chronic severe primary MR involving anterior leaflet or both leaflets when successful and durable repair can be accomplished. **(AUC Score 8)[1,2,3,4]**

E. Concomitant MV repair or replacement is indicated in patients with chronic severe primary MR undergoing cardiac surgery for other cardiac indications. **(AUC Score 8)[1,2,3,4]**

F. MV repair is reasonable for asymptomatic patients with chronic severe non-rheumatic primary MR and preserved LV function with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure greater than 50 mm Hg). **(AUC Score 7)[1,2,3,4]**

G. Mitral valve surgery (repair, commissurotomy, or valve replacement) is indicated in patients that are:

1. Severely symptomatic (NYHA class III to IV) with severe MS (mitral valve area less than or equal to 1.5 cm^2)**. (AUC Score 9)[1,2,3,4]**
2. Not high risk for surgery and are not candidates for or who have failed previous percutaneous mitral balloon commissurotomy. **(AUC Score 8)[1,2,3,4]**
3. Concomitant mitral valve surgery is indicated for patients with severe MS (mitral valve area ≤ 1.5 cm^2) undergoing cardiac surgery for other indications. **(AUC Score 7)[1,2,3,4]**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

B. Before Mitral Valve replacement or repair can be considered in a patient with a failing Mitral Valve the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[1,2,3,]

IV. PROCEDURE

A. In order to review for medical determination, the following items must be submitted for review

1. Latest Cardiology or Cardiothoracic Surgeon's Note
2. Most recent Echocardiogram or TEE (if applicable)
3. Recent Cardiac Catheterization report

B. Primary codes appropriate for this service are: 33422, 33425, 33426, 33427, 33430. 33530 – Reoperation, CABG or valve surgery, more than 1 month after original operation

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Otto et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. JACC VOL. 77, NO. 4, 2021
2. Nishimura RA, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation June 2017 Volume 135 Number 25, Pages e1159-e1195
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Cardio Policy:

Tricuspid Valve Surgery

POLICY NUMBER UM CARDIO_1100	SUBJECT Tricuspid Valve Surgery		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 01/28/16, 11/23/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 04/06/11, 11/07/12, 08/22/13, 06/28/14, 08/12/15, 01/28/16, 11/23/16, 12/21/16, 10/31/17, 08/01/18, 02/21/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Tricuspid Valve Surgery.

II. DEFINITIONS

Tricuspid valve surgery (repair/replacement) is a cardiac surgery procedure frequently done during mitral valve surgery in which a patient's regurgitant or stenotic tricuspid valve is either repaired or replaced. An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

III. POLICY

Indications for Tricuspid Valve Surgery are as follows:

A. Tricuspid valve surgery is recommended for patients with severe TR undergoing left-sided valve surgery. **(AUC Score 7)**[1,2,3,4]

B. Tricuspid valve repair can be beneficial for patients with mild, moderate, or greater functional TR (at the time of left-sided valve surgery with either 1) tricuspid annular dilation greater than 40 mm or 2) evidence of right HF). **(AUC Score 7)**[1,2,3,4]

C. Tricuspid valve surgery is recommended for patients with severe TS at the time of operation for left-sided valve disease. **(AUC Score 7)**[1,2,3,4]

D. Tricuspid valve surgery is recommended for patients with isolated, symptomatic severe TS. **(AUC Score 7)**[1,2,3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical determination, the following items must be submitted for review
   1. Latest Cardiology or Cardiothoracic Surgeon's note
   2. Most recent Echocardiogram or TEE
   3. Recent Cardiac Catherization

B. Primary codes appropriate for this service are: 33463, 33464. 33465 33530-Reoperation, CABG or Valve Surgery, more than 1 month after original operation.

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Otto et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. JACC VOL. 77, NO. 4, 2021
2. Nishimura RA, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation June 2017 Volume 135 Number 25, Pages e1159-e1195
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5. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Cardiac Electrophysiology Study without Arrhythmia Induction

POLICY NUMBER UM CARDIO_1101	**SUBJECT** Cardiac Electrophysiology Study without Arrhythmia Induction	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 04/06/11, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/21/19, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 04/06/11, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/21/19, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Cardiac Electrophysiology Study without Arrhythmia Induction.

II. DEFINITIONS

An electrophysiological study (EP study) is an invasive procedure that evaluated abnormal heart rhythm disturbances. During an EP study, small, thin wire electrodes are inserted through a vein in the groin (or neck, in some cases). The wire electrodes are threaded into the heart, using a special type of X-ray, called fluoroscopy. Once in the heart, electrical signals are measured. Electrical signals are sent through the catheter to stimulate the heart tissue to try to initiate the abnormal heart rhythm disturbances for evaluation.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost – effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[7]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,4,5,6].

III. POLICY

Patients should be on maximally tolerated GDMT. Indications for approving a request for medical necessity are:

A. EPS is being performed for a patient with symptomatic syncope or near syncope suspected of having sinus node dysfunction but a causal relation between an arrhythmia and the symptoms cannot be established by other means. **(AUC Score 8)[2,3,4,5]**

B. EPS is being performed for a patient with symptomatic syncope or near syncope suspected or diagnosed His Purkinje second or third-degree AV block. **(AUC Score 8)[,2,3,4,5]**

C. Patients with second or third-degree AV block treated with a pacemaker who remain symptomatic (with syncope or near syncope) in whom ventricular tachyarrhythmia is suspected as a cause of symptoms. **(AUC Score 8)[,2,3,4,5]**

D. EPS being performed for a patient with symptomatic syncope and or near syncope with chronic bundle branch block (RBBB with Left anterior or posterior hemi block) where ventricular arrhythmia is suspected. **(AUC Score 7)[,2,3,4,5]**

E. EPS is being performed for a patient with narrow QRS tachycardia poorly responsive to drug therapy or with associated drug side effects. **(AUC Score 8)[1,,6]**

F. EPS is being performed for a patient with wide QRS complex tachycardia (sustained and/or symptomatic). **(AUC Score 8)[1,2,3,4,5]**

G. EPS is being performed in a patient with W-P-W who participates in high risk occupation/activities, has a family history of premature sudden death or is undergoing cardiac surgery for other reasons. **(AUC Score 7)[1,2,3,4,5]**

H. EPS is being performed in a patient with suspected antidromic tachycardia. **(AUC Score 7)[,6]**

I. EPS is being performed in a patient with prolonged QT interval syndrome and evidence of sustained ventricular tachycardia or sudden death. **(AUC Score 8)[2,3,4,5]**

J. EPS is being performed in a patient with unexplained syncope with known, suspected or without structural heart disease. **(AUC Score 8)[,2,3,4,5]**

K. EPS is being performed in a patient surviving a cardiac arrest. **(AUC Score 8)[,2,3,4,5]**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

B. Before proceeding with comprehensive EPS study for a patient with established atrial or ventricular arrhythmia the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[1,2,3,4,5,6]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or EP Progress Note that prompted request
   2. Recent EKG (within 10 days)
   3. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis)

B. Primary codes appropriate for this service: 93619 (EPS without induction)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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2. Sana M. Al-Khatib, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death - A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 138: e272–e391
3. S. Adam Strickberger, MD, etc. AHA/ACCF Scientific Statement on the Evaluation of Syncope. From the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation In Collaboration With the Heart Rhythm Society. Circulation 2006 Volume 113 Number 2, Pages 316-327.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. Cronin EM, et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. Europace. 2019 Aug 1;21(8):1143-1144. doi: 10.1093/europace/euz132. Erratum in: Europace. 2019 Aug 1;21(8):1144. Erratum in: J Arrhythm. 2020 Jan 12;36(1):214. Erratum in: Europace. 2020 Mar 1;22(3):505.
6. DuPage RL, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2016 Apr 5;67(13):e27-e115.
7. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy:

Cardiac Telemetry

POLICY NUMBER UM CARDIO_1112	SUBJECT Cardiac Telemetry		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 04/24/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 08/11/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/23/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 04/24/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 08/11/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Cardiac Telemetry.

II. DEFINITIONS

Cardiac telemetry is a means of sending a real-time tracing of the electrical activity of the heart to a view screen somewhere within the vicinity of the patient's telemetry monitor. Cardiac telemetry can also be sent from home using a base station.

III. POLICY

Indications for approving a request for medical necessity are:

A. The patient requires monitoring for known non-life-threatening arrhythmias such as Paroxysmal atrial fibrillation, other paroxysmal supraventricular arrhythmias, brady-arrhythmias, or intermittent bundle branch block with no prior cardiac telemetry done within the last 3 months. **(AUC Score7)**[1,2,3,4]

B. The patient is recovering from cardiac surgery and has documented atrial arrhythmias with no prior cardiac telemetry done since cardiac surgery. **(AUC Score 7)**[1,2,3,4]

C. The patient presents with recurrent severe symptoms (i.e., recurrent syncope or presyncope) with no prior cardiac telemetry done within the last 3 months. **(AUC Score 7)**[1,2,3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or Electro physiologist progress note that prompted request
   2. Recent EKG (within 10 days), if available
   3. Most recent Holter or event monitor or device interrogation report, if available

B. Primary codes appropriate for this service: 93228, 93229

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L33380). Long-Term Wearable Electrocardiographic Monitoring (WEM). Retrieved from https://www.cms.gov [Accessed December 19, 2023].
2. Joshi AK, Kowey PR, Prystowsky EN, et al. 'First Experience with a Mobile Cardiac Outpatient Telemetry (MCOT) System for the diagnosis and Management of Cardiac Arrhythmia.' American Journal of Cardiology, 2005;95(7).
3. Olson JA, Fouts AM, Padanilam BJ, et al. "Utility of Mobile Cardiac Outpatient Telemetry for the Diagnosis of Palpitations, Presyncope, Syncope, and the Assessment of Therapy Efficacy." Journal of Cardiovascular Electrophysiology, Accessed Online March 2007.
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Cardio Policy
Cardiac Magnetic Resonance Imaging (MRI)

POLICY NUMBER UM CARDIO_1113	SUBJECT Cardiac Magnetic Resonance Imaging (MRI)		DEPT/PROGRAM UM Dept	PAGE 1 OF 15
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 02/17/15, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/21/19, 03/07/19, 04/25/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 11/10/21, 11/09/22, 10/18/23, 12/20/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 03/10/14, 02/17/15, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/21/19, 03/07/19, 04/25/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 11/10/21, 11/09/22, 10/18/23, 12/20/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE

CMR is an imaging modality used to assess cardiac or vascular anatomy, function, perfusion, and tissue characteristics in a single examination. In lesions affecting the right heart, CMR provides excellent visualization and volume determination regardless of RV shape. This is particularly useful in patients with congenital heart disease.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] **.**

SPECIAL NOTE

Since many cardiac patients have cardiac implanted electrical devices, the risk of CMR to the patient and the device must be weighed against the benefit to the patient in terms of clinical value in optimal management. [6, 7, 8, 9]

See* Legislative Requirements *for specific mandates in Washington State

INDICATIONS FOR CARDIAC MAGNETIC RESONANCE

Cardiomyopathy & Heart Failure [10, 11, 12]

- To assess systolic and diastolic function in the evaluation of a newly diagnosed cardiomyopathy (AUC 7) [10]
- Suspected infiltrative disease such as amyloidosis, sarcoidosis [13], hemochromatosis, or endomyocardial fibrosis if PET has not been performed (AUC 8) [10]
- Suspected inherited or acquired cardiomyopathy (AUC 7) [10]
- Diagnosis of acute myocarditis, with suspicion based upon new, unexplained findings such as:
    - Rise in troponin not clearly due to acute myocardial infarction
    - Change in ECG suggesting acute myocardial injury or pericarditis, without evident myocardial infarction
- Assessment of hypertrophic cardiomyopathy [14] (AUC 8) [10]
    - When TTE is inadequate for diagnosis, management, or operative planning, or when tissue characterization (degree of fibrosis) will impact indications for ICD
    - For patients with LVH when there is a suspicion of alternative diagnoses, including infiltrative or storage disease as well as athlete's heart
    - For patients with obstructive HCM in whom the autonomic mechanism of obstruction is inconclusive on echocardiography, CMR is indicated for selection and planning of SRT (septal reduction therapy)
    - For patients with HCM, repeat imaging on a periodic basis (every 3-5 years) for the purpose of SCD risk stratification to evaluate changes in LGE, EF, development of apical aneurysm or LV wall thickness
- Arrhythmogenic right ventricular cardiomyopathy to aid in identification and diagnosis (assessment of myocardial fat, fibrosis, and RV tissue characteristics), based upon reason for suspicion, such as:
    - Nonsustained ventricular tachycardia (VT)
    - Unexplained syncope
    - ECG abnormalities
    - First-degree relatives with positive genotype for ARVD
- Noncompaction cardiomyopathy to aid in the diagnosis (measurement of compacted to noncompacted myocardium) when TTE is suggestive
- Viability assessment when SPECT, PET or Dobutamine Echo has provided "equivocal or indeterminate" results
- Clinical symptoms and signs consistent with a cardiac diagnosis known to cause presyncope/syncope (including, but not limited to, hypertrophic cardiomyopathy) (AUC 7) [10]
- Pulmonary hypertension in the absence of severe valvular disease (AUC Score 7) [10]
- Cardiomyopathy
    - Hemosiderosis
    - Restrictive cardiomyopathy (AUC 7) [10]
    - Cardio toxic chemotherapy

Valvular Heart Disease

- Evaluation of valvular stenosis, regurgitation, or valvular masses when transthoracic echocardiography (TTE) is inadequate (AUC 7) [15]
- Pre-TAVR assessment if the patient has not undergone cardiac CT [16]
- Prior to transcatheter mitral valve intervention, when TTE and TEE result in uncertain assessment of the severity of mitral regurgitation [17, 18]
- Suspected clinically significant bioprosthetic valvular dysfunction and inadequate images from TTE and TEE [15] (AUC 7) [15]

Evaluation of Intra- and Extra-Cardiac Structures

- Initial evaluation of cardiac mass, suspected tumor or thrombus, or potential cardiac source of emboli (AUC 7) [10]
- Re-evaluation of intracardiac mass when findings would change therapy; no prior imaging in the last three months (AUC 7) [10]
- Evaluation of pericardial disease to provide structural and functional assessment and differentiate constrictive vs restrictive physiology(AUC 8) [10]
- Assessment of left ventricular pseudoaneurysm, when TTE was inadequate
- Identification and characteristics of coronary aneurysms or anomalous coronary arteries (AUC 7) [10]

Pre-procedure Evaluation for Closure of ASD or PFO (AUC 7) [10]

- For assessment of atrial septal anatomy and atrial septal aneurysm
- For assessment of suitability for percutaneous device closure

Assessment Following LAA Occlusion

- For surveillance at 45 days or FDA guidance, if TEE or Heart CT was not done, to assess:
    - Device stability
    - Device leaks
    - To exclude device migration

Pre-Ablation Planning

- Evaluation of left atrium and pulmonary veins prior to radiofrequency ablation for atrial fibrillation, if cardiac CT has not been done

Aortic Pathology

- CT, MR, or echocardiogram can be used for screening and follow-up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta (AUC 8) [10]

- Screening of first-degree relatives with a history of thoracic aortic aneurysm or dissection (AUC 7) [10]
- Six-month follow-up after initial diagnosis of thoracic aortic aneurysm to measure rate of change
- Annual follow-up for an enlarged thoracic aortic aneurysm (usually defined as > 4.4.cm)
- Biannual (2x/year) follow-up of enlarged aortic root or showing growth rate ≥ 0.5 cm/year
- Screening of first-degree relative with a bicuspid aortic valve
- Re-evaluation (<1 y) of the size and morphology of the aortic sinuses and ascending aorta in patients with a bicuspid AV and an ascending aortic diameter >4 cm with 1 of the following:
    - Aortic diameter >4.5 cm
    - Rapid rate of change in aortic diameter
    - Family history (first-degree relative) of aortic dissection
- Patients with Turner's syndrome annually if an abnormality exists; if initial study normal, can have imaging every 5 - 10 years [19]
- Evaluation in patients with known or suspected connective tissue disease or genetic condition that predispose to aortic aneurysm or dissection, such as Marfan syndrome, Ehlers-Danlos or Loeys-Dietz syndrome (at the time of diagnosis and 6 months thereafter), followed by annual imaging (can be done more frequently if > 4.5 cm or rate of growth > 0.5 cm/year- up to twice per year) (AUC 8) [10]

Congenital Heart Disease (CHD) [20]

For all indications below, either CT or CMR can be done

- All lesions: evaluation prior to planned repair and evaluation for change in clinical status and/or new concerning signs or symptoms
- Patent Ductus Arteriosus: routine surveillance (1-2 years) in a patient with postprocedural aortic obstruction (AUC 7) [20]
- In the absence of prior imaging documenting congenital heart disease, a cardiac MRI is appropriate for anomalous pulmonary venous drainage and pulmonary outflow tract obstruction
- Eisenmenger Syndrome and Pulmonary Hypertension associated with CHD: (AUC 7) [20]
    - Evaluation due to change in pulmonary arterial hypertension-targeted therapy
    - Initial evaluation with suspicion of pulmonary hypertension following CHD surgery
- Aortic Stenosis or Regurgitation:
    - Routine surveillance (6-12 months) in a child with aortic sinus and/or ascending aortic dilation with increasing size (AUC 8) [20]
    - Routine surveillance (2–3 years) in a child with aortic sinus and/or ascending aortic dilation with stable size (CMR only) (AUC 7) [20]
- Aortic Coarctation and Interrupted Aortic Arch: (AUC 8) [20]

    - In the absence of prior imaging documenting congenital heart disease, a cardiac MRI is appropriate for suspected Coarctation (AUC Score 8) [20]
    - Routine surveillance (3–5 years) in a child or adult with mild aortic coarctation
    - Post procedure (surgical or catheter-based) routine surveillance (3–5 years) in an asymptomatic patient to evaluate for aortic arch aneurysms, in-stent stenosis, stent fracture, or endoleak
- Coronary anomalies
- Tetralogy of Fallot:
    - Postoperative routine surveillance (2–3 years) in a patient with pulmonary regurgitation and preserved ventricular function (CMR only) (AUC 7) [20]
    - Routine surveillance (2–3 years) in an asymptomatic patient with no or mild sequelae (CMR only) (AUC 7) [20]
    - Routine surveillance (2–3 years) in a patient with valvular or ventricular dysfunction, right ventricular outflow tract obstruction, branch pulmonary artery stenosis, arrhythmias, or presence of an RV-to-PA conduit (AUC 8) [20]
- Double Outlet Right Ventricle: Routine surveillance (3–5 years) in an asymptomatic patient with no or mild sequelae (CMR only)
- D-Loop Transposition of the Great Arteries (postoperative):
    - Routine surveillance (3–5 years) in an asymptomatic patient (AUC 7)
    - Routine surveillance (1–2 years) in a patient with dilated aortic root with increasing size, or aortic regurgitation (AUC 8)
    - Routine surveillance (3–12 months) in a patient with ≥moderate systemic AV valve regurgitation, systemic RV dysfunction, LVOT obstruction, or arrhythmias
- Congenitally Corrected Transposition of the Great Arteries: (AUC 7) [20]
    - Unrepaired: routine surveillance (3–5 years) in an asymptomatic patient
    - Postoperative: routine surveillance (3–5 years) in an asymptomatic patient
    - Postoperative anatomic repair: routine surveillance (6–12 months) in a patient with valvular or ventricular dysfunction, right or left ventricular outflow tract obstruction, or presence of an RV-to-PA conduit
    - Postoperative physiological repair with VSD closure and/or LV-to-PA conduit: routine surveillance (3–12 months) in a patient with ≥moderate systemic AV valve regurgitation, systemic RV dysfunction, and/or LV-to-PA conduit dysfunction
- Truncus Arteriosus: routine surveillance (1–2 years) in an asymptomatic child or adult with ≥ moderate truncal stenosis and/or regurgitation (AUC 7) [20]
- Single-Ventricle Heart Disease:
    - Postoperative routine surveillance (1–2 years) in an asymptomatic patient
    - Routine surveillance (1–2 years) in an asymptomatic adult postoperative Stage 2 palliation (CMR only) (AUC 7) [20]
- Ebstein's anomaly and Tricuspid Valve dysplasia (only CMR indicated):
    - Evaluation prior to planned repair and evaluation for change in clinical status and/or new concerning signs or symptoms (AUC 7) [20]
- Pulmonary Stenosis (only CMR indicated) (AUC 7) [20]

    - Unrepaired: routine surveillance (3–5 years) in an asymptomatic adult with PS and pulmonary artery dilation
    - Postprocedural (surgical or catheter-based): routine surveillance (1–3 years) in an asymptomatic adult with moderate or severe sequelae
- Pulmonary Atresia (postprocedural complete repair): routine surveillance (1–3 years) in an asymptomatic adult with ≥ moderate sequelae (AUC 7) [20]

Coronary Artery Disease Evaluation (CMR as an alternative to pharmacologic MPI)

- CMR, which is done pharmacologically, is used for the assessment of coronary artery disease, and can be performed if the patient would otherwise be a candidate for a pharmacologic MPI.
- Assessment of LV wall motion to identify patients with akinetic segments that would benefit from coronary revascularization
- To identify the extent and location of myocardial necrosis in patients with chronic or acute ischemic heart disease
- Follow-up of known CAD
    - Coronary stenosis of unclear significance on previous coronary angiography [12, 21]
- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA) as documented in provider notes (no MPI diversion required). [22]

LEGISLATIVE REQUIREMENTS

State of Washington [23]

- 20211119A – Use of Cardiac Magnetic Resonance Angiography (CMRA) in Adults and Children
    - **HTCC coverage determination**
        - CMRA is a covered benefit for adults or children with known or suspected coronary vessel anomalies or congenital heart disease
        - CMRA is a covered benefit with conditions for stable symptomatic adults with known or suspected coronary artery disease (CAD)
    - **HTCC reimbursement determination**
        - **Limitations of coverage**
            - CMRA should not be a first line diagnostic tool in patients with stable symptoms consistent with CAD. CMRA is covered with conditions for stable symptomatic adults with known or suspected CAD when the following conditions are met:
                - In consultation with a cardiologist, **and**
                - The patient is unable to tolerate or safely participate in other noninvasive anatomic or functional testing.

- CMRA is not a covered service in coronary artery bypass graft (CABG) patients without CAD symptoms, or in those requiring cardiac lead placement unless cardiac vascular anomalies are suspected.

Codings and Standards

CPT Codes: 75557, 75559, 75561, 75563 +75565
NCQA Standards: UM2
Applicable Lines of Business: Commercial, Exchange, Medicaid

BACKGROUND [24]

CMR in CAD [21, 25, 26] is often required when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) provide inadequate imaging data.

Stress CMR for assessment of coronary artery disease (CAD) is performed pharmacologically either as a vasodilator perfusion imaging with gadolinium contrast or dobutamine inotropic wall motion (ventriculography).

With respect to CAD evaluation, since CMR is only pharmacologic (non-exercise stress), and stress echocardiography (SE) or myocardial perfusion imaging (MPI) provide similar information about CAD:

- Requests for stress CMR require diversion to exercise SE first, and to exercise MPI second.
- Exemptions for the diversion to SE or exercise MPI:
    - If body habitus or marked obesity (e.g., BMI ≥ 40) would interfere significantly with imaging with SE and MPI [27]
    - Evaluation of young (< 55 years old) patients with documented complex CAD, who are likely to need frequent non-invasive coronary ischemia evaluation and/or frequent radiation exposure from other testing [28]

Heart magnetic resonance imaging (MRI) is an imaging method that uses powerful magnets and radio waves to create pictures of the heart. It does not use radiation (x-rays).

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. Stable patients without known CAD fall into 2 categories: [21, 25, 26]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online
    - **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

2. The THREE Types of Chest Pain or Discomfort
    - **Typical Angina (Definite)** is defined as including all **3** characteristics:
        - Substernal chest pain or discomfort with characteristic quality and duration
        - Provoked by exertion or emotional stress
        - Relieved by rest and/or nitroglycerine
    - **Atypical Angina (Probable)** has only **2** of the above characteristics
    - **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics

3. The medical record should provide enough detail to establish the type of chest pain. From those details, The Pretest Probability of obstructive CAD is estimated from the **Diamond Forrester Table** below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability: [21]

Diamond Forrester Table [29, 30]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very low:** < 5% pretest probability of CAD, usually not requiring stress evaluation[22]
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CA

For additional information on stress imaging, please refer to NIA guideline CG 024 Myocardial Perfusion Imaging (aka Nuclear Cardiac Imaging Study).

ACRONYMS / ABBREVIATIONS

ARVD/C	Arrhythmogenic right ventricular dysplasia/cardiomyopathy
ASD	Atrial septal defect
CABG	Coronary artery bypass grafting surgery
CAD	Coronary artery disease
CMR	Cardiac magnetic resonance (imaging)
CT	Computed tomography
ECG	Electrocardiogram
EF	Ejection fraction
HCM	Hypertrophic cardiomyopathy
ICD	Implantable cardioverter-defibrillator
LAA	Left atrial appendage
LBBB	Left bundle-branch block
LGE	Late gadolinium enhancement
LV	Left ventricle
LVH	Left ventricular hypertrophy
LVOT	Left ventricular outflow
MPI	Myocardial perfusion imaging
MR	Mitral regurgitation
MR(I)	Magnetic resonance (imaging)
PA	Pulmonary artery
PET	Positron emission tomography
PFO	Patent foramen ovale
PS	Pulmonary stenosis
RV	Right ventricle
SCD	Sudden cardiac death
SE	Stress echocardiography
SRT	Septal reduction therapy
TAVR	Transcatheter Aortic Valve Replacement
TTE	Transthoracic Echo
TEE	Transesophageal Echo
VT	Ventricular tachycardia

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Cardio Policy:

Cardiovascular Stress Test

POLICY NUMBER UM CARDIO_1114	**SUBJECT** Cardiovascular Stress Test		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 04/23/19, 07/30/19, 12/11/19, 05/13/20, 11/11/20, 03/10/21, 05/12/21, 08/12/21, 11/10/21, 09/14/22, 12/14/22, 02/01/23, 12/20/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 03/10/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 04/23/19, 07/30/19, 12/11/19, 05/13/20, 11/11/20, 03/10/21, 05/12/21, 08/12/21, 11/10/21, 09/14/22, 12/14/22, 02/01/23, 12/20/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Cardiovascular Stress Test.

II. DEFINITIONS

Cardiovascular stress test is a test used to measure cardiovascular response to external stress through treadmill/bicycle exercise in a controlled clinical environment.

Cardiovascular stress tests compare the coronary circulation while the patient is at rest with the same patient's circulation observed during maximum physical exertion, showing any abnormal blood flow to the myocardium as depicted by the continuously monitored EKG. The results can also be interpreted as a reflection on the general physical condition of the test patient (blood pressure response and exercise tolerance).

Intermediate global CAD risk is defined as 10 year CAD risk from 10-20%.

High global CAD risk is defined as 10 year CAD risk of greater than 20%. CAD equivalents (e.g., DM, PAD) can also define high risk.

10 year CAD risk (%) is defined based on the risk factors: sex, age, race, total cholesterol, HDL-cholesterol, systolic blood pressure, and treatment for high blood pressure, diabetes mellitus, and smoker.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC

is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[14]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[2,3,9,10,11,12,13].

III. POLICY

Patients should be on maximally tolerated GDMT for CAD, when applicable. Indications for approving a request for medical necessity are:

A. To evaluate prognosis and functional capacity in patients with CAD soon after MI (6-8 weeks after uncomplicated MI) with no prior stress test done after MI. **(AUC Score 7)[1,2,3,4]**

B. To assess patients before and after revascularization

   1. CABG Testing may be considered, if revascularization is incomplete in asymptomatic patient **(AUC Score 7)[1,2,3,4]** or if the patient is asymptomatic and had CABG greater than or equal to 5 years ago. **(AUC Score 7)[1,2,3,4]**
   2. PCI Testing may be done in asymptomatic patient if PCI was done greater than or equal to 2 years. **(AUC Score 7)[1,2,3,4]**

C. Exercise stress test is appropriate to detect CAD in patients with high global CAD risk and with interpretable ECG and able to exercise with no prior stress test done within the last 12 months. **(AUC Score 7)[1,2,3,4]**

D. Follow up testing with exercise stress test is appropriate when a prior test (less than 90 days) with Coronary CT Calcium is abnormal (Agatston score greater than 100) and no prior revascularization has been performed with no prior stress test done within the last 12 months. **(AUC Score 7)[1,2,3,4]**

E. Follow up testing with exercise stress test is appropriate in asymptomatic or with stable symptoms when prior (greater than 90 days) Coronary Calcium Agatston score greater than 400 with no prior stress test done within the last 12 months. **(AUC Score 7)[1,2,3,4]**

F. Testing is being performed to evaluate functional capacity, effects of therapy/interventions, prognosis and/or severity of known CAD, vascular, congenital, and/or myocardial disease with no prior stress test done within the last 12 months. **(AUC Score 7)[1,2,3,4]**

G. Initial evaluation of exercise capacity of selected patients with valvular heart disease with related symptomatology with no prior stress test done within the last 6 months. **(AUC Score 7)[1,2,3,4]**

H. Testing is being performed to assess functional capacity prior to entering cardiac rehabilitation with a qualifying diagnosis, and again at 12 weeks. **(AUC Score 8)[1,2,3,4]**

I. Testing is being performed to evaluate a patient with known or suspected exercise induced arrhythmias, sustained VT or frequent PVC's or syncope, and prior to initiation of antiarrhythmic therapy in high global CAD risk patients with no prior stress test done within the last 6 months. **(AUC Score 7)**[1,2,3,4]

J. Annual testing is with Exercise Stress test is appropriate to assess the presence or absence of CAD for cardiac transplant patient and in patients in high risk occupation for clearance. **(AUC Score 7)**[1,2 3,4]

K. Exercise Stress test is indicated in patients who need cardiac clearance prior to high risk occupation i.e. Pilots or high endurance physical training. **(AUC Score 8)**[1,2,3,4]

L. Exercise stress test is appropriate to perform for cardiovascular risk stratification, prior to any organ transplant. No stress test done within the last 6 months. **(AUC Score 7)**[5,6,7,8]

M. Please refer to *UM_1175 Perioperative Cardiovascular Evaluation and Care Before Non-Cardiac Surgery* and *UM_1119 Nuclear Stress Test Pharmacological/Myocardial Perfusion Imaging (MPI)* if a request is received for pre-operative cardiac clearance prior to noncardiac and cardiovascular related surgery.

Limitations:

A. Stress testing with imaging i.e. echo. SPECT, PET is the preferred modality for patients with significant EKG abnormalities including but not limited to but not limited to inverted T-waves, greater than or equal to 1mm ST segment depressions, greater than or equal to 1mm ST segment elevations, or a combination thereof in 2 or more contiguous leads.

B. Apart from the specific scenarios indicated above, stress testing of asymptomatic individuals is not appropriate unless there are other signs of cardiac pathology e.g., new EKG abnormalities, new wall motion abnormalities on an echo, or a new decrease in LVEF as detected by another modality

C. Before Cardiovascular Stress Test can be performed in a patient with CAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT. [2,3,9,10,11,12,13]

D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Recent EKG (within 10 days)
   3. Most recent Holter or prior stress test results (if applicable)

B. Primary codes appropriate for this service: 93015, Supervision only (without interpretation and report) 93016, Tracing only (without interpretation and report), Tracing only (without interpretation and report) 93017, Interpretation and report only 93018.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy
Coronary and/or Cardiac Computed Tomographic Angiography

POLICY NUMBER UM CARDIO_1115	**SUBJECT** Coronary and/or Cardiac Computed Tomographic Angiography	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 17**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 12/17/13, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 07/08/20, 01/13/21, 05/12/21, 08/11/21, 09/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 12/17/13, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 02/21/19, 05/08/19, 12/11/19, 07/08/20, 01/13/21, 05/12/21, 08/11/21, 09/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE

Indications for determining medical necessity for Coronary and/or Cardiac Computed Tomographic Angiography (CCTA). Patients should be on maximally tolerated guideline directed medical therapy (GDMT), when applicable.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

INDICATIONS for CORONARY COMPUTED TOMOGRAPHIC ANGIOGRAPHY (CCTA) [6, 7, 8, 9]

EVALUATION IN SUSPECTED CORONARY ARTERY DISEASE (CAD) [10, 11, 12, 13, 14]

Probability

- Low pretest probability patients should be considered for exercise treadmill test (ETT) unless other criteria for CCTA are met [6]
- Intermediate and high pretest probability patients [15]
- Exercise ECG stress test with intermediate Duke Treadmill (- 10 to + 4)

Asymptomatic Patients

- Asymptomatic patients without known CAD
    - Previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see Uninterpretable baseline ECG section)
    - Previously unevaluated pathologic Q waves (see Uninterpretable baseline ECG section)
    - Previously unevaluated left bundle branch block

Symptomatic Patients

- CCTA is being performed to avoid performing cardiac catheterization in patients with chest pain syndrome with intermediate pretest probability of CAD, uninterpretable ECG and are not able to exercise with no prior CCTA done within the last 12 months who have: [15, 16]
    - Equivocal, borderline, or discordant stress evaluation with continued symptoms concerning for CAD **(AUC 8)** [8]
    - Repeat testing in patient with new or worsening symptoms since prior normal stress imaging **(AUC Score 7)** [8]
    - Chest pain of uncertain etiology, when non-invasive tests are negative, but symptoms are typical and management requires that significant coronary artery disease be excluded **(AUC Score 7)** [8]

Heart Failure

- Newly diagnosed clinical systolic heart failure or diastolic heart failure, with reasonable suspicion of cardiac ischemia unless invasive coronary angiography is planned (SE diversion not required) [17, 18]**(AUC Score7)** [8]

Heart Valve

- Before valve surgery or transcatheter intervention as an alternative to coronary angiography [16, 19, 20]
- To establish the etiology of mitral regurgitation [20]
- Pre-TAVR evaluation as an alternative to coronary angiography [21, 22]

Heart Anomaly or Aneurysm

- Evaluation of coronary anomaly or aneurysm [23, 24, 25, 26, 27]
    - Evaluation prior to planned repair
    - Evaluation due to change in clinical status and/or new concerning signs or symptoms
    - Kawasaki disease and MIS-C follow up – for medium sized or greater aneurysms [28] periodic surveillance can be considered every 2-5 years. Once aneurysmal

size has reduced to small aneurysms, surveillance can be performed every 3-5 years. No further surveillance once normalized.

- Evaluation of suspected pulmonary embolism

NOTE: CMR is favored in younger patients for coronary anomaly evaluation [29, 23]

PCI or CABG

- Prior PCI or CABG history
  - Symptomatic patient with prior PCI or CABG history, with angina interfering in performing daily activities, despite being on guideline directed medical therapy, and with an equivocal stress test results. No prior CCTA done within the last 12 months **(AUC Score 7)** [8]
- Evaluation of coronary artery bypass grafts, to assess: [8, 30]
  - Patency and location when invasive coronary arteriography was either nondiagnostic or not performed/planned **(AUC Score 7)** [8]
  - Location of grafts prior to cardiac or another chest surgery **(AUC Score 7)** [8]

Limited Prior or Replacement Imaging

- CCTA may be performed in patients who cannot tolerate moderate sedation that is required during TEE, for pre procedural evaluation for Left Atrial Appendage Occlusion to look for LA/LAA thrombus, spontaneous contrast, LAA morphology and dimensions. *TEE however remains the preferred choice of modality for this procedure.*

Electrophysiologic Procedure Planning

- Evaluation of anatomy (pulmonary vein isolation planning) prior to radiofrequency ablation

Codings and Standards

CPT Codes: 75574
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

A coronary computerized tomography angiogram (CCTA) is a noninvasive imaging study that uses intravenously administered contrast material and high-resolution, rapid imaging computed tomography (CT). [31, 32]

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score – 4-6

Rarely Appropriate Care - Median Score 1-3

REDUCTION IN CCTA TEST QUALITY

The following can reduce the quality of the test in patients with: [8]

- Morbid Obesity
- High or irregular heart rates
- Severe coronary calcification

PATIENT SELECTION CRITERIA

Patient selection for CCTA must be considered and may be inappropriate for the following:

- Known history of severe and/or anaphylactic contrast reaction
- Inability to cooperate with scan acquisition and/or breath-hold instructions
- Pregnancy
- Clinical instability (e.g., acute myocardial infarction, decompensated heart failure, severe hypotension)
- Renal Impairment as defined by local protocols
- Image quality depends on keeping HR optimally < 60 bpm (after beta blockers), a regular rhythm, stents > 3.0 mm in diameter, and vessels requiring imaging ≥ 1.5 mm diameter [33]

DEFINITIONS

1. Stable patients without known CAD fall into 2 categories: [6, 7, 8]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section)
    - **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD

2. Three Types of Chest Pain or Discomfort:
    - **Typical Angina (Definite)** is defined as including ALL **3** characteristics:

    - Substernal chest pain or discomfort with characteristic quality and duration
    - Provoked by exertion or emotional stress
    - Relieved by rest and/or nitroglycerin
- **Atypical Angina (Probable)** has only **2** of the above characteristics
- **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics

3. The medical record should provide enough detail to establish the type of chest pain. From those details, The Pretest Probability of significant CAD is estimated from the Diamond Forrester Table below, recognizing that additional coronary risk factors could increase pretest probability: [8]

Diamond Forrester Table [34, 35]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very Low:** < 5% pretest probability of CAD
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

4. An uninterpretable baseline ECG includes: [6]
    - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST - T wave changes
    - Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
    - LVH with repolarization abnormalities, WPW, a ventricular paced rhythm, or left bundle branch block
    - Digitalis use with associated ST - T abnormalities
    - Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload
    - Note: RBBB with less than 1 mm ST depression at rest may be suitable for ECG treadmill testing

5. Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    a. > 40 ms (1 mm) wide
    b. > 2 mm deep
    c. > 25% of depth of QRS complex

6. ECG Stress Test Alone versus Stress Testing with Imaging
   Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise: [8]
    - The (symptomatic) low pretest probability patient who can exercise and has an interpretable ECG [8]
    - The patient who is under evaluation for exercise-induced arrhythmia
    - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
    - For the evaluation of syncope or presyncope during exertion [36]

7. Duke Exercise ECG Treadmill Score [37]
   Calculates risk from ECG treadmill alone**:**
    - Duke treadmill score (DTS) equation is:
      DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
    - The score ranges from - 25 to + 15 with values corresponding to low-risk (score of ≥ + 5), intermediate risk (scores ranging from - 10 to + 4), and high-risk (score of ≤ - 11) categories

8. Scenarios that can additionally support a CCTA over a regular exercise treadmill test in the low probability scenario [38]
    - Inability to Exercise
        - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
        - The patient has limited functional capacity (< 4 METS) such as **ONE** of the following:
            - Unable to take care of their activities of daily living (ADLs) or ambulate
            - Unable to walk 2 blocks on level ground
            - Unable to climb 1 flight of stairs
            - Unable to vacuum, dust, do dishes, sweep, or carry a small grocery bag
    - Other Comorbidities
        - Prior cardiac surgery (coronary artery bypass graft or valvular)

    - Left ventricular ejection fraction ≤ 50%
    - Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
    - Poorly controlled hypertension, with systolic blood pressure (BP) > 180 or Diastolic BP > 120
- ECG and Echo-Related Baseline Findings
    - Pacemaker or implantable cardioverter defibrillator (ICD)
    - Resting wall motion abnormalities on echocardiography
    - Complete LBBB
- Risk-Related scenarios
    - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs
    - Arrhythmia risk with exercise

9. Global Risk of Cardiovascular Disease
    - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
        - **CAD Risk—Low**
          10 - year absolute coronary or cardiovascular risk less than 10%
        - **CAD Risk—Moderate**
          10 - year absolute coronary or cardiovascular risk between 10% and 20%
        - **CAD Risk—High**
          10 - year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* [39, 40, 41, 42, 43]

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

With addition of Coronary Artery Calcium Score, for CAD-only risk	

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

10. **Definitions of Coronary Artery Disease** [6, 7, 44, 45, 46]
    Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
    - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a **risk stratification** tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
    - Stenoses ≥ 70% are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses ≤ 70% are considered non-obstructive coronary artery disease [44]
    - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
        - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69% [8]
        - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum luminal cross-sectional area on IVUS ≤ 6 square mm [6, 46, 45]
        - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [46, 45]
        - iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel [46, 47, 48, 49]
        - Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
    - A major vessel would be a coronary vessel that would be amenable to revascularization, if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
    - FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
    - Newer technology that estimates FFR from CCTA images is covered under the separate NIA Guideline for FFR-CT.

11. Anginal Equivalent [6, 36, 50]
    Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the

documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope, per se, is not an anginal equivalent.

ACRONYMS/ABBREVIATIONS

ACS	Acute coronary syndrome
ADLs	Activities of daily living
CABG	Coronary artery bypass grafting surgery
CAD	Coronary artery disease
CCS	Coronary calcium score
CCTA	Coronary computed tomography angiography
CT(A)	Computed tomography (angiography)
COPD	Chronic obstructive pulmonary disease
DTS	Duke Treadmill Score
ECG	Electrocardiogram
EF	Ejection fraction
FFR	Fractional flow reserve
ICD	Implantable cardioverter-defibrillator
iFR	Instantaneous wave-free ratio or instant flow reserve
IVUS	Intravascular ultrasound
LBBB	Left bundle branch block
LVH	Left ventricular hypertrophy
MESA	Multi-Ethnic Study of Atherosclerosis
METS	Metabolic equivalents
MI	Myocardial infarction
MPI	Myocardial perfusion imaging
PCI	Percutaneous coronary intervention
PFT	Pulmonary function test
RBBB	Right bundle branch block
SE	Stress echocardiography
TTE	Transthoracic echocardiography
WPW	Wolff-Parkinson-White syndrome

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Cardio Policy

Enhanced External Counter Pulsation

POLICY NUMBER UM CARDIO_1117	SUBJECT Enhanced External Counter-Pulsation (EECP)		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request (including list of current medications)
    - Records from last EECP treatment (if applicable)
    - Most recent Echocardiogram, Stress test
    - Most recent cardiac catheterization report
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

II. Purpose

Indications for determining medical necessity for Enhanced External Counter Pulsation (EECP).

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care [1, 2, 3, 4, 5]

IV. Indications for Enhanced External Counter Pulsation

An initial treatment course of 35 one-hour sessions, given 5 days per week will be considered for:

- Patients with chronic coronary disease, refractory angina pectoris, or with Class III or IV angina symptoms per New York Heart Association (NYHA) or Canadian Cardiovascular Society (CCS) and on maximally tolerated guideline-directed medical therapy (GDMT) [6, 7]
- Patients who are not amenable for revascularization either percutaneously (PCI) or surgically (CABG) due to [7]
    - Inoperative condition or high risk of operative complications or post-op failure
    - Recurrent angina pectoris despite multiple revascularization procedures

- Unsuitable coronary anatomy
- Additional co-morbid states which could create excessive risk.

Repeat courses of EECP will be considered on a case-by-case basis for patients with refractory angina pectoris if all the following criteria are met [7]

- Patients meets medical necessity criteria for EECP **AND**
- Prior EECP has resulted in a sustained improvement in symptoms, with a significant (greater than 25%) reduction in frequency of angina symptoms
- Improvement by one or more angina classes (NYHA or CCS) **AND**
- Three or more months has elapsed from the prior EECP treatment.

V. Contraindication of Enhanced External Counter Pulsation [6, 7]

- Decompensated heart failure
- Severe Aortic Regurgitation
- Severe Peripheral Artery Disease
- Recent myocardial infarction within the last 3 months
- Recent surgical intervention within the last 6 weeks
- Recent cardiac catheterization (1-2 weeks) or arterial femoral puncture
- Unstable angina pectoris
- Severe hypertension > 180/110 mm Hg
- Heart rate of <35 or >125 beats per minute
- Arrhythmias that interfere with EECP triggering
- Severe venous disease (thrombophlebitis, deep vein thrombosis, or pulmonary embolism)
- Severe lower extremity vaso-occlusive disease
- Presence of a documented aortic aneurysm requiring surgical repair
- Pregnancy

VI. Background

A. Definitions

Enhanced External Counter pulsation is a nonsurgical outpatient treatment of angina pectoris and coronary artery disease (CAD) refractory to medical and/or surgical therapy. This therapy increases blood flow to the heart by compressing blood vessels in the lower extremities. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient's cardiac cycle.

Although EECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force.

New York Heart Association Grading Scale for Heart Failure: [8]

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or chest pain.
- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or chest pain

- Class IV: Symptoms of heart failure at rest. Any physical activity causes further discomfort

Canadian Cardiovascular Society Grading Scale for Angina: [9]

- Class I: Ordinary physical activity does not cause angina, such as walking or climbing stairs. Angina occurs with strenuous, rapid or prolonged exertion.
- Class II: Slight limitation of ordinary activity. Angina occurs only during vigorous physical activity, such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals in cold, wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
- Class III: Marked limitation of ordinary physical activity. It is induced by walking one or two-level blocks and climbing one flight of stairs in normal conditions and at a normal pace
- Class IV: Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.

B. AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9
May be Appropriate Care - Median Score 4-6
Rarely Appropriate Care - Median Score 1-3

C. Acronyms/Abbreviations

CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CCS	Canadian Cardiovascular Society
EECP	Enhanced External Counter Pulsation
FDA	Food and Drug Administration
GDMT	Guideline-Directed Medical Therapy
NYHA	New York Heart Association
PCI	Percutaneous Coronary Intervention

VII. Coding and Standard

- **Primary codes**
  - G0166: A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week.
  - I20.0: Unstable angina
  - I20.1: Angina pectoris with documented spasm
  - I20.8: Other forms of angina pectoris
  - I20.9: Angina pectoris, unspecified

- **Review**
  - Utilization Management Department

- **Final Approval**
  - Utilization Management Committee

VIII. References

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Cardio Policy
Pharmacological Nuclear Stress Test/Myocardial Perfusion Imaging (MPI)

POLICY NUMBER UM CARDIO_1119	SUBJECT Pharmacological Nuclear Stress Test/Myocardial Perfusion Imaging (MPI)		DEPT/PROGRAM UM Dept	PAGE 1 OF 17
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 05/21/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/23/19, 07/30/19, 12/11/19, 05/13/20, 01/13/21, 03/10/21, 05/12/21, 07/14/21, 08/12/21, 11/10/21, 07/13/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 03/10/14, 05/21/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/23/19, 07/30/19, 12/11/19, 05/13/20, 01/13/21, 03/10/21, 05/12/21, 07/14/21, 08/12/21, 11/10/21, 07/13/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines, state/national recommendations, and CMS policies when applicable.

SPECIAL NOTE

Medical necessity for myocardial perfusion imaging (MPI) will consider the preference for appropriate alternatives, such as stress echocardiography (SE), when deemed more suitable, unless contraindications are present (see DEFINITIONS section). Preference toward stress echocardiography will be denoted by SE

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] .

INDICATIONS for MPI [6, 7, 8, 9, 10]

SUSPECTED CORONARY ARTERY DISEASE (CAD)

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** *The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the Diamond Forrester table in the Definitions section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to definitions) and utilized below.*
    - Less-likely anginal symptoms (AUC 4-6)
        - When a patient cannot walk a treadmill

        - When baseline EKG makes standard exercise test inaccurate (see Definitions section). (SE)
        - When a noncardiac explanation is provided for symptoms, no testing is required (AUC 8)

    - Likely Anginal Symptoms (typical angina)
        - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (AUC = 7). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
        - ≥ 50 year old (AUC 8)
    - Repeat testing in a patient with new or worsening symptoms **AND** negative result at least one year prior **AND** meets one of the criteria above. (SE)

- **Asymptomatic patients without known CAD AUC Score = 7**
    - A pharmacologic MPI is indicated for those unable to exercise with previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see DEFINITIONS section).
    - Previously unevaluated pathologic Q waves (see DEFINITIONS section)
    - Previously unevaluated complete left bundle branch block

ABNORMAL CALCIUM SCORES (CAC) [8, 11, 12, 13, 14]

AUC Score = 7

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months [9] (SE)
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months [9] (SE)
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior stress imaging done within the last 12 months (SE)

INCONCLUSIVE CAD EVALUATION AND OBSTRUCTIVE CAD REMAINS A CONCERN;

- Exercise stress ECG with low-risk Duke treadmill score (≥5), (see DEFINITIONS section) but patient's current symptoms indicate increasing likelihood of disease **AUC score = 8**
- Exercise stress ECG with an intermediate Duke treadmill score (SE) *(of note, SE diversion is not required* for symptoms consistent with likely anginal symptoms)
- Intermediate coronary computed tomography angiography (CCTA) (40 - 70% lesions) performed less than 90 days ago. **(AUC Score = 7)**

- Non-diagnostic exercise stress test with inability to achieve target heart rate (THR) defined as greater than 85% age predicted maximal heart rate by physiologic exercise). **AUC Score = 8**
- An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (SE or CMR) within the last 12 months
- Coronary stenosis of unclear significance on previous coronary angiography not previously evaluated [8]

FOLLOW-UP OF PATIENT'S POST CORONARY REVASCULARIZATION (PCI or CABG) [8]

- **Asymptomatic follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (whichever is later) is appropriate for patients with: (AUC = 6) SE *(of note, SE diversion is not required* for post CABG patients)
    - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
    - a history of silent ischemia or
    - a history of a prior left main stent

  OR

- For patients with high occupational risk, associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers and firefighters SE (of note, *SE diversion not required for post-CABG patients*)

- **New, recurrent, or worsening symptoms, treated medically or by revascularization** is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. (AUC Score 8) [9]

FOLLOW-UP OF KNOWN CAD

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or FFR ≤ 0.80 or significant stenosis in a major vessel (≥ 50% left main coronary artery or ≥ 70 % LAD, LCX, RCA)), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management. SE

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

AUC Score = 8

Unevaluated ACS

- Prior acute coronary syndrome (with documentation in MD notes), without invasive or non-invasive coronary evaluation within last 12 months
- Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has myocardial ischemia. No imaging stress test within the last 12 months

Heart Failure

- Newly diagnosed systolic heart failure or diastolic heart failure, *with reasonable suspicion of cardiac ischemia (prior events, risk factors*), unless invasive coronary angiography is immediately planned. [6, 15, 16, 17] No imaging stress test done within the last 12 months.

Viability

- LVEF requiring myocardial viability assessment to assist with decisions regarding coronary revascularization (AUC Score 9) [9, 8]

Suboptimal Revascularization

- MPI is being done to evaluate the effectiveness of the intervention in a high-risk patient who has undergone cardiovascular re-perfusion (CABG or Percutaneous Coronary Intervention, PCI) with suboptimal and/or incomplete revascularization results. No imaging stress test has been done within the last 12 months. (AUC Score 7) [9, 8]

Arrhythmias

- Ventricular arrhythmias (AUC Score = 7)
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not immediately planned [18]
    - Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, or frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed [19]

Anti-arrhythmic Drug Therapy

- Class IC antiarrhythmic drug
    - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide) in
    - annually intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide) [20]

Coronary Anomaly and Aneurism SE

- Assessment of hemodynamic significance of one of the following documented conditions:
    - Anomalous coronary arteries [21]
    - Myocardial bridging of coronary artery

- Coronary aneurysms in Kawasaki's disease [22] or due to atherosclerosis

Radiation and Chemotherapy (SE)

- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter [23]

Sarcoidosis and Amyloidosis (PYP study)

- Cardiac sarcoidosis: as a combination study with Heart PET for the evaluation and treatment of cardiac sarcoidosis [24]
- Cardiac amyloidosis: for the diagnosis of cardiac transthyretin amyloidosis (ATTR) **Not** to be used for the diagnosis of cardiac light chain amyloidosis (AL) [25]

PRIOR TO ELECTIVE NON-CARDIAC SURGERY IN ASYMPTOMATIC PATIENT

AUC score = 8

- An intermediate or high risk surgery with of one or more risk factors (see below), AND documentation of an inability to walk (or <4 METs) AND there has not been an imaging stress test within 1 year [26, 27, 28]
    - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL
    - **Surgical Risk:**
        - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
        - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
        - **Low risk surgery**: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative MPI, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service. [7, 29]

POST CARDIAC TRANSPLANT (SE diversion not required)

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

Codings and Standards

CPT Codes: 78451, 78452, 78453, 78454, 78466, 78468, 78469, 78481, 78483, 78499, +0742T, 93015, 93016, 93017, 93018, A9505, A9502, A9500, J1245, J0153, J2785, A9500
NCQA Standards: UM2

Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease and determining prognosis. Myocardial perfusion imaging is a cardiac radionuclide imaging procedure that evaluates blood flow to the cardiac muscle during rest or stress. Stress may be provided by exercise or with pharmacologic agents. A variety of radionuclides may be used, including Technetium tc-99M sestamibi, thallium201 and Technetiumtc-99M tetrofosmin.

For those patients who are unable to complete the exercise protocol without achieving >85% of predicted maximal heart rate, a pharmacological nuclear stress test is recommended. This testing method uses a drug to mimic the response of the cardiovascular system to exercise. Adenosine, Persantine, Dobutamine, or Regadenoson are vasodilators used in pharmacological nuclear stress testing. A gamma camera is used to record images in planar or tomographic (single photon emission computed tomography, SPECT) projections.

High global CAD risk is defined as 10-year CAD risk of >20%. CAD equivalents (e.g., DM, PAD) can also define high risk.

10 year CAD risk (%) is defined based on the risk factors- Sex, Age, Race, Total Cholesterol, HDL Cholesterol, Systolic Blood Pressure, and Treatment for High Blood Pressure, Diabetes Mellitus, and Smoker.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. Stable patients without known CAD fall into 2 categories: [6, 7, 8]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
    - **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD (below):

2. The medical record should provide enough detail to establish the type of chest pain:
    a. **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine or both.
    b. **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
3. **Risk Factors for Coronary disease include (but not limited to)**: diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.
4. Beginning 2023, the classification terms for angina were updated within the ACC's Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to "Typical Angina", "Atypical Angina" and "Non-Anginal" symptoms, defined by the Diamond Forrester Table. We still provide this information for your reference: [6, 7, 8]

Diamond Forrester Table [30, 31]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40-49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50-59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very low:** < 5%pretest probability of CAD, usually not requiring stress evaluation
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

5. An uninterpretable baseline ECG includes: [6]
    - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST - T wave changes
    - Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
    - Bundle Branch Blocks
    - LBBB
    - RBBB or IVCD, containing ST or T wave abnormalities
    - LVH with repolarization abnormalities

- ventricular paced rhythm
- Digitalis use with associated ST segment abnormalities
- Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload

6. Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    a. 40 ms (1 mm) wide
    b. 2 mm deep
    c. 25% of depth of QRS complex

7. ECG Stress Test Alone versus Stress Testing with Imaging
   Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise: [8]
    - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG [8]
    - The patient who is under evaluation for exercise-induced arrhythmia
    - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
    - For the evaluation of syncope or presyncope during exertion [32]

   When exercise cannot be performed, pharmacologic stress can be considered.

8. Duke Exercise ECG Treadmill Score [33]
   Calculates risk from ECG treadmill alone**:**
    - The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
    - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of ≥ + 5), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ - 11) categories

9. MPI may be performed without diversion to a SE in any of the following: [8, 34]
    - Inability to Exercise
        - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
        - Limited functional capacity (< 4 METS) **such as one** of the following:
        - Unable to take care of their ADLs or ambulate
        - Unable to walk 2 blocks on level ground
        - Unable to climb 1 flight of stairs
    - Other Comorbidities

        - Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
        - Poorly controlled hypertension, with systolic BP > 180 or diastolic BP > 120 (and clinical urgency not to delay MPI)
    - ECG and Echo-Related Baseline Findings
        - Prior cardiac surgery (coronary artery bypass graft or valvular)
        - Documented poor acoustic imaging window
        - Left ventricular ejection fraction ≤ 40%
        - Pacemaker or ICD
        - Persistent atrial fibrillation
        - Resting wall motion abnormalities that would make SE interpretation difficult
        - Complete left bundle branch block (LBBB)
    - Risk-Related scenarios
        - High pretest probability in suspected CAD
        - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs (prior to initiation of therapy and annually)
        - Arrhythmia risk with exercise
        - Previously unevaluated pathologic Q waves (in two contiguous leads)

10. Global Risk of Cardiovascular Disease
    - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
        - **CAD Risk—Low**
          10-year absolute coronary or cardiovascular risk less than 10%.
        - **CAD Risk—Moderate**
          10-year absolute coronary or cardiovascular risk between 10% and 20%.
        - **CAD Risk—High**
          10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* [35, 36, 37, 38, 39]

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/

Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

10. Definitions of Coronary Artery Disease [6, 7, 12, 40]
    Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
    - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
    - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
        - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69% [8]
        - For a left main artery, suggested by a percentage stenosis ≥ 50% [6, 40, 41]
        - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [40, 41]
        - Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
    - FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion. Less than or equal to 0.80 is considered a significant reduction in coronary flow.

11. Anginal Equivalent [6, 32]
    Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia). This may include respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

ACRONYMS / ABBREVIATIONS

ADLs	Activities of daily living
BSA	Body surface area in square meters
CABG	Coronary artery bypass grafting
CAD	Coronary artery disease
CMR	Cardiac magnetic resonance imaging
CTA	Computed tomography angiography
ECG	Electrocardiogram
FFR	Fractional flow reserve
IVUS	Intravascular ultrasound
LBBB	Left bundle-branch block
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
MI	Myocardial infarction
MET	Estimated metabolic equivalent of exercise
MPI	Myocardial perfusion imaging
PCI	Percutaneous coronary intervention
PFT	Pulmonary function test
PVCs	Premature ventricular contractions
SE	Stress echocardiography
THR	Target heart rate
VT	Ventricular tachycardia
VF	Ventricular fibrillation
WPW	Wolf Parkinson White

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Cardio Policy
Radionuclide Angiography/(MUGA SCAN)

POLICY NUMBER UM CARDIO_1120	**SUBJECT** Radionuclide Angiography/MUGA		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 06/10/20, 05/12/21, 07/14/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 06/10/20, 05/12/21, 07/14/21, 08/11/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE [1, 2, 3, 4]

Multiple-gated acquisition (MUGA) scanning uses radiolabeled red blood cells to scan right and left ventricular images in a cine loop format that is synchronized with the electrocardiogram.

A prior MUGA scan is not an indication for repeat MUGA (if another modality would be suitable, i.e., TTE).

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [5, 6, 7, 8, 9] .

Indications for Multiple Gated Acquisition (MUGA) Scan [10]

- To evaluate left ventricular function in a patient with coronary artery disease, valvular heart disease, myocardial disease, or congenital heart disease, in any of the following scenarios:
    - When ventricular function is required for management, and transthoracic echocardiography (TTE) or other imaging has proven inadequate [1, 11]
    - Radionuclide ventriculography is being performed for assessment of RV function with no prior MUGA done within the last 3 months

- In the course of treatment with cardiotoxic medication when TTE images are inadequate to evaluate left ventricular systolic function: [1, 12, 13, 14, 11]
    - Baseline assessment prior to initiation of therapy
    - Monitoring during therapy. The frequency of testing should be left to the discretion of the ordering provider but in the absence of new abnormal findings, generally no more often than every 6 weeks while on active therapy
    - Long term surveillance after completion of therapy may be required, especially for those who have been exposed to anthracycline medication. The frequency of testing is generally every 6-12 months, or at the discretion of the provider

CODING and STANDARDS

CPT Codes: 78472, 78473, 78494, +78496**,** A9560/A9512
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

The two types of radionuclide studies commonly used for cardiac evaluation are myocardial perfusion imaging and ventriculography. Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease. Ventriculography is sometimes referred to as multiple gated acquisition scanning (MUGA) and is primarily used to evaluate valvular disease and cardiomyopathies. Either type of study may be obtained at rest or stress.

Radionuclide Ventriculography is a medical imaging test used to determine a patient's cardiac function in the right, or more typically, left ventricle. Cardiac ventriculography involves injecting a radioisotope into the heart's ventricle(s) through a peripheral vein to measure the volume of blood pumped. Both regional and global left ventricular function (ejection fraction) as well as left ventricular size is measured.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [5]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

ACRONYMS/ABBREVIATIONS

EF	Ejection Fraction
MUGA	Multiple Gated Acquisition (nuclear scan of ventricular function)
TTE	Transthoracic echocardiography

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Cardio Policy

Transthoracic Echocardiography (TTE)

POLICY NUMBER UM CARDIO_1121	SUBJECT Transthoracic Echocardiography (TTE)		DEPT/PROGRAM UM Dept	PAGE 1 OF 34
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 05/21/14, 09/21/14, 11/12/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/24/19, 07/30/19, 12/11/19, 05/13/20, 07/31/20, 10/14/20, 01/13/21, 05/12/21, 07/21/21, 08/11/21, 11/10/21, 01/12/22, 02/09/22, 03/09/22, 12/14/22, 01/27/23, 02/01/23, 03/16/23, 05/10/23, 12/20/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 03/10/14, 05/21/14, 09/21/14, 11/12/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/24/19, 07/30/19, 12/11/19, 05/13/20, 07/31/20, 10/14/20, 01/13/21, 05/12/21, 07/21/21, 08/11/21, 11/10/21, 01/12/22, 02/09/22, 03/09/22, 12/14/22, 01/27/23, 02/01/23, 03/16/23, 05/10/23, 12/20/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE

Transthoracic echocardiography (TTE) uses ultrasound to image the structures of the heart providing 2-dimensional, cross-sectional images. The addition of Doppler ultrasound derives hemodynamic data from flow velocity versus time measurements, as well as from color-coded two-dimensional representations of flow velocities.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] .

INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) [6]
ADULT PATIENTS

(Indications for pediatric patients follow this section)

Evaluation of Cardiac Structure and Function

- When initial evaluation including history, physical examination, electrocardiogram (ECG), remote monitor or other testing suggests a cardiac etiology for symptoms, including but not limited to: **(AUC 9)** [7]
    - Chest pain when another study is not planned to evaluate
    - Shortness of breath
    - Palpitations
- Hypotension suggestive of cardiac etiology not due to other causes, such as: **(AUC 8)** [7]
    - Medications, dehydration, or infection
- ECG Abnormalities
    - Previously unevaluated pathological Q waves (in two contiguous leads) defined as the following:
        - 40 ms (1 mm) wide
        - > 2 mm deep
        - > 25% of depth of QRS complex
    - New left bundle branch block. **(AUC 7)** [7]
        - New isolated RBBB is **not** an indication for TTE.
    - Symptomatic or asymptomatic patients with previously unevaluated left ventricular hypertrophy (i.e., concern for hypertrophic cardiomyopathy). **(AUC 9)** [7]

Murmur or Click

- Initial evaluation when there is a reasonable suspicion for valvular or structural heart disease such as: **(AUC 9)** [8]
    - High grade ≥ 3/6: Note that TTE can be approved for documented concern that murmur suggests a **specific valve pathology** (such as “aortic valve sclerosis/stenosis” or “mitral regurgitation”) **regardless of grade of murmur**
    - Holosystolic
    - Continuous
    - Diastolic

Arrhythmias

- Frequent premature ventricular contractions (PVCs, greater than 30 per hour on remote monitoring or ≥ 1 PVC on 12 lead ECG) **(AUC 7)** [7]
    - Isolated premature atrial complexes (PACs) are not an indication for TTE.
- Sustained or nonsustained ventricular tachycardia (VT) or ventricular fibrillation (VF), or ventricular bigeminy **(AUC 9)** [7]
- New onset atrial fibrillation (as documented in MD notes and on ECG) which was not evaluated by a prior transthoracic echocardiogram (TTE) **(AUC 8)** [7]

- Initial evaluation of SVT seen on ECG or remote monitoring without other evidence of heart disease **(AUC 6)** [9]

Syncope [8, 9]

- History, physical examination, or electrocardiogram (ECG) consistent with a cardiac diagnosis known to cause presyncope or syncope, including but not limited to: **(AUC 9)** [7]
    - Structural heart disease (including but limited to):
        - Hypertrophic cardiomyopathy
        - Systolic heart failure
    - Exercise-induced syncope

  And not due to other causes such as:
    - Vaso-vagal syncope, neurogenic orthostatic syncope
    - Orthostasis related to medication or dehydration

Perioperative Evaluation [10, 11]

- Preoperative left ventricular function assessment in patients who are candidates for solid organ transplantation (can be done yearly prior to transplant) **(AUC 8)** [7]

Pulmonary Hypertension

- Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure **(AUC 9)** [7]
- Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam or a need to change medications [12] such as: **(AUC 8)** [7]
    - New chest pain
    - Worsening shortness of breath
    - Syncope
    - Increased murmur
    - Worsening rales on lung examination
- Initial evaluation of patients with pulmonary embolism to risk stratify and initiate appropriate therapy [13]
    - Repeat TTE can be approved for persistent dyspnea 3-6 months after PE [14] to evaluate for possible chronic thromboembolic pulmonary hypertension (CTEPH)
- Annual screening can be performed for pulmonary hypertension in patients with: [12, 15]
    - Scleroderma
    - Portal hypertension (including evaluation prior to TIPS procedure)
    - Carriers of Bone Morphogenic Protein Receptor 2 (BMPR2) mutation
    - Sickle cell disease

Known Valvular Heart Disease

Symptomatic

- ***New clinical signs and symptoms*** (SOB/fatigue) with known **mild** valvular heart disease or known **moderate to severe** valvular heart disease. **(AUC 9)** [8]

Native Valvular Stenosis [8]

Asymptomatic (Routine re-evaluation)

- Routine surveillance (≥ 3 yrs.) of bicuspid aortic valve, or mild valvular stenosis
- Re-evaluation (≥ 1 yr) of moderate stenosis
- Re-evaluation of severe aortic stenosis (AS) every 6 - 12 months
- Re-evaluation after control of hypertension in patients with low flow/low gradient severe aortic stenosis

Native Valvular Regurgitation [8, 17, 18]

- **Asymptomatic (Routine re-evaluation)**
  - ≥ 3 yrs. of mild valvular regurgitation **(AUC 8)** [8]
  - ≥ 1 yr. of moderate valvular regurgitation
  - Asymptomatic patient every 6 - 12 months with severe valvular regurgitation

Prosthetic Valves/Native Valve Repair [19]

- Initial evaluation of prosthetic valve or native valve repair, for establishment of baseline, typically 6 weeks to 3 months postoperative **(AUC 9)** [8]
- **Routine surveillance (Asymptomatic)**
  - Surgical bioprosthetic valve
    - Every 3 years after surgery **(AUC 7)** [8]
  - Surgical bioprosthetic and mechanical valve
    - 10 years postoperatively and annually thereafter **(AUC 9)** [8]
  - Surgical mitral valve repair
    - 1-year post-op and then every 2-3 years **(AUC 8)** [8]
- Evaluation of prosthetic valve or native valve repair with suspected dysfunction, with symptoms including but not limited to: **(AUC 9)** [8]
  - Chest pain
  - Shortness of breath
  - New or Increased murmur on heart examination
  - New rales on lung examination
  - Elevated jugular venous pressure on exam

Transcatheter Heart Interventions

Transcatheter Aortic Valve Replacement (TAVR) [8, 16, 20]

- Pre TAVR evaluation
- Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually **(AUC 8)** [8]
- Assessment post TAVR when there is suspicion of valvular dysfunction, including but not limited to: **(AUC 8)** [8]
    - Chest pain
    - Shortness of breath
    - New or increased murmur on heart examination
    - CVA post TAVR (AUC 7)
- Assessment of stroke post TAVR **(AUC 7)** [8]

Percutaneous Mitral Valve Repair (TMVR) [8, 16, 17]

- Pre-procedure evaluation **(AUC 8)** [8]
- Reassessment for degree of MR and left ventricular function (1, 6 months, and annually) **(AUC 9)** [7]
- Assessment post TMVR when there is suspicion of valvular dysfunction, including but not limited to: (AUC 8) [8]
    - Chest pain
    - Shortness of breath
    - New or increased murmur on heart examination
    - CVA post TMVR

Closure of PFO or ASD [7]

- Pre-procedure evaluation **(AUC 9)** [21]
- Routine follow-up post procedure for device position and integrity (see Table 2: Adult and Pediatric Congenital Heart Disease Follow-Up) **(AUC 9)** [21]
- Evaluation for clinical concern for infection, malposition, embolization, or persistent shunt **(AUC 9)** [21]
- Routine surveillance of an asymptomatic patient with a PFO is **not** indicated [21]

Left Atrial Appendage (LAA) Occlusion [7]

- Pre-procedure evaluation **(AUC 8)** [7]

Pericardial Disease [13, 7, 22, 23]

- Suspected pericarditis or pericardial effusion **(AUC 9)** [7]
- Re-evaluation of a significant known pericardial effusion when findings would lead to change in management **(AUC 7)** [7]

- Suspected pericardial constriction or reevaluation of status when management would be changed

Evaluation of Cardiac Source of Emboli or Cardiac Mass [8]

- Embolic source in patients with recent transient ischemic attack (TIA), stroke, or peripheral vascular emboli **(AUC 9)** [7]
- Evaluation of intracardiac mass or re-evaluation of known mass. No echo performed within the last three months [24] **(AUC 8)** [7]

Infective Endocarditis (Native or Prosthetic Valves) [8, 16, 25]

- Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur **(AUC 9)** [8]
- Re-evaluation
    - Infective endocarditis with, but not limited to: **(AUC 9)** [8]
        - Changing cardiac murmur
        - Evidence of embolic phenomena such as TIA or CVA
        - New chest pain, shortness of breath, or syncope
        - A need to change medications due to ongoing fever, positive blood cultures, or evidence of new AV block on ECG
    - Infective endocarditis at high risk of progression or complication (extensive infective tissue/large vegetation, or staphylococcal, enterococcal, or fungal infections) **(AUC 7)** [8]
- At completion of antimicrobial therapy and serial examinations at 1, 3, 6, and 12 months during the subsequent year [25]

Thoracic Aortic Disease [26, 27, 28, 29, 30, 31]

In the absence of recent computed tomography (CT) or cardiovascular magnetic resonance (CMR), which are preferred for imaging beyond the proximal ascending aorta

- Screening of first-degree relatives of individuals with:
    - Thoracic aortic aneurysm (defined as ≥ 50% above normal) or dissection
    - Bicuspid aortic valve
    - Presence of an aortopathic syndrome (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz, or Turner's)
- If one or more first-degree relatives of a patient with a known thoracic aortic aneurysm or dissection, have thoracic aortic dilatation, aneurysm, or dissection; then imaging of 2nd degree relatives is reasonable
- Six-month follow-up after initial finding of a dilated thoracic aorta
- Annual follow-up of enlarged thoracic aorta that is above top normal for age, gender, and body surface area

- Biannual (twice/year) follow-up of enlarged aortic root ≥ 4.5 cm or showing growth rate ≥ 0.5 cm in one year or ≥ 0.3cm per year in 2 consecutive years for sporadic aneurysms and ≥ 0.3cm in 1 year for heritable thoracic aortic disease or bicuspid aortic valve [27]
- Evaluation of the ascending aorta in known or suspected connective tissue disease or genetic conditions that predispose to aortic aneurysm or dissection (e.g., Marfan syndrome, Ehlers-Danlos or Loeys-Dietz syndromes) at time of diagnosis and 6 months thereafter for growth rate assessment, followed by annual imaging, or biannual (twice yearly) if diameter ≥ 4.5 or expanding ≥ 0.3 cm/yr. **(AUC 8)** [7]
- Turner's Syndrome:
    - Baseline evaluation at the time of diagnosis to assess for bicuspid aortic valve, coarctation of the aorta, aortic root and ascending aortic dilatation and other congenital defects.
    - Surveillance imaging (initial imaging normal and no additional risk factors for dissection such as HTN or bicuspid aortic valve):
        - Children: every 5 years
        - Adults: every 10 years
        - Prior to planned pregnancy
        - Annual imaging can be approved if an abnormality is found[27] (such as bicuspid aortic valve)
- Re-evaluation of known ascending aortic dilation or history of aortic dissection with one of the following:
    - New chest pain
    - Shortness of breath
    - Syncope
    - TIA or CVA
    - New or increased aortic valve murmur on clinical examination
    - New rales on lung examination or increased jugular venous pressure
    - **OR** when findings would lead to referral to a procedure or surgery
- Follow-up of aortic disease when there has been no surgical intervention:
    - Acute dissection: 1 month, 6 months, 12 months, then annually
    - Chronic dissection: annually
- Follow-up thoracic aortic aneurysm repair: chest CTA or chest MRA are the recommended surveillance imaging modalities.
- Follow-up post either: Root repair or AVR plus ascending aortic root/arch repair: baseline post-op, then annually
- Evaluation of sinus of Valsalva aneurysms and associated shunting secondary to rupture. [30]

Hypertension (HTN) (Adult) [7, 27]

- Initial evaluation of suspected hypertensive heart disease including but not limited to the following:

    - Left ventricular hypertrophy on ECG
    - Cardiomegaly
    - Evidence of clinical heart failure
- Initial evaluation of uncontrolled, resistant HTN without symptoms on three or more anti-hypertensive drugs.

Hypertension (HTN) (Pediatric) [32]

(AUC 9) [33]

- Initial evaluation at time of consideration of pharmacologic treatment of HTN
- Re-evaluation at 6–12-month intervals for:
    - Persistent HTN despite treatment
    - Concentric LVH on prior study
    - Reduced LVEF on prior study
- Re-evaluation of patients without LVH on initial evaluation can have TTE annually for:
    - Stage 2 HTN (BP ≥140/90 mmHg)
    - Secondary HTN
    - Chronic stage 1 HTN (BP between 130/80 mmHg and 139/89 mmHg) incompletely treated, including drug resistance and noncompliance

Heart Failure [7, 34, 35, 36]

- Initial evaluation of suspected HF (systolic or diastolic) based on symptoms, signs, or abnormal test result, including but not limited to: **(AUC 9)** [7]
    - Dyspnea
    - Orthopnea
    - Paroxysmal nocturnal dyspnea
    - Worsening edema
    - Elevated BNP
- Re-evaluation
    - Known HF (systolic or diastolic)
        - With a change in clinical status or cardiac exam (as listed above)
        - Asymptomatic patient with change in GDMT

Cardiomyopathy [7, 35, 36, 37, 38, 39]

- Initial evaluation of suspected inherited or acquired cardiomyopathy, including but not limited to: **(AUC 9)** [7]
    - Restrictive
    - Infiltrative/Depositional (i.e., hemochromatosis/iron overload, mucopolysaccharidoses, mitochondrial or metabolic storage disease (e.g., Danone disease, Fabry disease))

        - Fabry disease: annual surveillance TTE may be approved for patients receiving enzyme replacement [24]
    - Dilated
    - Hypertrophic
    - Re-evaluation of known cardiomyopathy if there is a need to monitor a change in medications or new symptoms, including but not limited to:
        - Chest pain
        - Shortness of breath
        - Palpitations
        - Syncope
- Heart failure (including Takotsubo cardiomyopathy) [24] with recovered left ventricular ejection fraction defined as (must meet all 3 criteria):
    - Documentation of a decreased LVEF <40% at baseline
    - ≥10% absolute improvement in LVEF
    - A second measurement of LVEF >40%: [40]
        - Repeat echocardiogram every 6 months until 12-18 months after recovery of EF, then annually for 2 years, then every 3-5 years
        - Higher risk patient (persistent left bundle branch block, genetic cardiomyopathy, higher biomarker profiles) may have annual follow-up
- Screening evaluation in first-degree relatives of a patient with an inherited cardiomyopathy **(AUC 9)** [7]
- Suspected cardiac sarcoidosis, including as a screening study in patients with biopsy proven extracardiac sarcoidosis [41]
- Suspected cardiac amyloid and to monitor disease progression and/or response to therapy, and to guide initiation and management of anticoagulation (TEE may be preferred) [39]
    - Light chain amyloidosis (AL): TTE may be repeated every 3-6 months
    - Transthyretin amyloidosis (ATTR): TTE may be repeated every 6-12 months [24]

Hypertrophic Cardiomyopathy (HCM) [38]

- Initial evaluation of suspected HCM
- Re-evaluation of patients with HCM with a change in clinical status or a new clinical event
- Evaluation of the result of surgical myomectomy or alcohol septal ablation
- Re-evaluation in patients with no change in clinical status or events every 1 - 2 years to assess degree of myocardial hypertrophy, dynamic obstruction, MR, and myocardial function
- Evaluation of patients with HCM who have undergone septal reduction therapy within 3-6 months after the procedure
- Screening for patients who are clinically unaffected or (genotype-positive and phenotype-negative):

    - Children and adolescents, every 1-2 years
    - Adults every 3-5 years
- Screening of first-degree relatives is recommended at the time HCM is diagnosed in the family member and serial follow-up as below:
    - Children and adolescents from genotype-positive families and families with early onset disease every 1-2 years
    - All other children and adolescents every 2-3 years
    - Adults every 3-5 years
- To guide therapy
    - Camzyos® (mevacamten): baseline TTE prior to initiation. Repeat TTE during therapy at the discretion of the ordering specialist. [42]

Imaging Surveillance for Cardiotoxic Exposures [43, 44]

- TTE is the method of choice for the evaluation of patients who will receive or have received cardiotoxic medication. TTE may be approved for:
    - Baseline assessment prior to initiation of therapy **(AUC 9)** [7]
    - Monitoring during therapy. The frequency of testing should be left to the discretion of the ordering physician, but in the absence of new abnormal findings, generally no more often than every 6 weeks while on active therapy. **(AUC 7)** [7]
    - Long term surveillance after completion of therapy may be required, especially for those who have been exposed to anthracycline medication. The frequency of testing is generally every 6-12 months, or at the discretion of the provider. (**AUC 7)** [7]

Imaging Surveillance for Previous Radiation Therapy with Cardiac Exposure [45]

- TTE is indicated for long term surveillance, generally at 5 years and at 10 years following radiation exposure. More frequent surveillance may be indicated at the discretion of the provider.

Device Candidacy or Optimization (Pacemaker, ICD, or CRT)

- Initial evaluation or re-evaluation after revascularization (≥ 90 days) and/or myocardial infarction (≥ 40 days) and/or 3 months of guideline-directed medical therapy when ICD is planned [46] **(AUC 9)** [7]
- Initial evaluation for CRT device optimization after implantation **(AUC 7)** [7]
- Re-evaluation for CRT device optimization in a patient with worsening heart failure **(AUC 8)** [7]
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings **(AUC 8)** [7]

Ventricular Assist Devices (VADs) and Cardiac Transplantation [7, 47]

- To determine candidacy for VAD **(AUC 9)** [7]
- Optimization of VAD settings and assessment of response post device **(AUC 8)** [7]
- Re-evaluation for signs/symptoms suggestive of VAD-related complications, including but not limited to: **(AUC 8)** [7]
    - TIA or stroke
    - Infection
    - Murmur suggestive of aortic insufficiency
    - Worsening heart failure

Post Heart Transplant Surveillance Imaging

- Monitoring at the discretion of the transplant center for rejection in a cardiac transplant recipient. [48] **(AUC 8)** [7]

Cardiovascular Disease in Pregnancy [37, 49]

- Valvular stenosis
    - Mild can be evaluated each trimester and prior to delivery
    - Moderate-severe can be evaluated monthly
- Valvular regurgitation
    - Mild-moderate regurgitation can be evaluated each trimester and prior to delivery
    - Severe regurgitation can be evaluated monthly
- Pre-pregnancy evaluation with mechanical or bioprosthetic heart valves (if not done within the previous year) **(AUC 9)** [8]
- Peripartum Cardiomyopathy: can be repeated at the end of the 1st and 2nd trimesters, 1 month prior to delivery, 1 month postpartum, and serially including up to 6 months after normalization of ejection fraction
- Aortopathic syndromes (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz Syndrome, or Turner's Syndrome) or known dilated aortic root or ascending aorta: may be approved for pre-pregnancy planning and for monitoring each trimester during pregnancy and again several weeks post-partum. More frequent imaging may be approved depending on aortic diameter, aortic growth rate and comorbidities predisposing to dissection (i.e., presence of an aortopathic syndrome, HTN). [27]

Adult Congenital Heart Disease [21, 50]

- Initial evaluation including history, physical examination, electrocardiogram (ECG), or other imaging modality suggest adult congenital heart disease
- Screening of first-degree relatives of patients with a bicuspid aortic valve **(AUC 8)** [8]

- Known adult congenital heart disease with a change in clinical status or cardiac exam, including but not limited to:
    - Chest Pain
    - Shortness of breath
    - New or increased murmur on physical exam
- Evaluation prior to surgical or transcatheter procedure
- For follow-up of specific lesions, see Table 1 **and** Table 2**: Adult and Pediatric Congenital Heart Disease Follow-up**

Inflammatory & Autoimmune

- Including any one of the following:
    - Suspected rheumatic fever [51]
    - Systemic lupus erythematosus [52]
    - Takayasu arteritis [53]
    - Multisystem Inflammatory Syndrome in children (MIS-C): at baseline and for surveillance when there is documented concern for coronary involvement or other late sequelae [54]
    - Kawasaki disease [55]
        - Upon diagnosis, 1-2 weeks later, and 4 to 6 weeks after diagnosis
        - For patients with important and evolving coronary artery abnormalities during the acute illness, echocardiograms may need to be more frequent. In the setting of increasing size of coronary aneurysms, echocardiogram can be performed up to twice per week until dimensions have stopped progressing, then at least once per week in the first 45 days of illness, and then monthly until the third month after onset.
        - For persistent coronary aneurysm after the acute illness, echocardiogram surveillance intervals are based on the size of the aneurysm:
            - Small: at 6 months. and then yearly
            - Medium: at 3, 6 and 12 months and then every 6-12 months
            - Large/Giant: at 3, 6, 9 and 12 months and then every 3-6 months

COVID-19 [56]

- Acute infection
    - Cardiopulmonary signs or symptoms (ECG abnormalities, elevated biomarkers, chest pain, dyspnea, syncope, palpitations)
- Post-Acute Sequelae (PASC) defined as new or returning cardiopulmonary symptoms 4 or more weeks and persisting more than 2 months following confirmed COVID infection, not explained by an alternative diagnosis (World Health Organization definition).
- Post Vaccination

- Symptoms or signs of myocarditis (ECG abnormalities, chest pain, elevated biomarkers)

Surveillance for Neuromuscular Disorders [57]

Asymptomatic surveillance intervals (genetically affected individuals with no signs or symptoms of cardiac involvement). Development of signs or symptoms of cardiac involvement necessitates more frequent assessment.

- Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD)
  - age <10 years, TTE every 2 years
  - age 10 years or older, TTE annually
- Emery-Dreifuss muscular dystrophy (EDMD)
  - X-linked form: at least annual TTE
  - Autosomal form: TTE at initial diagnosis, surveillance TTE only if initial TTE abnormal
- Myofibrillar myopathy (MFM)
  - Annual TTE
- Barth (BTHS)-X linked recessive (only males develop disease)
  - Infant males TTE every 6 months
  - Age 1 year or older, annual TTE
- Limb-Girdle muscular dystrophy (LGMD)
  - TTE may be performed annually
- Friedrich's ataxia (FA)
  - TTE can be performed at least annually
- Myotonic dystrophy (DM)
  - TTE every 2-4 years

INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) PEDIATRIC PATIENTS (PATIENTS UNDER THE AGE OF 18) [33]

- Hypertension (see section: Hypertension (Pediatric) **(AUC 9)** [33]
  - Initial evaluation (one time only)
  - Persistent hypertension despite two or more medications can be performed annually [58]
- Initial evaluation of Renal failure **(AUC 7)** [33]
- Palpitations, if one:
  - Family history at age < 50 of either: **(AUC 7)** [33]
    - Sudden cardiac death/arrest **OR**
    - Pacemaker or ICD
  - History or family history of cardiomyopathy **(AUC 9)** [33]
- Chest pain, if one or more of the following:
  - Exertional chest pain **(AUC 8)** [33]

    - Abnormal ECG **(AUC 7)** [33]
    - Family history with unexplained sudden death or cardiomyopathy **(AUC 8)** [33]
- Syncope, if any of the following:
    - Abnormal ECG **(AUC 7)** [33]
    - Exertional syncope **(AUC 9)** [33]
    - Family history at age < 50 of either one: **(AUC 9)** [33]
        - Sudden cardiac death/arrest **OR**
        - Pacemaker or ICD
    - Family history of cardiomyopathy
- Signs and/or symptoms of heart failure, including, but not limited to: **(AUC 9)** [33]
    - Respiratory distress
    - Poor peripheral pulses
    - Feeding difficulty
    - Decreased urine output
    - Edema
    - Hepatomegaly
- Abnormal physical findings, including any one of the following:
    - Clicks, snaps, or gallops
    - Fixed and/or abnormally split S2
    - Decreased pulses
    - Central cyanosis **(AUC 8)** [33]
- Arrhythmia, if one of the following:
    - Supraventricular tachycardia **(AUC 7)** [33]
    - Ventricular tachycardia **(AUC 9)** [33]
- Murmur
    - Pathologic sounding or harsh murmur, diastolic murmur, holosystolic or continuous murmur, late systolic murmur, grade 3/6 systolic murmur or louder, or murmurs that are provoked and become louder with changes in position **(AUC 9)** [33]
    - Presumptively innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease **(AUC 7)** [33]
- Abnormal basic data, including any one of the following:
    - Abnormal ECG **(AUC 7)** [33]
    - Abnormal cardiac biomarkers **(AUC 9)** [33]
    - Desaturation on pulse oximetry **(AUC 9)** [33]
    - Abnormal chest x-ray **(AUC 9)** [33]
- Sickle cell **(AUC 8)** [33]
    - One time screening for risk stratification for pulmonary hypertension in children ≥ 8 years of age [58]
- Suspicion of Structural Disease, including any one of the following:
    - Premature birth where there is suspicion of a Patent Ductus Arteriosus
    - Vascular Ring, based upon either one:

        - Difficulty breathing with stridor and eating solid foods that might suggest a vascular ring
        - Abnormal barium swallow or bronchoscopy suggesting a vascular ring **(AUC 7)** [33]
- Genetic & Syndrome Related, including any one of the following: **(AUC 7)** [33]
    - Genotype positive for cardiomyopathy, family history of hypertrophic cardiomyopathy or heritable pulmonary arterial hypertension
    - Patient with a known syndrome associated with congenital or acquired heart disease (Down's syndrome, Noonan's syndrome, DiGeorge syndrome, William's syndrome, Trisomy Thirteen, Trisomy Eighteen, Alagille syndrome, chromosomal abnormality associated with cardiovascular disease)
    - Abnormalities of visceral or cardiac situs
    - Known or suspected connective tissue diseases that are associated with congenital or acquired heart disease. (e.g., Marfan's, Loeys-Dietz)
    - Patients with a first-degree relative with a genetic abnormality, such as cardiomyopathies (hypertrophic, dilated, arrhythmogenic right ventricular dysplasia, restrictive, left ventricular noncompaction).
- Maternal-Fetal related, including any one of the following:
    - Maternal infection during pregnancy or delivery with potential fetal/neonatal cardiac sequelae **(AUC 7)** [33]
    - Maternal phenylketonuria **(AUC 7)** [33]
    - Suspected cardiovascular abnormality on fetal echocardiogram **(AUC 9)** [33]

CONGENITAL HEART DISEASE FOLLOW-UP‡* [21]

ADULT AND PEDIATRIC

[‡All surgical or catheter-based repairs allow evaluation PRIOR to the procedure and POSTPROCEDURAL evaluation (within 30 days)]

- For all lesions, TTE is indicated for change in clinical status and/or development of new signs or symptoms
- Infant with any degree of unrepaired valvular AS/AR may have surveillance TTE every 1 – 4 weeks as needed
- Surveillance interval for patients with subvalvular stenosis **plus** aortic regurgitation will be dictated by the magnitude of the more significant abnormality (e.g., mild stenosis with moderate regurgitation would have surveillance interval as though stenosis were also moderate).
- Infant with any degree of unrepaired MS may have surveillance TTE every 1 – 4 weeks as needed
- After any surgical or catheter-based repair, evaluation (3-12 months) for a patient with heart failure symptoms

- Annual surveillance in a child with normal prosthetic mitral valve function and no LV dysfunction
- Surveillance (3-12 months) in a child with prosthetic mitral valve and ventricular dysfunction and/or arrhythmia
- Annual surveillance for incomplete or palliative repair (including but not limited to Glenn shunt, Fontan procedure and RV-PA conduit)
- TTE may be unnecessary in a year when cardiac MRI is performed unless clinical indication warrants otherwise

[*Note: See tables below for specific surveillance intervals.]

Infancy is defined as between birth and 2 years of age; childhood from 2-12 years of age; and adolescence from 12 to 21 years of age [59]

Table 1: Unrepaired Lesion Follow-Up‡ [21]

‡Blue shading indicates lifetime surveillance interval

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Aortic Stenosis (AS) and/or aortic regurgitation (AR) (See section above for surveillance intervals for infants)			Child Asymptomatic ≥ moderate AS/AR	Child Asymptomatic mild AS/AR	
Bicuspid aortic valve with ≤ mild AS/AR and no aortic dilation in a child				For adolescent	**3 Years**
Atrial septal defect				**Moderate size (6-12mm)**	**Small size (3-6mm)**
Double outlet right ventricular (DORV): with balanced systemic and pulmonary circulation	Infant	Child			

Mitral regurgitation (MR)	Infant with ≥ moderate MR		Infant with mild MR. Child with ≥ moderate MR.		Child with mild MR (2-5 years)
Mitral Stenosis (MS) (See section above for surveillance intervals for infants)		Child with ≥ moderate MS		Child with mild MS	
Congenitally corrected transposition of the Great Arteries (ccTGA)		Infant	**Moderate or greater A-V valve regurgitation**	**< Moderate A-V valve regurgitation**	
Tricuspid regurgitation (TR)		Infant with ≥ moderate TR	Child with ≥ moderate TR	Child with mild TR	

Unrepaired Lesion	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
Patent Ductus Arteriosus		Infant		Child	**Adult**
Pulmonary stenosis (PS)		Infant		Child **Adult**	
Coarctation		Infant		Child **Adult**	
Ventricular septal defect (VSD)	Infant with ≥ moderate VSD			Child with non-muscular VSD	Child with small muscular VSD **Adult with any VSD**
Anomalous coronary arteries				**Moderate to large coronary fistula**	**Small coronary fistula or RCA arising from left coronary sinus (2-5 years)**
Subvalvular AS See section above for information on surveillance intervals for stenosis **plus** regurgitation	Infant with any degree of stenosis		Child with ≥ moderate stenosis **Adult with ≥ moderate stenosis**	Child with mild stenosis **Adult with mild stenosis**	

Supravalvular AS		Infant with any degree of stenosis	Child with ≥ moderate stenosis **Adult with ≥ moderate stenosis**	Child with mild stenosis **Adult with mild stenosis**	**2-5 years** **Adult with ≥ moderate stenosis**
Total anomalous pulmonary venous connection (TAPVC)	Prior to planned repair or for change in clinical status and/or development of new signs and symptoms				

Note: Despite surgical or catheter-based procedures, most patients with congenital heart disease are left with disorders or **sequelae** that are known consequences of the reparative intervention. These disorders can include arrhythmias, valvular and myocardial dysfunction, and vascular and non-cardiovascular abnormalities. These sequelae can be categorized as mild, moderate, or severe. Use clinical judgement to assess the nature of the sequelae when adjudicating cases based on the follow-up criteria below.

Table 2: Postprocedural Follow-up‡ [21]

‡Blue shading indicates lifetime surveillance interval

Post-procedure: Surgical or Catheter-Based	Surveillance Intervals				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
Post-procedural treatment of AS or AR with repair or replacement	Infant with ≥ moderate AS or AR or LV dysfunction	Infant with ≤ mild AS or AR and no LV dysfunction	Child with ≥ moderate AS or AR	Child with ≤ mild AS or AR	
ASD device closure: no or mild sequelae	Within 1st year	Within 1st year	At 1 year		**2-5 years**
ASD surgical repair: no or mild sequelae			Within 1st year		**2-5 years**
ASD: device closure or surgical repair with residual shunt,		**3-12 months**			

valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension					
DORV: no or mild sequelae			Within 1st year	**1-2 Years**	
DORV: valvular or ventricular dysfunction, outflow obstruction, arrythmias, branch pulmonary artery stenosis, presence of RV-PA conduit		**3-12 months**			

Post-procedure: Surgical or Catheter-Based	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
Tricuspid valve surgery or catheter-based procedure: no or mild sequelae				**1-2 years**	
Tricuspid valve surgery or catheter-based procedure: valvular or ventricular dysfunction or arrhythmias			Child	**Adult**	
Pulmonary Stenosis: no or mild sequelae			Child with moderate or severe sequelae	Child with no or mild sequelae	**Adult**
Coarctation:		Within 1st year		**After 1st year**	

no or mild sequelae					
PDA: no or mild sequelae				Annually within 1st two years	**Five years after 1st two years***
PDA: post-procedural left PA stenosis or aortic obstruction				**1-2 years**	
Tetralogy of Fallot (ToF): after transcatheter pulmonary valve replacement, with no or mild sequelae	1 month	6 months		**Annually**	
Post-Procedure: Surgical or Catheter-Based	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
ToF: patient with conduit dysfunction valvular or ventricular dysfunction, pulmonary artery stenosis, or arrhythmias			**6-12 months**		
Congenitally corrected transposition on the Great Arteries (ccTGA): no or mild sequelae		Within 1st year		**1-2 years**	
ccTGA: valvular or ventricular dysfunction, outflow obstruction,		**3-12 months**			

ventricular - PA conduit					
d-TGA: no or mild sequelae	Infant with moderate sequelae	Within 1st year		**1-2 years**	
d-TGA: moderate or greater valvular or ventricular dysfunction, outflow obstruction, branch pulmonary artery stenosis or arrhythmias, presence of RV-PA conduit		**3-12 months**			
Post-Procedure: Surgical or Catheter-Based	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
d-TGA: dilated neoaortic root and increasing Z-Score or neoaortic regurgitation				**1-2 years**	
Truncus Arteriosus (TA): no or mild sequelae	Within 1st year		**After 1st year**		
TA: moderate or greater truncal stenosis / regurgitation		**3-6 months**			
TA: residual VSD, RV-PA conduit, branch		**3-12 months**			

pulmonary artery obstruction					
VSD: no or mild sequelae or small residual shunt			Within 1st year		**2-3 years**
VSD: significant residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		**3-12 months**			
Post-procedure: Surgical or Catheter-Based	**Surveillance Intervals**				
	1-3 months	**3-6 months**	**6-12 months**	**1-2 years**	**3-5 years**
Anomalous coronary arteries	Within 1st year	Infant with or without ventricular or valvular dysfunction Child or adult with ventricular or valvular dysfunction		**Annually**	
Subvalvular AS See section above for information on surveillance intervals **plus** regurgitation	Infant with ≥ moderate stenosis	Infant with ≤ mild stenosis		Child with ≤ mild stenosis and/or AR **Adult with ≤ mild stenosis and/or AR**	
Subvalvular AS *continued*		3-12 months Child ≥ moderate stenosis **3-12 months**			

		Adult ≥ moderate stenosis			
Supravalvular AS			**Patient with ≥ moderate stenosis**		**2-5 years Patient with ≤ mild stenosis**
Total anomalous pulmonary venous connection		Infant with mild or no sequelae		Child with mild or no sequelae	**Adult with mild or no sequelae**

***PDA lifetime surveillance applies only to device closure; PDA lifetime surveillance is not indicated for surgical closure.**

Codings and Standards

CPT Codes: 93303, 93304, 93306, 93307, 93308, +93320, +93321, +93325, +93356, **93674**
NCQA Standards: UM2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

ACRONYMS/ ABBRVIATIONS

AS	Aortic stenosis
AR	Aortic regurgitation
ASD	Atrial septal defect
BNP	B-type natriuretic peptide or brain natriuretic peptide
CABG	Coronary artery bypass grafting surgery
CAD	Coronary artery disease
ccTGA	Congenitally corrected transposition of the Great Arteries
CMR	Cardiovascular magnetic resonance
CRT	Cardiac resynchronization therapy
CT	Computed tomography
CVA	Cerebrovascular accident
DORV	Double outlet right ventricle
d-TGA	D-Transposition of the Great Arteries
ECG	Electrocardiogram
EF	Ejection fraction
HCM	Hypertrophic cardiomyopathy
HTN	Hypertension
HF	Heart failure
ICD	Implantable cardioverter-defibrillator
LAA	Left atrial appendage
LV	Left ventricular/ventricle
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
MI	Myocardial infarction
MR	Mitral regurgitation
MS	Mitral stenosis
PA	Pulmonary artery
PAC	Premature atrial complex
PDA	Patent ductus arteriosus
PFO	Patent foramen ovale
PS	Pulmonary stenosis
PVC	Premature ventricular contraction
RV	Right ventricular/ventricle
TA	Truncus arteriosus
TAVR	Transcatheter aortic valve replacement
TEE	Transesophageal echocardiogram
TIA	Transient ischemic attack
ToF	Tetralogy of Fallot
TR	Tricuspid regurgitation
TTE	Transthoracic echocardiogram
VAD	Ventricular assist device

VF	Ventricular fibrillation
VSD	Ventricular septal defect
VT	Ventricular tachycardia

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Cardio Policy

Transesophageal Echocardiography (TEE)

POLICY NUMBER UM CARDIO_1122	**SUBJECT** Transesophageal Echocardiography (TEE)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 10**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 05/21/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 03/10/21, 08/11/21, 02/09/22, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 05/08/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 03/10/14, 05/21/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 03/10/21, 08/11/21, 02/09/22, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 05/08/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

PURPOSE

Transesophageal echocardiography (TEE) enables cardiac ultrasound imaging from within the esophagus, which provides a window for enhanced quality images as well as additional views, beyond that acquired by standard transthoracic echocardiography (TTE).

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] **.**

INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

General Criteria [6, 7, 8, 9, 10]

- TEE may be performed after a nondiagnostic transthoracic echocardiogram (TTE) due to inadequate visualization of relevant structures, or if there is a high likelihood of a nondiagnostic TTE **(AUC 7)** [11]

Aortic Pathology

- Suspected acute aortic pathology, such as aortic dissection [6, 12]
- Dilated aortic sinuses or ascending aorta on TTE **(AUC 7)** [11]

- Evaluation of aortic sinuses, sinotubular junction, or ascending aorta in patients with bicuspid aortic valve when morphology cannot be assessed by TTE, and other imaging including CT or MRI (Magnetic Resonance Imaging) have not been done **(AUC 7)** [11]

Valvular Disease [6, 13]

- Discordance between clinical assessment and TTE assessment of the severity of mitral regurgitation (MR) **(AUC 9)** [6]
- Evaluation of mitral stenosis, when there is a discrepancy between clinical signs or symptoms, and TTE is inadequate
- Discordance between clinical assessment and TTE assessment of the severity of aortic regurgitation (AR) **(AUC 8)** [6]
- Evaluation of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE is inadequate **(AUC 8)** [6]
- Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy, (and TTE is inadequate) **(AUC 7)** [6]

Infective Endocarditis [6, 14, 15]

- Suspected infective endocarditis (IE) of native valve, prosthetic valve, or endocardial lead with positive blood culture or new murmur **(AUC 8)** [6]
- Moderate to high pretest probability of IE (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative **(AUC 9)** [6]
- Re-evaluation of IE in a patient with a change in clinical status or cardiac examination (e.g., new murmur, embolism, persistent fever, heart failure (HF), abscess, or atrioventricular block) **(AUC 8)** [6]
- Re-evaluation of IE if the patient is at elevated risk for progression/complications or when the findings alter therapy, when TTE is inadequate

Cardiac Mass or Source of Emboli

- Initial evaluation of patient to exclude cardiac origin of TIA or ischemic stroke [6] **(AUC 7)** [6]
- Evaluation of cardiac mass, suspected tumor, or thrombus, when other cardiac imaging is inconclusive [6, 15]
- Re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation), when the findings would change therapy **(AUC 7)** [6]

Atrial Fibrillation/Flutter [6]

- Evaluation for clinical decision-making regarding anticoagulation, cardioversion, and/or radiofrequency ablation

TAVR (Transcatheter Aortic Valve Replacement/Repair) [6, 16]

(AUC Score 7) [6]

- Pre-procedural assessment of annular size and shape, number of cusps, and degree of calcification, when computed tomography (CT) or CMR (Cardiovascular Magnetic Resonance) cannot be performed
- Post-procedural assessment of degree of aortic regurgitation (including valvular and paravalvular) with suspicion of valve dysfunction, if TTE is inadequate

Patent Foramen Ovale or Atrial Septal Defect [6, 17]

(AUC Score 8) [11]

- Evaluation for anatomy, potential cardiac source of emboli, and suitability for percutaneous device closure
- Evaluation post device closure with clinical concern for infection, malposition, embolization, or persistent shunt

Left Atrial Appendage Occlusion [11]

- Evaluation of anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement **(AUC 9)** [11]
- Surveillance at 45 days and 1 year or FDA (U.S. Food and Drug Administration) guidance/guidelines for follow-up to assess device stability and device leak, and exclude migration, displacement, or erosion [18, 19] **(AUC 8)** [11]
    - Reassessment at 6 months if 45-day TEE shows incomplete closure of left atrial appendage [18, 19]

Percutaneous Mitral Valve Repair [6]

- Determination of patient eligibility for percutaneous mitral valve procedures **(AUC 9)** [6]
- Procedural evaluation for percutaneous mitral valve procedures may be performed in addition to CT imaging [20]
- To exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days of) the procedure **(AUC 9)** [6]

Hypertrophic Cardiomyopathy [21]

- When TTE is inconclusive in planning for myectomy,[17] to exclude subaortic membrane or mitral regurgitation, or to assess need for septal ablation

Adult Congenital Heart Disease [17, 22]

- Imaging with provocative maneuvers (Valsalva, cough) to assess the presence of right-to-left cardiac shunt **(AUC 7)** [17]
- Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
    - Isolated secundum atrial septal defect **(AUC 7)** [17]
    - Sinus venosus defect and/or partial anomalous pulmonary venous connection **(AUC 7)** [17]
    - Congenital mitral stenosis or mitral regurgitation **(AUC 7)** [17]
    - Subvalvular aortic stenosis **(AUC 7)** [17]
    - Transposition of the Great Arteries **(AUC 8)** [17]
- Evaluation postoperative or post catheter-based repair due to change in clinical status and/or new concerning signs or symptoms when TTE, CMR, or CT are not adequate **(AUC 7)** [17]

Ventricular Assist Devices [6, 23]

- Preoperative evaluation of suitability for ventricular assist device (VAD)
- Re-evaluation of VAD-related complication or suspected infection **(AUC 7)** [11]

Codings and Standards

CPT Codes: 93312, 93313, 93314, 93315, 93316, 93317, 93318, 93319, +93320, +93321, +93325, 93674
NCQA Standards: UM2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

AUC Score:

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

ACRONYMS/ABBREVIATIONS

AR	aortic regurgitation
CMR	cardiac magnetic resonance
CT(A)	computed tomography (angiography)
HF	heart failure
IE	infective endocarditis
MR	mitral regurgitation
MRI	magnetic resonance imaging
TAVR	transcatheter aortic valve replacement/repair
TEE	transesophageal echocardiography
TIA	transient ischemia attack
TTE	transthoracic echocardiography
VAD	ventricular assist device

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Cardio Policy
Stress Echocardiography

POLICY NUMBER UM CARDIO_1123	SUBJECT Stress Echocardiography with or without doppler		DEPT/PROGRAM UM Dept	PAGE 1 OF 18
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 05/21/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/08/19, 09/11/19, 12/11/19, 05/13/20, 01/13/21, 03/10/21, 06/09/21, 08/11/21, 02/09/22, 07/13/22, 12/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 03/10/14, 05/21/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 04/08/19, 09/11/19, 12/11/19, 05/13/20, 01/13/21, 03/10/21, 06/09/21, 08/11/21, 02/09/22, 07/13/22, 12/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE

This guideline is for stress imaging, specifically Stress Echocardiography (SE) with appropriate preference for suitable alternatives, such as an exercise treadmill exam without imaging, when more suitable, unless otherwise stated (refer to **Background section**)**.**

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] **.**

INDICATIONS for STRESS ECHO [6, 7, 8]

SUSPECTED CORONARY ARTERY DISEASE (CAD)

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** *The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the Diamond Forrester table in the Definitions section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to definitions) and utilized below.*
    - Less-likely anginal symptoms (AUC 4-6)
        - When baseline EKG makes standard exercise test inaccurate (see Definitions section).

        - When a noncardiac explanation is provided for symptoms, no testing is required (AUC 8)

    - Likely Anginal Symptoms (typical angina)
        - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (AUC = 7). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
        - ≥ 50 year old (AUC 8)
    - Repeat testing in patient with new or worsening symptoms and negative result at least one year ago AND meets one of the criteria above

- **Asymptomatic patients without known CAD**
    - Previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see Background section)
    - Previously unevaluated pathologic Q waves (see Background section)
    - Previously unevaluated complete left bundle branch block

ABNORMAL CALCIUM SCORES (CAC) [6, 9, 10, 11, 12]

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months [9]
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months [9]
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior stress imaging done within the last 12 months

INCONCLUSIVE CAD EVALUATION AND OBSTRUCTIVE CAD REMAINS A CONCERN

- Exercise stress ECG with low-risk Duke treadmill score ≥5, but patient's current symptoms indicate an indicate increasing likelihood of disease
- Exercise stress ECG with an intermediate Duke treadmill score
- A previously unevaluated ventricular wall motion abnormality demonstrated by another imaging modality and stress echo is being performed to determine if the patient has myocardial ischemia. [14, 6] **(AUC Score 8)** [6]
- Intermediate coronary computed tomography angiography (CCTA) defined as:
    - 40 -70% lesion
- Coronary stenosis of unclear significance on previous coronary angiography not previously evaluated [6]

FOLLOW-UP OF PATIENTS POST CORONARY REVASCULARIZATION (PCI or CABG) [15]

- **Asymptomatic follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (whichever is later) is appropriate for patients with: (AUC = 6)
    - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
    - a history of silent ischemia or
    - a history of a prior left main stent

  OR
- For patients with high occupational risk, associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers and firefighters
- **New, recurrent, or worsening symptoms, treated medically or by revascularization** is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. (AUC Score 8) [9]

FOLLOW-UP OF KNOWN CAD

- **Routine follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or FFR ≤ 0.80 or significant stenosis in a major vessel (≥ 50% left main coronary artery or ≥ 70% LAD, LCX, RCA)), over two years ago without intervening coronary revascularization, is an appropriate indication for stress imaging

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

- Prior acute coronary syndrome (with documentation in MD notes), within last 12 months, without a prior stress test or coronary angiography performed since that time
- Newly diagnosed systolic heart failure or diastolic heart failure, ***with reasonable suspicion of cardiac ischemia (prior events, risk factors*)**, unless invasive coronary angiography is immediately planned [9, 15] **(AUC Score 8)** [6]
- Ventricular arrhythmias:
  AUC Score = 7 [6]
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography has not been performed [16]
    - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring), when an exercise ECG cannot be performed [16]
- For intermediate and high-risk global patients who require initiation of Class IC antiarrhythmic drugs. It can be performed annually thereafter until discontinuation of drug use [17] **(AUC Score 7)** [6]

- Hemodynamic assessment of ischemia in one of the following documented conditions:
    - Anomalous coronary arteries in an asymptomatic individual without prior stress echocardiography; [18]
    - Myocardial bridging of a coronary artery [19]
- Coronary aneurysms in Kawasaki's disease [20]
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter [21]

CHRONIC VALVULAR DISEASE

Evaluation with Inclusion of Doppler [22, 13, 23, 24]

- For the evaluation of aortic stenosis and flow (contractile) reserve in symptomatic patients with severe aortic stenosis by calculated valve area, low flow / low gradient, and ejection fraction < 50% **(AUC Score 8)** [25]
- For evaluation of asymptomatic moderate or severe aortic stenosis (AS) for measurement of changes in valve hemodynamics **(AUC Score 8)** [25]
- Non-severe aortic regurgitation (AR) with symptoms: Assessment of functional capacity and to assess for other causes of symptoms [15, 6] **(AUC Score 7)** [25]
- For evaluation of mitral stenosis (MS) if there is:
    - Exertional shortness of breath which suggests the amount of MS is worse than is seen on the resting echocardiogram **(AUC Score 8)** [25]
- For evaluation for mitral regurgitation (MR) if there is:
    - Exertional shortness of breath which suggests the amount of MR is worse than is seen on the resting echocardiogram, **(AUC Score 8)** [25] **OR**
    - The echocardiogram is not able to distinguish whether the MR is moderate or severe in a patient that is asymptomatic **(AUC Score 7)** [25]
- For symptomatic patients with HCM, who do not have resting or provocable outflow tract gradient ≥50 mm Hg on TTE, for detection and quantification of dynamic LVOT obstruction [26]
- For asymptomatic patients with HCM who do not have a resting or provocable outflow tract gradient ≥ 50 mm Hg on TTE (Class 2A)

DIASTOLIC FUNCTION

- For unexplained dyspnea and suspected heart failure with preserved LVEF [6] (HFpEF) with normal or equivocal diastolic function on resting images

PRIOR TO ELECTIVE NON-CARDIAC SURGERY [7, 27, 28, 29]

- An intermediate or high-risk surgery with of one or more risk factors (see below), AND documentation of an inability to walk (or <4 METs) **AND** there has not been an imaging stress test within 1 year [27, 29, 30] **(AUC Score 8)**

- **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL.
- **Surgical Risks:**
  - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
  - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
  - **Low risk surgery**: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery

PRE ORGAN-TRANSPLANT

- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service. [7, 31] **(AUC Score 8)**

POST CARDIAC TRANSPLANTATION

- Annually, post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

Codings and Standards

CPT Codes: 93350, 93351, +93320, +93321, +93325, +93352, +93356
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

Stress echocardiography is an exercise stress test which utilizes echocardiography to provide information on exercise tolerance, ischemic burden, and structural heart disease including valvular disease and provides analysis of left ventricular function.

Stress echocardiography (SE) refers to ultrasound imaging of the heart during exercise electrocardiography (ECG) testing, during which visualized wall motion abnormalities can provide evidence of potential significant coronary artery disease (CAD).

While drug-induced stress with dobutamine can be an alternative to exercise stress testing in patients who are unable to exercise, this guideline does not require use of this modality. Hence, reference in this document to SE predominantly refers to exercise stress echocardiography.

Although SE provides comparable accuracy without radiation risk, relative to myocardial perfusion imaging (MPI), scenarios which do not permit effective use of SE might be better suited for stress imaging with MPI, cardiovascular magnetic resonance imaging (CMR) or positron emission tomography (PET), or coronary computed tomography angiography (CCTA).

Cardiac Doppler ultrasound is a form of ultrasound that can detect and measure blood flow. Doppler ultrasound depends on the Doppler Effect, a change in the frequency of a wave resulting from the motion of a reflector, the red blood cell. There are three types of Doppler ultrasound performed during a cardiac Doppler examination:

- Pulsed Doppler
- Continuous wave Doppler
- Color flow Doppler

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. Stable patients without known CAD fall into 2 categories: [6, 7, 8]
    - **Asymptomatic patients**, for whom Global Risk of CAD events can be determined from coronary risk factors using calculators available online (see Websites for Global Cardiovascular Risk Calculators section)
    - **Symptomatic patients,** for whom we estimate the Pretest Probability that their chest-related symptoms are due to clinically significant CAD (see below):
2. The medical record should provide enough detail to establish the type of chest pain:
    a. **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine or both.
    b. **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
3. **Risk Factors for Coronary disease include (but not limited to)**: diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.

4. Beginning 2023, the classification terms for angina were updated within the ACC's Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to "Typical Angina", "Atypical Angina" and "Non-Anginal" symptoms, defined by the Diamond Forrester Table. We still provide this information for your reference: [6, 7, 8]

Diamond Forrester Table [34, 35]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very low:** < 5% pretest probability of CAD, usually not requiring stress evaluation[3]
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

5. MPI may be performed without diversion to SE in any of the following: [6, 36]
    - Inability to exercise
        - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
        - Limited functional capacity (< 4 metabolic equivalents) **such as one** of the following:
            - Cannot take care of their activities of daily living (ADLs) or ambulate
            - Cannot walk 2 blocks on level ground
            - Cannot climb 1 flight of stairs
            - Cannot vacuum, dust, do dishes, sweep, or carry a small grocery bag
    - Other Comorbidities
        - Severe chronic obstructive pulmonary disease with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
        - Poorly controlled hypertension, with systolic BP > 180 or Diastolic BP > 120 (and clinical urgency not to delay MPI)

- ECG and Echo-Related Baseline Findings
    - Prior cardiac surgery (coronary artery bypass graft or valvular)
    - Documented poor acoustic imaging window
    - Left ventricular ejection fraction ≤ 40%
    - Pacemaker or ICD
    - Persistent atrial fibrillation
    - Resting wall motion abnormalities that would make SE interpretation difficult
    - Complete LBBB
- Risk-related scenarios
    - High pretest probability in suspected CAD
    - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs (prior to initiation of therapy and annually)
    - Arrhythmia risk with exercise
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    a. 40 ms (1 mm) wide
    b. 2 mm deep
    c. 25% of depth of QRS complex

6. ECG Stress Test Alone versus Stress Testing with Imaging
   Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) are inferred from the guidelines presented above, often requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise: [6]
    - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG
    - The patient who is under evaluation for exercise-induced arrhythmia[9]
    - For the evaluation of syncope or presyncope during exertion[27]
    - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription

   When exercise cannot be performed, pharmacologic stress can be considered.

7. Duke Exercise ECG Treadmill Score [37]
   Calculates risk from ECG treadmill alone**:**
    - The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
    - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of ≥ + 5), intermediate risk (with scores ranging from - 10 to + 4),

and high-risk (with a score of ≤ -11) categories.

8. An uninterpretable baseline ECG includes: [8]
    - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST- T wave changes
    - Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
    - LVH with associated STT abnormalities, pre-excitation pattern such as WPW, a ventricular paced rhythm, or left bundle branch block
    - Digitalis use
    - Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload

9. Global Risk of Cardiovascular Disease
    - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. There are rare exemptions, such as patients requiring IC antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug.
        - **CAD Risk—Low**
          10-year absolute coronary or cardiovascular risk less than 10%.
        - **CAD Risk—Moderate**
          10-year absolute coronary or cardiovascular risk between 10% and 20%.
        - **CAD Risk—High**
          10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* [38, 39, 40, 41, 42]

Risk Calculator	Link to Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/

MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have known CAD are already at high global risk and are not applicable to the calculators.

10. **Definitions of Coronary Artery Disease** [7, 8, 10, 43, 44]
    Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
    - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into Global Risk can be achieved by using the MESA risk calculator.
    - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate), generally implies at least one of the following:
        - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69% [6]
        - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross-sectional area on IVUS ≤ 6 square mm [8, 44, 45]
        - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [44, 45]
    - FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow

11. Anginal Equivalent [8, 46, 47]
    Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia). This may include respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

ACRONYMS/ABBREVIATIONS

AAD	Antiarrhythmic drug
ADLs	Activities of daily living
BSA	Body surface area in square meters
CABG	Coronary artery bypass grafting surgery
CAC	Coronary artery calcium
CAD	Coronary artery disease
CCTA	Coronary computed tomography angiography
CMR	Cardiovascular magnetic resonance imaging
CT(A)	Computed tomography (angiography)
DTS	Duke Treadmill Score
ECG	Electrocardiogram
FFR	Fractional flow reserve
HCM	Hypertrophic cardiomyopathy
IVUS	Intravascular ultrasound
LBBB	Left bundle-branch block
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
LVOT	Left ventricular outflow tract
MESA	Multi-Ethnic Study of Atherosclerosis
MET	Estimated metabolic equivalent of exercise
MI	Myocardial infarction
MPI	Myocardial perfusion imaging
MR	Mitral regurgitation
MS	Mitral stenosis
PCI	Percutaneous coronary intervention
PET	Positron emission tomography
PFT	Pulmonary function test
PVCs	Premature ventricular contractions
SE	Stress echocardiography
TTE	Transthoracic echocardiography
VT	Ventricular tachycardia
VF	Ventricular fibrillation
WPW	Wolff-Parkinson-White

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Cardio Policy
Positron Emission Tomography (PET) Myocardial Imaging

POLICY NUMBER UM CARDIO_1124	SUBJECT Positron Emission Tomography (PET) Myocardial Imaging		DEPT/PROGRAM UM Dept	PAGE 1 OF 19
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 06/10/20, 03/10/21, 06/09/21, 08/11/21, 07/13/22, 01/11/23, 02/01/23, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 03/10/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 06/10/20, 03/10/21, 06/09/21, 08/11/21, 07/13/22, 01/11/23, 02/01/23, 03/08/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

SPECIAL NOTE

Indications for determining medical necessity for Position Emission Tomography Myocardial Imaging with appropriate preference for suitable alternatives, such as stress echocardiography (SE), when more suitable, unless otherwise stated (see DEFINITIONS section).

*Indicated when all the criteria for MPI are met **AND** there is likely to be equivocal imaging results because of BMI, large breasts or implants, mastectomy, chest wall deformity, pleural or pericardial effusion, or prior thoracic surgery or results of a prior MPI.* [1, 2]**(AUC Score 7)** [3]

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [4, 5, 6, 7, 8] .

INDICATIONS FOR HEART PET [9, 10, 11]

SUSPECTED CAD

When neither SE nor MPI have provided or are expected to provide optimal imaging

- **Symptomatic patients without known CAD (use Diamond Forrester Table)**
  AUC Score = 9 [3]

    - Low or intermediate pretest probability and unable to exercise *(SE diversion not required)*
    - High pretest probability *(SE diversion not required)*
    - Repeat testing in a patient with new or worsening symptoms and negative result at least one year ago **AND** meets one of the criteria above
- **Asymptomatic patients without known CAD** *(SE diversion not required)*
    - Previously unevaluated ECG evidence of possible myocardial ischemia including substantial ischemic ST segment or T wave abnormalities (see section in Background***)***
    - Previously unevaluated pathologic Q waves ***(***see section in Background***)***
    - Unevaluated complete left bundle branch block **(AUC Score 8)** [3]

ABNORMAL CALCIUM SCORES (CAC) [9, 12, 13, 14, 15]

When neither SE nor MPI have provided**,** or are expected to provide**,** optimal imaging

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months [16]
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months [16]
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior MPI done within the last 12 months

INCONCLUSIVE CAD EVALUATION AND OBSTRUCTIVE CAD REMAINS A CONCERN

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- Exercise stress ECG with low-risk Duke treadmill score ***(***≥5***)*** ***(***see section in Background***)*** but patient's current symptoms indicate an intermediate or high pretest probability *(SE diversion not required for high pretest probability)*
- Exercise stress ECG with an intermediate Duke treadmill score ***(****SE diversion not required for symptoms consistent with high pretest probability****)*** **(AUC Score 8)** [3]
- Inconclusive/borderline coronary computed tomography angiography (CCTA) or SPECT nuclear stress testing (e.g.**,** 40 - 70% lesions) **(AUC Score 9)** [3]
- Cardiac PET stress-rest perfusion and metabolic activity study (with ^{18}F-FDG PET) is appropriate in patients with ischemic cardiomyopathy to determine myocardial viability prior to revascularization following an inconclusive SPECT [17, 9] **(AUC Score 9)** [3]
- Non-diagnostic exercise stress test with physical inability to achieve target heart rate (THR) *(SE diversion not required)*
- An intermediate evaluation by prior stress imaging *(SE diversion not required)*
- Coronary stenosis of unclear significance on previous coronary angiography [9] **(AUC Score 8)** [3]

FOLLOW-UP OF PATIENT'S POST CORONARY REVASCULARIZATION (PCI or CABG)

When neither SE nor MPI have provided**,** or are expected to provide**,** optimal imaging [9]

- **Asymptomatic, follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG), or percutaneous coronary intervention (PCI), (whichever is later), is appropriate only for patients with:
    - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
    - a history of silent ischemia or
    - a history of a prior left main stent

    OR

- For patients with high occupational risk (e.g.**,** associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers**,** and firefighters)

New, recurrent, or worsening symptoms post coronary revascularization are an indication for stress imaging, if it will alter management (SE diversion not required for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization)

FOLLOW-UP OF KNOWN CAD [9]

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or FFR ≤ 0.80 or significant stenosis in a major vessel (≥ 50% left main coronary artery or ≥ 70% LAD, LCX or RCA)), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

When neither SE nor MPI have provided**,** or are expected to provide**,** optimal imaging

Unevaluated ACS

- Prior acute coronary syndrome (as documented in MD notes), without subsequent invasive or non-invasive coronary evaluation within the last 12 months
- Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has myocardial ischemia. No imaging stress test within the last 12 months

Heart Failure

- Newly diagnosed systolic heart failure or diastolic heart failure, *with reasonable suspicion of cardiac ischemia (prior events, risk factors***),** unless invasive coronary

angiography is immediately planned or adequate stress imaging has been done within the last 12 months [10, 18, 19] **(AUC Score 9)** [3]

Viability

- Reduced LVEF ≤ 50% requiring myocardial viability assessment to assist with decisions regarding coronary revascularization. (Diversion from PET not required when LVEF less than or equal to 40%) [18, 19, 20] **(AUC Score 9)** [3]

Ischemia and Nonobstructive Coronary Artery Disease (INOCA)

- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (*no MPI diversion required*).

Arrhythmias

- Ventricular arrhythmias
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not the immediately planned test [21]
    - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVC's (defined as greater than or equal to 30/hour on remote monitoring***)*** without known cause or associated cardiac pathology, when an exercise ECG cannot be performed

Anti-arrhythmic Drug Therapy

- Class IC antiarrhythmic drug
    - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide)
    - Annually for intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide) [22] **(AUC Score 7)** [3]

Coronary Anomaly and Aneurysm

- Assessment of hemodynamic significance of one of the following documented conditions***:*** [23]
    - Anomalous coronary arteries [24]
    - Muscle bridging of coronary artery [9, 25]
- Coronary aneurysms in Kawasaki's disease [26] or due to atherosclerosis

Radiation

- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter [27]

Cardiac Sarcoidosis [28, 29, 30]
May be approved as a combination study with MPI for the evaluation and treatment of sarcoidosis. [31]

- Evaluation and therapy monitoring in patients with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR has not been performed
- Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion [30]
- Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy [30]**(AUC Score 9)** [3]
- Initial and follow-up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years

Infective Endocarditis

- In suspected infective endocarditis with moderate to high probability (i.e.**,** staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications [32, 33]

Aortitis

- For diagnosis and surveillance of Aortitis, PET/CT or PET/MRI‡ hybrid imaging [34]

  ‡**NOTE:** If PET/MR study is requested, there is no specific CPT Code for this imaging study and a Health Plan review will be required.

PRIOR TO ELECTIVE NON-CARDIAC SURGERY

When neither SE nor MPI have provided or are expected to provide optimal imaging

- An intermediate or high-risk surgery with of one or more risk factors (see below), **AND** documentation of an inability to walk (or <4 METs) **AND** there has not been an imaging stress test within 1 year [35, 36, 37]
  - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL.
  - **Surgical Risk:**
    - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss

    - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
    - **Low risk surgery**: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service [38]

POST CARDIAC TRANSPLANT

SE diversion not required [39]

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

Codings and Standards

CPT Codes: 78459, 78491, 78492, +78434**,** A9555, 93015, 93016, 93017, 93018*,* 78472
NCQA Standards: UM2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND [1, 2]

A PET study is a diagnostic test used to evaluate blood flow to the heart. During the test, a small amount of radioactive tracer is injected into a vein. A special camera, called a gamma camera, detects the radiation released by the tracer to produce computer images of the heart. Combined with a medication, the test can help determine if there is adequate blood flow to the heart during activity versus at rest. The medication simulates exercise for patients unable to exercise on a treadmill or stationary cycle.

PET prefusion studies illustrate myocardial blood flow by demonstrating tracer uptake. PET metabolic evaluation studies are used to demonstrate inflammation produced by infiltrative disease such as sarcoidosis, but also enhance the detection of viable (hibernating) myocardium. Hybrid PET-CT scanning combines anatomical information with blood flow assessment and is useful for assessing viable myocardium, especially in CHF patients with global ischemia, or in patients with multivessel diffuse coronary artery disease as opposed to focal stenotic lesions.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [4]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

DEFINITIONS

1. Stable patients without known CAD fall into 2 categories: [10, 11, 9]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
    - **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD (below):

2. The THREE Types of Chest Pain or Discomfort
    - **Typical Angina (Definite)** is defined as including all **3** characteristics:
        - Substernal chest pain or discomfort with characteristic quality and duration
        - Provoked by exertion or emotional stress
        - Relieved by rest and/or nitroglycerine
    - **Atypical Angina (Probable)** has only **2** of the above characteristics
    - **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics

3. The medical record should provide enough detail to establish the type of chest pain. From those details, The Pretest Probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability: [10, 11, 9]

Diamond Forrester Table [40, 41]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40-49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50-59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very low:** < 5%pretest probability of CAD, usually not requiring stress evaluation
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

4. An uninterpretable baseline ECG includes: [10]
    - ST segment depression 1 mm or more; (not for non-specific ST- T wave changes)
    - Ischemic looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
    - Bundle Branch Blocks
        - LBBB
        - RBBB or IVCD, either containing ST or T wave abnormalities (see above)
    - LVH with repolarization abnormalities
    - ventricular paced rhythm
    - Digitalis use with associated ST segment abnormalities
    - Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload

5. Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    a. 40 ms (1 mm) wide
    b. 2 mm deep
    c. 25% of depth of QRS complex

6. ECG Stress Test Alone versus Stress Testing with Imaging
   Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise: [9]
    - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG [9]
    - The patient who is under evaluation for exercise-induced arrhythmia
    - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
    - For the evaluation of syncope or presyncope during exertion [42]

7. Duke Exercise ECG Treadmill Score [43]
   Calculates risk from ECG treadmill alone**:**
    - The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
    - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of ≥ + 5), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ - 11) categories

8. Coronary application of PET includes evaluation of stable patients without known CAD, who fall into two categories [10, 9, 11]

- **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
- **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≧ 50%) CAD (below):

9. An uninterpretable baseline ECG includes*:* [10]
    - ST segment depression 1 mm or more (not for non-specific ST- T wave changes)
    - Ischemic looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
    - LVH with repolarization abnormalities, pre-excitation pattern such as WPW, ventricular paced rhythm, or left bundle branch block
    - Digitalis use with associated ST segment abnormalities

10. Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
    - > 40 ms (1 mm) wide
    - > 2 mm deep
    - > 25% of depth of QRS complex

11. Global Risk of Cardiovascular Disease
    - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. **High global risk by itself generally lacks scientific support as an indication for stress imaging.** There are rare exceptions, such as patients requiring IC antiarrhythmic drugs who might require coronary risk stratification prior to initiation of the drug**.**
        - **CAD Risk—Low**
          10-year absolute coronary or cardiovascular risk less than 10%
        - **CAD Risk—Moderate**
          10-year absolute coronary or cardiovascular risk between 10% and 20%
        - **CAD Risk—High**
          10-year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* [44, 45, 46, 47, 48]

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes	http://www.reynoldsriskscore.org/

Unique for use of family history	
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

12. Definitions of Coronary Artery Disease [10, 11, 13]
    Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
    - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
    - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
        - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69%[40]
        - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross-sectional area on IVUS ≤ 6 square mm [10, 49]
        - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [49]
        - Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
    - A major vessel would be a coronary vessel that would be amenable to revascularization if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
    - FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
    - Newer technology that estimates FFR from CCTA image is covered under the separate NIA Guideline for FFR-CT.

13. Anginal Equivalent [10, 42]

    Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are

not due to other organ systems (e.g.**,** dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data**,** such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Most syncope per se is not an anginal equivalent.

ACRONYMS / ABBREVIATIONS

ADLs	Activities of daily living
BMI	Body mass index
CABG	Coronary artery bypass grafting
CAC	Coronary artery calcium
CAD	Coronary artery disease
CCTA	Coronary computed tomography angiography
CMR	Cardiac magnetic resonance imaging
CT(A)	Computed tomography (angiography)
DTS	Duke Treadmill Score
ECG	Electrocardiogram
FFR	Fractional flow reserve
IVUS	Intravascular ultrasound
LBBB	Left bundle-branch block
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
MESA	Multi-Ethnic Study of Atherosclerosis
MET	Estimated metabolic equivalent of exercise
MI	Myocardial infarction
MPI	Myocardial perfusion imaging
MR(I)	Magnetic resonance (imaging)
PCI	Percutaneous coronary intervention
PET	Positron emission tomography
PFT	Pulmonary function test
PVCs	Premature ventricular contractions
SE	Stress echocardiography
TEE	Transesophageal echocardiography
THR	Target heart rate
TTE	Transthoracic echocardiography
VF	Ventricular fibrillation
VT	Ventricular tachycardia
WPW	Wolff-Parkinson-White

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Cardio Policy:

Renal/Retroperitoneal Vascular Duplex Ultrasound

POLICY NUMBER UM CARDIO_1125	**SUBJECT** Renal/Retroperitoneal Vascular Duplex Ultrasound		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 06/30/14, 08/22/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 09/11/19, 12/11/19, 08/12/20, 04/14/21, 08/11/21, 09/08/21, 12/08/21, 12/14/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 06/30/14, 08/22/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 09/11/19, 12/11/19, 08/12/20, 04/14/21, 08/11/21, 09/08/21, 12/08/21, 12/14/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Renal/Retroperitoneal Vascular Duplex Ultrasound.

II. DEFINITIONS

Renal Duplex ultrasound images the renal arteries via spectral/color flow Doppler and B-mode scanning to assess abnormalities in the blood flow there by identifying areas of blockage.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity:

A. Follow up testing in asymptomatic patient with Renal Artery Stenosis to determine hemodynamic significance of stenosis. **(AUC Score 7)**[1,2,3,5]

B. Evaluation for Renal Artery Stenosis with worsening of renal function test (Creatinine) in presence of malignant hypertension. **(AUC Score 8)**[1,2,3,5]

C. Evaluation for Renal Artery Stenosis with resistant hypertension (patient has uncontrolled hypertension after being on at least 3 medications including diuretics). **(AUC Score 8)**[1,2,3,5]

D. Evaluation for Renal Artery Stenosis in an asymptomatic patient with hypertension who in younger than 30 years old. **(AUC Score 8)**[1,2,3,5]

E. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine and hypertension in young person (age less than 35 years). **(AUC Score 8)**[1,2,3,5]

F. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine and hypertension with evidence of size discrepancy between kidneys noted on other imaging modalities as CT/MR. **(AUC Score 7)**[1,2,5]

G. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine and hypertension. **(AUC Score 7)**[1,2,5]

H. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine (greater than 50% increase from baseline) and/or hypertension with recent addition of ACEI/ARBs. **(AUC Score 8)**[1,2,5]

I. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine and/or hypertension with epigastric bruit. **(AUC Score 7)**[1,2,5]

J. Evaluation for Renal Artery Stenosis in symptomatic patient, with elevated creatinine and/or hypertension **(AUC Score 8)**[1,2,5]

K. Baseline surveillance within one month after Renal Artery revascularization. **(AUC Score 8)**[1,2,5]

L. Renal Duplex in a patient after Renal Artery Revascularization with new or worsening symptoms related to renal artery stenosis. **(AUC Score 8)**[1,2,5]

M. To evaluate patients presenting with signs or symptoms such as epigastric or periumbilical postprandial pains that last for 1-3 hours and/or with associated weight loss resulting from decreased oral intake which may indicate chronic intestinal (mesenteric or celiac artery) ischemia. **(AUC Score 6)**[1,2,5]

N. Baseline surveillance in asymptomatic patients one month after mesenteric revascularization, and once again at 3-5 months post, 6-8 months post, and 9-12 months post **(AUC Score 8)**[1,2,5] imaging beyond one year is rarely necessary.

O. To evaluate for suspected portal hypertension or portal vein thrombosis in the presence of hepatic disease, no prior ultrasound within the last 6 months. **(AUC Score 7)**[1,2,5]

P. Surveillance ultrasound to assess for complications status post hepatic or renal or pancreas transplant may be performed as per the protocol of the transplant facility. **(AUC Score 7)**[4,5]

Q. Surveillance ultrasound to assess for development of hepatocellular carcinoma may be performed every 6 months in patients with the following primary liver conditions: Hepatitis C, EtOH liver disease, hereditary hemochromatosis, primary biliary cholangitis, autoimmune hepatitis, or alpha 1-atitrypsin deficiency. **(AUC Score 6)**[6]

R. To evaluate patients with pain or swelling of scrotal contents which may be as a result of suspected obstruction in arterial inflow or venous outflow to the testicles or related structures. The

use of duplex scanning of scrotal contents should only be performed after conventional diagnostic test, such as ultrasound, have proven to be “non-definitive.” **(AUC Score 7)**[7]

S. Renal Duplex is appropriate to perform, to evaluate retroperitoneal vasculature structures as initial workup, prior to any organ transplant, no prior ultrasound within the last 6 months. **(AUC Score 7)** [8,9,10,11]

Limitations:

A. Screening of asymptomatic patients for Renal Artery Stenosis with evidence of atherosclerotic vascular disease in other beds is inappropriate.

B. Screening of asymptomatic patients for Renal Artery Stenosis with unexplained size discrepancy between kidneys noted on other imaging modalities is inappropriate.

C. Follow up testing for Renal Artery Stenosis as surveillance in asymptomatic patients is inappropriate.

D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request
2. Most recent renal duplex ultrasound of CT/MR report (if applicable)

B. Primary code appropriate for this service:

93975 for complete study of the abdominal, pelvic, scrotal contents and/or retroperitoneal organs

93976 for limited study.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy:

Abdominal Aortic Ultrasound

POLICY NUMBER UM CARDIO_1126	**SUBJECT** Abdominal Aortic Ultrasound		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 03/10/14, 06/16/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 10/14/20, 04/14/21, 06/09/21, 08/11/21, 08/10/22, 12/14/22, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 03/10/14, 06/16/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/13/19, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 10/14/20, 04/14/21, 06/09/21, 08/11/21, 08/10/22, 12/14/22, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for an abdominal aortic ultrasound.

II. DEFINITIONS

An abdominal ultrasound uses reflected sound waves to obtain anatomic and physiologic information of the abdominal aorta. It is commonly performed to diagnose an abdominal aortic aneurysm. An abdominal aortic aneurysm is defined as an increased internal diameter of the abdominal aorta of 3 cm or greater.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Evaluation of a patient who has sustained trauma to the abdominal, pelvic, and/or retroperitoneal area resulting in a possible injury to the arterial inflow and/or venous outflow of the abdominal, pelvic, and/or retroperitoneal organs. **(AUC Score 7)**[1,5,6]

B. Evaluation of a patient with an abdominal bruit. **(AUC Score 7)**[1,2,3,7,8]

C. Confirm a suspicion of an abdominal or iliac aneurysm raised by a physical examination or noted as an incidental finding on another radiological examination. The physical examination usually reveals a palpable, pulsatile, and non-tender abdominal mass. **(AUC Score 7)**[1,2,37,8]

D. Surveillance of known Iliac artery aneurysm with duplex:

1. Less than 3.0 cm does not require surveillance
2. 3.0 to 3.5 cm, follow-up with ultrasound initially at 6 months, then yearly if stable **(AUC Score 7)**[6]
3. Greater than 3.5 cm, follow up with ultrasound every 3-6 months until intervention **(AUC Score 7)**[6]

E. Surveillance of known AAA with duplex:

1. Aortic diameter less than 2.5 cm is inappropriate
2. Aortic diameter 2.5 to 2.9 cm, can follow-up with ultrasound in 10 years **(AUC Score 7)**[5]
3. 3.0 to 3.9 cm, follow-up with ultrasound scan every 3 years **(AUC Score 7)**[5]
4. 4.0 to 4.9 cm, once every year **(AUC Score 7)**[5]
5. Greater than or equal to 5.0 cm, once every 6 months **(AUC Score 7)**[5]
6. Any size AAA with new or worsening symptoms **(AUC Score 7)**[1,2,3,7,8]

F. Surveillance after AAA intervention (Stents or Surgical repair):

1. Any new or worsening lower extremity symptoms post intervention. **(AUC Score 8)**[1,2,3,7,8]
2. Duplex after aortic and/or iliac endograft or stent can be done within 1 month after intervention, as a baseline. **(AUC Score 8)**[1,2,3,7,8]
3. Duplex for Aortic endograft leak and /or increasing residual aneurysm sac size can be done at 6 months after baseline study. **(AUC Score 8)**[1,2,3,7,8]
4. Duplex for Aortic endograft or open repair without endo leak and/or increasing residual aneurysm sac size is appropriate annually, after the baseline study. **(AUC Score 7)**[1,2,3,7,8]

G. Evaluate patients for AAA, presenting with signs and symptoms of thoracic aneurysm measuring greater than or equal to 4.0cm. **(AUC Score 8)**[1,2,3,7,8]

H. One-time Screening in asymptomatic patients:

1. Men age 65-75 years who have ever smoked. **(AUC Score 8)**[3,8]
2. Men age 65-75 years who have never smoked but have first degree relative with an AAA. **(AUC Score 7)**[3,8]

   **Screening is not recommended in men or women of any age who have neither smoking history nor a family history of AAA.*

I. Initial evaluation of a patient presenting with signs and symptoms such as intermittent claudication in the calf muscles, thighs and/or buttocks, rest pain, weakness in legs or feeling of tiredness in the buttocks, etc. which may suggest occlusive disease of the aorta and iliac arteries. **(AUC Score 6)**[1,2,3,7,8]

J. To evaluate patients presenting with complaints of pain in the calf or thigh, slight swelling in the involved leg, tenderness of the iliac vein, etc. which may suggest phlebitis or thrombophlebitis of the iliac vein or IVC. **(AUC Score 6)**[1,2,3,7,8]

K. Abdominal Duplex is appropriate to perform, to evaluate retroperitoneal vasculature structures as initial workup, prior to any organ transplant, no prior ultrasound within the last 6 months. **(AUC Score 7)**[10,11,12,13]

Limitations:

A. Surveillance with AAA duplex for Aortic diameter less than 3.0 cm is inappropriate

B. Screening for AAA is not routinely recommended in men aged 65-75 years who have never smoked as evidence indicate that the net benefit of screening all men in this group is small. To determine whether this service is appropriate, patients and clinicians should consider the patient's medical history, family history for AAA, other risk factors, and personal values

C. USPSTF recommends against routine screening for AAA with ultrasonography in women who have never smoked and have no family history of AAA.

D. USPSTF recommends against routine screening for AAA in women aged 65-75 years who have ever smoked or have a family history of AAA due to insufficient evidence to assess the balance of benefits and harms for screening for AAA.

E. Duplex testing should be reserved for specific indications for which the precise anatomic information obtained by this technique is likely to be useful. Therefore, it would be rare to see duplex scanning being performed for conditions in which another diagnostic test is recommended (e.g., an aortic dissection is better diagnosed with a chest x-ray, Trans esophageal echocardiogram or aortography).

F. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review
   1. Cardiologist or Vascular Surgeon's note that prompted the request
   2. Previous AAA duplex/CTA/MRA aorta/Angiogram or AAA operative report

B. Primary codes appropriate for this service: 93978- (complete duplex scan of abdominal vasculature including aorta, IVC, illiacs, or bypass grafts), 93979- (limited duplex scan for abdominal aorta or IVC or illiacs or bypass grafts only), 76706- (Screening for AAA – once in a patient lifetime if criteria for screening are met).

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy
Diagnostic Heart Catheterization

POLICY NUMBER UM CARDIO_1127	SUBJECT Diagnostic Heart Catheterization		DEPT/PROGRAM UM Dept	PAGE 1 OF 15
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 05/01/18, 02/13/19, 03/13/19, 12/11/19, 02/12/20, 08/12/20, 01/13/21, 04/14/21, 06/09/21, 08/11/21, 12/08/21, 01/12/22, 02/09/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 03/13/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 07/22/11, 12/12/12, 08/22/13, 06/28/14, 05/15/15, 08/12/15, 11/23/16, 12/21/16, 10/10/17, 05/01/18, 02/13/19, 03/13/19, 12/11/19, 02/12/20, 08/12/20, 01/13/21, 04/14/21, 06/09/21, 08/11/21, 12/08/21, 01/12/22, 02/09/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24, 03/13/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

PURPOSE

Heart catheterization is an invasive angiographic procedure used to evaluate the presence and extent of coronary artery disease (CAD).

In addition to angiography, it can also include ventriculography, aortography, acquisition of hemodynamic data, measurement of cardiac output, detection and quantification of shunts and flows, intravascular ultrasound (IVUS), and fractional flow reserve (FFR)/instantaneous wave free ratio (iFR) for determination of a lesion's hemodynamic severity. CAD stenosis ≥70% (≥50% in the left main coronary artery) is considered clinically significant or obstructive CAD. [1, 2, 3, 4]

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [5, 6, 7, 8, 9] .

INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY [10, 1, 11, 12]

General

- Typical angina with new onset or evolving ischemic EKG changes
- Prinzmetal's or variant angina (pain experienced at rest with ST elevation) on GDMT
- New onset or worsening of the patient's previously known anginal symptoms in a patient with a history of CABG or PCI (AUC 7) [2]
- Symptomatic patients with a high pretest probability (AUC 7) [2]

- Unheralded syncope (not near syncope), where the etiology is unclear
- Patient with CAD and symptoms of angina with intermediate or high risk findings on non-invasive imaging stress test including stress induced LV dysfunction.

Stable Ischemic Heart Disease

- Exercise electrocardiogram (ECG) stress test with high-risk findings, such as Duke Score ≤ -11, ST segment elevation, hypotension, exercise-induced ventricular tachycardia (VT), or greater than 1.0mm persistent ST depression in multiple leads into recovery for 5 minutes or greater [11]
- Ischemia at low threshold on stress-testing with or without an abnormal decrease in normal systolic blood pressure response during exercise.
- Stress imaging with high-risk findings (see Definitions)
- Stress imaging with intermediate risk findings (see Background section) in a patient with one of the following:
    - Symptoms consistent with ischemia unresponsive to guideline directed medical therapy (GDMT) [11]
    - Unsatisfactory quality of life due to angina; interfering with the patient's occupation or the ability to perform usual activities [1]
    - Ejection fraction (EF) < 50% [1]
- Non-invasive test with low-risk findings with new, worsening, or limiting symptoms with reasonable suspicion of cardiac origin despite optimal medical therapy (GDMT) or inability to tolerate GDMT [10, 1, 11]
- New, worsening, or limiting symptoms, with known unrevascularized obstructive coronary artery disease (CAD), in a patient eligible for revascularization [10, 1]
- Post STEMI with "culprit only" revascularization and plan for further PCI of non-culprit lesion [13]
- Before high-risk non-cardiac surgery in patients who have evidence of ischemia by non-invasive testing.
- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following: [11, 2, 3]
    - Low risk stress imaging with high-risk stress ECG response or stress induced typical angina [11]
    - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability [1, 11]

CCTA Abnormalities

- Symptomatic patient with one of the following: [1, 11, 12]
    - One vessel with ≥ 50% stenosis (AUC 7) [2]
    - A stenosis of 40-90% and FFR-CT ≤0.8 [14] (AUC 8) [2]
    - ≥ 50% left main stenosis, **even if asymptomatic**

Heart Failure with Left Ventricular Dysfunction

- New heart failure, cardiomyopathy, or wall motion abnormality in patients who are candidates for coronary revascularization; including one of the following: [1, 11, 2, 15, 16] (AUC 8) [2]
    - Newly recognized heart failure in patients with known or suspected CAD
    - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality [1, 11]
    - Structural abnormality (severe mitral regurgitation or ventricular septal defect) with reason to suspect ischemic origin
    - Deterioration in clinical status of heart failure or cardiomyopathy requiring invasive evaluation for guidance or alteration in therapy
    - Clarification of the diagnosis of myocarditis versus acute coronary syndrome [17]

Ventricular Arrhythmias

- Ventricular arrhythmias, without identified non-cardiac cause:
    - Following recovery from unexplained sudden cardiac arrest [18]
    - Sustained VT or VF [11] (AUC 7) [2]
    - Exercise-induced VT [11] (AUC 7) [2]

Prior to Non-Coronary Intervention and Cardiac Surgery

- Evaluation of coronary anatomy, with consideration of coronary revascularization, prior to cardiac surgery in patients with any of the following: [19, 20, 21, 22]
    - Symptoms of angina
    - Stress imaging with evidence of ischemia
    - Decreased LV systolic function (EF < 50%)
    - History of CAD
    - Coronary risk factors, including men > 40 and postmenopausal women
    - Non-invasive data that is inconclusive
    - Severe valve disease
    - Requirement for detailed assessment of coronary artery anatomy prior to aortic valve homograft surgery, pulmonary autograft (Ross procedure), or aortic root procedure
    - Patients undergoing transcatheter aortic valve replacement (TAVR) or other transcatheter valve procedures
    - Can be done pre-organ transplant when required by transplant center protocol in place of, but not in addition to an imaging study

Hypertrophic Cardiomyopathy

- Patients with HCM, who are candidates for SRT, and for whom there is uncertainty of LVOT obstruction on noninvasive imaging studies, invasive hemodynamic assessment with cardiac catheterization is recommended [23]
- In patients with symptoms or evidence of myocardial ischemia (CCTA also allowed)

- Prior to surgical myectomy in HCM patients who are at risk for coronary atherosclerosis (CCTA also allowed)

Post Cardiac Transplantation [24]

- Assessment for allograft vasculopathy annually

Hemodynamic Assessment

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology [11, 19, 25]
    - Assessment of bioprosthetic valve when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) were inadequate, and cardiac magnetic resonance (CMR) or cardiac computed tomography (CCT) are not available
    - Assessment of mechanical valve prostheses when TTE and TEE are inadequate and CCTA is not available
    - Discordance between non-invasive data and clinical impression of severity of valvular disease
    - Evaluation of indeterminate shunt anatomy or shunt flows/ratio
- Indications for hemodynamic assessment only [11, 25]
    - Assessment of constrictive and restrictive physiology
    - Assessment of pulmonary hypertension when non-invasive data provides inadequate information for management, or to evaluate response to intravenous drug therapy
    - Assessment of hemodynamics in heart failure, cardiomyopathy, or adult congenital heart disease, when
        - Non-invasive data is discordant or conflicts with the clinical presentation
        - Non-invasive data is inadequate for clinical management

INDICATIONS FOR ASCENDING AORTOGRAPHY: [20, 19, 21]

- Evaluation of aortic root dilatation in patients with severe aortic stenosis and regurgitation prior to valve surgery
- Evaluation of aortic root, ascending aortic aneurysm prior to repair
- Evaluation central shunts, Coarctation and great vessels
- Bypass graft identification at the time of left heart cath
- Disease affecting the aorta and coronary arteritis in which coronary artery involvement is suspected.

CODINGS and STANDARDS

CPT Code: 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, +93462, +93463, +93464, 93547, 93531, 93532, 93533, 93563, 93564, +93565, +93566, +93567, +93568, 93573, 93574, 93595, 93596, 93597, 93598
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

Heart catheterization is the passage of a thin flexible tube (catheter) into the left or right heart systems via arteries or veins, respectively, for the purposes of hemodynamic measurements, acquisition of blood samples from specific locations, and/or the injection of radiopaque medium for the purposes of visualizing vascular anatomy. Coronary angiography is the passage of a catheter into the left side of the heart to diagnose or treat blockages of coronary arteries.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [5]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. Stable Patients without Known CAD fall into 2 categories: [1, 2, 3]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Global Cardiovascular Risk Calculators section)
    - **Symptomatic,** for whom the pretest probability that chest-related symptoms are due to clinically significant CAD is estimated

2. The Three Types of Chest Pain or Discomfort and Pretest Probability of CAD
    - **Typical Angina (Definite)** is defined as including all **3** characteristics:
        - Substernal chest pain or discomfort with characteristic quality and duration
        - Provoked by exertion or emotional stress
        - Relieved by rest and/or nitroglycerine
    - **Atypical Angina (Probable)** has only **2** of the above characteristics
    - **Non-anginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics

3. The medical record should provide enough detail to establish the type of chest pain. From those details, The Pretest Probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability. [1, 2]

Diamond Forrester Table [26, 27]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Non-anginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

4. Coronary Risk Categories Derived from Non-invasive Testing [1, 12]
    - **High risk (> 3% annual death or MI)**
        - Severe resting left ventricular (LV) dysfunction (LVEF < 35%) not readily explained by non-coronary causes
        - Resting perfusion abnormalities ≥ 10% of the myocardium in patients without prior history or evidence of myocardial infarction (MI)
        - Stress ECG findings including ≥ 2 mm of ST-segment depression at low workload or persisting into recovery, exercise-induced ST-segment elevation, or exercise-induced ventricular tachycardia (VT)/ventricular fibrillation (VF)
        - Severe stress-induced left ventricular (LV) dysfunction (peak exercise EF < 45% or drop in EF with stress ≥ 10%)
        - Stress-induced perfusion abnormalities involving ≥ 10% myocardium or stress segmental scores indicating multiple abnormal vascular territories
        - Stress-induced LV dilation. Transient ischemic dilation (TID) is the ratio of left ventricular area immediately post-exercise divided by the area of the 4-hour redistribution image, with an abnormal ratio defined as > 1.12 [28]
        - Inducible wall motion abnormality (involving ≥ 2 segments or ≥2 vascular territories)

- Wall motion abnormality developing at low dose of dobutamine (≤ 10 mg/kg/min) or at a low heart rate (< 120 beats/min)
- Multivessel obstructive CAD (≥ 70% stenosis) or left main stenosis (≥ 50% stenosis) on CCTA

- **Intermediate risk (1% to 3% annual death or MI)**
  - Mild or moderate resting LV dysfunction (EF 35% to 49%) not readily explained by non-coronary causes
  - Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of MI
  - ≥1 mm of ST-segment depression occurring with exertional symptoms
  - Stress-induced perfusion abnormalities involving 5% to 9.9% of the myocardium or stress segmental scores (in multiple segments) indicating 1 vascular territory with abnormalities but without LV dilation
  - Inducible wall motion abnormality involving 1 segment or 1 vascular territory
  - CAC score 100 to 399 Agatston units (only for use in primary prevention, not for heart catheterization decision making) [1, 11, 3, 29]
  - One vessel CAD with $\geq$ 70% stenosis or moderate CAD stenosis (50% to 69% stenosis) in $\geq$ 2 arteries on CCTA

- **Low risk (< 1% annual death or MI)**
  - Low-risk treadmill score (score ≥ 5) or no new ST segment changes or exercise-induced chest pain symptoms, when achieving maximal levels of exercise
  - Normal or small myocardial perfusion defect at rest or with stress involving < 5% of the myocardium
  - Normal stress or no change of baseline wall motion abnormalities during stress
  - CAC score < 100 Agatston units (only for use in primary prevention, not for heart catheterization decision making) [1, 11, 3, 29]
  - No coronary stenosis > 50% on CCTA

5. Global Risk of Cardiovascular Disease
   - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
     - **CAD Risk—Low**
     - 10-year absolute coronary or cardiovascular risk less than 10%
     - **CAD Risk—Moderate**
       10-year absolute coronary or cardiovascular risk between 10% and 20%
     - **CAD Risk—High**
       10-year absolute coronary or cardiovascular risk of greater than 20%

NOTE: High global risk by itself generally lacks scientific support as an indication for stress imaging. [30] There are rare exemptions, such as patients requiring I-C antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

Websites for Global Cardiovascular Risk Calculators* [29, 31, 32, 33, 34]

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

6. Definitions of Coronary Artery Disease [1, 12, 3, 35]
   Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
   - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
   - Ischemia-producing disease (also called hemodynamically or functionally significant disease, or obstructive coronary disease for which revascularization might be appropriate) implies at least one of the following:
     - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69% [11]
     - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum luminal cross-sectional area on IVUS ≤ 6 square mm [1, 4, 35]
     - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [4, 35]
     - iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel [4, 36, 37, 38]

- A major vessel would be a coronary vessel that would be amenable to revascularization, if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
- FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Instantaneous wave-free ratio (iFR) measures the ratio of distal coronary to aortic pressure during the wave free period of diastole, with a value ≤ 0.89 considered hemodynamically significant. [36, 37, 38]

7. Anginal Equivalent [1, 39, 40]

   Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

8. Optimal Medical Therapy (OMT)

   In general, a trial of OMT includes
   - Anti-platelet therapy
   - Lipid-lowering therapy
   - Beta blocker
   - Angiotensin converting enzyme (ACE) inhibitor

ACRONYMS / ABBREVIATIONS

CABG	Coronary artery bypass grafting surgery
CAC	Coronary artery calcium
CAD	Coronary artery disease
CCT	Cardiac computed tomography
CCTA	Coronary computed tomographic angiography
CMR	Cardiac magnetic resonance
CT(A)	Computed tomography (angiography)
ECG	Electrocardiogram
EF	Ejection fraction
FFR	Fractional flow reserve
FFR-CT	Fractional flow reserve – computed tomography
HCM	Hypertrophic cardiomyopathy
iFR	Instantaneous wave-free ratio
IVUS	Intravascular ultrasound
LV	Left ventricular

LVEF	Left ventricular ejection fraction
LVOT	Left ventricular outflow tract
MESA	Multi-Ethnic Study of Atherosclerosis
MI	Myocardial infarction
MR	Mitral regurgitation
OMT	Optimal medical therapy
PCI	Percutaneous coronary intervention
PFT	Pulmonary function test
SRT	Septal reduction therapy
TAVR	Transcatheter aortic valve replacement
TID	Transient ischemic dilation
TTE	Transthoracic echocardiography
TEE	Transesophageal echocardiography
VT	Ventricular tachycardia
VF	Ventricular fibrillation

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Cardio Policy:

Thoracic Surgical Services Request Process

POLICY NUMBER UM CARDIO_1129	SUBJECT Thoracic Surgical Services Request Process		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 07/22/11, 12/12/12, 08/22/13, 06/28/14, 10/14/15, 11/28/16, 12/21/16, 10/31/17, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 07/22/11, 12/12/12, 08/22/13, 06/28/14, 10/14/15, 11/28/16, 12/21/16, 10/31/17, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

The purpose of the policy is to outline the utilization review process for medical request determinations for the New Century Health division of Thoracic Surgery.

II. DEFINITIONS

Thoracic Surgery: is any surgery performed in the chest (thorax). Thoracic surgery is used to treat diseased or injured organs in the thorax, including the trachea, pleura mediastinum, chest wall, diaphragm, and lungs. The most common diseases requiring thoracic surgery include lung, cancer, chest trauma, esophageal cancer, emphysema, and lung transplantation.

III. POLICY

New Century Health will evaluate all thoracic surgical procedure requests following involved regulatory bodies guidelines for timeliness and provider/facility routing.

The purpose for evaluating a Thoracic Surgical medical request for determination at New Century Health will follow the established guidelines as outlined through the Utilization Management Department.

A. Upon receiving a thoracic surgical procedure request for the Thoracic Surgical Department, the New Century Health non-clinical staff will validate the provider and facility.

   1. Provider routing: The New Century Health non-clinical staff will validate the requesting provider as a valid credentialed provider with New Century Health and/or health plan participating network provider.

2. Site of Service: The New Century Health non-clinical staff will validate the desired service facility as a participating facility for the identified health plan and/or with New Century Health.

B. The New Century Health peer reviewer will evaluate the medial request and issue a determination based on appropriateness/medical necessity of service request and service CPT codes based on documentation provided by requesting provider.

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review

1. Progress notes that prompted request
2. CT/PET/Pathology Reports

B. Primary codes appropriate for this service: 31615, 31620, 31622-31641, 31643, 31645-31649, 31651, 31660, 31661, 31717, 31720, 31725, 31730, 32035, 32036, 32100, 32110, 32120, 32124, 32140, 32141, 32150, 32151, 32160, 32200, 32215, 32220, 32225, 32310, 32320, 32440, 32442, 32445, 32480, 32482, 32484, 32486, 32488, 32491, 32501, 32503, 32504, 32540, 32550, 32551-32557, 32560-32562, 32601, 32604, 32606, 32650-32666, 32810-32815, 32820, 32900-32998, 39000-39561, 32800, 32096-32674, 38746, 31652-31654, 39401, 39402, 43117-43135

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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6. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Electrophysiology Study with Arrhythmia Induction

POLICY NUMBER UM CARDIO_1139	SUBJECT Electrophysiology Study with Arrhythmia Induction		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 09/14/22, 09/13/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 09/14/22, 09/13/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Electrophysiology Study with Arrhythmia Induction.

II. DEFINITIONS

An electrophysiological study (EP study) is an invasive procedure that evaluated abnormal heart rhythm disturbances. During an EP study, small, thin wire electrodes are inserted through a vein in the groin (or neck, in some cases). The wire electrodes are threaded into the heart, using a special type of X-ray, called fluoroscopy. Once in the heart, electrical signals are measured. Electrical signals are sent through the catheter to stimulate the heart tissue to try to initiate the abnormal heart rhythm disturbances for evaluation.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. EPS is being performed for a patient with ischemic cardiomyopathy and symptomatic syncope or near syncope suspected of having sinus node dysfunction but a causal relation between an arrhythmia and the symptoms cannot be established by other means. **(AUC Score 8)**[1,2,3,4,5]

B. EPS is being performed for a patient with symptomatic syncope or near syncope suspected or diagnosed bundle branch block with impending high degree AV block. **(AUC Score 8)**[1,2,3,4,5]

C. Patients with second or third-degree AV block treated with a pacemaker who remain symptomatic (with syncope or near syncope) in whom ventricular tachyarrhythmia is suspected as a cause of symptoms. **(AUC Score 8)**[1,2,3,4,5]

D. EPS being performed for a patient with symptomatic syncope and or near syncope with chronic bundle branch block (RBBB with Left anterior or posterior hemi block) where ventricular arrhythmia is suspected. **(AUC Score 7)**[1,2,3,4,5]

E. EPS is being performed for a patient with narrow QRS tachycardia poorly responsive to drug therapy or with associated drug side effects. **(AUC Score 8)**[1,2,3,4,5]

F. EPS is being performed for a patient with wide QRS complex tachycardia (sustained and/or symptomatic). **(AUC Score 8)**[1,2,3,4,5]

G. EPS is being performed in a patient with W-P-W who participates in high risk occupation/activities, has a family history of premature sudden death or is undergoing cardiac surgery for other reasons. **(AUC Score 7)**[1,2,3,4,5]

H. EPS is being performed in a patient with suspected antidromic tachycardia. **(AUC Score 7)**[1,2,3,4,5]

I. EPS is being performed in a patient with prolonged QT interval syndrome and evidence of sustained ventricular tachycardia or sudden death. **(AUC Score 8)**[1,2,3,4,5]

J. EPS is being performed in a patient surviving a cardiac arrest. **(AUC Score 8)**[1,2,3,4,5]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Cardiologist or EP Progress Note that prompted request
2. Recent EKG (within 10 days)
3. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis, etc.)

B. Primary codes appropriate for this service: 93620

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Sana M. Al-Khatib, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death - A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 138: e272–e391
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3. Cynthia D. Adams, et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death—Executive Summary A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society. Journal of the American College of Cardiology Sep 2006; Volume 48 Issue 5, Pages 1064-1108.
4. Blomström-Lundqvist C, et al. ACC/AHA/ESC guidelines for the management of patients with supraventricular arrhythmias--executive summary. a report of the American college of cardiology/American heart association task force on practice guidelines and the European society of cardiology committee for practice guidelines (writing committee to develop guidelines for the management of patients with supraventricular arrhythmias) developed in collaboration with NASPE-Heart Rhythm Society. Journal of the American College of Cardiology. Volume 42, Issue 8, Pages 1493-1531.
5. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
6. NCQA UM 2023 Standards and Elements.

Cardio Policy:

EPS with Transseptal Left Heart Cath with Arrhythmia Induction and VT Ablation

POLICY NUMBER UM CARDIO_1140	**SUBJECT** Electrophysiology Study with Trans-septal Left Heart Cath with Arrhythmia Induction and VT Ablation		**DEPT/PROGRAM** UM Dept **PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 03/10/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 03/10/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare

I. PURPOSE

Indications for determining medical necessity for Electrophysiology Study with Trans-septal Left Heart Catheterization with Arrhythmia Induction and VT Ablation.

II. DEFINITIONS

A cardiac electrophysiology study (EPS) is a test performed to analyze the electrical activity of the heart. It uses cardiac catheters and sophisticated computers to generate EKG tracings and electrical measurements. Radiofrequency ablation consists of the application of unmodulated, high frequency alternating current flow to the heart to injure cells for the purpose of destroying ectopic foci.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[5]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,4].

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Ablation is indicated in patients who have symptomatic and sustained monomorphic VT that is drug resistant, who are drug intolerant, or who do not wish long-term drug therapy. **(AUC Score 7)[1,2,3,4]**

B. Ablation is indicated in patients with idiopathic or outflow tract or bundle-branch reentrant VT or in those who are drug intolerant or who do not desire long-term drug therapy. **(AUC Score 7)[1,2,3,4]**

C. Ablation is indicated as adjunctive therapy in patients with an ICD who are receiving multiple shocks as a result of sustained VT that is not manageable by reprogramming or changing drug therapy or who do not wish long-term drug therapy. **(AUC Score 7)[1,2,3,4]**

D. Ablation can be useful therapy in patients who have frequent symptomatic monomorphic PVCs that are drug resistant or who are drug intolerant or who do not wish long-term drug therapy. **(AUC Score 5)[1,2,3,4]**

E. Ablation of Purkinje fiber potentials may be considered in patients with ventricular arrhythmia storm consistently provoked by PVCs of similar morphology. **(AUC Score 4)[1,2,3]**

F. Ablation of asymptomatic relatively infrequent PVCs is not indicated.

G. Ablation of asymptomatic PVCs (with a burden of greater than or equal to 20% by ambulatory monitoring) may be considered when the PVCs are very frequent to avoid or treat tachycardia-induced cardiomyopathy. **(AUC Score 4)[1,2,3,4]**

H. For patients who require arrhythmia suppression for symptoms or declining ventricular function suspected to be due to frequent PVCs (with a burden of greater than or equal to 20% by ambulatory monitoring) and for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference. **(AUC Score 8) [1,2,3,4]**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

B. Before proceeding with ventricular arrhythmia ablation for a patient with established ventricular arrhythmia the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[1,2,3,4]

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or EP Progress Note that prompted request
   2. Recent EKG (within 10 days)
   3. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis)

B. Primary codes appropriate for this service: Trans Septal Left Heart Cath: 93462. VT Ablation: 93654

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Al-Khatib SM, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. Circulation Sep 2018 Volume 138 Number 13, Pages e272-e391.
2. Douglas P. Zipes MD, et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death—Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). Journal of the American College of Cardiology. Sept 2006. Volume 48, Issue 5, Page 1064-1108.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. Cronin EM, et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. Europace. 2019 Aug 1;21(8):1143-1144. doi: 10.1093/europace/euz132. Erratum in: Europace. 2019 Aug 1;21(8):1144. Erratum in: J Arrhythm. 2020 Jan 12;36(1):214. Erratum in: Europace. 2020 Mar 1;22(3):505.
5. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy:

EPS with AI, Pacing after DI and Atrial or SVT and AP Ablation

POLICY NUMBER UM CARDIO_1141	**SUBJECT** Electrophysiology Study with Arrhythmia Induction, Pacing After Drug Infusion and Atrial or Supraventricular Foci Ablation and Accessory Pathway	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Electrophysiology Study with Arrhythmia Induction, pacing after Drug Infusion and Atrial or Supraventricular Foci Ablation, including accessory pathway.

II. DEFINITIONS

An electrophysiological study (EP study) is an invasive procedure that evaluated abnormal heart rhythm disturbances. During an EP study, small, thin wire electrodes are inserted through a vein in the groin (or neck, in some cases). The wire electrodes are threaded into the heart, using a special type of X-ray, called fluoroscopy. Once in the heart, electrical signals are measured. Electrical signals are sent through the catheter to stimulate the heart tissue to try to initiate the abnormal heart rhythm disturbances for evaluation.

Radiofrequency ablation consists of the application of unmodulated, high frequency alternating current flow to the heart to injure cells for the purpose of destroying ectopic foci.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[5]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,4]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Patient presenting with frequent or poorly tolerated episodes of narrow QRS tachycardia or atrial flutter not adequately responding to therapy. **(AUC Score 8)[1,2,3,4]**

B. Patient presenting with narrow QRS tachycardia that prefers ablative therapy to pharmacologic management. **(AUC Score 8)[1,2,3,4]**

C. Patient presenting with frequent episodes of narrow QRS tachycardia and there is concern about side effects of the antiarrhythmic drug. **(AUC Score 8)[1,2,3,4]**

D. Patient presenting with ventricular pre-excitation that is asymptomatic, yet his livelihood or profession could be affected by possibility of tachyarrhythmia's or an abnormal EKG. **(AUC Score 6)[1,2,3,4]**

E. Patient with documented symptomatic wide complex tachycardia and with evidence of WPW/Pre-excitation syndrome. **(AUC Score 8)[1,2,3,4]**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

B. Before proceeding with ablation for a patient with SVT the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT.[1,2,3,4]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or EP Progress Note that prompted request
   2. Recent EKG (within 10 days)
   3. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis)

B. Primary codes appropriate for this service: Drug Infusion-93623, SVT/Aflutter Ablation- 93653, Accessory Pathway Ablation- 93653

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Brugada J,et.al. 2019 ESC Guidelines for the Management of Patients With Supraventricular Tachycardia: The Task Force for the management of patients with supraventricular tachycardia of the European Society of Cardiology (ESC): Developed in collaboration with the Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J 2020;41:655-720
2. Page RL, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Journal of the American College of Cardiology. April 2016. Volume 67, Issue 13, Pages e27-115.
3. Blomström-Lundqvist C, et al. ACC/AHA/ESC guidelines for the management of patients with supraventricular arrhythmias--executive summary. a report of the American college of cardiology/American heart association task force on practice guidelines and the European society of cardiology committee for practice guidelines (writing committee to develop guidelines for the management of patients with supraventricular arrhythmias) developed in collaboration with NASPE-Heart Rhythm Society. Journal of the American College of Cardiology. Oct 2003. Volume 42, Issue 8, Page 1493-531
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy:

EPS with AI for AFib AVN and AP Ablation

POLICY NUMBER UM CARDIO_1142	SUBJECT Electrophysiology Study with Arrhythmia Induction for Atrial Fibrillation Ablation, AV Node Ablation and Accessory Pathway		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/05/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/05/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 02/01/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Electrophysiology Study with Arrhythmia Induction for Atrial Fibrillation ablation, AV Node Ablation and Accessory pathway Ablation.

II. DEFINITIONS

An electrophysiological study (EP study) is an invasive procedure that evaluated abnormal heart rhythm disturbances. During an EP study, small, thin wire electrodes are inserted through a vein in the groin (or neck, in some cases). The wire electrodes are threaded into the heart, using a special type of X-ray, called fluoroscopy. Once in the heart, electrical signals are measured. Electrical signals are sent through the catheter to stimulate the heart tissue to try to initiate the abnormal heart rhythm disturbances for evaluation.

Radiofrequency ablation consists of the application of unmodulated, high frequency alternating current flow to the heart to injure cells for the purpose of destroying ectopic foci.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[5]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,4,5,6].

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Newly discovered Atrial Fibrillation (Atrial Fibrillation Ablation and Accessory pathway Ablation)
   1. Patient with EKG evidence of pre-excitation or WPW syndrome with disabling arrhythmia related symptoms. **(AUC Score 7)**[1,2,3,4]
   2. Patient with newly discovered Atrial Fibrillation with disabling arrhythmia related symptoms and evidence of rate control and/or anti-arrhythmic drug (at least 1 Class I or III)/EC treatment failure with evidence of a normal or mildly dilated left atrium, normal or mildly decreased LV function and absence of pulmonary hypertension when a rhythm control strategy is desired. **(AUC Score 9)**[1,2,3,4]

B. Paroxysmal Atrial Fibrillation (Atrial Fibrillation Ablation and Accessory Pathway Ablation)
   1. Patient with EKG evidence of pre-excitation or WPW syndrome with disabling arrhythmia related symptoms. **(AUC Score 7)**[1,2,3,4]
   2. Patient with symptomatic recurrence of Atrial Fibrillation with evidence of rate control and/or anti arrhythmic drug (at least 1 Class I or III)/EC treatment failure with evidence of a normal or mildly dilated left atrium, normal or mildly decreased LV function and absence of pulmonary hypertension when a rhythm control strategy is desired. **(AUC Score 9)**[1,2,3,4]

C. Persistent Atrial Fibrillation (Atrial Fibrillation Ablation and Accessory Pathway Ablation)
   1. Patient with EKG evidence of pre-excitation or WPW syndrome with disabling arrhythmia related symptoms. **(AUC Score 7)**[1,2,3,4]
   2. Patient with persistent Atrial Fibrillation with evidence of rate control and / or anti arrhythmic drug (at least 1 Class I or III) /EC treatment failure with evidence of a normal or mildly dilated left atrium, or normal or mildly decreased LV function and absence of pulmonary hypertension. **(AUC Score 9)**[1,2,3,4]

D. Permanent Atrial Fibrillation (AV Nodal Ablation and Accessory Pathway Ablation)
   1. Patient with EKG evidence of pre-excitation or WPW syndrome with disabling arrhythmia related symptoms. **(AUC Score 7)**[1,2,3,4]
   2. Frequent or poorly tolerated episodes of narrow QRS tachycardia (rapid ventricular response), not adequately responding to guideline directed medical therapy. **(AUC Score 6)**[1,2,3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

B. Before proceeding with ablation for a patient with Atrial Fibrillation the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT.[1,2,3,4,5,6]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or EP Progress Note that prompted request
   2. Recent EKG (within 10 days)
   3. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis, etc.)

B. Primary codes appropriate for this service: AV Nodal Ablation-93650, Accessory Pathway Ablation- 93653, Atrial Fibrillation Ablation- 93656, 93657

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Joglar et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation. JACC VOL. 83, NO. 1, 2024, JANUARY 2/9, 2024:109–279110
2. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
3. January CT, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2019 Jul 9;74(1):104-132.
4. Douglas Packer, MD et.al. Ablation Versus Drug Therapy for Atrial Fibrillation in Heart Failure. Results From the CABANA Trial. Circulation. 2021; 143:1377–13904.
5. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy:

Non-Invasive Programmed Stimulation of AICD

POLICY NUMBER UM CARDIO_1143	**SUBJECT** Non-Invasive Programmed Stimulation of AICD		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 11/10/21, 11/09/22, 10/18/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 11/10/21, 11/09/22, 10/18/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Non-Invasive Programmed Stimulation (NIPS) of AICD.

II. DEFINITIONS

NIPS is a cardiac test performed to analyze the electrical activity of the heart in a patient that has an implanted AICD. The AICD is used to create the programmed stimulation.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Patients with history of VT or presence of structural heart disease with inducible VT who are unstable to undergo final programmed stimulation. **(AUC Score 7)**[1,2,3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or EP Progress Note that prompted request
   2. Other previous monitoring tests pertinent to referral (Holter, Event Monitoring, Device Analysis, etc.)

B. Primary codes appropriate for this service: 93642, 93644-testing for Sub Q device

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Al-Khatib SM, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. Oct 2018, Volume 15, Issue 10, Pages e190-e252.
2. Douglas P. Zipes MD, et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death—Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). Journal of the American College of Cardiology. Sept 2006. Volume 48, Issue 5, Page 1064-1108.
3. Frankel DS, et al. Noninvasive programmed ventricular stimulation early after ventricular tachycardia ablation to predict risk of late recurrence. Journal of the American College of Cardiology. April 2012. Volume 59, Issue 17, Pages 1529-35.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Automatic Implantable Cardioverter Defibrillator Battery Replacement

POLICY NUMBER UM CARDIO_1144	**SUBJECT** Automatic Implantable Cardioverter Defibrillator Battery Replacement		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 08/12/20, 08/11/21, 01/12/22, 02/09/22, 01/11/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 10/31/17, 03/13/19, 12/11/19, 08/12/20, 08/11/21, 01/12/22, 02/09/22, 01/11/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for automatic implantable Cardioverter defibrillator (AICD) Battery Replacement.

II. DEFINITIONS

The automatic implantable cardioverter defibrillator (AICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmia's or Brady arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing, and defibrillation.

The AICD is checked periodically, amongst other parameters, for battery voltage. Once its longevity is reaching effective replacement index (ERI) or once it has reached end of life (EOL) the defibrillator will create an alert for replacement.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. AICD/S-ICD implantation for Primary prevention of Sudden Cardiac Death with recent interrogation showing no clinically relevant Ventricular Arrhythmias but with battery voltage at ERI or Battery voltage less than 2.7v or EOL and LVEF less than or equal to 35%. **(AUC Score 9)**[1,2,3]

B. AICD/S-ICD implantation for Primary prevention of Sudden Cardiac Death with recent interrogation showing clinically relevant Ventricular Arrhythmias since implant and with battery voltage at ERI or Battery voltage less than 2.7v or EOL with LVEF greater than or equal to 35%. **(AUC Score 9)**[1,2,3]

C. AICD/S-ICD implanted for secondary prevention with no Ventricular arrhythmia since implant and recent interrogation showed no Ventricular Arrhythmia since implant and battery voltage at ERI or Battery voltage less than 2.7v or EOL **(AUC Score 9)**[1,2,3]

D. AICD/S-ICD implanted for secondary prevention and recent interrogation Ventricular arrhythmia since implant showed Ventricular arrhythmia since implant and battery voltage at ERI or Battery voltage less than 2.7v or EOL. **(AUC Score 9)**[1,2,3]

E. Lead repositioning/replacement/removal may be performed in the presence of evidence of lead malfunctioning on recent interrogation or if a lead recall has been issued. **(AUC Score 7)** [1,2]

F. Repositioning/relocation of the skin pocket for the device may be performed in the presence of infection, the development of overlying skin erosion/tissue necrosis, if any other anatomical factor prevents the device from properly functioning, or if device migration has resulted in significant patient discomfort. **(AUC Score 7)**[3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review
   1. Progress note that prompted request
   2. Device analysis data that triggered battery replacement
   3. Most recent Echocardiogram

B. Primary codes appropriate for this service: 33262 - Single lead, 33263 - Dual lead, 33264 - Multiple leads, 33241- Removal of Generator only, 33244 - Removal of single or dual ICD electrode(s), 33215 - Repositioning of PM or ICD lead, 33216 - Insertion of single lead, 33217 - Insertion of 2 leads PM or ICD, 33218 - Repair single lead PM or ICD, 33220 - Repair 2 leads for PM or ICD, 93640 - Electrophysiologic eval of single or dual ICD leads including defibrillation threshold prior to being connected to device, 93641 - Electrophysiologic eval of single or dual ICD leads including defibrillation threshold after being connected to device, 33223 - Relocation of skin pocket for device.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Russo AM, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy. Journal of the American College of Cardiology. March 2013. Volume 61, Issue 12, Pages 1318-68.
2. Epstein AE, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Journal of the American College of Cardiology. May 2008. Volume 51, Issue 21, Pages e1-62.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. Ranasinghe I., et al. Long-Term Risk for Device-Related Complications and Reoperations after Implantable Cardioverter-Defibrillator Implantation: An Observational Cohort Study. Ann Intern Med 2016 (from the National Cardiovascular Data Registry).
5. NCQA UM 2022 Standards and Elements.

Cardio Policy

Pacemaker Battery and Lead(s) Replacement

POLICY NUMBER UM CARDIO_1145	**SUBJECT** Pacemaker Battery and Lead(s) Replacement		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 11/08/18, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 01/11/23, 01/10/24, 05/08/24	**APPROVAL DATE** May 08, 2024	**EFFECTIVE DATE** May 31, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 11/08/18, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 07/13/22, 01/11/23, 01/26/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Device analysis data that triggered battery replacement

II. Purpose

Indications for determining medical necessity for Pacemaker Battery and Lead(s) Replacement.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

A. Indications For Battery Replacement:

- Recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)
- Battery has been recalled by manufacturer

B. Indications For Lead Replacement [6]

- Evidence of lead malfunctioning/recall on recent interrogation in previously implanted device requiring repositioning/replacement/removal
- Lead has been recalled by manufacturer

C. Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A pacemaker is a medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.

The pacemaker is checked periodically, amongst other parameters, for battery voltage. Once its longevity has reached the effective replacement index or end of life the pacemaker will create an alert for replacement.

A. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

VI. Coding and Standards

- **Primary Codes**
  - 33227, 33228, 33229
- **Related codes**
  - 33210, 33211, 33214, 33215, 33216, 33217, 33218, 33220, 33222, 33233, 33234, 33235, 33236, 33237, 33238
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

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[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] F. M. Kusumoto, M. H. Schoenfeld, B. L. Wilkoff, C. I. Berul, U. M. Birgersdotter-Green, R. Carillo, Y.-M. Cha, J. Clancy, A. A. Hussein, C. Kennergren, A. Krahn, R. Lee, C. J. Love, R. A. Madden, H. A. Mazzetti, J. C. Moore, J. Parsonnet, K. K. Patton, M. A. Rozner, K. A. Selzman, M. Shoda, K. Srivathsan, N. F. Strathmore, C. D. Swerdlow, C. Tompkins and O. Wazni, "2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction," *Heart Rhythm,* 2017.

Cardio Policy:

Implantation of Loop Recorder Systems

POLICY NUMBER UM CARDIO_1146	**SUBJECT** Implantation of Loop Recorder Systems		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 05/01/18, 02/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 01/12/22, 02/09/22, 12/14/22, 10/18/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 05/01/18, 02/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 01/12/22, 02/09/22, 12/14/22, 10/18/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Implantation of Loop Recorder System.

II. DEFINITIONS

The implantable loop recorder (ILR) is a patient-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The device is a programmable cardiac event recorder with looping memory and is implanted subcutaneously usually in a left pectoral or mammary location with a battery life of 15-18 months. The electrodes that sense the heart's activity are on the surface of the device, so no trans venous leads are necessary. This device allows continuous rhythm monitoring that is stored either when manually activated by a patient/parent or automatically when high or low rate parameters are met.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cos –effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. For patients with recurrent syncopal episodes (greater than 2 episodes within 3 months) of uncertain etiology with negative initial work up including Holter and Event monitor. **(AUC Score 9)**[1,2,3,4,5,6]

B. Implantable Loop Recorder is appropriate in patients with recent evidence of cryptogenic stroke to rule out arrhythmic etiology for stroke after initial negative arrhythmic work up with Holter/Event monitor. **(AUC Score 8)**[1,2,3,4,5,6]

C. Removal of ILR for end of battery life. **(AUC Score 8)**

D. Removal of ILR due to pain, discomfort, infection at ILR site, or patient desires the device to be removed. **(AUC Score 8)**

Limitations:

A. There is not enough evidence to support Loop implantation in presence of another Cardiac device (AICD/PPM/CRT etc.) and will not be reviewed/approved.

B. Loop Implantation post Afib ablation is not routinely indicated and will be addressed case by case basis.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review

1. Progress note that prompted request
2. Most recent EKG
3. Latest device interrogation report with strips

B. Primary codes appropriate for this service: 33285- Implantation of Loop Recorder, 33286- Removal of Implantable Loop Recorder

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. National Coverage Determination (NCD) for Electrocardiographic Services (20.15), 2004. [Accessed December 19, 2023].
2. Sana M. Al-Khatib, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death - A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 138: e272–e391

3. Calkins H, et al. European Heart Rhythm Association (EHRA); European Cardiac Arrhythmia Society (ECAS); American College of Cardiology (ACC); American Heart Association (AHA); Society of Thoracic Surgeons (STS). HRS/EHRA/ECAS expert Consensus Statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2007; 4 (6):816-861.
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6. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
7. NCQA UM 2022 Standards and Elements.

Cardio Policy
Pacemaker Implantation

POLICY NUMBER UM CARDIO_1147	SUBJECT Pacemaker Implantation		DEPT/PROGRAM UM Dept	PAGE 1 OF 11
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 11/03/17, 02/08/18, 02/13/19, 03/08/19, 04/25/19, 07/30/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 11/03/17, 02/08/18, 02/13/19, 03/08/19, 04/25/19, 07/30/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

PURPOSE

This guideline is not intended to specify the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines. Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care [1, 2, 3, 4, 5].

INDICATIONS FOR PACEMAKERS IN ADULTS

Excludes conditions that are expected to resolve

Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses [6, 7]
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or cardiac monitoring data (Holter/MCOT/Electrocardiography (ECG)) recording data [6, 7]
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment [6, 7]

- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia [6]
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia [8, 7]
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS) [6]

Acquired Atrioventricular (AV) Block

First-Degree AV Block

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block [7]
- First-degree AV block with "pacemaker syndrome" symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise [7]

Second-Degree AV Block (Mobitz Types I and II)

- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block [6, 7]
- Second-degree AV block with "pacemaker syndrome" symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise [6]
- Second-degree Mobitz Type II AV block regardless of symptoms [6, 7]
- Advanced second-degree AV block [6]
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction [6]
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II [6]

Third-Degree/Complete AV Block

- Third-degree (complete) AV block, intermittent or persistent, regardless of symptoms [6]
- High-grade AV block, regardless of symptoms [7]

AF/Other

- Atrial fibrillation while awake, with pauses ≥ 5 seconds, or symptomatic bradycardia [6]
- In sinus rhythm (with AV block) while awake, pauses ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node [6]
- Following catheter ablation of the AV junction [6]
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment [6, 7]
- Exercise-induced second- or third-degree AV block without myocardial ischemia [6, 7]

Neuromuscular Disorders

- Marked first-degree or higher AV block, or an H-V interval ≥ 70 ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb's dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms [6, 7]

Chronic Fascicular (Including any of RBBB, LBBB, LAHB, LPHB) Block

- Alternating bundle-branch block [6, 7]
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia [6]
- Syncope and bundle branch block with an HV interval ≥ 70 ms, or evidence of infranodal block at EPS [7]
- Incidental findings at EPS study of an H-V interval ≥ 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients [6]

Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole ≥ 3 seconds [6], or AV block, or ≥ 50 mmHg drop in systolic BP
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) ≥ 3 seconds [6]
- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by ECG recording data [9, 10]

Pacing to Terminate or Prevent Tachycardia

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment [6]
- Prevention of pause-dependent ventricular tachycardia (VT) [6]

Recommendations for Permanent Pacing in Patients with Hypertrophic Cardiomyopathy (HCM):

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction

Recommendations for Leadless Pacemaker Include:

- Patients with bradycardia and need only single chamber (RV) pacing in VVI or VVIR mode:
    - Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF).

- Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
- Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity

INDICATIONS FOR CONGENITAL HEART DISEASE PACING (PEDIATRIC AND ADULT)

Children, Adolescents (< 19 years), and ADULT Patients with Congenital Heart Disease (CHD)

Sinus Node Dysfunction (SND)

- SND with symptomatic age- and activity-inappropriate bradycardia [7]
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds [8]
- CHD and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony
- Asymptomatic sinus bradycardia following repair of CHD with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds
- CHD and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia[4, 6, 7]

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output [8]
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction [7]
- Congenital third-degree AV block in the infant with a ventricular rate < 55 bpm or with congenital heart disease and a ventricular rate < 70 bpm
- Congenital third-degree AV block after 1 year of age with an average heart rate < 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence [7]
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction [7, 8]
- Adults with congenital complete AV block, regardless of symptoms [7]

- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after excluding other causes of syncope
- Congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS, and normal ventricular function

Scenarios in which Pacemakers are Not Indicated [11, 8]

- SND in patients that are asymptomatic, or symptoms occur without documented bradycardia
- Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
- Asymptomatic fascicular block (Including any of RBBB, LBBB, LAHB, LPHB)
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB where a higher degree of heart block has not been demonstrated
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB after surgery for CHD without prior transient complete AV block

Codings and Standards

CPT Codes: 33206, 33207, 33208, 33212, 33213, 33274, 33275. 33215, 33216, 33217, 33218, 33220
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (x-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into their tips. Timed electrical impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner [3].

- Appropriate Care – Median Score 7-9
- May be Appropriate Care – Median Score 4-6
- Rarely Appropriate Care – Median Score 1-3

Heart Block Definitions [6]

- First-Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200 ms)
- Second-Degree: Intermittent failure of conduction of single beats from atrium to ventricles
    - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles
    - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles
    - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats with some conducted beats
- Third-Degree: No atrial beats are conducted from atrium to ventricle

Abbreviations

AV	Atrioventricular
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (same as biventricular pacing)
ECG	Electrocardiogram
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HV	His-ventricular
ICD	Implantable cardioverter-defibrillator
LAHB	Left Anterior Hemiblock
LBBB	Left bundle-branch block
LPHB	Left Posterior Hemiblock
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
RBBB	Right Bundle Branch Block
s	Seconds
STEMI	ST-elevation Myocardial Infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia

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Cardio Policy:

Synchronized Electrical Cardioversion

POLICY NUMBER UM CARDIO_1148	**SUBJECT** Synchronized Electrical Cardioversion		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 01/12/22, 01/11/23, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 02/18/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 01/12/22, 01/11/23, 02/01/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Synchronized Electrical Cardioversion.

II. DEFINITIONS

Synchronized electrical cardioversion is a medical procedure by which an abnormally fast heart rate or cardiac arrhythmia is converted to a normal rhythm using a therapeutic dose of electric current to the heart, at a specific moment in the cardiac cycle.

Good Candidacy for Synchronized electrical cardioversion is defined as a patient who had failed guideline directed medical therapy or has mildly dilated Left Atrium and/or normal or mildly decreased LV function with absence of Pulmonary Hypertension.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[6]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when

prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,3,4,5,6]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Evidence of first episode or recurrent Atrial Flutter with failed on pharmacological therapy and patient is a suitable candidate for synchronized cardioversion. **(AUC Score 8)[1,2,3,4]**

B. Newly discovered or recurrent or persistent Atrial Fibrillation with or without pre-excitation, in a patient with rate control and/or antiarrhythmic drug treatment failure and is a suitable candidate for synchronized cardioversion. **(AUC Score 8)[1,2,3,4]**

C. Internal cardioversion is appropriate to perform for indications A and B in patients with Cardiovascular Implantable Electronic Device (CIED: AICD, CRT-D) to restore sinus rhythm. **(AUC Score 8)[1,2,3,4]**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

B. Before proceeding with synchronized electrical cardioversion for a patient with arrhythmias the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT in a patient that is adequately anticoagulated.[1,2,3,4,5,6]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress notes that prompted request (including medication list)
   2. Recent EKG (less than 10 days)
   3. Most recent Holter/Event monitor/loop recorder/device interrogation strips report, if applicable.

B. Primary codes appropriate for this service: 92960, 92961

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy
Cardiac Resynchronization Therapy Implantation

POLICY NUMBER UM CARDIO_1149	**SUBJECT** Cardiac Resynchronization Therapy Implantation		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 8**
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 02/13/19, 03/08/19, 07/30/19, 12/11/19, 08/12/20, 10/14/20, 07/14/21, 08/11/21, 07/13/22, 02/01/23, 03/16/23, 12/20/23, 01/10/24, 03/13/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 02/13/19, 03/08/19, 07/30/19, 12/11/19, 08/12/20, 10/14/20, 07/14/21, 08/11/21, 07/13/22, 02/01/23, 03/16/23, 12/20/23, 01/10/24, 03/13/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline describes the medical necessity for cardiac resynchronization therapy (CRT). Indications for CRT for patients are based upon left ventricular (LV) ejection fraction (LVEF), QRS duration, New York Heart Association (NYHA) functional class (presence or absence of symptoms) and need for ventricular pacing regardless of etiology (ischemic or non-ischemic cardiomyopathy) [1, 2, 3].

Cardiomyopathy

Indications

NOTE: The following indications only apply to patients

A. Who have been on GDMT for 3 months or

B. Who have been on GDMT and are 40 days after MI, or

C. With implantation of pacing or defibrillation device for special indications (class indicates NYHA functional class)

Class I Through Class IV [1, 2, 4]

- Ischemic cardiomyopathy, LVEF ≤ 30%, QRS ≥ 150, LBBB, Sinus Rhythm (AUC 7-9)

Class II Through Class IV [1, 2, 4]

- Ischemic and non-ischemic cardiomyopathy, LVEF ≤ 35%, QRS ≥ 120ms, LBBB, Sinus Rhythm (AUC 7-9)
- Nonobstructive HCM, LVEF < 50%, LBBB, CRT therapy for symptom reduction

Class III Through Class IV [1, 5]

- Ischemic and non-ischemic cardiomyopathy, LVEF ≤ 35%, QRS ≥ 150ms, non-LBBB, Sinus Rhythm (AUC 7)

Special Situations: Independent/Regardless of NYHA Heart Failure Class

- Patients with an indication for ventricular pacing and high degree AV block or are expected to be paced more than 40% of the time; this includes patients with Atrial fibrillation [5, 1]
- Patients with Atrial fibrillation and LVEF ≤ 35% who requires ventricular pacing or otherwise meets CRT criteria; AND AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT
  - For patients with atrial fibrillation and LVEF≤ 50%, if a rhythm control strategy fails and ventricular rates remain rapid despite medical therapy, atrioventricular nodal ablation with implantation of a CRT device is reasonable [4]
  - As CRT has not been studied in ATTR-CM, those with HFrEF should follow guidelines for Class II-Class IV indications

Not Indicated

- NYHA class I and non-LBBB pattern with QRS duration < 150 ms [2, 1], except as in Special Situations section above
- Comorbidities and/or frailty expected to limit survival with good functional capacity to <1 year [6]
- Active bloodstream infection
- Reversible causes are present such as toxic-, metabolic- or tachycardic-mediated cardiomyopathy, would require reassessment once the situation is corrected
- Cardiogenic shock or symptomatic hypotension while in stable baseline rhythm

Adult Congenital Heart Disease

Indications

Class I Through Class IV

- Systemic ventricle with any EF (not restricted), intrinsic narrow QRS complex, and undergoing new device placement or replacement with anticipated requirement for significant (>40%) ventricular pacing (AUC 7-8) [1, 6].

Class II Through Class IV

- Systemic LV EF ≤ 35%, sinus rhythm and wide QRS complex ≥ 130 ms [6]
- Any CHD, wide QRS complex ≥ 150 ms due to a complete RBBB, with a severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload [6]

Class IV

- Severe ventricular dysfunction, and would otherwise be candidates for heart transplantation or mechanical circulatory support [6]

Not Indicated

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to < 1 year [6]

INDICATIONS FOR CRT AS THE APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS WITH < 3 MONTHS OF GDMT [1, 7]

Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or pacemaker and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or < 40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. This avoids a second implantation procedure within less than 3 months.

CODING and STANDARDS

CPT Codes: 33221, 33224, 33225, 33231, 33241, 33249
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

Overview

CRT, which paces the left and right ventricle in rapid sequence, also known as biventricular pacing, improves coordination of ventricular contraction in the presence of a wide QRS complex in systolic heart failure.

CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. In the proper patient population, improved survival in patients with CRT can be greater than that provided by ICD insertion alone.

Guiding principles in the consideration of CRT:

- NYHA class is an important qualifying factor, with candidacy based on functional class, EF, and QRS duration.
- Bundle branch block or intraventricular conduction delay should be persistent, not rate related [1].
- GDMT should have been in place continuously for at least 3 months and recovery of LVEF from myocardial infarction (40 days) if no intervening revascularization or > 3 months if revascularization was performed. Reversible causes (e.g., ischemia) should be excluded [2, 4].

- The patient should have expected survival with reasonably good functional status for more than 1 year [2, 6].

Definitions

NYHA Class Definitions [1, 3]

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Heart Block Definitions [2]

- First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200 ms.
- Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
    - Type I: Conducted beats have variable conduction times from atrium to ventricles.
    - Type II: Conducted beats have uniform conduction times from atrium to ventricles.
    - Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
- Third Degree: No atrial beats are conducted from atrium to ventricle.

Guideline-Directed (or Optimal) Medical Therapy in Heart Failure [4]

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker

Other options/considerations for GDMT

- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73m2 and K+ < 5.0, NYHA class II-IV
- Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor

ARB	Angiotensin receptor blocker
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
CHD	Congenital heart disease
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (also known as biventricular pacing)
CRT-D	Cardiac resynchronization therapy defibrillator
ECG	Electrocardiogram
EF	Ejection Fraction
eGFR	Estimated glomerular filtration rate
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HCM	Hypertrophic Cardiomyopathy
HF	Heart failure
HFrEF	Heart failure with reduced ejection fraction
HV	His-ventricular
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle branch block
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
NYHA	New York Heart Association
RBBB	Right bundle branch block
RV	Right ventricle
SND	Sinus node dysfunction
SR	Sinus rhythm
STEMI	ST-Elevation Myocardial Infarction
VT	Ventricular tachycardia

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Cardio Policy:

Device Physiologic CV Data Element Interrogation

POLICY NUMBER UM CARDIO_1152	**SUBJECT** Device Physiologic CV Data Element Interrogation		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 01/08/14, 10/14/15, 11/28/16, 07/13/17, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 10/13/21, 10/12/22, 09/13/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 01/08/14, 10/14/15, 11/28/16, 07/13/17, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 10/13/21, 10/12/22, 09/13/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Device Physiologic CV Data Element Interrogation also known as Intra Cardiac Monitoring, ICM (Optivol).

II. DEFINITIONS

Some implantable device systems have a sophisticated computerized data analysis system to detect changes in blood volume. These data elements from one or more internal sensors (such as right ventricular, left atrial or an index of lung water) and/or external sensors (such as blood pressure or body weight) are used for patient assessment and management.

The Optivol fluid trend tracks intrathoracic impedance changes over time. This allows the clinician to better understand how the patient's fluid status compares with changes in medications, clinical events and outcomes, and overall patient status. As the patient's lungs become congested, intrathoracic impedance tends to decrease. Similarly, an increase in intrathoracic impedance may indicate the patient's lungs are becoming drier. Optivol monitoring to predict worsening heart failure is not intended to replace assessments which are part of standard clinical practice.

III. POLICY

Indications for approving a request for medical necessity are:

A. The patient has an AICD/CRT-D/CRT-P device which have Optivol monitoring capability.

B. A device interrogation for ICM has not been performed within the last 3O days. **(AUC Score 5)**[1,2,3,4]

Frequency Guidelines:

A. Remote interrogation AICD/CRT for Optivol – 30 days **(AUC Score 5)**[1,2,3,4]

B. Remote interrogation AICD/CRT for Optivol - 90 days **(AUC Score 7)**[1,2,3,4]

C. In person interrogation AICD/CRT for Optivol – 30 days **(AUC Score 5)**[1,2,3,4]

D. In person interrogation AICD/CRT for Optivol – 90 days **(AUC Score 7)**[1,2,3,4]

Limitations:

A. Approval for Optivol monitoring is limited to those patients who carry a diagnosis of congestive heart failure.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

   1. Progress note that prompted the request
   2. Latest device interrogation for ICM report with strips

B. Primary codes appropriate for this service: In Person-93290, Remote-93297; G2066 – technical code for remote device interrogation of an implantable cardiovascular physiologic monitor system.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Slotwiner, D, et al. HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Devices. Heart Rhythm, July 2015. Volume 12, No 7, Pages e69-e100.
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4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2023 Standards and Elements.

Cardio Policy

Microvolt T-Wave Alternans

POLICY NUMBER UM CARDIO_1158	SUBJECT Microvolt T-Wave Alternans		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24, 03/13/23	APPROVAL DATE March 13, 2024	EFFECTIVE DATE March 29, 2024	COMMITTEE APPROVAL DATES 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*

II. Purpose

Indications for determining medical necessity for Microvolt T-Wave Alternans testing.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications for Microvolt T-Wave Alternans

The non-invasive Microvolt T-Wave Alternans is not recommended for risk stratification of patients with ventricular arrythmias or who are at risk for developing life threatening arrythmias. (Priori, et al., 2015) Data on the use of Microvolt T-Wave Alternans is inconclusive and not routinely used in clinical practice. (Al-Khatib, et al., 2018)

V. Background

A. Definitions

1. **Electrocardiogram (ECG)**: is a recording of the heart's electrical activity to review the electrical conduction system of the heart

2. **Sudden Cardiac Death (SCD)**: sudden or unexpected death due to a cardiovascular cause and occurs within an hour of onset of symptoms
3. **Ventricular Arrhythmias**: abnormal heart rhythm affecting the ventricular chambers of the heart
    - Premature Ventricular Complexes (PVCs)
    - Nonsustained Ventricular Tachycardia (NSVT)
    - Ventricular Tachycardia (VT)
    - Torsades de pointes
    - Ventricular Flutter
    - Ventricular Fibrillation

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. (Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

ECG	Electrocardiogram
MTWA	Microvolt T-Wave Alternans
NSVT	Nonsustained Ventricular Tachycardia
PVC	Premature Atrial Contractions
SCD	Sudden Cardiac Death
VT	Ventricular Tachycardia

VI. Codings and Standards

- **Primary Codes**
    - 93025
- **Review**
    - Utilization Management Department
- **Final Approval**
    - Utilization Management Committee

VII. References

[1] Al-Khatib, S., Stevenson, W., Ackerman, M., Bryant, W., Callans, D., Curtis, A., . . . et al. (2018, Sept 25). 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Circulation*, e272-e391. doi:10.1161/CIR.0000000000000549

[2] Bonow, R., Douglas, P., Buxton, A., Cohen, D., Curtis, J., Delong, E., . . . American College of Cardiology Foundation. (2011, Sept). ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation, 124*(13), 1483-502. doi:10.1161/CIR.0b013e31822935fc

[3] Fitch, K., Bernstein, S. J., Aguilar, M. D., Burnand, B., LaCalle, J. R., Lazaro, P., . . . Kahan, J. P. (2001). *The RAND/UCLA Appropriateness Method User's Manual.* Santa Monica, CA: RAND Corporation. Retrieved from https://www.rand.org/pubs/monograph_reports/MR1269.html

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[6] Patel, M., Spertus, J., Brindis, R., Hendel, R., Douglas, P., Perterson, E., . . . American College of Cardiology Foundation. (2005, Oct). ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol, 46*(8), 1606-13. doi:10.1016/j.jacc.2005.08.030

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Cardio Policy:

Tilt Table Testing

POLICY NUMBER UM CARDIO_1159	SUBJECT Tilt Table Testing		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 07/13/22, 07/18/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 07/13/22, 07/18/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Tilt Table Testing.

II. DEFINITIONS

Tilt table testing is used to evaluate the autonomic nervous system control of cardiovascular function in patients with syncope, generally after other, potentially more harmful, likely, or readily managed causes have been ruled out by history, physical examination or other appropriate tests. The test utilizes a specialized table which passively takes the patient from a supine position to a head-up position (60 or 90 degrees). Heart rate, blood pressure and ECG are continuously monitored.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Evaluation of recurrent syncope or a single syncopal event in a high-risk setting, e.g., commercial vehicle driver), where there is no evidence of structural heart disease. **(AUC Score 8)**[1,2,3,4]

B. Evaluation of syncope in patients without structural heart disease for whom the diagnosis of syncope is not evident from the history and who have a negative carotid sinus massage. **(AUC Score 8)**[1,2,3,4]

C. Evaluation of syncope in patients with structural heart disease who have had a complete evaluation including a negative electrophysiology study. **(AUC Score 8)**[1,2,3,4]

D. Further evaluation of patients in whom a specific cause for syncope has been established, but where demonstration of susceptibility to reflex mediated syncope could affect management. **(AUC Score 7)**[1,2,3,4]

E. Evaluating patients with unexplained recurrent falls but without a history of prodromal symptoms characteristic of vasovagal syncope. **(AUC Score 6)**[1,2,3,4]

F. Evaluation of syncope associated with exercise when a thorough history and physical, with 12-lead ECG, echo, and cardiovascular stress test demonstrate no evidence of organic heart disease. **(AUC Score 7)**[1,2,3,4]

G. Suspected Postural Orthostatic Tachycardia Syndrome including follow-up evaluation of therapies **(AUC Score 5)**[1,2,3,4]

Limitations:

Tilt-table testing is not considered a reasonable and necessary test for any of the following:

A. Single syncopal episodes, without injury and not in a high-risk setting, with clear vasovagal features.

B. Syncope in which an alternative specific cause has been established, as by recordings during actual events or the reproduction of symptoms during diagnostic studies, in which additional demonstration of reflex- mediated susceptibility would not alter treatment plan.

C. Tilt-table testing will not be covered when used to evaluate isolated autonomic symptoms or sensory disturbances such as lightheadedness, weakness, visual disturbances, sweating, flushing, warmth, nausea, unless syncope has been documented in association with such symptoms.

D. The office or facility setting where the test is performed must be staffed and equipped to provide advanced cardiopulmonary resuscitation.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Most recent progress note that prompted request
   2. Most recent EKG
   3. Other previous monitoring or EPS testing pertinent to request

B. Primary codes appropriate for this service: 93660

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Shen WK, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Journal of the American College of Cardiology. Aug 2017. Volume 70, Issue 5, Pages e39-e110.
2. Moya A, et al. Guidelines for the diagnosis and management of syncope (version 2009). European Heart Journal. Nov 2009. Volume 30, Issue 21, Pages 2631-71.
3. Brignole M, et al. Guidelines on management (diagnosis and treatment) of syncope--update 2004. Nov 2004. Volume 6, Issue 6, Pages 467-537.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2023 Standards and Elements.

Cardio Policy
Endovascular Aortic and Iliac Artery Aneurysm Repair

POLICY NUMBER UM CARDIO_1162	SUBJECT Endovascular Aortic and Iliac Artery Aneurysm Repair		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 02/18/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/02/18, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 02/18/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/02/18, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*

II. Purpose

Indications for determining medical necessity for endovascular repair of an abdominal aortic or iliac artery aneurysm.

III. Clinical reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

- When commercial grafts or stents are used for endovascular repair of aortic aneurysms, implantation must follow the device's specific instructions for use
- **Ruptured Aneurysm**
    - Repair is indicated in patients presenting with a ruptured aneurysm(s). [6, 7, 8]
- **Unruptured Aneurysm**
    - In patients with unruptured, **symptomatic** aneurysms, repair is indicated even for small aneurysms. [6, 7, 8] Symptoms include abdominal and/or back pain and embolic events that do not breach the aortic wall. [8]
        - For abdominal aortic aneurysms (AAA), endovascular repair is recommended over open surgical repair for patients with high- or moderate-high perioperative risk. [7] For patients with AAA and low-moderate perioperative risk, both endovascular and open surgical repair are indicated.
    - In patients with unruptured, **asymptomatic** aneurysms, repair is indicated when the maximal diameter of the artery enlarges to a threshold, which varies by anatomical location:
        - For abdominal aortic aneurysms (AAA), repair is indicated when maximal aneurysm diameter is ≥5.5 cm in men or ≥5.0 cm in women. [7, 8] Endovascular repair is recommended over open surgical repair for patients with high- or moderate-high perioperative risk. [7]
            - For patients with AAA and low-moderate perioperative risk, both endovascular

and open surgical repair are indicated.

- For iliac artery aneurysms, repair is indicated when the maximal diameter is ≥3.5 cm. [7] Both endovascular and open surgical repair are indicated.

- In patients with unruptured AAA and aneurysm growth rate of ≥0.5 cm in 6 months, endovascular repair to reduce the risk of rupture may be reasonable [7]

- **Limitations**
  - Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
  - When commercially-available grafts are used for endovascular repair of aortic aneurysms, implantation must follow the device's specific instructions for use. Modified grafts should only be used as part of a clinical trial.
  - Both endovascular and open surgical repair procedures require advanced skill sets. If these are not available, the provider should consider transferring the member/patient to a facility that can perform the appropriate procedure.
  - Elective repair of AAA, by either endovascular or open surgical procedures, is not recommended in patients with a limited life expectancy (<2-3 years) [8]
  - Open surgical repair of AAA is preferred over endovascular procedures in patients with long life expectancies (>10-15 years) [8]

V. Background

A. Definitions

Endovascular AAA repair involves the placement of a stent graft within the affected blood vessel by retrograde access through the femoral artery, which seals the aneurysm sac from within without touching the wall of the aneurysm itself. Features associated with an increased risk of rupture include: rapid aneurysm growth (≥0.5 cm/year), symptomatic aneurysm(s), a significant change in aneurysm appearance, and saccular aneurysms or presence of penetrating atherosclerotic ulcers. [7]

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AAA	Abdominal aortic aneurysm
AUC	Appropriate use criteria
CT	Computed tomography
OOS	Out of scope
TAAA	Thoracoabdominal aortic aneurysm

VI. Coding and Standards

- **Primary Codes**
  - 34701, 34702-34718, 34808, 34812, 34813, 34820, 34833, 34834, 34841-34848
- **Related Codes**
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] E. L. Chaikof, R. L. Dalman, M. K. Eskandari, B. M. Jackson, W. Anthony Lee, M. Ashraf Mansour, T. M. Mastracci, M. Mell, M. Hassan Murad, L. L. Nguyen, G. S. Oderich, M. S. Patel, M. L. Schermerhorn and B. W. Starnes, "The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm," *J Vasc Surg,* vol. 67, no. 1, pp. 2-77, 2018.

[7] E. M. Isselbacher, O. Preventza, J. Hamilton Black III, J. G. Augoustides, A. W. Beck, M. A. Bolen, A. C. Braverman, B. E. Bray, M. M. Brown-Zimmerman, E. P. Chen, T. J. Collins, A. DeAnda Jr., C. L. Fanola, L. N. Girardi, C. W. Hicks, D. S. Hui, W. Schuyler Jones, V. Kalahasti, K. M. Kim, D. M. Milewicz, G. S. Oderich, L. Ogbechie, S. B. Promes, E. Gyang Ross, M. L. Schermerhorn, S. Singleton Times, E. E. Tseng, G. J. Wang and J. Woo, "2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines," *Circulation,* vol. 146, no. 24, pp. e334-e482, 2022.

[8] A. Wanhainen, I. Van Herzeele, F. B. Gonclaves, S. B. Montoya, X. Berard, J. R. Boyle, M. D'Oria, C. F. Prendes, C. D. Karkos, A. Kazimierczak, M. J. Koelemay, T. Kolbel, K. Mani, G. Melissano, J. T. Powell, S. Trimarchi and N. Tsilimparis, "European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms," *Eur J Vasc Endovasc Surg,* vol. 67, no. 2, pp. 192-331, 2024.

Cardio Policy:

Carotid Endarterectomy

POLICY NUMBER UM CARDIO_1163	**SUBJECT** Carotid Endarterectomy		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Carotid Endarterectomy.

II. DEFINITIONS

Carotid endarterectomy (CEA) is a surgical procedure used to prevent stroke, by correcting stenosis (narrowing) in the common or internal carotid artery. Endarterectomy is the removal of material on the inside of an artery.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Patients at an average or low surgical risk who experience non-disabling ischemic stroke or transient cerebral ischemic symptoms, including hemispheric events or amaurosis fugax, within 6 months (symptomatic patients) should undergo CEA if the diameter of the lumen of the ipsilateral internal carotid artery is reduced more than 70% as documented by noninvasive imaging or more

than 50% as documented by catheter angiography and the anticipated rate of perioperative stroke or mortality is less than 6%. **(AUC Score 9)**[1,2,3]

B. It is reasonable to perform CEA in asymptomatic patients who have more than 70% stenosis of the internal carotid artery if the risk of perioperative stroke, MI, and death is low. **(AUC Score 6)**[1,2,3]

C. It is reasonable to choose CEA over Carotid Artery Stenting (CAS) when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention. **(AUC Score 9)**[1,2,3]

D. When revascularization is indicated for patients with TIA or stroke and there are no contradictions to early revascularization, intervention within 2 weeks of the index event is reasonable rather than delaying surgery. **(AUC Score 9)**[1,2,3]

Limitations:

A. Except in extraordinary circumstances, carotid revascularization by CEA is not recommended when atherosclerosis narrows the lumen by less than 50%. Carotid revascularization is not recommended for patients with chronic total occlusion of the targeted carotid artery. Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risk and benefits of the procedure with an understanding of patient's preferences.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note from vascular surgeon that prompted the request
   2. Latest imaging report supporting request
   3. All non-invasive Vascular Studies performed applicable to the request

B. Primary codes appropriate for this service: 35301

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Brott TG, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease. Journal of the American College of Cardiology. Feb 2011. Volume 57, Issue 8, Pages e16-94.
2. Ralph L. Sacco, et al. Guidelines for Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack. A Statement for Healthcare Professionals from the American Heart Association/American Stroke Association Council on Stroke: Co-Sponsored by the Council on Cardiovascular Radiology and Intervention: The American Academy of Neurology affirms the value of this guideline. Stroke. Feb 2006. Volume 37, Issue 2, Pages 577-617.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Femoral Popliteal Bypass Surgery

POLICY NUMBER UM CARDIO_1164	**SUBJECT** Femoral Popliteal Bypass Surgery		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/02/18, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 03/09/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/02/18, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 03/09/22, 02/01/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Femoral Popliteal Bypass Surgery.

II. DEFINITIONS

Femoral popliteal artery bypass, grafting is surgery utilizing a saphenous vein or synthetic or composite graft to bypass an occluded or narrowed section of the femoral artery and restore blood flow to the leg.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[11]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,4,6,7]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity:

A. Surgical procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication with inadequate response to GDMT, acceptable perioperative risk, and technical factors suggesting advantages over endovascular procedures. **(AUC Score 6)**[1,2,3,4,5,6,7,8,9,10]

B. When surgical revascularization is performed, bypass to the popliteal artery with autogenous vein is recommended in preference to prosthetic graft material. **(AUC Score 9)**[1,2,3]

C. Thromboendarterectomy with or without patch graft if performed during bypass graft is done to remove plaque causing stenosis from artery if not amenable for percutaneous intervention. **(AUC Score 7)**[1,2,3]

Technical Considerations:

A. Bypasses to the popliteal artery above the knee should be constructed with autogenous vein when possible.

B. Bypasses to the popliteal artery below the knee should be constructed with autogenous vein when possible.

C. The use of synthetic grafts to the popliteal artery below the knee is reasonable only when no autogenous vein from ipsilateral or contralateral legs or arms is available.

D. Femoral-tibial artery bypasses with prosthetic graft material should not be used for the treatment of claudication

E. Surgical procedures should not be performed in patients with PAD solely to prevent progression to Chronic Limb Ischemia.

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

B. Before proceeding with bypass surgery for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[1,2,4,6,7].

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review

1. Progress note from vascular surgeon that prompted the request
2. Latest imaging report supporting request

Primary codes appropriate for this service are: Bypass graft using vein - 35539-35572. In situ Vein – 35583-35587. Bypass graft using other than vein - 35646-35671. Bypass graft using composite grafts - 35681-35683. Excision, Exploration, Repair, Revision - 35700-35721, 35741, 35860, 35879-35884, 35903. Thromboendartectomy including patch graft - 35302, 35303, 35304, 35306, 35351, 35355, 35361, 35363, 35371, 35372. Open femoral artery exposure for delivery of endovascular prosthesis by groin incision, unilateral (add-on code to a primary procedure) – 38412

B. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy:

Hemodialysis Access Creation

POLICY NUMBER UM CARDIO_1165	SUBJECT Hemodialysis Access Creation		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 05/24/16, 11/28/16, 12/21/16, 10/10/17, 05/01/18, 09/02/18, 03/13/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 09/08/21, 01/12/22, 02/09/22, 01/11/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 05/24/16, 11/28/16, 12/21/16, 10/10/17, 05/01/18, 09/02/18, 03/13/19, 12/11/19, 05/13/20, 02/10/21, 08/11/21, 09/08/21, 01/12/22, 02/09/22, 01/11/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Hemodialysis Access Creation.

II. DEFINITIONS

Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally. This type of dialysis achieves the extracorporeal removal of waste products such as creatinine and urea and free water from the blood when the kidneys are in a state of kidney failure. Hemodialysis is one of three renal replacement therapies (the other two being kidney transplant and peritoneal dialysis). Hemodialysis requires vascular access. Three primary methods are used to gain access to the blood for hemodialysis: an intravenous catheter, an arteriovenous fistula (AV) and AV graft.

Arteriovenous fistula (AV fistula) is a surgical procedure where a vein is connected to an artery. This artificial connection allows the vein to become larger and for the walls of the vein to thicken, a process termed maturation. A mature fistula makes it easier for the vein to be punctured repeatedly for dialysis. Maturation typically takes three to six months to occur. An arteriovenous fistula is the preferred type of vascular access due to lower rate of infection and clot formation, resulting in greater longevity than other types of vascular access. However, not everyone is a good candidate for an arteriovenous fistula, particularly older patients, and patients with small veins.

AV Graft is considered if the patient is not a suitable candidate for an arteriovenous fistula. An arteriovenous graft is a piece of artificial tubing, generally made from Teflon or fabric, that is attached on one end to an artery, and on the other end to a vein. The tube is placed entirely under the skin and the tube itself is punctured during dialysis. An arteriovenous graft can in general be used two to three

weeks after the operation. However, arteriovenous grafts are more prone to infection and clotting than fistulas. The lifespan of an arteriovenous graft is approximately two to three years.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. It is recommended that preparation for kidney replacement therapy (dialysis or transplant) occur when a permanent state of end-stage renal failure has developed and it is presumed that the patient will require permanent renal replacement therapy over and above what can be accomplished by central venous access, as ascertained by a nephrologist. **(AUC Score 9)**[1,2,3,4]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note from the nephrologist or vascular surgeon that prompted the request (including pertinent labs)
   2. All non-invasive Vascular Studies performed applicable to the request

B. Primary codes appropriate for this service: 36800-Insertion of cannula for hemodialysis, other purpose (separate procedure); vein to vein, 36810-Insertion of cannula for hemodialysis, other purpose (separate procedure); arteriovenous, external (Scribner type), 36815-Insertion of cannula for hemodialysis, other purpose (separate procedure); arteriovenous, external revision, or closure, 36818-Arteriovenous anastomosis, open; by upper arm cephalic vein transposition, 36819-Arteriovenous anastomosis, open; by upper arm basilic vein transposition, 36820-Arteriovenous anastomosis, open; by forearm vein transposition, 36821-Arteriovenous anastomosis, open; direct, any site (e.g., Cimino type), 36825-Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft, 36830-Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); non-autogenous graft (e.g., biological collagen, thermoplastic graft), and 36835-Insertion of Thomas shunt (separate procedure). Unilateral Venogram-36005- Injection procedure for extremity venography (including introduction of needle or intra catheter), 36010-Introduction of catheter, superior or inferior vena cava, 36011- Selective catheter placement, venous system;

first order branch (e.g., renal vein, jugular vein), 75820- Venography, extremity, unilateral, radiological supervision and interpretation, 75822-Venography, extremity, bilateral, radiological supervision, and interpretation.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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~~4.~~5. NCQA UM 2022 Standards and Elements.

Cardio Policy

Central Venous Access Procedures

POLICY NUMBER UM CARDIO_1166	SUBJECT Central Venous Access Procedures		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 11/10/21, 11/09/22, 12/14/22, 10/18/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 11/10/21, 11/09/22, 12/14/22, 10/18/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, a progress note from the vascular surgeon that prompted the request must be submitted.

II. Purpose

Indications for determining medical necessity for Central Venous Access Device implantation and removal.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Policy

A. Indications for CVAD implantation [6, 7]

INDICATIONS	USUALLY APPROPRIATE	MAY BE APPROPRIATE	USUALLY NOT APPROPRIATE
ADMINISTRATION OF IV MEDICATION (> 2 WEEKS) (EXCLUDING CHEMOTHERAPY)	PICC, Tunneled CVC	Chest port, Arm port	Nontunneled CVC
ADMINISTRATION OF IV MEDICATION THAT MAY IRRITATE PERIPHERAL ENDOTHELIUM	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
FREQUENT BLOOD SAMPLING	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port

HEMODIALYSIS PRIOR TO AVF CREATION	Nontunneled CVC (≤2 weeks), Tunneled CVC	Nontunneled CVC (>2 weeks)	Arm port, Chest port, PICC
HEMODYNAMIC MONITORING	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
ADMINISTRATION OF CHEMOTHERAPY (> 2 WEEKS)	Chest port, Arm port	PICC, Tunneled CVC	Nontunneled CVC

Table 1:IV = intravenous, PICC = peripherally inserted central catheter, CVC = central venous catheter, AVF = atriovenous fistula

B. Indications for CVAD removal

- If the central venous access is no longer clinically needed
- Catheter occlusion
- Central venous thrombosis
- Fibrin sheath formation
- Catheter-related infection
- Catheter kinking

C. Limitations

Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Definitions

Central Venous Access Device (CVAD): a catheter that is placed in a vein that leads directly to the right side of the heart. There are a number of central veins and for each of these there are a variety of techniques. Catheters are available which differ in length, internal diameter, number of channels, method of insertion, material and means of fixation.

B. AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

C. Abbreviations

AVF: Arteriovenous fistula
CVAD: Central venous access device
CVC: Central venous catheter
IV: Intravenous
PICC: Peripherally inserted central catheter

VI. Coding and Standards

- **Primary codes**
  - CVAD Insertion-36556, 36561, 36563, 36565, 36566, 36558.
  - CVAD removal- 36589, 36590
  - CVAD replacement- 36578, 36580, 36581, 36583
  - CVAD repair – 36575, 36576, 36582, 36597
- **Related codes**
  - Fluoroscopic guidance/Contrast – 76000, 36598, 32552, 77001.
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

References

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[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

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Cardio Policy

Introduction of Inferior Vena Cava Filter Device

POLICY NUMBER UM CARDIO_1168	**SUBJECT** Introduction of Inferior Vena Cava Filter Device		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 07/07/17, 10/11/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 09/08/21, 09/14/22, 09/13/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 07/07/17, 10/11/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 09/08/21, 09/14/22, 09/13/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Venous duplex/CT/MR imaging report

II. Purpose

Indications for determining medical necessity for introduction and removal of Inferior Vena Cava (IVC) Filter Device.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications for Inferior Vena Cava Filter Device

- Presence of DVT or PE with any of the following conditions:
    - Failure or major complication of anticoagulation, or contraindication to anticoagulation (Kaufman, et al., 2020; Minocha, et al., 2018)
    - Recurrent PE despite anticoagulation (Minocha, et al., 2018)
    - Poor compliance with anticoagulation (DeYoung & Minocha, 2016)
    - Massive PE with residual DVT in a patient at risk for further PE (DeYoung & Minocha, 2016)
    - PE and limited cardiac reserve

- For patients at high risk of developing a clinically significant procedure-related PE
    - Prophylactic in patients with severe trauma, spinal cord injury, or paraplegia (Minocha, et al., 2018)
    - As prophylaxis before surgery (in patients with DVT) (Kaufman, et al., 2020)

- Protection during DVT thrombolysis (Minocha, et al., 2018; Kaufman, et al., 2020)

*Indications for removal and repositioning of IVC filter needs to be documented in provider notes

Potential Exclusions

- Absolute contraindications for Insertion of IVC filter:
  - Lack of access into IVC
- Relative contraindications for Insertion of IVC filter:
  - Bleeding Diathesis
  - Total thrombosis of IVC
  - Bacteremia, sepsis, or both
  - Caval diameter less than 15mm
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

An inferior vena cava filter, also IVC filter is a type of vascular filter. This device is implanted into the inferior vena cava to prevent fatal pulmonary emboli (PE).

Placing a filter in the inferior vena cava (IVC) is an important way to prevent significant pulmonary embolism (PE) arising from a deep vein thrombosis (DVT). This procedure is currently performed under radiological guidance via femoral vein or jugular vein access.

AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

VI. Coding and Standards

- **Primary Codes**
  - 37191, 37192, 37193
- **Place/Site of Service**
  - Inpatient Hospital (21)
- **Review**

- Utilization Management Department

- **Final Approval**
  - Utilization Management Committee

VII. References

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Cardio Policy:

Catheter Based Carotid Artery Digital Angiography

POLICY NUMBER UM CARDIO_1169	SUBJECT Catheter Based Carotid Artery Digital Angiography		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 01/20/18, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 08/11/21, 01/12/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 01/20/18, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 08/11/21, 01/12/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Catheter Based Carotid Artery Digital Angiography.

II. DEFINITIONS

Digital subtraction carotid artery angiography is a procedure performed in order to visualize the arterial supply to the brain and to ascertain presence of blockage in the extra cranial carotid arteries.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. When an extra cranial source of ischemia is not identified in patients with transient retinal or hemispheric neurological symptoms of suspected ischemic origin, angiography can be useful to search for intracranial vascular disease. **(AUC Score 6)**[1,2,3,4]

B. When intervention for significant carotid stenosis detected by carotid duplex ultrasonography is planned, catheter-based contrast angiography can be useful to evaluate the severity of stenosis and to identify intrathoracic or intracranial vascular lesions that are not adequately assessed by duplex ultrasonography. **(AUC Score 6)**[1,2,3,4]

C. When noninvasive imaging is inconclusive or not feasible because of technical limitations or contraindications in patients with transient retinal or hemispheric neurological symptoms of suspected ischemic origin, or when noninvasive imaging studies yield discordant results, it is reasonable to perform catheter-based contrast angiography to detect and characterize extra cranial and/or intracranial cerebrovascular disease. **(AUC Score 5)**[1,2,3,4]

D. Catheter-based angiography may be necessary in some cases for definitive diagnosis or to resolve discordance between non-invasive imaging findings **(AUC Score 5)**[1,2,3,4]

E. Angiography may be the preferred method for evaluation of extra cranial vascular disease (ECVD) when obesity, renal dysfunction, or in dwelling ferromagnetic material renders CTA or MRA technically inadequate or impossible. **(AUC Score 4)**[1,2,3,4]

F. Subclavian Angiography can be performed at the time of carotid angiography if medical history is consistent with upper extremity claudication, acute or chronic arterial trauma, thoracic outlet obstruction disease, certain vasculitis, and / or subclavian steal syndrome. **(AUC Score 5)**[1,2,3,4]

G. Subclavian Angiography can be performed at the time of left heart diagnostic catheterization if medical history strongly indicates medical necessity for CABG (Subclavian Angiography is performed to identify Internal Mammary artery anatomy prior to CABG). **(AUC Score 6)**[1,2,3,4]

H. Follow-up carotid angiogram can be performed in patients for surveillance who undergo intracranial intervention at 3 months, 6 months, 24 months, and then once in 3-5 years to assess the patency of intervented vessel**. (AUC Score 7)**[4,6]

Limitations:

A. Catheter-based angiography is unnecessary for diagnostic evaluation of most patients with extra cranial vascular disease (ECVD) and is used increasingly as a therapeutic revascularization maneuver in conjunction with stent deployment. *This procedure cannot be reported if performed at the same setting along with Carotid stenting 37215 or 37216.*

B. Carotid Angiogram when performed with Subclavian Angiography needs to be reported as 36225. No additional Carotid Angiogram codes needs to be reported.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Carotid duplex/CTA/MRA Carotid report

B. Primary codes appropriate for this service:
   36215 - Selective Catheter placement, arterial system, first order, (Thoracic or Brachiocephalic)
   36216 -Selective Catheter placement, arterial system, second order, (Thoracic or

Brachiocephalic)

36217 -Selective Catheter placement, arterial system, third order, (Thoracic or Brachiocephalic)

36218 - Additional Second order and beyond, (Thoracic or Brachiocephalic)

36221 - non-selective catheter placement, Thoracic Aorta, with angiography of the extracranial carotid, vertebral and/or intracranial vessels

36222 - Carotid Angiography Selective Catheter placement – Common Carotid, unilateral

36223 - Selective Catheter placement – Common Carotid, unilateral, with angiography of the ipsilateral extracranial carotid circulation

36224 - Selective Catheter placement – Internal Carotid, unilateral, with angiography of the ipsilateral intracranial carotid circulation

36225- Selective Catheter placement –Subclavian, unilateral, with angiography of the ipsilateral external carotid circulation

36226 - Selective Catheter placement – Vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation

36227 - Selective Catheter placement – External Carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation

36228 - Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L36767). Aortography and peripheral angiography. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
2. Centers for Medicare and Medicaid Services. Illinois. Local Coverage Determination (LCD) (L33557). Cardiac Catheterization and Aortography. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2023 Standards and Elements.
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Cardio Policy:

Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff

POLICY NUMBER UM CARDIO_1170	**SUBJECT** Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 10/13/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 06/10/20, 05/12/21, 10/13/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff.

II. DEFINITIONS

Abdominal aortography is performed to identify vessel narrowing in patients with leg claudication or cramps, caused by reduced blood flow down the legs and to the feet. This is done routinely through the femoral artery but can also be performed through the brachial or axillary (arm) artery. Any stenosis found may be treated with percutaneous interventions.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I

recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[1,2,4,6,7]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Significant disability despite medical therapy (GDMT) with documentation of outflow or inflow peripheral arterial disease by prior non-invasive study and further study is needed by angiography with the intent of subsequent intervention **(AUC Score 9)**[1,2,3,4,5,6,7,8,9,10,11]

B. Following: [**(AUC Score 9)**[1,2,3,4]

1. detection of aneurysm and other primary vascular abnormalities that require further investigation for effective treatment
2. the detection of occlusive disease, including evaluation for acute or chronic intestinal ischemia
3. stabilization of GI hemorrhage as an outpatient/elective procedure

Decisions regarding the potential utility of invasive therapeutic interventions (percutaneous or surgical) in patients with lower extremity peripheral arterial disease should be made with a complete anatomic assessment of the affected arterial territory, including imaging of the occlusive lesion, as well as arterial inflow and outflow with angiography or a combination of angiography and noninvasive vascular techniques.

Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation.

Diagnostic peripheral angiography performed at the time of an interventional procedure is separately reportable if at least one indication for medical necessity for a stand-alone lower extremity is met AND one of the following is also met:

A. No prior catheter-based angiographic study is available, and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study, or

B. A prior study is available, but as documented in the medical record:

1. the patient’s condition with respect to the clinical indication has changed since the prior study; or
2. there is inadequate visualization of the anatomy or pathology; or
3. there is a clinical change during the interventional procedure that requires new evaluation outside the target area of intervention.

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

B. Before proceeding with bypass surgery for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[1,2,3,5,7,8]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. ABI/PVR/Arterial Duplex/CTA /MRA legs report

B. Primary codes appropriate for this service: 36200, 36245- 36248, 75625, 75630, 75710, 75716, 75726, G0278

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L36767). Aortography and peripheral angiography. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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3. Klein AJ, et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. Catheterization Cardiovascular Interventions. Oct 2017. Volume 90, Issue 4, E90-E110.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
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12. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Carotid Artery Stenting

POLICY NUMBER UM CARDIO_1171	**SUBJECT** Carotid Artery Stenting		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/13/19, 12/11/19, 05/13/20, 05/28/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Carotid Artery Stenting.

II. DEFINITIONS

Carotid stenting is a procedure that opens clogged arteries to prevent or treat stroke. The carotid arteries are located on each side of the neck and are the main arteries supplying blood to the brain. The procedure involves temporarily inserting and inflating a tiny balloon where the carotid artery is clogged to widen the artery and placement of a small metal coil called a stent in the clogged artery. The stent helps prop the artery open and decreases the chance of it narrowing again.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Carotid Artery Stenting (CAS) may be appropriate in symptomatic high surgical risk patients with severe stenosis greater than 70% in whom the stenosis is difficult to access surgically, and medical conditions present greatly increase the surgical risk including presence of radiation induced stenosis or restenosis after Carotid Endarterectomy (CEA). **(AUC Score 6)**[1,2,3]

B. CAS is appropriate in asymptomatic patients with high surgical risk, with severe stenosis greater than 70% when revascularization is indicated in patients with neck anatomy is unfavorable for CEA. **(AUC Score 7)**[1,2,3]

C. CAS is appropriate in symptomatic patients with intermediate surgical risk as an alternative to CEA when the diameter of lumen of the internal carotid artery is reduced by greater than 70% by noninvasive imaging or greater than 50% by catheter angiography. **(AUC Score 8)**[1,2,3]

D. CAS may be appropriate in asymptomatic patients with severe stenosis greater than 70%, where neck anatomy is unfavorable for CEA. **(AUC Score 6)**[1,2,3]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Carotid Duplex/CTA/MRA Carotids/Carotid Angiogram report

B. Primary codes appropriate for this service: 37215 or 37216.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. National Coverage Determination- 20.7 [Accessed December 19, 2023].
2. Brott TG, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Neuro Interventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. Journal of the American College of Cardiology. Feb 2011. Volume 57, Issue 8, Pages e16-94.

3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. NCQA UM 2022 Standards and Elements.

Cardio Policy:

Endovascular Iliac Interventions

POLICY NUMBER UM CARDIO_1172	SUBJECT Endovascular Iliac Interventions		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/14, 06/28/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/13/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/14, 06/28/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/13/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Endovascular Iliac Interventions.

II. DEFINITIONS

Endovascular intervention is the treatment of peripheral arterial disease with angioplasty and/or primary stenting. It is performed by opening up the blood vessel with a balloon placed on the end of a catheter. A stent is often used with angioplasty to help keep the artery open.

Rutherford Classification (RC) for Peripheral Artery Disease (PAD) or Chronic Limb Ischemia (CLI) is defined as follows:

Classification 0	Asymptomatic
Classification 1	Mild Claudication (calf pain climbing more than two flights of stairs)
Classification 2	Moderate Claudication (calf pain climbing less than two flights of stairs)
Classification 3	Severe Claudication (calf pain climbing less than one flight of stairs)
Classification 4	Ischemic Rest Pain (foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
Classification 5	Minor Tissue Loss (cutaneous ischemic ulceration)
Classification 6	Major Tissue Loss (skin necrosis and gangrene)

Trans-Atlantic Inter-Society Consensus (TASC II) classification of aorto-iliac lesions for endovascular intervention:

A. Type A lesions:

1. Unilateral or bilateral stenosis of Common Iliac Artery (CIA)
2. Unilateral or bilateral single short (≤ 3cm) stenosis of External Iliac Artery (EIA)

B. Type B lesions:
1. Short (≤ 3 cm) stenosis of infra renal aorta
2. Unilateral CIA occlusion
3. Single or multiple stenosis totaling 3-10 cm involving EIA not extending into Common Femoral Artery (CFA).
4. Unilateral EIA occlusion not involving the origins of internal iliac or CFA.

C. Type C lesions:
1. Bilateral CIA occlusions
2. Bilateral EIA stenosis 3-10cm, not extending into CFA.
3. Unilateral EIA stenosis extending to CFA.
4. Unilateral EIA occlusion that involves the origin of internal iliac and/or CFA

D. Type D lesions:
1. Infra Renal Aorto-Iliac occlusion
2. Diffuse disease involving the aorta and both iliac arteries
3. Diffuse multiple stenosis involving the unilateral CIA, EIA CFA
4. Unilateral occlusions of both CIA and EIA
5. Bilateral occlusions of EIA

Lesion length. Categorized into focal (less than or equal to 4 cm) and diffuse (greater than 4 cm), which is consistent with the definitions used for the peripheral vascular interventions SCAI AUC document.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[7,8,9,10,11,12]

III. POLICY

Before a patient with intermittent claudication and or rest pain is offered the option of any invasive revascularization therapy, (endovascular or surgical), the following considerations must be considered:

A. Predicted or observed lack of adequate response to exercise therapy and claudication pharmacotherapies (GDMT) [,7,8,9,10,11,12]

B. Presence of a severe disability, with the patient either being unable to perform normal work or having very serious impairment of other activities important to the patient or having rest pain (RC2-6).

C. Absence of other disease that would limit exercise even if the claudication was improved (e.g., angina or chronic respiratory disease)

D. Morphology of the lesion, which must be such that the appropriate intervention would have low risk and a high probability of initial and long-term success. (See TASC Classification)

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Balloon angioplasty is appropriate for focal lesions of the common iliac artery (CIA), external iliac artery (EIA) **(AUC Score 4)**[1,2,3,4,5]

B. Primary balloon-expandable placement is appropriate for aorto-iliac bifurcation lesions, focal and diffuse CIA lesions **(AUC Score 8)**[1,2,3,4] and for EIA lesions, moderate to severe calcified lesions, and CTO **(AUC Score 5)**[1,2,3,4,5]

C. Provisional self-expanding placement is indicated for use in diffuse CIA lesions, EIA lesions **(AUC Score 8)**[1,2,3,4,5] and for aorto-iliac bifurcation lesions, focal CIA lesions, moderate to severe calcified lesions, and CTO **(AUC Score 5)**[1,2,3,4,5]

D. Stenting with a balloon-expandable covered stent is appropriate for aorto-iliac bifurcation lesions, focal and diffuse CIA lesions, moderate to severe focal and diffuse calcified lesions **(AUC Score 8)**[1,2,3,4], focal and diffuse EIA lesions, CTO, and ISR **(AUC Score 5)**[1,2,3,4,5]

E. Stenting with a self-expanding covered stent is appropriate for *diffuse* EIA lesions, moderate to severe calcified lesions, CTO, and ISR. **(AUC Score 5)**[1,2,3,4,5]

Limitations:

A. Endovascular interventions are not appropriate in Aorto-Iliac stenosis less than 50%

B. Endovascular interventions are not appropriate in Aorto-Iliac stenosis less than 50% with RC1

C. PTA using drug-coated or other specialty balloons, and atherectomy are not appropriate for treating aorto-iliac disease

D. PTA alone is not appropriate for treating aorto-iliac disease except in rare cases of focal iliac disease and ISR

E. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

F. Before proceeding with endovascular iliac intervention for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[7,8,9,10,11,12]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Angiographic testing pertinent to the request
   3. Non-invasive vascular testing

B. Primary codes appropriate for this service: 37220, 37221, 37222,37223

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L33763). Vascular Stenting of Lower Extremity Arteries. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237.

10. Anderson JL, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Apr 2;127(13):1425-43.
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12. Fakhry F, et.al. Long-term clinical effectiveness of supervised exercise therapy versus endovascular revascularization for intermittent claudication from a randomized clinical trial. British Journal of Surgery 2013; 100: 1164–1171. 7. David L Dawson MD et.al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. The American Journal of Medicine. Volume 109, Issue 7, November 2000, Pages 523-530.
13. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Endovascular Femoropopliteal Interventions

POLICY NUMBER UM CARDIO_1173	**SUBJECT** Endovascular Femoropopliteal Interventions		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 7**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/28/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 09/08/21, 11/09/21, 09/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/28/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 09/08/21, 11/09/21, 09/14/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Endovascular Femoropopliteal Interventions.

II. DEFINITIONS

Endovascular intervention is the treatment of peripheral arterial disease with angioplasty and/or primary stenting. It is performed by opening up the blood vessel with a balloon placed on the end of a catheter. A stent is often used with angioplasty to help keep the artery open.

Rutherford Classification (RC) for Peripheral Artery Disease (PAD) or Chronic Limb Ischemia (CLI) is defined as follows:

Classification 0	Asymptomatic
Classification 1	Mild Claudication (calf pain climbing more than two flights of stairs)
Classification 2	Moderate Claudication (calf pain climbing less than two flights of stairs)
Classification 3	Severe Claudication (calf pain climbing less than one flight of stairs)
Classification 4	Ischemic Rest Pain (foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
Classification 5	Minor Tissue Loss (cutaneous ischemic ulceration)
Classification 6	Major Tissue Loss (skin necrosis and gangrene)

TASC II Classifications of Femoral and Popliteal Lesions amenable for endovascular intervention:

A. Type A lesion:
    1. Single stenosis ≤ 10cm
    2. Single occlusion ≤ 5cm

B. Type B lesion:
    1. Multiple lesions, each ≤ 5cm
    2. Single stenosis or occlusion≤ 15cm not involving infrageniculate popliteal artery
    3. Single Popliteal stenosis
    4. Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for distal bypass.

C. Type C lesion:
    1. Multiple stenosis or occlusion >15cm with or without heavy calcification

Lesion length is categorized info *focal* (<10 cm), *intermediate* (10-20 cm), and *diffuse* (>20 cm), which is consistent with the definitions used for the SCAI peripheral vascular interventions AUC document.[3]

For the purpose of this document, *intended definitive therapy* is defined as what is known to be medically appropriate at the time of the initiation of the service. *Adjunctive therapy* is defined as a service that becomes necessary during the intended definitive therapy, e.g., as a bailout/salvage procedure.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[7,8,9,10,11,12]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Before a patient with intermittent claudication and or rest pain is offered the option of any invasive revascularization therapy, (endovascular or surgical), the following must be considered:

1. When applicable, optimal GDMT for PAD (*as outlined in UM CARDIO_1432 Guidelines for Medical Management of Peripheral Artery Disease*) must have been implemented, with a focus on therapies with Class I recommendations that have demonstrated reductions in the risk of MI, stroke, heart failure, and cardiovascular deaths. [6,7,8,9,10,11,12]
2. Presence of a severe disability, with the patient either being unable to perform normal work or having very serious impairment of other activities important to the patient or having rest pain (RC 2-6).
3. Absence of other disease that would limit exercise even if the claudication was improved (e.g., angina or chronic respiratory disease)
4. Morphology of the lesion, which must be such that the appropriate intervention would have low risk and a high probability of initial and long-term success. (See TASC Classification)

B. The approval criteria for requests will be based upon updated clinical scenarios from reference (2) as indicated in tables A and B below.

Table A. AUC score for device selection as the *Intended Definitive Therapy* in the femoral-popliteal arterial interventions:

	PTA	Specialty balloon	BMS (Self-expanding)	DES	DCB	Laser Atherectomy	Orbital/ Directional/ Excisional / Aspiration Atherectomy
CFA bifurcation lesion	4	4	5	4	4	1	1
Above knee popliteal lesion	1	1	6	8	9	1	1
Ostial SFA lesion	4	4	6	8	9	1	1
Focal SFA lesion	4	1	6	8	9	1	1
Intermediate SFA lesion	1	4	6	8	9	1	1
Diffuse SFA lesion	1	1	5	8	8	1	1

Mod to severe calcified, focal lesion	4	4	4	7	7	1	1
Mod to severe calcified, intermediate lesion	1	1	4	7	7	1	1
Mod to severe calcified, diffuse lesion	1	1	4	7	7	1	1
CTO, focal lesion	4	1	5	8	8	1	1
CTO, intermediate lesion	1	1	5	8	8	1	1
CTO, diffuse lesion	1	1	4	8	8	1	1
ISR, focal lesion	4	1	1	4	8	5	1
ISR, intermediate lesion	1	1	1	4	8	5	1
ISR, diffuse lesion	1	1	1	4	8	5	1

Abbreviations: PTA, percutaneous transluminal angioplasty; BMS, bare metal stent; DES, drug eluting stent; DCB, drug coated balloon CFA, common femoral artery; SFA superficial femoral artery; CTO, Chronic Total Occlusion; ISR, in-stent restenosis.

Table B. AUC score for device selection as the *Adjunctive Therapy* in the femoral-popliteal arterial interventions:

	Specialty balloons	Laser Atherectomy	Directional Atherectomy	Orbital/ Rotational Atherectomy	Excisional / Aspiration Atherectomy
CFA bifurcation lesion	4	1	4	4	1
Above knee popliteal lesion	1	1	1	1	1
Ostial SFA lesion	4	1	4	4	1
Focal SFA lesion	1	1	1	1	1
Intermediate SFA lesion	1	1	1	1	1
Diffuse SFA lesion	1	1	1	1	1

Mod to severe calcified, Undilatable focal lesion	4	4	1	4	4
Mod to severe calcified, Undilatable intermediate lesion	4	4	1	4	4
Mod to severe calcified, Undilatable diffuse lesion	4	4	1	4	4
Mod to severe calcified, dilatable focal lesion	4	1	1	4	1
Mod to severe calcified, dilatable intermediate lesion	4	1	1	4	1
Mod to severe calcified, dilatable diffuse lesion	4	1	1	4	1
CTO, focal lesion	1	5	1	1	1
CTO, intermediate lesion	1	1	1	1	1
CTO, diffuse lesion	1	1	1	1	1
ISR, focal lesion	1	5	1	1	1
ISR, intermediate lesion	1	5	1	1	1
ISR, diffuse lesion	1	5	1	1	1

Abbreviations: CFA, common femoral artery; ISR, in-stent restenosis; SFA, superficial femoral artery.

Limitations:

A. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity peripheral arterial disease.

B. With few exceptions, laser, directional, orbital/rotational, and excisional/aspiration atherectomy procedures are Class III LOR. Such cases involve laser atherectomy (approvable only for in-stent restenosis (ISR)), and moderate to severe lesions that are documented to be heavily calcified and undilatable.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

D. Before proceeding with endovascular femoropopliteal intervention for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT.[7,8,9,10,11,12]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request
2. Angiographic testing pertinent to the request

3. Non-invasive vascular testing

B. Primary codes appropriate for this service: 37224(PTA), 37225 (PTA with Atherectomy), 37226 (PTA with Stent),37227 (PTA with Atherectomy and Stent), Ultrasound guided vascular access-76937.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L33763). Vascular Stenting of Lower Extremity Arteries. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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8. Bailey SR, et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol. 2019 Jan 22;73(2):214-237. 4
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12. David L Dawson MD et.al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. The American Journal of Medicine. Volume 109, Issue 7, November 2000, Pages 523-530.
13. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Endovascular Tibio-Peroneal Interventions

POLICY NUMBER UM CARDIO_1174	**SUBJECT** Endovascular Tibio-Peroneal Interventions	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/14/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 08/22/13, 06/30/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/14/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23, 01/10/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Endovascular Tibio-Peroneal Interventions.

II. DEFINITIONS

Endovascular intervention is the treatment of peripheral arterial disease with angioplasty and/or primary stenting. It is performed by opening the blood vessel with a balloon placed on the end of a catheter. A stent is often used with angioplasty to help keep the artery open.

Rutherford Classification (RC) for Peripheral Artery Disease (PAD) or Chronic Limb Ischemia (CLI) is defined as follows:

Classification 0	Asymptomatic
Classification 1	Mild Claudication (calf pain climbing more than two flights of stairs)
Classification 2	Moderate Claudication (calf pain climbing less than two flights of stairs)
Classification 3	Severe Claudication (calf pain climbing less than one flight of stairs)
Classification 4	Ischemic Rest Pain (foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
Classification 5	Minor Tissue Loss (cutaneous ischemic ulceration)
Classification 6	Major Tissue Loss (skin necrosis and gangrene)

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[6,7,8,9,10,11]

III. POLICY

A. Before a patient with intermittent claudication and or rest pain is offered the option of any invasive revascularization therapy, (endovascular or surgical), the following considerations must be taken into account:

1. Predicted or observed lack of adequate response to exercise therapy and claudication pharmacotherapies (GDMT) [5,6,7,8,9,10,11]
2. Presence of a severe disability, with the patient either being unable to perform normal work or having very serious impairment of other activities important to the patient or having rest pain (RC2-6)
3. Absence of other disease that would limit exercise even if the claudication was improved (e.g., angina or chronic respiratory disease)
4. Morphology of the lesion, which must be such that the appropriate intervention would have low risk and a high probability of initial and long-term success.

B. Prior to considering Infra Popliteal (IP) intervention, all hemodynamically significant inflow disease (aortoiliac and/or Femoral- Popliteal) should be treated to normalize inflow to the IP circulation. Then, if deemed clinically necessary, one may proceed with management of the IP disease.

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. Balloon PTA of infrapopliteal lesions with length less than 100mm is considered appropriate in symptomatic patients (RC 2-6). **(AUC Score 7)**[1,2,3,4]

B. Balloon PTA of infrapopliteal lesions with length greater than or equal to 100mm is considered appropriate in symptomatic patients (RC 2-6). **(AUC Score 7)**[1,2,3,4]

C. Atherectomy may be appropriate in symptomatic patients (RC2-6) with infrapopliteal heavily calcified lesions that are non-amenable to balloon PTA. **(AUC Score 5)**[1,2,3,4]

Limitations:

A. Primary atherectomy and Stenting of IP lesions is not currently recommended due to lack of evidence in improving clinical outcomes.

B. The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of IP arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well established.

C. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity peripheral arterial disease.

D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

E. Before proceeding with endovascular tibioperoneal intervention for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[7,8,9,10,11,12]

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Angiographic testing pertinent to the request
   3. Non-invasive vascular testing

B. Primary codes appropriate for this service: 37228, 37229, 37230, 37231, 37234, 37235

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L33763). Vascular Stenting of Lower Extremity Arteries. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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11. David L Dawson MD et.al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. The American Journal of Medicine. Volume 109, Issue 7, November 2000, Pages 523-530
12. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Endovascular Venous Laser/Radiofrequency Ablation

POLICY NUMBER UM CARDIO_1252	**SUBJECT** Endovascular Venous Laser/Radiofrequency Ablation		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 7**
DATES COMMITTEE REVIEWED 11/14/13, 12/17/13, 03/03/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 06/12/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 04/12/23, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 11/14/13, 12/17/13, 03/03/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 06/12/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 04/12/23, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Lower Extremity Endovenous Laser/Radiofrequency Ablation.

II. DEFINITIONS

Varicose veins are a manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension which are superficially located, dilated (greater than 3mm), tortuous, veins of the lower extremities. These dilated superficial veins of the lower limbs are considered pathologic when they are 5 mm or greater in diameter or sometimes 3 mm or greater in diameter when measured in the upright position and have greater than 500milliseconds of reflux by duplex scan.

Spider veins are intradermal venules of less than 1 mm, also known as telangiectasia or thread veins. Reticular veins are intradermal venules of 1-3 mm. Superficial veins are truncal (GSV/SSV) and accessory/tributary veins located nearest to the skin. Perforator veins are the veins linking the superficial and deep veins. Deep veins are located deep to the muscular fascia, such as the common femoral vein. These can cause clinically significant pain and result in a decrease in quality of life and even disability which may necessitate treatment.

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences-edema and skin changes-should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A

duplex ultrasound scan of the deep and superficial venous systems must support the examination findings.

Classification for chronic venous disorders (CVD and CVI) is based on clinical severity (C), etiology (E), anatomy (A), and pathophysiology (P) to improve the accuracy of the diagnosis.

C 0 – no visible or palpable signs of venous disease
C 1 – Telangiectasias or reticular veins less than 3 mm
C 2 – Simple varicose veins (3 or larger)
C 3 – Ankle edema of venous origin (not foot edema)
C 4a – Skin pigmentation or eczema
C 4b – Lipodermatosclerosis or atrophic blanche
C 5 – Healed venous ulcer
C 6 – Open venous ulcer

S – Symptomatic, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction

A – Asymptomatic

Etiologic

Classification:
Ec – Congenital
Ep – Primary
Es – Secondary (post-thrombotic)
En – No venous cause identified

Anatomic classification:
As – Superficial veins
Ap – Perforator veins
Ad – Deep veins
An – No venous location identified

Pathophysiologic classification:
Pr – Reflux
Po – Obstruction
Pr, o – Reflux and obstruction
Pn – No venous pathophysiology

Venous Clinical Severity Score:
Pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning)
None=0: None
Mild=1: Occasional pain or discomfort that does not restrict daily activities
Moderate=2: Daily pain or discomfort that interferes with, but does not prevent, regular daily activities
Severe=3: Daily pain or discomfort that limits most regular daily activities

Varicose Veins
None=0: None
Mild=1: Few, scattered, varicosities that are confined to branch veins or clusters. Includes “corona phlebectatica” (ankle flare), defined as greater than 5 blue telangiectasia at the inner or sometimes the outer edge of the foot
Moderate=2: Multiple varicosities that are confined to the calf or the thigh

Severe=3: Multiple varicosities that involve both the calf and the thigh

Venous Edema
None=0: None
Mild=1: Edema that is limited to the foot and ankle
Moderate=2: Edema that extends above the ankle but below the knee
Severe=3: Edema that extends to the knee or above

Skin Pigmentation
None=0: None, or focal pigmentation that is confined to the skin over varicose veins
Mild=1: Pigmentation that is limited to the peri-malleolar area
Moderate=2: Diffuse pigmentation that involves the lower third of the calf
Severe=3: Diffuse pigmentation that involves more than the lower third of the calf

Induration
None=0: None
Mild=1: Induration that is limited to the peri-malleolar area
Moderate=2: Induration that involves the lower third of the calf
Severe=3: Induration that involves more than the lower third of the calf

Active Ulcer Number
None=0: None
Mild=1: One Ulcer
Moderate=2: Two Ulcers
Severe=3: Three Ulcers

Active Ulcer
None=0: No active ulcers
Mild=1: Ulceration present for less than 3 months
Moderate=2: Ulceration present for 3-12 months
Severe=3: Ulceration present for greater than 12 months

Active Ulcer Size
None=0: No active ulcer
Mild=1: Ulcer less than 2 cm in diameter
Moderate=2: Ulcer 2-6 cm in diameter
Severe=3: Ulcer greater than 6 cm in diameter

Use of Compression Therapy based on compliance
None=0: Not used
Mild=1: Intermittent use
Moderate=2: Wears stockings most days
Severe=3: Full compliance stockings

Endovenous Radiofrequency Ablation is a minimally invasive endovenous thermal ablation procedure that involves using ultrasound guidance to puncture the vein, position a catheter and perform tumescent anesthesia. Radiofrequency current is delivered resulting in heat destruction while an inflammatory response enhances wall destruction. The purpose of RFA is to damage the collagen of the vein wall resulting in fibrosis and occlusion of a vein segment to eliminate reflux. This procedure may be performed in the outpatient setting.

Endovenous Laser Ablation is a minimally invasive alternative to high ligation and saphenous vein stripping (HL/S). It is only a treatment option for sufficiently straight superficial vein segments that will allow passage of the device. The purpose of EVLA is to damage the endothelium of the vein resulting in fibrosis and occlusion of a vein segment to eliminate reflux. The thermal ablation techniques are appropriate for the primary treatment of the GSV and/or SSV, and incompetent accessory (AAGSV, PAGSV) saphenous veins.

Mechanochemical Ablation, also referred to as MOCA, MECA is a technique used to ablate superficial veins with an oscillating wire that rotates and disrupts the endothelial lining of target veins while a sclerosant is injected to penetrate the deep layers of the vein causing vein sclerosis. This technique is appropriate for the treatment of truncal veins.

The objective of Endovenous techniques is to cause injury to the vessel, causing retraction and subsequent fibrotic occlusion of the vein thereby eliminating reflux.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

All below indications are applicable only if there is documentation of failure of compression therapy for 90 days except in presence of non-healing ulcers.

A. Patients with C2 disease and VCSS score less than 6, symptomatic GSV (greater than or equal to 5mm in size with greater than or equal to 500ms in duration of reflux) and for SSV (greater than or equal to 3mm in size with greater than or equal to 500ms in duration of reflux) endovenous laser and radiofrequency ablation(s). GSV and SSV ablation can be performed at the same time or staged. **(AUC Score 6)**[1,2,3,4,5,6,7,8]. Ablation of perforator vein(s) is not indicated during initial truncal (GSV/SSV) ablation, due to insufficient evidence in literature.

B. For patients with C2 disease and VCSS score greater than 6, endovenous laser and radiofrequency ablation(s) of symptomatic **GSV** (greater than or equal to 5mm in size with greater than or equal to 500ms in duration of reflux), **Accessory/Tributaries** Saphenous Vein (greater than or equal to 3mm in size with duration of reflux greater than or equal to 500ms) or **SSV** (greater than or equal to 3mm in size with greater than or equal to 500ms in duration of reflux) can be performed. These veins can be performed at the same time or staged **(AUC Score 6)**[1,2,3,4,5,6,7,8]

C. For patients with C3-C6 disease, endovenous laser and radiofrequency ablation(s) of **GSV** (greater than or equal to 5mm in size with duration of reflux greater than or equal to 500ms), **Accessory/Tributaries** Saphenous Vein (greater than or equal to 3mm in size with duration of reflux greater than or equal to 500ms) or **SSV** (greater than or equal to 3mm in size with duration

of reflux greater than or equal to 500ms) can be performed. These veins can be performed at the same time or staged. **(AUC Score 8)**[1,2,3,4,5,6,7,8]

D. For patients with C3-C6 disease, Perforator veins(s) endovenous laser and radiofrequency ablation(s) requires below criteria to be met **(AUC Score 7)**[1,2,3,4,5,6,7,8]
   1. C3-C6 disease and,
   2. greater than or equal to 3.5mm, duration of reflux greater than or equal to 5500ms and,
   3. Refluxing isolated perforator vein(s) lies beneath or contiguous to a healed or active venous ulcer and/or
   4. At the same time of GSV/Accessory Saphenous/SSV ablation in presence of ulcer or,
   5. Perforator vein(s) ablation can be performed during a redo GSV/SSV intervention when criteria 1 and 2 are met, for the same leg at the same time.

E. Redo EVLA for GSV/SSC can be done only once every 3 years **(AUC Score 8)**[1,2,3,4,5,6,7,8]

F. Endovenous mechanochemical ablation of GSV (at least 5mm in size with duration of reflux greater than or equal to 500ms) for patients with C3-C6 disease or C2 with VCSS less than 6 or C2 with VCSS less than 6, can be performed instead of Endovenous Laser or Radiofrequency ablation **(AUC Score 8)**[1,2,5,6,7,8]

G. Endo Chemical Venous Ablation also called as glue embolization can be performed for GSV (greater than or equal to 5mm in size with duration of reflux greater than or equal to 500ms) and SSV (at least greater than or equal to 3mm in size with duration of reflux greater than or equal to 500ms) **(AUC Score 8)**[1,2,5,6,7,8]

A complete Venous Duplex after each venous intervention is preferred to demonstrate the result of intervention on the intervened vein(s) and to reassess presence of reflux on next target vein(s) of the same extremity.

Limitations:

A. This procedure cannot be performed in presence of aneurysm, thrombosis, or vein tortuosity in target segment or if maximum vein diameter greater than or equal to 20mm.

B. Venous Insufficiency due to DVT is a contraindication for this procedure.

C. Repeated procedures for venous ablation performed more than twice, on the same area of the same vein, in separate surgical procedures, are considered not medically necessary.

D. The treatment of C1 disease (spider telangiectasia and their feeding reticular veins) is considered cosmetic, and therefore, will not be eligible for this treatment coverage except in patients with spontaneous and/or traumatic venous hemorrhage.

E. The treatment of CEAP clinical classification C0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.

F. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted the request

2. Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins with CEAP classification and VCSS score.
3. Prior venous intervention report

B. Primary codes appropriate for this service:

Endo Mechanochemical Ablation: 36473 (Single vein), 36474 (Subsequent veins)

Endovenous Radiofrequency Ablation: 36475 (Single vein), 36476 (Subsequent veins)

Endovenous Laser Ablation 36478 (Single vein), 36479 (Subsequent veins)

Endo Chemical Venous Ablation 36482 (Single vein), 36483 (Subsequent veins)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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9. NCQA UM 2023 Standards and Elements.

Cardio Policy

Lower Extremity Venous Ligation/Stripping

POLICY NUMBER UM CARDIO_1253	**SUBJECT** Lower Extremity Venous Ligation/Stripping		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 9**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/11/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/11/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- The treatment of CEAP clinical classification C_0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted the request includes fully documented complete history and physical with symptoms, CEAP score, site of varicose veins, h/o prior interventions along with documentation of target veins and extremity for intervention.
    - Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins.

II. PURPOSE

Indications for determining medical necessity for Lower Extremity Venous Ligation/Stripping.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications

- Ablation is considered the gold standard of care for symptomatic varicose veins and

axial reflux and ligation is considered when ablation is not available or venous anatomy prevents endovenous treatment. (Gloviczki, et al., 2022; Gloviczki, et al., 2024). Trial of compression stockings for a minimum of 3months is no longer required prior to venous intervention, unless it is patients' preference. (Gloviczki et al 2024)

    - Isolated thrombosis of varicose tributaries or limited involvement of the GSV

- Superficial truncal vein aneurysm located within 3 cm of the Saphenofemoral Junction (SFJ) or Saphenopopliteal Junction (SPJ) (using high proximal and distal ligations)
- Superficial truncal vein aneurysm and symptomatic saphenous reflux (limited stripping of the distal saphenous vein)

V. Background

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences (edema and skin changes) should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A duplex ultrasound scan of the deep and superficial venous systems must support the examination findings.

A. DEFINITIONS

1. **Accessory/tributary veins**

   Located nearest to the skin

2. **Deep veins**

   Located deep to the muscular fascia (e.g., common femoral vein), can cause clinically significant pain resulting in a decrease in quality of life or disability which may necessitate treatment.

3. **Perforator veins**

   Link the superficial and deep veins.

4. **Reticular veins** (Gloviczki, et al., 2024)

   Subdermal veins between 1 and < 3 mm in diameter

5. **Telangiectasia veins** (Gloviczki, et al., 2024)

   Subdermal spider veins <1 mm in diameter

6. **Superficial veins**

   Truncal veins (GSV, SSV, AAGSV, PAGSV)

7. **Varicose veins** (Gloviczki, et al., 2022; Gloviczki, et al., 2024)

   A manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension and valvular incompetence. Superficially located, dilated (≥ 3mm), tortuous, veins of the lower extremities are considered **pathologic reflux** when they have > 500 ms of reflux (in the superficial truncal veins, tibial, deep femoral, and popliteal veins),

minimum value of > 1 second of reflux (in common femoral, femoral, and popliteal veins). There is no minimum diameter required to have a pathologic reflux.

Pathologic perforating veins with CEAP clinical class C2 includes those with a >500 ms outward flow and a diameter of > 3.5 mm on duplex ultrasound scan.

B. Classification for Chronic Venous Disease (CVD) (Lurie, et al., 2020)

CVD and CVI is based on CEAP categories; Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

Clinical (C) Classifications (C Classes present in Limb)

- C_0 – No visible or palpable signs of venous disease
- C_1 – Telangiectasias or reticular veins (< 3mm)
- C_2 – Simple varicose veins (≥ 3mm diameter)
    - C_{2r} – Recurrent varicose veins
- C_3 – Ankle edema of venous origin (not foot edema)
- C_4 – Changes in skin and subcutaneous tissue secondary to CVD
    - C_{4a} – Pigmentation or eczema
    - C_{4b} – Lipodermatosclerosis or atrophie blanche
    - C_{4c} – Corona phlebectatica
- C_5 – Healed venous ulcer
- C_6 – Open venous ulcer
    - C_{6r} – Recurrent active venous ulcer

Subscripts of C Classes Indicating presence or absence of symptoms

- **S - Symptomatic**
    - Ache
    - Pain
    - Tightness
    - Skin irritation
    - Heaviness
    - Muscle cramps
    - Other complaints attributable to venous dysfunction
- **A – Asymptomatic**

Etiologic (E) Classification

- E_c – Congenital
- E_p – Primary

- E_s – Secondary
    - E_{si} – Secondary – intravenous
    - E_{se} – Secondary – extravenous
- E_n – No cause identified

Anatomic (A) Classification

- A_s – Superficial veins
    - Telangiectasia
    - Reticular Veins
    - Great saphenous vein above knee
    - Great saphenous vein below knee
    - Small saphenous vein
    - Anterior accessory saphenous vein
    - Nonsaphenous vein
- A_p – Perforator veins
    - Thigh perforator vein
    - Calf perforator vein
- A_d – Deep veins
    - Inferior vena cava
    - Common iliac vein
    - Internal iliac vein
    - External iliac vein
    - Pelvic veins
    - Common femoral vein
    - Deep femoral vein
    - Femoral vein
    - Popliteal vein
    - Crural (tibial) vein
    - Peroneal vein
    - Anterior tibial vein
    - Posterior tibial vein
    - Muscular veins
    - Gastrocnemius vein
    - Soleal vein
- A_n – No venous anatomic location identified

Pathophysiologic (P) Classification

- P_r – Reflux

- P_o – Obstruction
- $P_{r,o}$ – Reflux and obstruction
- P_n – No venous pathophysiology

C. Venous Clinical Severity Score (Vasquez, et al., 2010)

Pain/Discomfort	None: 0	Mild: 1	Moderate: 2	Severe: 3
e.g., aching, fatigue, soreness, heaviness, burning		Occasional pain that does not restrict daily activities	Daily pain may interfere with regular daily activities (does not prevent)	Daily pain limiting most regular daily activities

Varicose Veins	None: 0	Mild: 1	Moderate: 2	Severe: 3
≥ 3 mm (diameter) in standing position		Few: scattered (varicosities confined to branch veins or clusters) Includes corona phlebectatica (ankle flare)	Multiple varicosities confined to the calf or the thigh	Multiple varicosities involves calf and thigh

Venous Edema	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin		Edema limited to the foot and ankle	Edema extends above the ankle but below the knee	Edema extends to the knee and above

Skin Pigmentation	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin Does not include focal pigmentation over varicose veins or due to other chronic diseases (e.g., vasculitis purpura)		Pigmentation is limited to perimalleolar area	Diffuse pigmentation that involves lower third of the calf	Wider distribution pigmentation above the lower third of the calf

Inflammation	None: 0	Mild: 1	Moderate: 2	Severe: 3
More than recent pigmentation (i.e., erythema, cellulitis, venous eczema, dermatitis)		Inflammation limited to perimalleolar area	Diffuse inflammation over lower third of calf	Wider distribution inflammation above lower third of calf

Induration	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin of secondary skin & subcutaneous changes (e.g., chronic edema with fibrosis, hypodermitis); includes white atrophy & Lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf

Active Ulcer Number	0	1	2	≥ 3
Active Ulcer Duration (longest active)	N/A	< 3 months	> 3 months but < 1 y	Not healed for > 1 y
Active Ulcer Size (largest active)	N/A	< 2 cm (diameter)	2-6 cm (diameter)	>6 cm (diameter)

Compression Therapy Use	0	1	2	3
	Not Used	Intermittent stocking use	Stocking use most days	Stocking use full compliance

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.(Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care – Median Score 7-9

May be Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

D. Acronyms/Abbreviations

AAGSV	Anterior Accessory Great Saphenous Vein
CEAP	Clinical-Etiology-Anatomy-Pathophysiology
GSV	Great Saphenous Vein
PAGSV	Posterior Accessory Great Saphenous Vein
QoL	Quality of Life
SFJ	Saphenofemoral Junction
SPJ	Saphenopopliteal Junction
SSV	Small Saphenous Vein
VCSS	Venous Clinical Severity Score

VI. Coding and Standards

- **Primary Codes**
  - 37700, 37718, 37722, 37735, 37761, 37780, 37785, 37500, 37760
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

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Cardio Policy

Lower Extremity Venous Sclerotherapy

POLICY NUMBER UM CARDIO_1254	SUBJECT Lower Extremity Venous Sclerotherapy		DEPT/PROGRAM UM Dept	PAGE 1 OF 10
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/01/19, 03/08/19, 05/08/19, 12/11/19, 01/23/20, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 12/17/13, 12/04/14, 02/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 02/01/19, 03/08/19, 05/08/19, 12/11/19, 01/23/20, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 01/11/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- The treatment of CEAP clinical classification C_0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.
- The treatment of CEAP clinical classification C_1 (telangiectasias or reticular veins) will be considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage except in patients with spontaneous and/or traumatic venous hemorrhage.
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted the request
    - Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins with CEAP classification and VCSS score
    - Prior venous intervention report

II. PURPOSE

Indications for determining medical necessity for Lower Extremity Venous Sclerotherapy

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications (Gloviczki, et al., 2022; Gloviczki, et al., 2024)

- Venous Tributaries
    - Symptomatic telangiectasias (subdermal veins < 1 mm in size) and reticular veins (veins < 3 mm in size) (use liquid or foam)

    NOTE: in CEAP Class C1 with bleeding or with severe symptoms (pain, burning) from moderate/severe telangiectasias or reticular veins, DUS evaluation to exclude associated venous incompetence before sclerotherapy

- Varicose Tributaries
    - Symptomatic varicosities (that were associated with symptomatic reflux in the GSV or SSV) concomitant ultrasound guided FS using physician-compounded foam (PCF) or polidocanol endovenous microfoam (PEM)
    - Symptomatic varicosities (that were associated with symptomatic reflux in the AAGSV or PAGSV) concomitant ultrasound guided FS with PCF or PEM
    - Recurrent/persistent symptomatic reflux in the major superficial venous trunk with varicosities that underwent initial ablation alone
        - Follow-up for > 3 months to assess need for ultrasound guided sclerotherapy (longer follow up is recommended for those with recurrence or more advanced CEAP class)
- Symptomatic recurrent varicosities or reflux due to neovascularization
- Acute bleeding varicose veins after leg elevation, direct compression, and sclerotherapy has been attempted before suture ligation to control bleeding

A complete Venous Duplex after each venous intervention is preferred to demonstrate the result of intervention on the intervened vein(s) and presence of reflux on target vein(s) of the same extremity.

V. Background

A. Sclerotherapy (Beneat & Oropallo, 2024)

A form of surgery that involves injecting special solutions into the veins to seal them. The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or chemical irritant), ultimately resulting in the occlusion of the vessel.

Types of Sclerosing agents

- Hyperosmolar agents cause nonspecific cellular destruction, burning, affects RBCs-dehydration. Examples include hypertonic saline usually mixed with Lidocaine.
- Detergent's cause cell surface disruption and extraction of proteins within seconds, lasting hours. Examples include Glycerin with Lidocaine and Epinephrine, Polidocanol (Asclera, Varithena, STS-Sodium tetradecyl sulfate.
- Chemical agents cause direct corrosive effect, disrupts the intercellular cement, poisons cell surface proteins, and affects chemical bonds immediately on vein wall exposure.

Sklermo or Chromex is a chemical agent and is not FDA approved for this procedure.

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences, edema, and skin changes should include the assessment of history and physical examination including the CEAP classification and revised VCSS. A DUS of the deep and superficial venous systems must support the examination findings.

B. Definitions

1. **Accessory/tributary veins**

   Located nearest to the skin

2. **Deep veins**

   Located deep to the muscular fascia (e.g., common femoral vein), can cause clinically significant pain resulting in a decrease in quality of life (QoL) or disability which may necessitate treatment.

3. **Perforator veins**

   Link the superficial and deep veins.

4. **Reticular veins** (Gloviczki, et al., 2024)

   Subdermal veins between 1 and < 3 mm in diameter

5. **Telangiectasia veins** (Gloviczki, et al., 2024)

   Subdermal spider veins <1 mm in diameter

6. **Superficial veins**

   Truncal veins (GSV, SSV, AAGSV, PAGSV)

7. **Varicose veins** (Gloviczki, et al., 2022; Gloviczki, et al., 2024)

   A manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension and valvular incompetence. Superficially located, dilated (≥ 3mm), tortuous, veins of the lower extremities are considered **pathologic reflux** when they have > 500 ms of reflux (in the superficial truncal veins, tibial, deep femoral, and popliteal veins), minimum value of > 1 second of reflux (in common femoral, femoral, and popliteal veins). There is no minimum diameter required to have a pathologic reflux.

   Pathologic perforating veins with CEAP clinical class C_2 includes those with a >500 ms outward flow and a diameter of > 3.5 mm on duplex ultrasound scan.

C. Classification for Chronic Venous Disease (CVD) (Lurie, et al., 2020)

CVD and CVI is based on CEAP categories; Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

Clinical (C) Classifications (C Classes present in Limb)

- C_0 – No visible or palpable signs of venous disease

- C_1 – Telangiectasias or reticular veins (< 3mm)
- C_2 – Simple varicose veins (≥ 3mm diameter)
    - C_{2r} – Recurrent varicose veins
- C_3 – Ankle edema of venous origin (not foot edema)
- C_4 – Changes in skin and subcutaneous tissue secondary to CVD
    - C_{4a} – Pigmentation or eczema
    - C_{4b} – Lipodermatosclerosis or atrophie blanche
    - C_{4c} – Corona phlebectatica
- C_5 – Healed venous ulcer
- C_6 – Open venous ulcer
    - C_{6r} – Recurrent active venous ulcer

Subscripts of C Classes Indicating presence or absence of symptoms

- **S - Symptomatic**
    - Ache
    - Pain
    - Tightness
    - Skin irritation
    - Heaviness
    - Muscle cramps
    - Other complaints attributable to venous dysfunction
- **A – Asymptomatic**

Etiologic (E) Classification

- E_c – Congenital
- E_p – Primary
- E_s – Secondary
    - E_{si} – Secondary – intravenous
    - E_{se} – Secondary – extravenous
- E_n – No cause identified

Anatomic (A) Classification

- A_s – Superficial veins
    - Telangiectasia

- Reticular Veins
- Great saphenous vein above knee
- Great saphenous vein below knee
- Small saphenous vein
- Anterior accessory saphenous vein
- Nonsaphenous vein

- A_p – Perforator veins
  - Thigh perforator vein
  - Calf perforator vein

- A_d – Deep veins
  - Inferior vena cava
  - Common iliac vein
  - Internal iliac vein
  - External iliac vein
  - Pelvic veins
  - Common femoral vein
  - Deep femoral vein
  - Femoral vein
  - Popliteal vein
  - Crural (tibial) vein
  - Peroneal vein
  - Anterior tibial vein
  - Posterior tibial vein
  - Muscular veins
  - Gastrocnemius vein
  - Soleal vein

- A_n – No venous anatomic location identified

Pathophysiologic (P) Classification

- P_r – Reflux
- P_o – Obstruction
- $P_{r,o}$ – Reflux and obstruction
- P_n – No venous pathophysiology

D. Venous Clinical Severity Score (Vasquez, et al., 2010)

Pain/Discomfort	None: 0	Mild: 1	Moderate: 2	Severe: 3
e.g., aching, fatigue, soreness,		Occasional pain that does not	Daily pain may interfere with	Daily pain limiting most

heaviness, burning		restrict daily activities	regular daily activities (does not prevent)	regular daily activities

Varicose Veins	**None: 0**	**Mild: 1**	**Moderate: 2**	**Severe: 3**
≥ 3 mm (diameter) in standing position		Few: scattered (varicosities confined to branch veins or clusters) Includes corona phlebectatica (ankle flare)	Multiple varicosities confined to the calf or the thigh	Multiple varicosities involves calf and thigh

Venous Edema	**None: 0**	**Mild: 1**	**Moderate: 2**	**Severe: 3**
Presumes venous origin		Edema limited to the foot and ankle	Edema extends above the ankle but below the knee	Edema extends to the knee and above

Skin Pigmentation	**None: 0**	**Mild: 1**	**Moderate: 2**	**Severe: 3**
Presumes venous origin Does not include focal pigmentation over varicose veins or due to other chronic diseases (e.g., vasculitis purpura)		Pigmentation is limited to perimalleolar area	Diffuse pigmentation that involves lower third of the calf	Wider distribution pigmentation above the lower third of the calf

Inflammation	**None: 0**	**Mild: 1**	**Moderate: 2**	**Severe: 3**
More than recent pigmentation (i.e., erythema, cellulitis, venous eczema, dermatitis)		Inflammation limited to perimalleolar area	Diffuse inflammation over lower third of calf	Wider distribution inflammation above lower third of calf

Induration	**None: 0**	**Mild: 1**	**Moderate: 2**	**Severe: 3**
Presumes venous origin of secondary skin & subcutaneous		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower

changes (e.g., chronic edema with fibrosis, hypodermitis); includes white atrophy & Lipodermatosclerosis				third of calf

Active Ulcer Number	**0**	**1**	**2**	**≥ 3**
Active Ulcer Duration (longest active)	N/A	< 3 months	> 3 months but < 1 y	Not healed for > 1 y
Active Ulcer Size (largest active)	N/A	< 2 cm (diameter)	2-6 cm (diameter)	>6 cm (diameter)

Compression Therapy Use	**0**	**1**	**2**	**3**
	Not Used	Intermittent stocking use	Stocking use most days	Stocking use full compliance

E. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. (Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

F. Acronyms/Abbreviations

AAGSV	Anterior Accessory Great Saphenous Vein
CEAP	Clinical-Etiology-Anatomy-Pathophysiology
CVD	Chronic Venous Disease
CVI	Chronic Venous Insufficiency
DUS	Duplex Ultrasound
FDA	Food and Drug Administration
GSV	Great Saphenous Vein
PAGSV	Posterior Accessory Great Saphenous Vein
PCF	Physician-compounded foam
PEM	Polidocanol endovenous microfoam

QoL	Quality of Life
RBCs	Red Blood Cells
SSV	Small Saphenous Vein
STS	Sodium tetradecyl sulfate
VCSS	Venous Clinical Severity Score

VI. Coding and Standards

- **Primary Codes**
  - 36470 – Injection of sclerosant; single incompetent vein (other than telangiectasia)
  - 36471 – Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
  - 36465 – Injection of non-compounded foam sclerosant with u/s compression maneuvers, inclusive of all imaging and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein).

    36466 – Injection of non-compounded foam sclerosant with u/s compression maneuvers, inclusive of all imaging and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg.
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

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Cardio Policy

Lower Extremity Venous Stab Phlebectomy

POLICY NUMBER UM CARDIO_1255	**SUBJECT** Lower Extremity Venous Stab Phlebectomy		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 10**
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 12/17/13, 12/18/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 04/12/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	**APPROVAL DATE** April 10, 2024	**EFFECTIVE DATE** April 26, 2024	**COMMITTEE APPROVAL DATES** 09/09/11, 01/09/13, 12/17/13, 12/18/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 02/13/19, 03/13/19, 05/08/19, 12/11/19, 05/13/20, 01/13/21, 05/12/21, 11/09/21, 04/13/22, 04/12/23, 05/10/23, 12/20/23, 01/10/24, 04/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- The treatment of CEAP clinical classification C_0 (no visible or palpable signs of venous disease) is considered cosmetic, and therefore, not reasonable, and necessary for the purposes of Medicare coverage.
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
- To review a request for medical necessity, the following items must be submitted for review:
  - Progress note that prompted the request
  - Latest venous duplex report supporting request describing reflux (location and duration of reflux) and anatomy of veins with CEAP classification and VCSS score
  - Prior venous intervention report

II. Purpose

Indications for determining medical necessity for lower extremity venous stab phlebectomy.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications [6, 7]

Symptomatic Varicose Veins and Axial Reflux

- In the AAGSV or PAGSV (phlebectomy if needed from treatment with endovenous (thermal or nonthermal) ablation))
- In the AAGSV or PAGSV (phlebectomy if needed from ligation and stripping of the accessory saphenous vein)

- In the AAGSV or PAGSV and high priority for long-term outcomes of treatment (improvement of quality of life (QoL) and reduced recurrences) (phlebectomy if needed from the treatment of the refluxing superficial trunk with endovenous laser ablation, radiofrequency ablation (RFA), or high ligation and stripping (HL&S)

Varicose Tributaries

- Symptomatic varicose tributaries:
  - Transilluminated powered phlebectomy (alternative treatment) for following:
    - Clusters of varicosities

- Symptomatic reflux in the GSV or SSV:
  - Concomitant phlebectomy of the varicosities
  - Staged phlebectomy of the varicosities if anatomical or medical reasons present
- Symptomatic reflux in the AAGSV or PAGSV:
  - Simultaneous phlebectomy of the varicosities when ablation of the refluxing venous trunk
  - Staged phlebectomy of the varicosities if anatomical or medical reasons present
- Recurrent/persistent symptomatic reflux in the major superficial trunks and associated varicosities that underwent ablation alone
  - Follow-up for > 3 months to assess the need for staged phlebectomy (longer follow-up is recommended for those with recurrence or more advanced CEAP class)
- Symptomatic recurrent varicosities or reflux due to neovascularization

Superficial Vein Thrombosis (SVT)

- Isolated thrombosis of varicose tributaries and/or limited involvement of the GSV

Superficial Vein Aneurysms

- Symptomatic saphenous reflux, phlebectomy of the distal saphenous vein

A complete Venous Duplex after each venous intervention preferred to demonstrate the result of intervention on the intervened vein(s) and presence of reflux on target vein(s) of the same extremity.

V. Background

The evaluation of a patient with lower extremity venous incompetence and its advanced consequences-edema and skin changes-should include the assessment of history and physical examination including the CEAP classification and revised Venous Clinical Severity Score (VCSS). A duplex ultrasound scan (DUS) of the deep and superficial venous systems must support the examination findings.

Stab Phlebectomy is also known as Ambulatory/Micro-Phlebectomy. It is a minimally invasive procedure performed under local anesthesia. It involves removal of varicose veins through small “stab”1-2mm incisions in the skin overlying the vein. The vein is then hooked and brought to surface at each incision site to release it from surrounding tissues and to severe any connections to other veins.

A. Definitions

1. **Accessory/tributary veins**
   Located nearest to the skin

2. **Deep veins**
   Located deep to the muscular fascia (e.g., common femoral vein), can cause clinically significant pain resulting in a decrease in quality of life (QoL) or disability which may necessitate treatment.

3. **Perforator veins**
   Link the superficial and deep veins.

4. **Reticular veins** [7]
   Subdermal veins between 1 and < 3 mm in diameter

5. **Telangiectasia veins** [7]
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6. **Superficial veins**
   Truncal veins (GSV, SSV, AAGSV, PAGSV)

7. **Varicose veins** [6, 7]
   A manifestation of chronic venous disease (CVD) caused by ambulatory venous hypertension and valvular incompetence. Superficially located, dilated (≥ 3mm), tortuous, veins of the lower extremities are considered **pathologic reflux** when they have > 500 ms of reflux (in the superficial truncal veins, tibial, deep femoral, and popliteal veins), minimum value of > 1 second of reflux (in common femoral, femoral, and popliteal veins). There is no minimum diameter required to have a pathologic reflux.
   Pathologic perforating veins with CEAP clinical class C_2 includes those with a >500 ms outward flow and a diameter of > 3.5 mm on duplex ultrasound scan.

B. Classification for Chronic Venous Disease (CVD) [8]

CVD and CVI is based on CEAP categories; Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

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- C_0 – No visible or palpable signs of venous disease
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    - Tightness
    - Skin irritation
    - Heaviness
    - Muscle cramps
    - Other complaints attributable to venous dysfunction
- **A – Asymptomatic**

Etiologic (E) Classification

- E_c – Congenital
- E_p – Primary
- E_s – Secondary
    - E_{si} – Secondary – intravenous
    - E_{se} – Secondary – extravenous
- E_n – No cause identified

Anatomic (A) Classification

- A_s – Superficial veins
    - Telangiectasia
    - Reticular Veins
    - Great saphenous vein above knee
    - Great saphenous vein below knee
    - Small saphenous vein
    - Anterior accessory saphenous vein
    - Nonsaphenous vein
- A_p – Perforator veins
    - Thigh perforator vein
    - Calf perforator vein
- A_d – Deep veins
    - Inferior vena cava
    - Common iliac vein
    - Internal iliac vein
    - External iliac vein
    - Pelvic veins
    - Common femoral vein

- Deep femoral vein
- Femoral vein
- Popliteal vein
- Crural (tibial) vein
- Peroneal vein
- Anterior tibial vein
- Posterior tibial vein
- Muscular veins
- Gastrocnemius vein
- Soleal vein

- A_n – No venous anatomic location identified

Pathophysiologic (P) Classification

- P_r – Reflux
- P_o – Obstruction
- $P_{r,o}$ – Reflux and obstruction
- P_n – No venous pathophysiology

C. Venous Clinical Severity Score [9]

Pain/Discomfort	None: 0	Mild: 1	Moderate: 2	Severe: 3
e.g., aching, fatigue, soreness, heaviness, burning		Occasional pain that does not restrict daily activities	Daily pain may interfere with regular daily activities (does not prevent)	Daily pain limiting most regular daily activities

Varicose Veins	None: 0	Mild: 1	Moderate: 2	Severe: 3
≥ 3 mm (diameter) in standing position		Few: scattered (varicosities confined to branch veins or clusters) Includes corona phlebectatica (ankle flare)	Multiple varicosities confined to the calf or the thigh	Multiple varicosities involves calf and thigh

Venous Edema	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin		Edema limited to the foot and ankle	Edema extends above the ankle but below the knee	Edema extends to the knee and above

Skin Pigmentation	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin Does not include focal pigmentation over varicose veins or due to other chronic diseases (e.g., vasculitis purpura)		Pigmentation is limited to perimalleolar area	Diffuse pigmentation that involves lower third of the calf	Wider distribution pigmentation above the lower third of the calf

Inflammation	None: 0	Mild: 1	Moderate: 2	Severe: 3
More than recent pigmentation (i.e., erythema, cellulitis, venous eczema, dermatitis)		Inflammation limited to perimalleolar area	Diffuse inflammation over lower third of calf	Wider distribution inflammation above lower third of calf

Induration	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin of secondary skin & subcutaneous changes (e.g., chronic edema with fibrosis, hypodermitis); includes white atrophy & Lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf

Active Ulcer Number	0	1	2	≥ 3
Active Ulcer Duration (longest active)	N/A	< 3 months	> 3 months but < 1 y	Not healed for > 1 y

Active Ulcer Size (largest active)	N/A	< 2 cm (diameter)	2-6 cm (diameter)	>6 cm (diameter)

Compression Therapy Use	**0**	**1**	**2**	**3**
	Not Used	Intermittent stocking use	Stocking use most days	Stocking use full compliance

D. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

E. Acronyms/Abbreviations

AAGSV	Anterior Accessory Great Saphenous Vein
CEAP	Clinical-Etiology-Anatomy-Pathophysiology
CVD	Chronic Venous Disease
CVI	Chronic Venous Insufficiency
DUS	Duplex Ultrasound
GSV	Great Saphenous Vein
PAGSV	Posterior Accessory Great Saphenous Vein
QoL	Quality of Life
SSV	Small Saphenous Vein
VCSS	Venous Clinical Severity Score

VI. Coding and Standards

- **Primary Codes**
  - 37765 Stab phlebectomy of varicose veins 1 extremity 10-20 incision
  - 37766 Stab phlebectomy of varicose veins 1 extremity more than 20 incisions
- **Review**
  - Utilization Management Department
- **Final Approval**

- Utilization Management Committee

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

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[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

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Cardio Policy

Device Interrogation

POLICY NUMBER UM CARDIO_1256	SUBJECT Device (PPM/CRT-P, AICD/CRT-D-P/Subcutaneous ICD, ILR, Life Vest/Wearable Defibrillator) Interrogation		DEPT/PROGRAM UM Dept	PAGE 1 OF 8
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 01/08/14, 08/12/15, 12/21/16, 07/26/17, 10/11/17, 02/14/18, 12/12/18, 03/13/19, 05/08/19, 07/31/19, 12/11/19, 02/12/20, 05/13/20, 02/10/21, 05/12/21, 11/09/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 08/03/11, 01/09/13, 01/08/14, 08/12/15, 12/21/16, 07/26/17, 10/11/17, 02/14/18, 12/12/18, 03/13/19, 05/08/19, 07/31/19, 12/11/19, 02/12/20, 05/13/20, 02/10/21, 05/12/21, 11/09/21, 07/13/22, 07/18/23, 12/20/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Latest device interrogation report with strips

II. Purpose

Indications for determining medical necessity for Automatic Implantable Cardioverter Defibrillator (AICD)/Cardiac Resynchronization Therapy-Defibrillator (CRT-D), Permanent Pacemaker (PPM)/Cardiac Resynchronization Therapy-Pacemaker (CRT-P)/Subcutaneous ICD/ Life Vest Defibrillator and Implantable Loop Recorder (ILR) Interrogation.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Device Interrogation

Pacemaker Interrogation [6]

- Interrogation can be performed every 3 months from last remote interrogation
    - Remote Interrogation (RI)
    - Trans telephonic Interrogation (TTM)

  NOTE: Interrogation of device is inclusive of programming service, if performed on the same day
- Routine or surveillance interrogation (leadless, single, dual leads) can be performed every 6 months as in person

AICD Interrogation [6]

- Routine or surveillance AICD/CRT-D/CRT-P/subcutaneous ICD interrogation can be done every 3 months irrespective of interrogation being done in person or remotely

  NOTE: Interrogation of device is inclusive of programming service, if performed on the same day

Loop Recorder Interrogation [7]

- Routine loop recorder interrogation in person or remotely can be done every month

Urgent Interrogation

- Life vest or wearable defibrillator interrogation is reasonable to perform every 30 days up until 3 months in person only
- Recent shock therapy through AICD/CRT-D or any symptom or findings since previous device evaluation for which an interrogation earlier than recommended guideline frequency could help yield a diagnosis, or if permanent adjustment(s) were made during the last evaluation
- Recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)

  NOTE: Interrogation of device is inclusive of programming service, if performed on the same day

- Device interrogation is indicated 2-12 weeks post device implantation or pulse generator replacement [7]

V. Potential Exclusions

- Devices with Automatic/Adaptive monitoring capabilities includes monitoring of pacing and sensing thresholds at periodic intervals and device determination of a target output based on the programmable safety margin and programmable minimum amplitude. A request for a device with auto capture capability will be considered a Device Interrogation request
- When a patient is monitored both during clinic visits and trans-telephonically or remotely, the combined frequency of monitoring will be considered in evaluating the reasonableness of the frequency of monitoring services received by the patient
- Remote and in-person interrogation cannot be reported at the same time
- Subcutaneous ICD and life vest/wearable defibrillator cannot be interrogated remotely
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

VI. Background

A. Definitions

1. **AICD/CRT-D, PPM/CRT-P/Subcutaneous ICD interrogation**:
   Measurement of previously programmed parameters including but not limited to, battery voltage, lead capture and sensing function, heart rhythm, absence, or presence of therapy for ventricular tachyarrhythmias. Once the device battery longevity is reaching effective replacement index (ERI) or once it has reached end of life (EOL) the device will create an alert for replacement.

2. **Automatic implantable cardioverter defibrillator (AICD) or implantable cardioverter defibrillator (ICD):**
   Electronic device designed to detect and treat life-threatening tachyarrhythmia or brady-arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing and defibrillation.

3. **CRT-D/CRT-P:**
   Cardiac device with multiple leads, Defibrillator or Pacemaker with pacing and sensing function in three or more chambers of heart.

4. **Implantable loop recorder (ILR):**
   Patient-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The physician utilizes a programmer to retrieve, display, and print data.

5. **ILR interrogation:**
   Previously programmed parameters and the heart rate and rhythm during recorded episodes from both patient-initiated, and device algorithm detected events, when present.

6. **Life Vest Interrogation:**
   Previously programmed parameters, battery status, and the heart rate and rhythm during recorded episodes from both patient-initiated, and device algorithm detected events, when present.

7. **Life Vest/Wearable Defibrillator:**
   Worn by patients that places them at risk for sudden cardiac death (SCD): [8]
   - Primary prevention (EF ≤ 35%) including:
     - After recent MI (coverage during the 40 day ICD waiting period)
     - Before and after CABG or PTCA (coverage during the 90 day ICD waiting period)
     - Listed for cardiac transplant
     - Recently diagnosed non-ischemic cardiomyopathy (coverage during the 3 month ICD waiting period)
     - NYHA Class IV heart failure
     - Terminal disease with life expectancy of less than 1 year
   - ICD indications when patient condition delays or prohibits ICD implantation
   - ICD explanation

   The life vest allows a patient's physician time to assess their long-term arrhythmic risk and make appropriate plans. It continuously monitors the patient's heart and if a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.

8. **Pacemaker:**
   Medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart because the heart's native pacemaker is not fast

enough or there is a block in the heart's electrical conduction system.

9. **Remote Interrogation (RI):**
   Remote evaluation of CIEDs using a wand-based radiofrequency platform to transfer data from patient's device to a home transceiver, then via telephone (analog phone line or cellular wireless data network) to a central repository. [7]

10. **Remote Monitoring (RM):**
    Remote evaluation of CIEDs using automated platform by set radiofrequency transmissions sent wirelessly to a transceiver (located by the patient) then to central repository by analog landline or wireless data networks. Minimal information includes battery status, lead integrity, and arrhythmic events. [7]

11. **Subcutaneous ICD:**
    Pulse generator, implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the breastbone with the use of the insertion tool. There are no electrodes/leads placed on (epicardial) or in (endocardial) the heart.

12. **Trans telephonic Monitoring (TTM)**: remote evaluation of CIEDs by analog transmission over a telephone line. Information includes sensing, capture, battery longevity data, and real time electrocardiogram. [7]

13. **Leadless Pacemaker**: A self-contained medical device that includes pacemaker electronics and battery that is inserted directly into right side of the heart without requiring the need for a surgical pocket and pacemaker leads. [9]

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AICD	Automatic Internal Cardiac Defibrillator
CABG	Coronary Artery Bypass Graft
CIEDS	Cardiovascular Implantable Electronic Devices
CRT-D	Cardiac Resynchronization Therapy with ICD
CRT-P	Cardiac Resynchronization Therapy with Pacemaker
EOL	End of Life
ERI	Elective Replacement Indications
ICD	Implantable Cardioverter Defibrillator
ILR	Implantable Loop Recorder
NYHA	New York Heart Association
PPM	Permanent Pacemaker
PTCA	Percutaneous Transluminal Coronary Angioplasty
RI	Remote Interrogation

RM	Remote Monitoring
SCD	Sudden Cardiac Death
TTM	Transtelephonic Monitoring

VII. Codings and Standards

- **Primary Codes**
  - PPM (single, dual, multi leads or leadless):
    - In person: 93288
    - Remote: 93294
    - Technical code for PPM (single, dual, multi leads or leadless) remote interrogation: 93296
    - Trans Telephonic Monitoring: 93293
    - Analyze Anti tachycardia pacemaker system: 93724
  - AICD (single, dual or multi leads):
    - In person: 93289
    - Remote: 93295
    - Technical code for remote interrogation: 93296
  - ILR:
    - In person: 93291
    - Remote: 93298
  - Subcutaneous ICD:
    - In person: 93261
  - Life Vest/Wearable Defibrillator:
    - In person: 93292
  - Optivol /Implantable Cardiovascular Monitoring:
    - In person: 93290
    - Remote: 93297
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VIII. References

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Cardio Policy

Device Programming

POLICY NUMBER UM CARDIO_1257	SUBJECT Device (PPM/CRT-P, AICD/CRT-D/ Subcutaneous ICD, ILR, Life Vest/Wearable Defibrillator) Programming		DEPT/PROGRAM UM Dept	PAGE 1 OF 8
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 01/08/14, 08/22/15, 03/28/16, 04/06/16, 11/28/16, 07/15/17, 10/11/17, 03/07/19, 09/11/19, 12/11/19, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 08/03/11, 01/09/13, 01/08/14, 08/22/15, 03/28/16, 04/06/16, 11/28/16, 07/15/17, 10/11/17, 03/07/19, 09/11/19, 12/11/19, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- Request for medical determination (the following items must be submitted for review):
    - Progress note that prompted request
    - Latest device interrogation report with strips

II. Purpose

Indications for determining medical necessity for Device Programming of an Automatic Implantable Cardioverter Defibrillator (AICD), Subcutaneous Implantable Cardioverter Defibrillator (SICD), Cardiac Resynchronization Therapy-Defibrillator (CRT-D) or -Pacemaker (CRT-P), Permanent Pacemaker (PPM), Implantable Loop Recorder (ILR), or Life Vest/Wearable Defibrillator.

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Device Programming

Device Programming involves modifying and documenting any iterative changes made to the device's operational parameters (e.g., sensing or pacing thresholds).

- **Routine Device Programming**
    - Device Programming is indicated within 72 hours of device implantation or pulse generator change, and may be indicated during a routine follow-up visit 2-12 weeks after device implantation. [6, 7]
    - Device Programming may also be indicated during routine follow-up visits that occur every 3-12 months for pacemakers, and every 3-6 months for ICDs and resynchronization devices. [6]

- **Patient-related Indications**
  - Changes in the clinical status or cardiovascular symptom frequency/severity that may affect device function. [8]
  - Changes in disease therapy or medication regimen if the change may influence the underlying cardiac rhythm or device functioning [9]
    - A lower rate cutoff is recommended for patients taking antiarrhythmic medications (e.g., Amiodarone, Multaq, Propafanone) that may reduce the heart rate at which clinical tachycardia is achieved

- **Disease-specific Programming** [6]
  - In patients with heart failure, AICD or CRT-D device programming through AV optimization to prevent recurrent heart failure decompensation is recommended
  - Unnecessary shocks due to rapid responses to supraventricular tachydysrhythmias (e.g., atrial fibrillation and flutter) and T-wave oversensing in channelopathies may occur. Device reprogramming may be indicated to reduce these occurrences.

- **Device-related Indications**
  - Device evaluation during Interrogation demonstrates lead malfunctioning, lead recall(s), or that the battery is approaching its end of life [6]
  - When the device delivers frequent or inappropriate shocks, device programming is indicated to optimize the programming therapy zones by modifying the device's operational parameters. Examples of operational parameters that can be adjusted during device programming include, but are not limited to: [9, 10]
    - Rate Threshold Sensing for identifying VT/VF
    - The duration of an identified VT/VF that partitions non-sustained vs. sustained VT/VF
    - Antitachycardia pacing
    - Discrimination of SVT vs VT
    - T-wave and lead-related oversensing
  - Device programming is indicated when one or more of the operational parameters are causing excessive battery depletion [6]
  - Device programming is also indicated when new permanent changes were done during the last device evaluation or deemed necessary after a recent remote interrogation.

- **Indications related to Remote Monitoring [8]**
  - For patients with devices that permit remote monitoring, alert parameters for cardiac events should be optimized to the patient's unique pathophysiology during office visit. Accordingly, device programming may be indicated if the device is over- or under-reporting actionable cardiac events and/or shock therapies.
  - For patients with ILR, Programming is indicated when there is frequent under sensing and/or oversensing. Alerts relating to actionable cardiac events, electrograms should be immediately reviewed to exclude misdiagnosis

- **Other Considerations**
  - Defibrillation threshold (DFT) testing for SICD, including for unique lead configurations, may be appropriate at the time of device implantation or generator replacement. [9] Examples of changeable parameters include shock vectors and timing.

- **Limitations**
  - Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
  - When a patient is monitored both during clinic visits and trans-telephonically or remotely, the combined frequency of monitoring will be considered in evaluating the reasonableness of the frequency of monitoring services received by the patient.
  - There are no frequency guidelines available for programming of Life Vest after initial set up.

V. Background

A. Definitions

1. **Device Programming** (is a non-invasive process that allows the physician to set, or modify, the operational parameters of the implanted cardiac device. Examples of Device Programming include:
   - For AICD, SICD, CRT-D, CRT-P, and PPM:
     1. Documented manual iterative temporary or permanent changes of capture and sensing thresholds.
     2. Changes in the pacing output of a pacing lead, heart rhythm, upper and lower heart rates, sensor rate response, AV intervals, pacing voltage, pulse duration, sensing value and checking battery voltage.
     3. In addition to these programming parameters, ventricular tachycardia detection and therapies are programmed based on device interrogation when medically necessary.
   - For an ILR:
     1. Tachycardia and bradycardia rate adjustment based on interrogation when medically necessary.
   - For a Life Vest/Wearable Defibrillator:
     1. Sensing thresholds and ventricular tachycardia detection and defibrillation therapies based on device interrogation when medically necessary. Note, there are no pacing capabilities in a Life Vest, and Programming is usually done during the initial setup of the device.
2. An **Automatic Implantable Cardioverter Defibrillator (AICD)** or Implantable Cardioverter Defibrillator (ICD), is an electronic device designed to detect and treat life-threatening tachyarrhythmias or bradyarrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing, and defibrillation.
3. A **Subcutaneous ICD** (pulse generator) is implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the

breastbone with the use of the insertion tool. There are no electrodes/leads placed on (epicardial) or in (endocardial) the heart.

4. **Cardiac Resynchronization Therapy-Defibrillators (CRT-D) and Cardiac Resynchronization Therapy-Pacemakers (CRT-P)** are cardiac device with pacing and sensing function in three or more chambers of heart.

5. A **Pacemaker** is a medical device that uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.

6. **Implantable cardiac loop recorders** continuously monitor and record ECG tracings, are indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The physician utilizes a programmer to retrieve, display and print stored data.

7. A **Life Vest/Wearable Defibrillator** is worn by patients that are at risk for sudden cardiac death (SCD) and allows their physician time to assess their long-term arrhythmic risk and make appropriate plans. It continuously monitors the patient's heart and, if a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.

8. **Defibrillator Threshold (DFT) Test** - It is an integral part of implantable cardioverter-defibrillator implantation. It is usually performed at the time of initial implantation or after generator replacement. It involves testing of the device and leads by arrhythmia induction and termination by delivering shock therapy through programmed parameters.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care – Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AICD	Automatic Implantable Cardioverter Defibrillator
AUC	Appropriate Use Criteria
AV	Atrioventricular
CRT-D	Cardiac Resynchronization Therapy Defibrillator
CRT-P	Cardiac Resynchronization Therapy Pacemaker
DFT	Defibrillation Threshold

ECG	Electrocardiogram
ICD	Implantable Cardioverter Defibrillator
ILR	Implantable Loop Recorder
OOS	Out of Scope
PPM	Permanent Pacemaker
SICD	Subcutaneous Implantable Cardioverter Defibrillator
SVT	Supraventricular tachycardia
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

VI. Coding and Standards

- **Primary Codes**
  - PPM – 93279, 93280, 93281
  - AICD – 93282, 93283, 93284
  - ILR – 93285
  - SICD – 93260
  - Life Vest/Wearable Defibrillator – 93745 *(for initial programming of system, usually done while patient is hospitalized after the cardiac event.)*
- **Related Codes**
  - 93640 (EP eval of single/dual ICD leads including DFT testing at the time of initial implant or replacement)
  - 93641 (EP eval of single/dual ICD leads and generator including DFT testing at the time of initial implant or replacement)
  - 93642 (EP eval of single/dual ICD leads including DFT testing and programming and reprogramming of sensing and therapeutic parameters)
  - 93644 (EP eval of Subcutaneous ICD leads including DFT testing and programming and reprogramming of sensing and therapeutic parameters)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

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Cardio Policy

Aorto-Renal Endarterectomy or Bypass Surgery

POLICY NUMBER UM CARDIO_1268	**SUBJECT** Aorto-Renal Endarterectomy or Bypass Surgery		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 05/24/16, 11/28/16, 12/21/16, 10/10/17, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 10/18/23, 01/10/24, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** March 29, 2024	**COMMITTEE APPROVAL DATES** 05/24/16, 11/28/16, 12/21/16, 10/10/17, 03/07/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 10/18/23, 01/10/24, 03/13/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
  - Cardiologist/Nephrologist/Vascular Surgeon note that prompted request
  - Renal Artery Duplex/Retroperitoneal Duplex/MRA Renal/CTA Renal/Renal Angiogram reports

II. Purpose

Indications for determining medical necessity for Aorto-Renal Endarterectomy or Bypass Surgery. Renal artery stenosis (RAS) is the narrowing of one or both renal arteries. Surgery may be recommended for people with RAS caused by fibromuscular dysplasia or RAS that does not improve with medication. In an endarterectomy, the plaque is cleaned out of the artery, leaving the inside lining smooth and clear. To create a bypass, a vein or synthetic tube is used to connect the kidney to the aorta.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Bonow, et al., 2011; Fitch, et al., 2001; Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Patel, et al., 2005)

IV. Indications for Aorto-Renal Endarterectomy or Bypass Surgery

NOTE: For patients who are not a candidate for percutaneous intervention (PI) (Aboyans, et al., 2018; Anderson, et al., 2013)

- Patients with fibro-muscular dysplastic RAS with:
  - complex disease that extends into the segmental arteries **AND**
  - macro-aneurysms **AND**

- Patients with atherosclerotic RAS with multiple small renal arteries **OR** early primary branching of the main renal artery
- Patients with atherosclerotic RAS in combination with pararenal aortic reconstructions (in treatment of aortic aneurysms or severe aortoiliac occlusive disease).

Potential Exclusions

- Advanced disease - Creatinine level > 3-4 mg/dL; kidney length < 8 cm
- Limited life expectancy
- Bleeding diathesis; recent myocardial infarction (MI)
- Pregnancy
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

V. Background

AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AU is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making. (Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

Acronyms

MI: myocardial infarction
PI: percutaneous intervention
RAS: renal artery stenosis

VI. Coding and Standards

- **Primary codes**
  - 35560
- **Place/Site of Service**
  - Inpatient hospital (21)
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

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Cardio Policy:

Coronary Fractional Flow Reserve

POLICY NUMBER UM CARDIO_1269	**SUBJECT** Coronary Fractional Flow Reserve		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Coronary Fractional Flow Reserve (FFR).

II. DEFINITIONS

Fractional flow reserve (FFR) is used to determine the functional significance of a coronary stenosis in angiographically “intermediate” or “indeterminant” lesions which allows the operator to decide when PCI may be beneficial or safely deferred. During coronary catheterization, a catheter is inserted into the femoral (groin) or radial arteries (wrist) using a sheath and guidewire. FFR uses a small sensor (transducer) on the tip of the wire to measure pressure, temperature, and flow in order to determine the exact severity of the lesion during maximal blood flow (hyperemia). Hyperemia is induced by injecting products such as adenosine or papaverine. A pullback of the pressure wire is performed, and pressures are recorded across the vessel. FFR is then calculated as the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia. A normal value for FFR is 1.0. FFR ≤0.80 in an angiographically intermediate lesion (50-70% stenosis) is considered to be a significant coronary lesion (>70% stenosis).

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Surgical procedures are reviewed and approved by Physicians and Nurses only. Utilization Management staff (pharmacists, intake coordinators or any other type of lower level medical staff) cannot review or approve surgical procedures within New Century Health.

Indications for approving a request for medical necessity are:

A. FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with Stable Ischemic Heart Disease. **(AUC Score 6)**[1,2,3,4,5,6]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Prior Diagnostic coronary angiogram
   3. Noninvasive vascular testing

B. Primary codes appropriate for this service:

   93571 – Coronary Flow Reserve Measurement, Initial vessel

   93572 – Coronary Flow Reserve Measurement – Each Additional vessel

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Michigan Local Coverage Determination (LCD) (L34761). Percutaneous Coronary Interventions. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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6. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
7. NCQA UM 2023 Standards and Elements.

Cardio Policy

Coronary Atherectomy

POLICY NUMBER UM CARDIO_1291	SUBJECT Coronary Atherectomy		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/09/21, 11/09/21, 08/10/22, 07/18/23, 01/10/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/09/21, 11/09/21, 08/10/22, 07/18/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Recent diagnostic coronary angiogram or CCTA report

II. Purpose

Indications for determining medical necessity for Coronary Atherectomy.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications for Coronary Atherectomy (Lawton, et al., 2022)

- Rotational atherectomy is reasonable as primary procedure for fibrotic or heavily calcified de novo lesions for lesion modification prior to angioplasty and stenting.
- Rotational atherectomy can be used as secondary approach after unsuccessful attempt to dilate calcified lesion by balloon angioplasty.
- Laser Coronary atherectomy is reasonable to perform for in stent restenosis (Farag, et al., 2023)

V. Limitations for Coronary Atherectomy (Sharma, et al., 2019)

- Rotational atherectomy is not recommended for below scenarios;
    - Occlusions for which a guidewire will not pass (risk of perforation)
    - Degenerated SV Graft lesion or thrombus
    - Lack of cardiac surgery
    - Patient is ineligible for CABG
    - Left ventricular dysfunction
    - Severe multivessel or unprotected left main coronary artery disease lesion length >25mm and lesion angulation >45˚
    - Rotational atherectomy should be used cautiously in presence of coronary dissection for plaque modification as guidewire is in true lumen of coronary artery
    - Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

VI. Background

A. Definitions

1. Coronary Atherectomy is a procedure that utilizes a catheter device that is inserted into coronary artery percutaneously to remove plaque from the inside of artery.

2. In the presence of coronary artery calcification with an arc >50%, thickness >0.5 mm and length >5 mm, adjunctive therapies for calcium modification should be considered, which are;
    - Rotational atherectomy, involves the use of a special burr or drill on the tip of a catheter that rotates to shave the plaque into tiny pieces
    - Directional atherectomy, a technique in which a small cutting device is pushed against the plaque to cut it away from the artery. The process can be repeated at the time the treatment is performed to remove a significant amount of disease from the artery, thus eliminating a blockage from atherosclerotic disease. Devices for directional coronary atherectomy are no longer marketed in the United States.
    - Excimer Laser atherectomy involves use of xenon chloride laser generator to generate laser (pulsating beams of light) to vaporize the calcified plaque in coronary arteries.
    - Orbital atherectomy uses a unique mechanism of action incorporating centrifugal forces via a standard 1.25mm eccentrically mounted and diamond coated burr to ablate calcified plaque to facilitate stent expansion.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. (Hendel, Lindsay, Allen, & et al., 2018)

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

CABG	Coronary Artery Bypass Graft

VII. Coding and Standards

- **Primary Codes**
  - 92924, 92925
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VIII. References

[1] Bonow, R., Douglas, P., Buxton, A., Cohen, D., Curtis, J., Delong, E., . . . American College of Cardiology Foundation. (2011, Sept). ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation, 124*(13), 1483-502. doi:10.1161/CIR.0b013e31822935fc

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Cardio Policy

Coronary Intra Vascular Arterial Ultrasound

POLICY NUMBER UM CARDIO_1292	SUBJECT Coronary Intra Vascular Arterial Ultrasound		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/2024, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Prior Diagnostic coronary angiogram
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

II. Purpose

Indications for determining medical necessity for Coronary Intra Vascular Arterial Ultrasound (IVUS).

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Coronary Intra Vascular Arterial Ultrasound

IVUS is recommended for:

- Assessing angiographically indeterminate left main (LM) artery lesion severity prior to revascularization. [6]
- Post cardiac transplantation within 4 to 6 weeks and 1 year to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information [6]
- Evaluating the mechanism of stent failure, stent restenosis and stent thrombosis [6, 8, 9]
- Assessing non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) [6]
- Coronary stent implantation guidance, particularly in cases of LM coronary artery stenting or complex coronary artery stenting including but not limited to: [6, 7, 8, 9]

    - adequate expansion and apposition in selected patients
- Assessing plaque extent (burden) and characteristics within the LM [7], particularly ostial stenosis in LM and daughter branches [7, 9]
- Assessing the severity and optimizing the treatment of unprotected LM lesions [9]

V. Limitations for Coronary Intra Vascular Arterial Ultrasound

IVUS is **NOT** indicated for:

- Routine lesion assessment when revascularization with PCI or CABG is not being contemplated. [6]
- Extreme vessel tortuosity and angulation [10]
- Patients not suitable for systemic anticoagulation or angiography or cardiac catheterization [10]

VI. Background

A. Definitions

IVUS is a specially designed catheter with a miniaturized ultrasound probe attached to the distal end of the catheter. IVUS when introduced in a coronary artery during cardiac catheterization, provides more precise information about the severity of stenosis and plaque morphology than does coronary angiography such as for the lumen of ostial lesions or where angiographic images do not visualize lumen segments adequately, such as regions with multiple overlapping arterial segments. It is also used to assess the effects of treatments of stenosis such as with hydraulic angioplasty expansion of the artery, with or without stents, and the results of medical therapy over time.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abrreviations

CABG	Coronary artery bypass grafting
IVUS	Intra Vascular Arterial Ultrasound
LMCAD	Left main coronary artery disease
PCI	Percutaneous coronary intervention

VII. Coding and Standard

- **Primary codes**
    - 92978 – IVUS (Initial Vessel)
    - 92979 – IVUS (Each Additional Vessel)
- **Review**

- Utilization Management Department

- **Final Approval**
  - Utilization Management Committee

VIII. References

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[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

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Cardio Policy:

Renal Angiography

POLICY NUMBER UM CARDIO_1293	**SUBJECT** Renal Angiography		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 12/11/19, 06/10/20, 06/09/21, 10/13/21, 11/09/21, 12/08/21, 12/14/22, 10/18/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 12/11/19, 06/10/20, 06/09/21, 10/13/21, 11/09/21, 12/08/21, 12/14/22, 10/18/23, 12/20/2023, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Renal Angiography.

II. DEFINITIONS

Renal angiography is X-ray study of blood vessels to the kidney. X-rays are taken while contrast dye is injected into a catheter (a tiny tube) that has been placed into the blood vessels of the kidneys to detect any signs of blockage, narrowing, or other abnormalities affecting the blood supply to the kidneys.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

Renal angiogram can be performed if:

A. Uncontrolled arterial hypertension despite being on maximal (greater than or equal to 3) tolerated medical therapy including diuretic with evidence of renal artery stenosis on non-invasive imaging study. **(AUC Score 8)**[1,2,3,4]

B. Accelerated, resistant, malignant hypertension or onset of hypertension at less than 30 years of age or severe hypertension at greater than 55 years of age with evidence of renal artery stenosis on non-invasive imaging studies. **(AUC Score 8)**[1,2,3,4]

C. Unexplained atrophic kidney or size discrepancy greater than 1.5 cm between kidneys with high index of suspicion of renal artery stenosis on non-invasive imaging. **(AUC Score 8)**[1,2,3,4]

D. Sudden, unexplained pulmonary edema or congestive heart failure with high degree of suspicion of renal artery stenosis on non-invasive imaging studies. **(AUC Score 8)**[1,2,3,4]

E. Unexplained renal dysfunction, including individuals starting renal replacement therapy with high degree of suspicion of renal artery stenosis on non-invasive imaging studies. **(AUC Score 8)**[1,2,3,4]

F. New azotemia or worsening renal function after administration of an ACE inhibitor or ARB with high degree of suspicion of renal artery stenosis on non-invasive imaging studies. **(AUC Score 8)**[1,2,3,4]

G. Evidence of unilateral or bilateral Renal Artery stenosis in asymptomatic patient (greater than or equal to 50%) on routine non-invasive imaging studies. **(AUC Score 8)**[1,2,3,4]

H. For the assessment of primary vascular abnormalities e.g., aneurysms and other vascular malformations, vasculitis, and renal neoplasms that have been identified on non-invasive imaging. **(AUC Score 8)**[1,2,3,4]

I. Pre- and postoperative evaluations for renal transplantations **(AUC Score 8)**[1,2,3,4]

J. Prior to interventional procedures on the renal arteries **(AUC Score 8)**[1,2,3,4]

K. Renal angiography, non-selective, performed at time of cardiac catheterization will be considered medically reasonable and necessary when the clinical index of suspicion for atherosclerotic renal artery stenosis (RAS) is high, as defined by the criteria listed below, AND there are reasonable anticipated therapeutic implications for which the results of this angiogram will be used AND when the results of noninvasive imaging studies cannot be obtained or are inconclusive for individuals falling into scenarios A through G above **(AUC Score 8)**[1,2,3,4]

Limitations:

A. Renal artery angiogram is considered inappropriate if there is:
   1. Unilateral, solitary, or bilateral RAS with controlled Blood Pressure and normal renal function.
   2. Unilateral, solitary, or bilateral RAS with kidney size less than 7 cm in pole-pole length on renal duplex.
   3. Unilateral, solitary, or bilateral RAS with chronic end stage renal disease on hemodialysis greater than 3 months.
   4. Unilateral, solitary, or bilateral renal artery chronic total occlusion.

B. Guideline-directed medical therapy must be documented as having been tried and failed in terms of determining the medical necessity for renal artery angiography.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist note that prompted request with list of medications
   2. Renal Artery Duplex and/or Retroperitoneal duplex/MRA Renal/CTA Renal reports
   3. Labs-Renal Function test

B. Primary codes appropriate for this service are: Renal Angiogram (Unilateral) 36251,75726 (Bilateral) 36252, 75726.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD)(L36767). Aortography and peripheral angiography. Retrieved from https://www.cms.gov [December 19, 2023].
2. Klein, Andrew, et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. May 2017. Oct 2017. Volume 90, Issue 4, Pages E90-E110.
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5. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Renal Artery Intervention

POLICY NUMBER UM CARDIO_1294	SUBJECT Renal Artery Intervention (Angioplasty or Stent)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/21/19, 06/10/20, 06/09/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/21/19, 06/10/20, 06/09/21, 11/09/21, 07/13/22, 05/10/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Renal Artery Intervention.

II. DEFINITIONS

Renal Artery Angioplasty is an endovascular procedure to widen narrowed or obstructed renal arteries typically to treat arterial atherosclerosis. An empty, collapsed balloon, known as a balloon catheter, is passed over a wire into the narrowed locations and then inflated to a fixed size. The balloon forces expansion of the stenosis (narrowing) within the vessel and the surrounding muscular wall, opening up the blood vessel for improved flow, and the balloon is then deflated and withdrawn. A stent may or may not be inserted at the time of ballooning to ensure the vessel remains open.

Hemodynamically significant RAS is defined as:

A. Evidence of RAS on Renal Angiogram with 50-70% stenosis with resting mean pressure gradient >10mm HG. OR

B. Evidence of RAS on Renal Angiogram with 50-70% stenosis with Systolic Hyperemic pressure gradient >20mm HG. Hyperemia is induced with intra renal bolus of papaverine 30mg or Dopamine at 50 µg/kg. OR

C. Evidence of RAS on Renal Angiogram with 50-70% stenosis with Renal Fractional Flow Reserve ≤0.8. OR

D. Evidence of RAS on Renal Angiogram with ≥70% stenosis.

Recent studies have not shown improved outcomes with Renal Artery Intervention when routinely performed in patients with RAS, when compared with medical therapy. Renal Artery Intervention is reserved only in limited indications.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

Renal Artery Percutaneous Angioplasty (PTA) and/or Stent can be performed if:

A. Cardiac Disturbance Syndromes (Flash Pulmonary Edema or acute coronary syndrome) with severe hypertension with renal artery stenosis on renal angiogram. **(AUC Score 9)**[1,2,3]

B. CKD Stage 4 with bilateral moderate RAS with resting mean trans-lesion gradient of ≥10mm Hg with kidney size >7cm in pole-pole length. **(AUC Score 8)**[1,2,3]

C. CKD Stage 4 and global renal ischemia (unilateral severe RAS with solitary kidney or bilateral severe RAS) without other explanation. **(AUC Score 6)**[1,2,3]

D. History of uncontrolled arterial hypertension despite being on maximal (≥ 3) tolerated medical therapy including diuretic with evidence of bilateral or solitary severe renal artery stenosis on renal angiogram. **(AUC Score 6)**[1,2,3]

E. New azotemia or worsening renal function after administration of an ACE inhibitor or ARB with evidence of renal artery stenosis on renal angiogram. **(AUC Score 6)**[1,2,3]

F. Ostial atherosclerotic RAS on renal angiogram. **(AUC Score 8)**[1,2,3]

G. Patients with Fibro Muscular Dysplasia with uncontrolled Hypertension despite being on optimal blood pressure control regimen or develops intolerable side effects to increasing doses of antihypertensive medications and/or worsening of renal function/ size, should undergo PTA. **(AUC Score 8)**[1,2,3]

H. Renal Artery Stenting in Fibromuscular Dysplasia is indicated when the pressure gradient cannot be obliterated with angioplasty alone; and when a renal artery dissection arises spontaneously or is created iatrogenically during intervention. **(AUC Score 6)**[1,2,3]

Limitations:

A. Advanced disease - Creatinine level greater than 3-4 mg/dL; kidney length less than 8 cm

B. Limited life expectancy

C. Bleeding diathesis; recent myocardial infarction (MI)

D. Pregnancy

E. Guideline-directed medical therapy must be indicated as having been tried and failed prior to any intervention.

F. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist note that prompted request with list of medications
   2. Renal Artery Duplex/Retroperitoneal duplex/MRA Renal/CTA Renal reports
   3. Labs-Renal Function test

B. Primary codes appropriate for this service are: Renal Angioplasty- 37246, 37247, Renal Angioplasty with Stent 37236, 37237.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Michigan Local Coverage Determination (LCD) (L35998). Vascular Stenting of Renal Arteries. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
2. Klein AJ, et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. Catheterization and Cardiovascular Interventions. Oct 2017. Volume 90, Issue 4, Pages E90-E110.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Transcatheter Aortic Valve Replacement (TAVR)

POLICY NUMBER UM CARDIO_1295	SUBJECT Transcatheter Aortic Valve Replacement (TAVR)		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 05/24/16, 11/28/16, 10/10/17, 03/08/19, 04/25/19, 08/12/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 12/20/23, 01/10/24, 02/14/24	APPROVAL DATE February 14, 2024	EFFECTIVE DATE February 23, 2024	COMMITTEE APPROVAL DATES 05/24/16, 11/28/16, 10/10/17, 03/08/19, 04/25/19, 08/12/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 12/20/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Transcatheter Aortic Valve Replacement (TAVR).

II. DEFINITIONS

Abbreviations[2]

Aortic Stenosis (AS): disorder of the aortic valve resulting in abnormal narrowing of the orifice

Transcatheter Aortic Valve Replacement (TAVR): minimally invasive cardiovascular procedure to remove diseased aortic valve and replace with an artificial prosthesis

Surgical Aortic Valve Replacement (SAVR): open cardiovascular procedure to remove diseased aortic valve and replace with an artificial valve prosthesis

Left Ventricular Ejection Fraction (LVEF): percentage (fraction) of volume of blood in the left ventricle ejected from the left ventricle into the aorta in systole (ventricular contraction).

Aortic Regurgitation (AR): backward flow of blood from aorta to left ventricle

Stages of Aortic Stenosis[3]

D1: Symptomatic severe high gradient aortic stenosis

Anatomy: Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening.

Symptoms: Exertional dyspnea, decreased exercise tolerance or heart failure, exertional angina, exertional syncope or pre-syncope.

D2: Symptomatic severe low-flow, low-gradient aortic stenosis with reduced LVEF

Anatomy: Severe leaflet calcification/fibrosis with severely reduced leaflet motion

Symptoms: Heart failure, angina, syncope or pre-syncope

D3: Symptomatic severe low-gradient aortic stenosis with normal LVEF or paradoxical low-flow severe aortic stenosis

Anatomy: Severe leaflet calcification/fibrosis with severely reduced leaflet motion

Symptoms: Heart failure, angina, syncope or pre-syncope

Risk Assessment for Surgical Valve Procedures

Combines Society of Thoracic Surgeons (STS) Score, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments. Modified from Otto et al 2020[3] and STS ACSD Operative Risk Calculator

	Low Risk (Must Meet ALL Criteria in This	**Intermediate Risk (Any 1 Criterion in This Column)**	**High Risk (Any 1 Criterion in This Column)**	**Prohibitive Risk (Any 1 Criterion in This Column)**
STS PROM	<4% **AND**	4% to 8% **OR**	**>8% OR**	***Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y*** **OR**
Frailty	None **AND**	1 Index (mild) **OR**	≥2 Indices (moderate to severe) **OR**	
Major organ system compromise not to be improved postoperatively	None **AND**	1 Organ system **OR**	No more than 2 organ systems **OR**	≥3 Organ systems **OR**
Procedure-specific impediment	None	Possible procedure- specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

Appropriate Use Criteria[2]

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost – effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[4]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. TAVR is recommended in patients who meet an indication for aortic valve replacement (AVR) but have a prohibitive risk for conventional surgical AVR and have a predicted post-TAVR survival greater than 12 months[3]. **(AUC Score 9)**

B. TAVR can be performed as an alternative to surgical AVR in patients with symptomatic severe AS (Stage D1) with preserved LVEF and have high surgical risk. **(AUC Score 9)[2,3]**

C. TAVR is a reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D1) with preserved EF and intermediate surgical risk. **(AUC Score 8)[2,3]**

D. TAVR is a reasonable alternative to surgical AVR in patients with severe symptomatic low flow-low gradient AS (Stage D2), with flow reserve on dobutamine echo, LVEF 20-49% and have high or intermediate surgical AVR risk. **(AUC Score 8)[2,3]**

E. TAVR is a reasonable alternative to surgical AVR in patients with severe symptomatic low flow-low gradient (Stage D3), LVEF greater than or equal to 50% and have high or intermediate surgical AVR risk. **(AUC Score 8)[2,3]**

F. TAVR is preferred over surgical AVR in patients with severe symptomatic AS/AR with degenerative surgical bioprosthesis size greater than or equal to 23mm with high surgical AVR risk. **(AUC Score 8)[2]**

Limitations:

Following are the exclusion criteria for TAVR

A. Life expectancy less than 12 months due to non-cardiac co-morbid conditions.

B. Evidence of an acute myocardial infarction less than or equal to 1 month before the intended treatment or evidence of intracardiac mass, thrombus, or vegetation.

C. Congenital unicuspid or bicuspid non-calcified Aortic Valve.

D. Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation) and/or severe mitral insufficiency.

E. Native aortic annulus size less than 18mm or greater than 25mm as measured by echocardiogram.

F. Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyper acute bend), aortic arch atheroma (especially if thick [greater than 5 mm], protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe “unfolding” and tortuosity of the thoracic aorta (applicable for transfemoral patients only).

G. Bulky calcified aortic valve leaflets near coronary ostia. Any therapeutic invasive cardiac procedure performed within 30 days of the index procedure, (or 6 months if the procedure was a drug eluting coronary stent implantation).

H. Untreated clinically significant coronary artery disease requiring revascularization.

I. Hemodynamic instability requiring inotropic support or mechanical circulatory support.

J. Iliofemoral vessel with severe obstructive calcification, severe tortuosity or vessels size less than 7 mm in diameter (applicable for transfemoral approach only).

K. Active bacterial endocarditis or other active infections

L. Hypertrophic cardiomyopathy with or without obstruction (HOCM).

M. Severe ventricular dysfunction with LVEF less than 20%.

N. Blood dyscrasias as defined: leukopenia (WBC less than 3000 mm^3), acute anemia (Hb less than 9 mg %), thrombocytopenia, (platelet count less than 50,000 cells/mm^3), history of bleeding diathesis or coagulopathy.

O. Active peptic ulcer or upper GI bleeding within the prior 3 months.

P. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated.

Q. Patient has been offered surgery but has refused surgery.

R. Recent (within 6 months) cerebrovascular accident (CVA) or a transient ischemic attack (TIA).

S. Renal insufficiency (creatinine greater than 3.0) and/or end stage renal disease requiring chronic dialysis.

T. Need for emergency surgery for any reason

U. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Interventional Cardiologist and/or Cardiothoracic Surgeon progress note that prompted request
2. Most recent ECHO, TEE, Cardiac Cath, CT aorta reports

B. Primary codes appropriate for this service:

1. TAVR with percutaneous femoral approach-33361
2. TAVR with open femoral approach-33362
3. TAVR with open axillary artery approach-33363
4. TAVR with open iliac artery approach -33364
5. TAVR with trans-aortic approach-33365
6. TAVR with trans-apical approach-33366

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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Cardio Policy:

Transcatheter Edge to Edge Repair (TEER) of Mitral Valve

POLICY NUMBER UM CARDIO_1296	SUBJECT Transcatheter Edge to Edge Repair (TEER) of Mitral Valve		DEPT/PROGRAM UM Dept	PAGE 1 OF 7
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 03/08/23, 12/20/23, 01/10/24, 02/14/24	APPROVAL DATE February 14, 2024	EFFECTIVE DATE February 23, 2024	COMMITTEE APPROVAL DATES 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 03/08/23, 12/20/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Transcatheter Edge to Edge Repair (TEER or MITRACLIP) of Mitral Valve.

II. DEFINITIONS

Mitral regurgitation (MR) is the most common type of heart valve insufficiency in the United States. Patients with MR are at risk of poor quality of life, marked limitation in activity, repeated heart failure hospitalizations, and increased mortality. Mitral valve comprises of two valve leaflets and is attached to papillary muscles which prevents the leaflets from prolapsing back into the left atrium. MR is the backward flow of blood during left ventricular (LV) systole, which over time may lead to progressive symptoms and structural changes to the heart, including progressive ventricular dilation and worsening left ventricular function. Primary (degenerative) MR results from structural failure of the mitral valve; secondary (functional) MR results from left ventricular (LV) dysfunction with a largely preserved mitral valve. The underlying left ventricular dysfunction may be caused by coronary artery disease or numerous other causes.

In assessing patient with chronic severe symptomatic MR, it is critical to distinguish between chronic primary (degenerative) MR and chronic secondary (functional) MR, as these 2 conditions have more differences than similarities.[5] These patients are clinically categorized as Stage D Chronic Primary MR or Stage D Chronic Secondary MR.

Table 1: Stage D Chronic Primary MR and Stage D Chronic Secondary MR[5]

Stage D	Etiology	Symptoms	Valve Anatomy and associated Cardiac findings	Hemodynamics
Primary MR	Degenerative-Severe Prolapse/Flail leaflets/Rheumatic/Prior IE/Thickening of leaflets due to Radiation	-Decreased exercise tolerance -Exertional dyspnea	-Severe mitral valve prolapse with loss of coaptation or flail leaflet -Rheumatic valve changes with leaflet restriction and loss of central coaptation -Prior IE -Thickening of leaflets with radiation heart disease	-Central jet MR >40% LA or holosystolic eccentric jet MR -ERO ≥0.40 cm^2 -Vena contracta ≥0.7 cm -Regurgitant volume ≥60mL -Regurgitant fraction ≥50% -Angiographic grade 3-4+ -Pulmonary HTN -Mod or Severe LA enlargement
Secondary MR	-Ischemic Cardiomyopathy (MI), LVEF 20-50% -Non-Ischemic Cardiomyopathy, LVEF 20-50%	-HF symptoms due to MR even after revascularization and optimization of medical therapy -Decreased exercise tolerance -Exertional dyspnea	-Regional wall motion abnormalities and/or LV dilation with severe tethering of mitral leaflet -Annular dilation with severe loss of central coaptation of the mitral leaflets	-ERO ≥0.40cm^2 -Regurgitant volume ≥60mL -Regurgitant fraction ≥50%

The need for treatment usually depends on the condition and function of the heart. The standard treatment for individuals with severe and symptomatic MR has been surgical treatment - repair or replacement of the mitral valve based on well-defined treatment guidelines. However, patients with severe Primary MR due to leaflet etiology, advanced age, LV dysfunction (EF less than 30%) and comorbidities were deemed as prohibitive risk surgical candidates (STS risk score of surgical mortality greater than 50% at one year) and therefore conventional open mitral valve repair or replacement was often not presented as an option for these individuals.[8] TEER which is a percutaneous mitral leaflet clipping procedure has shown improved outcomes in this patient population. TEER involves clipping together a portion of the mitral valve leaflets as a treatment for reducing severe Primary MR with the intended outcomes to improve recovery of the heart from overwork, improve function and potentially halt the progression of heart failure. The procedure is performed under general anesthesia via echocardiographic and fluoroscopic guidance.

Society of Thoracic Surgeons (STS) Score: This score is used to calculate a patient's risk of mortality and other morbidities, such as long length of stay, risk of stroke, risk of prolonged ventilation, infection, and renal failure etc. The STS score risk calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments[5]

	Low Risk (Must Meet ALL Criteria in This Column)	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)
STS PROM*	<3% AND	4% to 8% OR	>8% OR	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y OR
Frailty†	None AND	1 Index (mild) OR	≥2 Indices (moderate to severe) OR	
Major organ system compromise not to be improved postoperatively	None AND	1 Organ system OR	1 to 2 organ systems OR	≥3 Organ systems OR
Procedure-specific impediment§	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use of the STS PROM (Predictive Risk of Mortality) is to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within 1 standard deviation of STS average observed/expected ratio for the procedure in question.[5]

†Seven frailty indices: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) and independence in ambulation (no walking aid or

assist required or 5 meter walk in less than 6 s). Other scoring systems can be applied to calculate no, mild-, or moderate-to-severe frailty.[5]

‡Examples of major organ system compromise: Cardiac-severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 less than 50% or DLCO2 less than 50% of predicted; CNS dysfunction (dementia, Alzheimer's disease, Parkinson's disease, CVA with persistent physical limitation); GI dysfunction-Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin less than 3.0; cancer-active malignancy; and liver-any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.[5]

§Examples: tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage.[5]

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[9, 10]

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[2, 3, 5, 6, 7, 8]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving for medical necessity are as follows:

A. TEER may be considered for severely symptomatic patients (NYHA Class III to IV) with chronic severe primary or degenerative MR (Stage D) who have favorable anatomy for the procedure with a reasonable life expectancy (greater than1 year) on optimal Guideline Directed Medical Therapy for Heart Failure and have a high STS score or prohibitive surgical risk of death or major morbidity greater than 50% at one year. [1, 2, 4, 5, 6, 7, 8] **(AUC Score 6)**

B. TEER may be considered for severely symptomatic patients (NYHA Class III to IV) with chronic moderately severe or severe secondary or functional MR (Stage D) who have favorable anatomy for the procedure with a reasonable life expectancy (greater than1 year) on optimal Guideline Directed Medical Therapy for Heart Failure and have an STS high or prohibited surgical risk of death or major morbidity greater than 8% or greater than 50% respectively, at one year or Frailty

index of greater than or equal to 2 or a possibility of no more than 2 major organ systems compromise not to be improved. [1, 2, 3, 4, 5, 6, 7, 8] **(AUC Score 5)**

Limitations:

Following are the exclusion criteria for TEER:

A. Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen

B. Life expectancy less than 12 months[6]

C. Active endocarditis of the mitral valve[2]

D. Rheumatic mitral valve disease with mitral stenosis (mean mitral gradient greater than 5 mm Hg or MV area less than 4.0 cm^2)[2]

E. Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

F. Leaflet pathology involves commissural segments, perforation, or clefts[2]

G. Severe leaflet/annular calcification in grasping area[2]

H. Grasping zone length less than 7mm[2]

I. Presence of coexisting aortic or tricuspid valve disease requiring surgery or transcatheter intervention; or COPD requiring continuous home oxygen therapy or chronic outpatient oral steroid use; or[1]

   1. ACC/AHA stage D heart failure; or[1]
   2. Estimated pulmonary artery systolic pressure (PASP) greater than 70 mmHg as assessed by echocardiography or right heart catheterization, unless active vasodilator therapy in the catheterization laboratory is able to reduce the pulmonary vascular resistance (PVR) to less than 3 Wood Units or between 3 and 4.5 Wood Units with a v wave less than twice the mean of the pulmonary capillary wedge pressure (PCWP); or[1]
   3. Hemodynamic instability requiring inotropic support or mechanical heart assistance; or[1]
   4. Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction; or[1]
   5. Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months[1]

J. In addition to the above A-I limitations, use of TEER (MitraClip Device) is not recommended for Primary (degenerative) MR if:

   1. Flail width greater than 15 mm and flail gap greater than 10 mm[2]
   2. Multi-segment pathology; highly mobile flail leaflet with multiple ruptured chords[2]
   3. LV End Systolic Dimension greater than 55 mm[2]

K. In addition to the above A-I limitations, the use of TEER (MitraClip Device) is not recommended for Secondary (Functional) MR if:

   1. LV End Systolic Dimension greater than 70mm[2]

L. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

M. Prior to performing TEER in a patient with chronic severe MR the following must be considered:

Predicted or observed lack of response to maximally tolerated to GDMT[2,3,6,7,8]

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
    1. Cardiologist/Interventional Cardiologist and Cardiothoracic surgeon progress notes that prompted request that would support that patient is not a candidate for mitral valve surgery
    2. Most recent ECHO, TEE, Cardiac Cath report
    3. STS surgical risk score report

B. Primary codes appropriate for this service: 33418, 33419 (additional prosthesis during same session)

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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2. Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2020 May 5;75(17):2236-2270. doi: 10.1016/j.jacc.2020.02.005.
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5. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP 3rd, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021 Feb 2;143(5):e72-e227. doi: 10.1161/CIR.0000000000000923 .
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Percutaneous Cardiovascular Interventions (EAPCI) of the ESC. Eur Heart J. 2021 Mar 31;42(13):1254-1269. doi: 10.1093/eurheartj/ehab086.

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10. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy
Peripheral Intravascular Arterial and Venous Ultrasound

POLICY NUMBER UM CARDIO_1318	**SUBJECT** Peripheral Intravascular Arterial and Venous Ultrasound	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 10/10/18, 03/13/19, 12/11/19, 06/10/20, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 10/10/18, 03/13/19, 12/11/19, 06/10/20, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 06/12/2024
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request
    - Prior diagnostic peripheral angiogram/venogram
    - Non-invasive vascular/venous testing

II. Purpose

Indications for determining medical necessity for peripheral (non-coronary) intravascular arterial and venous ultrasound (IVUS).

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

Intravascular ultrasound is primarily indicated in the lower extremities. However, approval and AUC Scores vary depending on the vessel being investigated.

- **Iliac Artery**
    - Preintervention Scenarios
        - Occlusion **(AUC Score 6) [6]**
        - Plaque morphology **(AUC Score 6) [6]**
        - Ambiguous lesion/severity **(AUC Score 7) [6]**
        - Filling defects **(AUC Score 6) [6]**
        - Vessel sizing **(AUC Score 7) [6]**
        - Minimizing contrast **(AUC Score 8) [6]**

- Intraprocedural Scenarios
    - Location of crossing track **(AUC Score 9) [6]**
    - Determination of next therapeutic step **(AUC Score 8) [6]**
    - Vessel sizing for device **(AUC Score 6) [6]**
- Postintervention optimization scenarios
    - Residual stenosis/plaque after debulking **(AUC Score 7) [6]**
    - Stent optimization/postdilation **(AUC Score 6) [6]**
    - Dissection detection **(AUC Score 8) [6]**

- **Femoropopliteal Artery**
    - Preintervention Scenarios
        - Occlusion **(AUC Score 6) [6]**
        - Plaque morphology **(AUC Score 6) [6]**
        - Ambiguous lesion/severity **(AUC Score 8) [6]**
        - Filling defects **(AUC Score 8) [6]**
        - Vessel sizing **(AUC Score 8) [6]**
        - Minimizing contrast **(AUC Score 8) [6]**
    - Intraprocedural Scenarios
        - Location of crossing track **(AUC Score 8) [6]**
        - Determination of next therapeutic step **(AUC Score 9) [6]**
        - Vessel sizing for device **(AUC Score 7) [6]**
    - Postintervention optimization scenarios
        - Residual stenosis/plaque after debulking **(AUC Score 7) [6]**
        - Stent optimization/postdilation **(AUC Score 7) [6]**
        - Dissection detection **(AUC Score 8) [6]**

- **Tibial Artery**
    - Preintervention Scenarios
        - Occlusion **(AUC Score 8) [6]**
        - Plaque morphology **(AUC Score 8) [6]**
        - Ambiguous lesion/severity **(AUC Score 7) [6]**
        - Filling defects **(AUC Score 8) [6]**
        - Vessel sizing **(AUC Score 8) [6]**
        - Minimizing contrast **(AUC Score 9) [6]**
    - Intraprocedural Scenarios **(AUC Score 8) [6]**

        - Location of crossing track
        - Determination of next therapeutic step
        - Vessel sizing for device
    - Postintervention optimization scenarios
        - Residual stenosis/plaque after debulking **(AUC Score 7) [6]**
        - Stent optimization/postdilation **(AUC Score 8) [6]**
        - Dissection detection **(AUC Score 8) [6]**

- **Iliofemoral Vein**
    - Preintervention Scenarios
        - Lesion characteristics **(AUC Score 8) [6]**
        - Lesion severity **(AUC Score 9) [6]**
        - Filling defects **(AUC Score 9) [6]**
        - Vessel sizing **(AUC Score 9) [6]**
        - Minimizing contrast **(AUC Score 9) [6]**
    - Intraprocedural Scenarios **(AUC Score 9) [6]**
        - Determination of next therapeutic step
        - Vessel sizing for device
    - Postintervention optimization scenarios **(AUC Score 9) [6]**
        - Stent optimization/postdilation

- **Other Indications**
    - Guiding of endovascular procedures for iliac vein outflow obstruction [7]
    - Assessment or guiding of treatment for aortic dissections or aneurysms [8]
    - Assessment of renal infarct etiology to evaluate secondary treatment options [8]
    - IVUS may be reasonable during peripheral arterial interventional procedures for complicated ilio-femoro-popliteal arterial lesions-TASC II class, longer lesion length, and narrower reference diameter, to aid in decision of treatment strategy including size and length of stent. [9]

- **Limitations**
    - Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
    - IVUS is not appropriate for routine evaluation of peripheral artery disease when revascularization is not being contemplated based on angiographic results.

V. Background

A. Definitions

Intravascular ultrasound (IVUS) is an invasive imaging modality that uses a specially designed catheter with a miniaturized ultrasound probe attached to the distal end of the catheter, which allows ultrasound imaging to be performed from within the lumen of the blood vessel. IVUS can be used to assess vessel/lumen diameter, lesion length, help determine the amount of plaque buildup in a vessel and its composition and check to ensure stents have been properly placed and fully deployed.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AUC	Appropriate use criteria
IVUS	Intravascular ultrasound

VI. Coding and Standards

- **Primary Codes**
  - 37252, 37253
- **Related Codes**
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

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Cardio Policy
Venogram Invasive Vein Mapping

POLICY NUMBER UM CARDIO_1319	SUBJECT Venogram/Invasive Vein Mapping		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 10/10/18, 03/13/19, 12/11/19, 06/10/20, 07/13/20, 06/09/21, 11/09/21, 03/09/22, 01/11/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 10/10/18, 03/13/19, 12/11/19, 06/10/20, 07/13/20, 06/09/21, 11/09/21, 03/09/22, 01/11/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress notes from the nephrologist or vascular surgeon that prompted the request (including pertinent labs)
    - All non-invasive Vascular Studies performed applicable to the request

II. Purpose

Indications for determining medical necessity for Venogram/Invasive Vein mapping.

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications [6]

- Diagnosis of deep vein thrombosis, under the following conditions:
    - Duplex ultrasound is limited or negative, but there is a high clinical suspicion for DVT or calf-vein thrombosis
    - The patient is not a candidate for CT or MR venogram, or the CT or MR venogram is limited
    - In the setting of symptomatic extremity after joint replacement
- Venous mapping before a surgical or interventional procedure
- Evaluation of venous conditions, including:
    - Perforator incompetency before sclerotherapy, thermal ablation, or subfascial endoscopic ligation
    - Venous stenosis, hypertension, or malformations

- Anatomic entrapment
- Deep pelvic, thoracic, or caval thrombosis in patients who are not candidates for CT or MR venogram, or when CT or MR venogram is limited

- Preoperative evaluation for tumor involvement, when CT or MR venogram is either limited or infeasible
- Evaluation for central venous catheter (CVC) placement, when anatomic landmarks, duplex ultrasound, CT venography, or MR venography are not feasible
  - May also be reasonable to assess the patency of a CVC when malfunctioning is suspected

Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Definitions

Conventional venography is an invasive procedure that uses X-rays and a contrast dye to create images of vein(s) for anatomic localization and hemodynamic quantification when non-invasive study like venous duplex is limited.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AV	Arteriovenous
AICD	Automated implantable cardioverter defibrillator
AUC	Appropriate use criteria
CRT-D	Cardiac resynchronization therapy defibrillator
CVC	Central venous catheter
OOS	Out of scope
PPM	Permanent pacemaker

VI.Coding and Standards

- **Primary Codes**
  - 36005 – Injection procedure for extremity venography (including introduction of needle or intra catheter)
  - 36010 – Introduction of catheter, superior or inferior vena cava

- 36011 – Selective catheter placement, venous system; first order branch (e.g., renal vein, jugular vein)
- 36012 - Selective catheter placement, venous system; second order branch (e.g., left adrenal vein, petrosal sinus)
- 75820 – Venography, extremity, unilateral, radiological supervision, and interpretation
- 75822 – Venography, extremity, bilateral, radiological supervision and interpretation
- 75825 – Venography, caval, inferior, with serialography, radiological supervision and interpretation
- 75827 – Venography, caval, superior, with serialography, radiological supervision and interpretation

- **Related Codes**
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

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Cardio Policy:

Percutaneous Left Atrial Appendage Closure

POLICY NUMBER UM CARDIO_1320	SUBJECT Percutaneous Left Atrial Appendage Closure		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 07/26/17, 10/11/17, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 12/20/23, 01/10/24, 02/14/24	APPROVAL DATE February 14, 2024	EFFECTIVE DATE February 23, 2024	COMMITTEE APPROVAL DATES 07/26/17, 10/11/17, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 12/20/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Percutaneous Left Atrial Appendage Closure.

II. DEFINITIONS

Patients with atrial fibrillation (AF), an irregular heartbeat, are at an increased risk of stroke. The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has been shown to be one potential source for blood clots that can cause strokes. While thinning the blood with anticoagulant medications has been proven to prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with AF.

The $CHADS_2$ score ≥ 2 (Congestive heart failure, hypertension, age > 75, diabetes, stroke/transient ischemia attack/thromboembolism) or CHA_2DS_2-VAS_C score ≥ 3 (Congestive heart failure, hypertension, age ≥ 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category) is widely used for evaluating thromboembolic risk in those with nonvalvular AF.[4,5]

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve

patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[6, 7]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity:

A. Patients with non-valvular Atrial Fibrillation with CHADS2 score ≥ 2 (Congestive heart failure, hypertension, age > 75, diabetes, stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASC score ≥ 3 (Congestive heart failure, hypertension, age ≥ 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category) or high HAS-BLED score (Hypertension, abnormal renal function, and/or liver function, stroke, prior bleeding, labile anticoagulation range, elderly age > 65, drug therapy such as antiplatelet drugs) and is deemed unable to tolerate long term anticoagulation.[1,4,5,7,8] **(AUC Score 5)**

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review

   1. Progress note that prompted request from Electrophysiologist/Interventional Cardiologist/Cardiologist

B. Primary code appropriate for this service: 33340

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare & Medicaid Services. 2016 October. [Online]. *Percutaneous Left Atrial Appendage Closure (LAAC), National Coverage Determination (NCD) (20.34).* Available: NCD - Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) (cms.gov). [Accessed November 2023].
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7. New Century Health Cardiology Policy: Appropriate Use Criteria Mapping and Rating Policy for Cardiovascular Services. August 2015.

Cardio Policy

Temporal Artery Biopsy

POLICY NUMBER UM CARDIO_1321	**SUBJECT** Temporal Artery Biopsy		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 07/26/17, 10/11/17, 08/08/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 05/08/24	**APPROVAL DATE** May 08, 2024	**EFFECTIVE DATE** May 31, 2024	**COMMITTEE APPROVAL DATES** 07/26/17, 10/11/17, 08/08/18, 03/13/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note that prompted request from Vascular Surgeon

II. Purpose

Indications for determining medical necessity for a temporal artery biopsy, which is primarily used to diagnose Giant Cell Arteritis and Temporal Arteritis.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Temporal Artery Biopsy

*Particularly when occurring in conjunction with patient age > 50 years and/or elevated CRP (≥ 10mg/liter) [6, 7]

- Vision problems including [6, 7, 8]:
    - Anterior ischemic optic neuropathy
    - Cotton wool spots
    - Cilio-retinal or central retinal artery occlusion
    - Cranial nerve palsy
    - Double vision
    - Sudden vision loss

- Jaw claudication [7, 6]
- Pulseless temporal artery [7]
- Temporal tenderness [7, 6]
- New onset, localized headache, particularly if presenting with [6, 8]
    - Night sweats
    - Weight loss
    - Malaise
    - Depression
- Elevated ESR (maximum ≥ 50 mm/hr) [7, 8]

Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Definitions

Temporal arteritis (TA) is an inflammatory vasculopathy affecting medium- and large-sized arteries, also referred to as giant cell arteritis leading to granulomatous pan arteritis with mononuclear cell infiltrates and giant cell formation within the vessel wall. It predominantly affects the cranial branches of arteries arising from the arch of the aorta, mainly the superficial temporal branch of the carotid artery. Mean onset for TA is at age 70 years.

Temporal Artery biopsy is a surgical procedure performed under local anesthesia where at least 1 cm of temporal artery on the symptomatic side is biopsied and looked under microscope for evidence of multinucleated giant cells. Biopsy of bilateral temporal arteries are usually not required. Temporal artery biopsy has a very low complication rate. Most commonly encountered complications are scarring, hematoma, wound infection, and skin necrosis.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. [1]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

VI. Coding and Standards

- **Primary Codes**
  - 37609
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

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[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

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Cardio Policy:

Automated Ambulatory Blood Pressure Monitoring

POLICY NUMBER UM CARDIO_1336	SUBJECT Automated Ambulatory Blood Pressure Monitoring		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 11/12/14, 08/12/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 11/09/21, 01/12/22, 11/17/22, 10/18/23, 12/20/23, 01/10/24	APPROVAL DATE January 10, 2024	EFFECTIVE DATE January 26, 2024	COMMITTEE APPROVAL DATES 11/12/14, 08/12/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 12/11/19, 02/12/20, 01/13/21, 11/09/21, 01/12/22, 11/17/22, 10/18/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Automated Ambulatory Blood Pressure Monitoring.

II. DEFINITIONS

Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Patients with suspected white coat hypertension, which is defined as an average office blood pressure of systolic blood pressure greater than 130 mm Hg but less than 160 mm Hg or diastolic blood pressure greater than 80 mm Hg but less than 100 mm Hg on two separate clinic/office visits with at least two separate measurements made at each visit and with at least two blood pressure measurements taken outside the office which are less than 130/80 mm Hg. **(AUC Score 8)**[1,2,3]

B. Patients with suspected masked hypertension, which is defined as average office blood pressure between 120 mm Hg and 129 mm Hg for systolic blood pressure or between 75 mm Hg and 79 mm Hg for diastolic blood pressure on two separate clinic/office visits with at least two separate measurements made at each visit and with at least two blood pressure measurements taken outside the office which are greater than or equal to 130/80 mm Hg. **(AUC Score 8)**[1,2,3]

C. Ambulatory BP monitoring can be performed if any of the below conditions are met **(AUC Score 8)**[2,3]

   1. Treatment plan indicates patient to self-monitor and record blood pressure readings at least once a day and,
   2. History of heart disease, renal disease and neurological condition that would require periodic BP monitoring, or,
   3. Patient on treatment including medications that affects blood pressure, or,
   4. Medications adjustments are based on daily blood pressure readings, or,
   5. Hypertensive disorders of pregnancy, childbirth, or the puerperium period.
   6. Hypertension, despite compliance with the treatment plan including adherence to lifestyle, smoking cessation, and diet.

Requesting Physician or clinical staff must educate the patient on self- measurement and recording of blood pressure, have fit the patient with appropriate cuff size.

Limitations:

A. The ABPM is not recommended to diagnose hypertension and assess cardiovascular disease risk.

B. ABPM is covered once per year by Medicare.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

   1. Progress note that prompted request
   2. Most recent EKG
   3. At least 2 recordings of BP on separate office visits

B. Primary codes appropriate for this service: 93784- Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report. 93786-Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only. 93788- Ambulatory blood pressure monitoring, utilizing report-generating

software, automated, worn continuously for 24 hours or longer; scanning analysis with report. 93790- Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) (20.19). Ambulatory Blood Pressure Monitoring. Retrieved from https://www.cms.gov [December 19, 2023].
2. ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2018;71:e127-e248.
3. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
4. NCQA UM 2023 Standards and Elements.

Cardio Policy

Abdominal Aorta and Iliac Aneurysm Open Repair

POLICY NUMBER UM CARDIO_1337	SUBJECT Abdominal Aortic and Iliac Artery Aneurysm Open Repair		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 01/19/14, 08/12/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/08/21, 09/14/22, 09/13/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 01/19/14, 08/12/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/08/21, 09/14/22, 09/13/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*

II. Purpose

Indications for determining medical necessity for open surgical repair of an abdominal aortic or iliac artery aneurysm.

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

- **Ruptured Aneurysm**
  - Repair is indicated in patients presenting with a ruptured aneurysm(s). [6, 7, 8]
- **Unruptured Aneurysm**
  - In patients with unruptured, **symptomatic** aneurysms, repair is indicated, even for small aneurysms. [6, 7, 8] Symptoms include abdominal and/or back pain and embolic events that do not breach the aortic wall. [8]
  - In patients with unruptured, **asymptomatic** aneurysms, repair is indicated when the artery enlarges to a maximal diameter threshold, which varies by location:
    - For abdominal aortic aneurysms (AAA), repair is indicated when maximal aneurysm diameter is ≥5.5 cm in men or ≥5.0 cm in women. [7, 8] **However:**
      - For patients with high or moderate-high perioperative risk, open surgical repair should only be considered if there is no endovascular alternative. [7] For patients with low-moderate perioperative risk, both open surgical and endovascular repair are indicated.
    - For iliac artery aneurysms, repair is indicated when the maximal diameter is ≥3.5 cm. [7] Both open surgical and endovascular repair are indicated.
  - In patients with unruptured AAA and aneurysm growth rate of ≥0.5 cm in 6 months, open surgical repair to reduce the risk of rupture may be reasonable. [7]

- Open surgical repair of AAA is preferred over endovascular procedures in patients with long life expectancies (>10-15 years) [8]
- In patients with the clinical triad of abdominal and/or back pain, a pulsatile abdominal mass, and hypotension, immediate surgical evaluation is indicated. [8]

- **Limitations**
  - Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.
  - Both open surgical and endovascular repair procedures require advanced skill sets. If these are not available, the provider should consider transferring the member/patient to a facility that can perform the appropriate procedure.
  - Elective repair of AAA, by either open surgical or endovascular techniques, is not recommended in patients with a limited life expectancy (<2-3 years) [8]

V. Background

A. Definitions

Open surgical AAA repair involves the placement of a graft within the affected blood vessel by dissecting the abdomen and accessing the aorta/aneurysm directly. Features associated with an increased risk of rupture include: rapid aneurysm growth (≥0.5 cm/year), symptomatic aneurysm(s), a significant change in aneurysm appearance, saccular aneurysms or presence of penetrating atherosclerotic ulcers. [7]

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AAA	Abdominal aortic aneurysm
AUC	Appropriate use criteria
CT	Computed tomography
OOS	Out of scope
TAAA	Thoracoabdominal aortic aneurysm

VI. Coding and Standards

- **Primary Codes**
  - Direct repair of aneurysm, pseudoaneurysm, or excision of aorta: 35081
    - with rupture: 35082
  - Aorta and visceral vessels: 35091
    - with rupture: 35092
  - Abdominal aorta and involving iliac vessels: 35102
    - with rupture: 35103

    - Iliac vessels only: 35131
        - with rupture: 35132

- **Related Codes**
- **Review**
    - Utilization Management Department
- **Final Approval**
    - Utilization Management Committee

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] E. L. Chaikof, R. L. Dalman, M. K. Eskandari, B. M. Jackson, W. Anthony Lee, M. Ashraf Mansour, T. M. Mastracci, M. Mell, M. Hassan Murad, L. L. Nguyen, G. S. Oderich, M. S. Patel, M. L. Schermerhorn and B. W. Starnes, "The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm," *J Vasc Surg,* vol. 67, no. 1, pp. 2-77, 2018.

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[8] A. Wanhainen, I. Van Herzeele, F. B. Gonclaves, S. B. Montoya, X. Berard, J. R. Boyle, M. D'Oria, C. F. Prendes, C. D. Karkos, A. Kazimierczak, M. J. Koelemay, T. Kolbel, K. Mani, G. Melissano, J. T. Powell, S. Trimarchi and N. Tsilimparis, "European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms," *Eur J Vasc Endovasc Surg,* vol. 67, no. 2, pp. 192-331, 2024.

Cardio Policy

Hemodialysis Access Maintenance

POLICY NUMBER UM CARDIO_1339	SUBJECT Hemodialysis Access Maintenance		DEPT/PROGRAM UM Dept	PAGE 1 OF 7
DATES COMMITTEE REVIEWED 06/30/14, 07/29/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24	APPROVAL DATE June 12, 2024	EFFECTIVE DATE June 28, 2024	COMMITTEE APPROVAL DATES 06/30/14, 07/29/14, 02/19/15, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 12/11/19, 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Progress note from the vascular surgeon that prompted the request
    - All non-invasive and invasive vascular studies for fistula

II. Purpose

Indications for determining medical necessity for hemodialysis access maintenance.

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

- AV access physical examination characteristics [6]
    - Infection at the AV access site
    - Distal steal syndrome
        - Ipsilateral signs of ischemia
    - Aneurysm or pseudoaneurysm, as evidenced from abnormal areas of dilation with overlying skin thinning
    - Ipsilateral extremity edema
    - Alterations in the pulse
    - Abnormal thrill with only a systolic component in the region of stenosis
    - Abnormal bruit (high pitched with a systolic component in the area of stenosis)
    - Failure of the fistula to collapse when the arm is elevated and lack of pulse augmentation

- Excessive collapse of the venous segment upon arm elevation

- Complications related to dialysis [6]
  - New difficulty with cannulation
  - Aspiration of clots
  - Inability to achieve the target dialysis blood flow
  - Prolonged bleeding beyond usual for a particular patient from the needle puncture site for 3 consecutive dialysis sessions
  - Unexplained (>0.2 units) decrease in the delivered dialysis dose on a constant dialysis prescription without prolongation of dialysis duration

- Other changes in surveillance measurements that may indicate stenosis within the AV access, (i.e., prior to the development of thrombosis) [6]
  - Reduced dialysis clearance without other known cause
  - Elevated venous and arterial pressures at the prescribed blood flow.

- AV fistula or grafts that have failed to mature after 4 to 6 weeks need to be further evaluated, preferably by the surgeon/operator who created the AV access, and treated, as necessary. [6, 7]

- For patients undergoing hemodialysis via a central venous catheter (CVC), maintenance may be indicated if the patient develops signs or symptoms of a central venous stenosis, including, but not limited to: [6]
  - Early signs
    - Asymmetric swelling
    - Pain in the extremity, such as aching and heaviness, when other symptoms have been excluded
    - Cutaneous changes, such as venous collaterals or skin discoloration
  - Late signs and symptoms
    - Swelling that has become more widespread, potentially affecting the arms, head, neck, and trunk (including the breasts).
    - Persistent pain that spreads to the chest or extended extremity heaviness
    - Advanced changes in cutaneous health, including the development of lymphatic blistering or weeping, stasis ulcers, phlebitis, infection, or non-healing wounds
  - Respiratory compromise, such as hoarse voice or respiratory distress
  - Neurological symptoms, such as visual or auditory disturbances, exophthalmos, cognitive disabilities, headaches, or seizures when all other causes have been excluded

- When clinically significant AV access lesion is suspected, confirmatory evaluation, including imaging of the dialysis access circuit, is reasonable. If imaging studies reveal a culprit lesion, prompt treatment is warranted. [6]
- **Endovascular repair is preferred as the initial treatment for hemodialysis access repair/maintenance of stenoses and/or thromboses:** [6, 7]
  - Balloon angioplasty is an acceptable primary treatment of AVF and AVG stenotic lesions

[6]

- When the overall goal is 6-month postintervention outcomes, self-expanding stent-grafts are preferred over angioplasty alone when treating graft-vein stenosis in AVG [6]
- When the overall goal is 6-month postintervention outcomes, stent-grafts are preferred over angioplasty alone when treating in-stent restenosis in AVF and AVG [6]

- **Open surgical repair of hemodialysis access stenoses or thromboses may be appropriate in the following scenarios:** [6, 7]
  - When endovascular treatment fails [6]
  - For lesions that are not amenable to endovascular repair [6]
  - Select lesions in which the open surgical approach is deemed more durable [6]

Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Definitions

Arteriovenous (AV) dialysis graft/fistula interventions are intended to restore and/or maintain functional patency of the AV dialysis access. These procedures encompass a number of percutaneous or open surgical procedures. Percutaneous AV dialysis access de-clotting, maintenance, or re-establishment of appropriate and adequate flow may encompass any of the procedures listed below. These need not all be performed on every dysfunctional access, but each may, under unique circumstances, be considered reasonable and medically necessary. Fistulae which are not maturing as expected need to be evaluated with duplex before it can be treated with percutaneous interventions.

Percutaneous interventions to enhance or re-establish patency of a hemodialysis AV access have proven useful in extending the life of the access, reducing the need for open repair, reconstruction, or replacement. An invasive procedure which, when successful, enlarges a narrowed vascular lumen.
Typically, a balloon-tipped catheter is introduced percutaneously into the narrowed vessel. The balloon is inflated at the site of vascular stenosis, stretching the vessel, and opening the lumen to restore adequate flow through the vessel. The balloon is removed after angioplasty.

- **Hemodialysis access maintenance** may include de-clotting or re-establishment of appropriate and adequate flow via mechanical and/or pharmacologic maneuvers to promote dissolution, fragmentation and/or removal of obstructing thrombotic materials from the AV dialysis access.
- **Open Dialysis Access Revision:** Surgical therapy for thrombosis or impaired AV dialysis access utilizes direct open access to the conduit and contiguous vessels. Residual vascular stenosis or obstructive lesions are removed and corrected using standard vascular surgical techniques. Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field.
- **Percutaneous Venous Transluminal Angioplasty:** AV shunt is artificially divided into two vessel segments- first segment is peripheral and extends from the peri-arterial anastomosis through the

axillary vein (or entire cephalic vein in the case of cephalic venous outflow). The

second segment includes the veins central to the axillary and cephalic veins, including the subclavian and innominate veins through the vena cava. Interventions performed in a single segment, regardless of the number of lesions treated, are considered as a single intervention.

- **Percutaneous Arterial Transluminal Angioplasty:** This is performed when there is a stenosis at the arterial anastomosis, extending across the anastomosis and involves the artery just proximal to and at the anastomosis as well as the outflow vessel or graft (also called as peri- anastomotic or juxta-anastomotic region).
- **Diagnostic Fistulogram:** A diagnostic angiography of the entire AV dialysis access circuit from the arterial anastomosis through the central vena cava is performed to identify the area or areas of narrowing or occlusion that are creating flow problems for the AV dialysis access. It is performed through an existing needle or sheath or via an injection of a vessel other than direct puncture of the AV dialysis access.
- **Stents:** They are used to salvage a graft or fistula after all other conservative measures to re-establish patency have failed.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AUC	Appropriate use criteria
AV	Arteriovenous
AVF	Arteriovenous fistula
AVG	Arteriovenous graft
OOS	Out of scope

VI. Coding and Standards

- **Primary codes**
  - Percutaneous Therapies of AV Fistula
    - AV Fistulogram - 36901
    - AV Fistulogram with PTA of Peripheral Dialysis segment - 36902
    - AV Fistulogram with PTA with Stent of Peripheral Dialysis segment - 36903
  - Mechanical Thrombectomy of AV Fistula - 36904
  - Mechanical Thrombectomy and PTA of Peripheral Segment of AV Fistula - 36905
  - Mechanical Thrombectomy and PTA with Stent of Peripheral Segment of AV Fistula - 36906

- PTA of Central Dialysis segment – 36907
- PTA with Stent of Central Dialysis segment – 36908
- Embolization or Occlusion of main or accessory veins of Dialysis circuit - 36909
- Surgical therapy for thrombosis or impaired AV dialysis access - 36831, 36832, 36833
- Ligation or banding of angio access arteriovenous fistula - 37607

- **Related codes**
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Department

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

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[7] American College of Radiology, "ACR–SIR PRACTICE PARAMETER FOR ENDOVASCULAR MANAGEMENT OF THE THROMBOSED OR DYSFUNCTIONAL DIALYSIS ACCESS," pp. 1-14, 2022.

Cardio Policy
Intra Cardiac Echocardiography (ICE)

POLICY NUMBER UM CARDIO_1358	**SUBJECT** Intra Cardiac Echocardiography (ICE)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 06/12/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 06/12/19, 12/11/19, 06/10/20, 06/14/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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I. General information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- In order to review a request for medical necessity, the following items must be submitted for review:
    - Cardiologist or Electrophysiologist note that prompted request

II. Purpose

Indications for determining medical necessity for Intracardiac Echocardiography (ICE).

III. Clinical Reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications

Intracardiac echocardiography (ICE) is indicated for:

- ICE is the preferred imaging modality during percutaneous closure of patent foramen ovale (PFO) or atrial septal defect (ASD) **(AUC Score 8) [6]**
- Intraprocedural guidance for a left atrial appendage occlusion device **(AUC Score 6) [6]**
- Preprocedural screening before intracardiac percutaneous interventions to detect emboli that may become dislodged during the procedure [7]
- As an alternative imaging module when TEE is infeasible [8, 9] or conscious sedation is desired [9]

Other medically appropriate applications of ICE may also include:

- Transseptal puncture and catheterization [7, 8, 9]
- Endomyocardial biopsy [7, 8, 9]
- Mitral and aortic valvuloplasty [7, 8, 9]
- Ablation of atrial [7] or ventricular [8] arrhythmias

- For positioning of left atrial appendage occlusive devices [7, 8, 9]

Limitations

- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Definitions

Intracardiac echocardiography (ICE) is a unique imaging modality able to provide high-resolution real time visualization of cardiac structures, continuous monitoring of catheter location within the heart, and early recognition of procedural complications, such as pericardial effusion or thrombus formation.

B. AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

ASD	Atrial septal defect
AUC	Appropriate use criteria
ICE	Intra cardiac echocardiography
OOS	Out of scope
PFD	Patent foramen ovale

VI.Coding and Standards

- **Primary Codes**
  - 93662
- **Related Codes**
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

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Cardio Policy:

Percutaneous Iliocaval Interventions

POLICY NUMBER UM CARDIO_1368	**SUBJECT** Percutaneous Iliocaval Interventions		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 09/11/19, 12/11/19, 08/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/11/19, 12/11/19, 08/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Percutaneous Iliocaval Intervention.

II. DEFINITIONS

Chronic venous insufficiency (CVI) as an advanced stage of chronic venous disease is a common problem that occurs in approximately 1–5% of the adult population. CVI has either a non-thrombotic (primary) or post thrombotic (secondary) cause involving reflux, obstruction, or a combination of both. The role of venous obstruction is increasingly recognized as a major cause of CVI, with obstructive lesions in the iliocaval segment being markedly more relevant than lesions at the levels of the crural and femoral veins.

Approximately 70–80% of iliac veins develop a variable degree of obstruction following an episode of acute deep venous thrombosis. Non-thrombotic iliac vein obstruction also known as May-Thurner or Cockett's syndrome is the most common cause of non-thrombotic iliac vein occlusion where left common iliac vein is being compressed by the overlying right common iliac artery. Such lesions are present in approximately 60% of the asymptomatic general population but are found in more than 90% of symptomatic patients.

Percutaneous Iliocaval Intervention is an invasive procedure when an occluded vein is opened by introduction of stent at the occluded site under fluoroscopy or Intra vascular ultrasound guidance.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for determining medical necessity are:

A. Stenting of the iliac veins should be considered in the presence of non-thrombotic obstructive venous lesions in the iliocaval segment with greater than 30% stenosis on Venogram. **(AUC Score 7)**[1,2,3,4,5]

B. Iliocaval stenting should be considered as an adjunct to interventional or surgical management of iliocaval thrombosis. **(AUC Score 7)**[1,2,3,4,5]

C. Iliocaval in-stent restenosis should be treated by stenting **(AUC Score 7)**[1,2,3,4,5] but may be treated with venous angioplasty. **(AUC Score 6)**[1,2,3,4,5]

Limitations:

A. Uncorrectable coagulopathy and local or systemic infection are absolute contraindications for iliocaval stenting.

B. Venous Angioplasty is not an effective treatment for Iliocaval obstruction (no prior intervention) due to high recurrence rate.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or Vascular Surgeon's note that prompted request
   2. Recent venogram report

B. Primary codes appropriate for this service: 37238 - Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein

   37239 - Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein; add on code

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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6. NCQA UM 2022 Standards and Elements.

Cardio Policy:

Pericardial Disease Interventions

POLICY NUMBER UM CARDIO_1369	**SUBJECT** Pericardial Disease Interventions		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 09/11/19, 12/11/19, 02/12/20, 01/13/21, 01/12/22, 01/11/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/11/19, 12/11/19, 02/12/20, 01/13/21, 01/12/22, 01/11/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Pericardial Disease Interventions.

II. DEFINITIONS

Pericardial syndromes include different clinical presentations of pericardial diseases with distinctive signs and symptoms that can be grouped in specific syndromes. The classical pericardial syndromes include pericarditis, pericardial effusion, cardiac tamponade and constrictive pericarditis. The etiology of pericardial diseases remains unresolved in many cases and may require invasive diagnostic procedures.

Pericardiocentesis - It is a procedure done to remove fluid that has built up in the sac around the heart (pericardium) using a needle and small catheter to drain excess fluid either fluoroscopy or echocardiography guided.

Pericardioscopy - This procedure permits visualization and biopsy of the pericardial sac with its epicardial and pericardial layers.

Intrapericardial treatment - This procedure involves introduction of antineoplastic treatment in patients with neoplastic pericardial effusion in setting of metastatic malignancy.

Pericardial window - A pericardial window is a cardiac surgical procedure to create a communication, or ‘window’, from the pericardial space to the pleural cavity. The purpose of the window is to allow a pericardial effusion (usually malignant) to drain from the space surrounding the heart into the chest cavity in order to prevent a large pericardial effusion and cardiac tamponade. A pericardial window may be created by video-assisted thoracoscopy or balloon pericardiotomy by a percutaneous intervention.

Pericardiectomy - It is the surgical removal of a portion or all of the pericardium. It is also called pericardial stripping. The pericardium is a double-walled, membrane sac that surrounds the heart.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Pericardiocentesis is indicated for symptomatic moderate to large effusion non-responsive to medical therapy. **(AUC Score 9)**[1,2,3,5]

B. Pericardiocentesis is indicated in case of a smaller effusion, when tuberculous, bacterial, or neoplastic pericarditis is suspected. **(AUC Score 7)**[1,2,3,4]

C. Pericardiocentesis is indicated in case of chronic (lasting more than three months), large pericardial effusion (greater than 20mm on echocardiography in diastole). **(AUC Score 9)**[1,2,3,5]

D. Pericardiocentesis is indicated in evidence of cardiac tamponade. **(AUC Score 9)**[1,2,3,5]

E. Intrapericardial instillation of medications like- triamcinolone, is indicated in refractory forms (failed conventional treatment of recurrent pericardial effusion) of Post pericardiotomy syndrome. **(AUC Score 7)**[1,2,3,5]

F. Intrapericardial instillation of cytostatic/sclerosing agent like cisplatin/Thiotepa is indicated in neoplastic recurrent pericardial effusion. **(AUC Score 7)**[1,2,3,5]

G. Intrapericardial instillation of fibrin glue along with pericardiocentesis may be performed in the setting of Post infarction Pericarditis and cardiac rupture. **(AUC Score 7)**[1,2,3,5]

H. Pericardial window may be indicated in neoplastic recurrent large pericardial effusion due to high recurrence rate. **(AUC Score 8)**[1,2,3,5]

I. Pericardiectomy is indicated to relieve constrictive pericarditis or to remove a pericardium that is calcified and fibrous. **(AUC Score 7)**[1,2,3,5]

J. Pericardial resection may be performed in severely symptomatic pericardial cyst after failed aspiration and intra pericardial instillation of sclerosing agent. **(AUC Score 6)**[1,2,3,4,5]

Limitations:

A. Pericardiocentesis for diagnostic purposes is not justified in cases of mild or moderate effusions (less than 20mm).

B. Aortic dissection and post-infarction rupture of the free wall are contraindications to pericardiocentesis.

C. Pericardiocentesis is relatively contraindicated in presence of uncorrected coagulopathy, thrombocytopenia less than 50,000/mm^3, small posterior and loculated effusions.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiothoracic Surgeon's note that prompted request
   2. Recent Echo/Cardiac CT/Cardiac MRI

B. Primary codes appropriate for this service:

   32601-Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy.

   32604-Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy.

   32658-Thoracoscopy, surgical; with removal of clot or foreign body from pericardial sac.

   32659-Thoracoscopy, surgical; with creation of pericardial window or partial resection of pericardial sac for drainage.

   32661-Thoracoscopy, surgical; with excision of pericardial cyst, tumor, or mass.

   33016-Pericardiocentesis, including imaging guidance, when performed

   33017-Pericardial drainage with insertion of indwelling catheter, percutaneous, 6 years and older without congenital cardiac anomaly

   33018-Pericardial drainage with insertion of indwelling catheter, percutaneous, any age with congenital cardiac anomaly

   33019-Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance

   33020-Pericardiotomy for removal of clot or foreign body (primary procedure).

   33025-Creation of pericardial window or partial resection for drainage.

   33030-Pericardiectomy, subtotal or complete; without cardiopulmonary bypass.

   33031-Pericardiectomy, subtotal or complete; with cardiopulmonary bypass.

   33050-Resection of pericardial cyst or tumor.

C. Place/Site of Service: Inpatient Hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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6. NCQA UM 2022 Standards and Elements.

Cardio Policy:

Thoracentesis and Pleurodesis

POLICY NUMBER UM CARDIO_1370	**SUBJECT** Thoracentesis and Pleurodesis		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 09/11/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 09/11/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 09/13/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Thoracentesis.

II. DEFINITIONS

Thoracentesis is a procedure that is done to remove a sample of fluid from around the lung. The lung is covered with a tissue called the pleura. The inside of the chest is also lined with pleura. The space between these two areas is called the pleural space.

The needle or tube is inserted through the skin, between the ribs and into the chest. This procedure may be done to remove fluid for testing or for treatment. The needle or tube is removed when the procedure is completed. If a person needs more fluid drained, sometimes the tube is left in place for a longer time.

Pleurodesis involves the administration of a drug or material in the pleural space to cause adhesions between the parietal and visceral pleura, and prevention of fluid re-accumulation. Talc is the most widely used pleurodesis agent and shown to be most effective pleurodesis agent. There are two delivery methods: talc poudrage (also known as insufflation), which is conducted during either surgical or medical thoracoscopy, when talc is blown in as a dry powder; or talc slurry, when talc mixed with sterile fluid is injected through a chest tube at the bedside.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are as follows:

A. Thoracentesis is indicated for any undiagnosed pleural effusion. Repeat procedure may be required to establish a diagnosis when initial studies fail to do so. **(AUC Score 8)**[1,2,3]

B. Thoracentesis can be performed for therapeutic relief of symptoms due to large pleural effusions. **(AUC Score 8)**[1,2,3]

C. Repeated Thoracentesis may be required for pleural effusions that reaccumulate e.g. malignancy, heart failure. **(AUC Score 8)**[1,2,3]

D. Chemical Pleurodesis by talc is recommended in patients with recurrent large pleural effusions to improve their symptoms related to pleural effusions. **(AUC Score 8)**[1,2,3]

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review
   1. Progress note that prompted request

B. Primary codes appropriate for this service:
   1. 32550: Tube Thoracostomy, includes connection to drainage system (e.g., water seal), when performed, open (separate procedure)
   2. 32552: Removal of indwelling tunneled pleural catheter with cuff
   3. 32554: Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance
   4. 32555: Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance
   5. 32556: Pleural drainage, percutaneous, with insertion of indwelling catheter; without imaging guidance
   6. 32557: Pleural drainage, percutaneous, with insertion of indwelling catheter; with imaging guidance
   7. 32560: Instillation, via chest tube/catheter, agent for pleurodesis (e.g., talc for recurrent or persistent pneumothorax

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Management of Malignant Pleural Effusions. An Official ATS/STS/STR Clinical Practice Guideline. Am J Respir Crit Care Med Vol 198, Iss 7, pp 839–849, Oct 1, 2018
2. Havelock T, Teoh R, Laws D, et al. Pleural procedures and thoracic ultrasound: British Thoracic Society Pleural Disease Guideline 2010. Thorax 2010; 65 Suppl 2:ii61.
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4. NCQA UM 2023 Standards and Elements.

Cardio Policy:

Endomyocardial Biopsy

POLICY NUMBER UM CARDIO_1388	**SUBJECT** Endomyocardial Biopsy		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for Endomyocardial Biopsy.

II. DEFINITIONS

Endomyocardial biopsy (EMB) is an invasive procedure used routinely to obtain small samples of heart muscle, primarily for detecting rejection of a donor heart following heart transplantation. It is also used as a diagnostic tool in some heart diseases. A bioptome which is a small pincer/grasper cutting instrument is used to gain access to the heart via a sheath inserted into the right internal jugular or less commonly the femoral vein. Guidance and confirmation of correct positioning of the bioptome is made by echocardiography or fluoroscopy before the biopsy specimen is taken and in the case of transplants, usually three or four or more samples are taken.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost – effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. It is reasonable to perform EMB in a Heart Transplant candidate suspected of having an infiltrative cardiomyopathy or an inflammatory process, such as giant cell myocarditis, amyloidosis, or sarcoidosis. **(AUC Score 6)**[1,3,4,6]

B. The standard of care for adult Heart Transplant recipients is to perform periodic EMB, every week for the first 4 weeks post heart transplant followed by every 3 months during the first 6 to 12 post-operative months for surveillance of HT rejection. **(AUC Score 8)**[1,3,4,6]

C. After the first post-operative year, EMB surveillance for an extended period (e.g., every 4–6 months) is recommended in Heart Transplant recipients who are at higher risk for late acute rejection. **(AUC Score 7)**[1,3,4,6]

D. The use of routine EMB later than 5 years after HT is optional in adults and is dependent on clinical judgment and the risk for late allograft rejection. **(AUC Score 5)**[1,3,4,6]

E. EMB can be performed in the setting of unexplained, new-onset heart failure of less than 2 weeks' duration associated with a normal-sized or dilated left ventricle in addition to hemodynamic compromise i.e. cardiogenic shock or require inotropic agents or mechanical assistance for circulatory support. Example: Giant Cell myocarditis, Necrotizing Eosinophilic Myocarditis. **(AUC Score 8)**[1,2,4,5,6]

F. EMB is reasonable in the clinical setting of unexplained heart failure of greater than 3 months' duration associated with a dilated left ventricle and new ventricular arrhythmias, Mobitz type II second- or third-degree AV heart block, or failure to respond to usual care within 1 to 2 weeks. Example: suspected Cardiac Sarcoidosis or Idiopathic Granulomatous Myocarditis. **(AUC Score 6)**[1,2,4,5,6]

G. EMB is reasonable to perform in heart failure patients with suspected cardiomyopathy related to cardiotoxic drugs like anthracycline or suspected restrictive cardiomyopathy. **(AUC Score 5)**[1,2,4,5,6]

Limitations

A. The accuracy of diagnosis by EMB depends on whether the correct site is biopsied. There is a risk that a diagnosis can be missed if the biopsy misses the diseased part of heart muscle, particularly with myocardial inflammation or fibrosis.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:

1. Progress note that prompted request
2. Echo / MUGA / Cardiac Cath report
3. Any previous Endomyocardial biopsy report

B. Primary codes appropriate for this service: 93505; Endomyocardial biopsy

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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7. NCQA UM 2022 Standards and Elements.

Cardio Policy

Subcutaneous ICD Device Implantation and Removal

POLICY NUMBER UM CARDIO_1389	SUBJECT Subcutaneous ICD Device Implantation and Removal		DEPT/PROGRAM UM Dept	PAGE 1 OF 6
DATES COMMITTEE REVIEWED 02/12/20, 01/13/21, 07/14/21, 07/13/22, 01/11/23, 02/01/23, 12/20/23, 01/10/24, 02/14/24, 05/08/24	APPROVAL DATE May 08, 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 02/12/20, 01/13/21, 07/14/21, 07/13/22, 01/11/23, 02/01/23, 12/20/23, 01/10/24, 02/14/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*

- To review a request for medical necessity, the following items must be submitted for review:
  - Progress note that prompted request
  - Echo or MUGA or Cardiac CATH for LV function
  - Previous Holter/Event/Loop recorder report

II. Purpose

Indications for determining medical necessity for Subcutaneous ICD (S-ICD) device.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Subcutaneous ICD Device Implantation and Removal

Patients should be on maximally tolerated GDMT.

For patients being considered for a S-ICD, a preimplant electrocardiogram (ECG) to establish QRS-T wave morphology is needed to reduce the risk of under sensing of VT/VF and the risk of inappropriate shocks. [6]

S-ICD is appropriate in patients with:

- Congenital heart diseases [6]

- No venous access and are unsuitable for transvenous ICD [6]
- Pacing for bradycardia or ventricular tachycardia (VT) termination or as part of cardiac resynchronization therapy (CRT) is neither needed nor anticipated [6]
- High-risk cases for infection: [6, 7]
    - Prior device infection
    - Hemodialysis
    - ESRD
    - Diabetes mellitus
    - Chronic immunosuppression therapy immunodeficiencies
    - Artificial heart valves.
- Candidates for cardiac transplant [6, 7]
- Hypertrophic cardiomyopathy where there is no indication for Anti-Tachycardia Pacing (ATP) [6, 8]
- Primary prevention of sudden cardiac death in patients with ischemic/non ischemic dilated cardiomyopathy where pacing indication for bradycardia or likelihood of first-time monomorphic VT is rare [7, 9]
- Procedures for lead repositioning or replacement are appropriate in cases of: [6, 7]
    - Lead complications
    - Inappropriate shocks
    - Oversensing
    - Other specified lead failure.

V. Limitations for Subcutaneous ICD Device Implantation and Removal

S-ICD is **NOT** indicated in patients with: [6, 7]

- Symptomatic bradycardia requiring permanent pacing.
- Systolic heart failure and left bundle branch block and has indication for cardiac resynchronization therapy (CRT).
- Recurrent sustained monomorphic VT treatable with ATP.
- Recurrent idiopathic ventricular fibrillation (VF) treated with catheter ablation due to high risk of T-wave oversensing
- Thin patients with poor subcutaneous tissue and abnormalities of chest wall like pectus excavatum.
- Before Subcutaneous ICD Device can be implanted in a patient with heart failure and/or ventricular arrhythmias the following must be considered:
    - Predicted or observed lack of adequate response to maximally tolerated GDMT

VI. Background

A. Definitions

The S-ICD System is a Subcutaneous (under the skin) Implantable Cardioverter Defibrillator for people who are at risk of Sudden Cardiac Arrest. Unlike a transvenous ICD, where the leads are fed into the heart through a vein and attached to the heart wall, the leads for S-ICD are placed just under the skin and not in the heart, leaving the heart and veins untouched and intact. The pulse generator is implanted on the left side of the chest next to the rib cage, just under the arm. The lead is vertically positioned in the subcutaneous tissue of the chest, parallel to and 1-2 cm to the left sternal midline followed by a horizontal segment, at the level of the 6th rib, until it reaches the left anterior axillary line. The lead has an 8-cm shock coil, flanked by two sensing electrodes - the distal one positioned adjacent to the manubriosternal junction and the proximal one adjacent to the xiphoid process.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

ATP	Anti-Tachycardia Pacing
CRT	Cardiac resynchronization therapy
ECG	Electrocardiogram
ESRD	End-stage renal disease
GDMT	Guideline Directed Medical Therapy
S-ICD	Subcutaneous Implantable Cardioverter Defibrillator
T-ICD	Transvenous Implantable Cardioverter Defibrillator
VF	Ventricular fibrillation
VT	Ventricular tachycardia

D. Guideline Directed Medical Therapy (GDMT)

GDMT are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

VII. Coding and Standards

- **Primary codes**
  - 33270 - Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia

termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

- 33271 - Insertion of subcutaneous implantable defibrillator electrode
- 33272 - Removal of subcutaneous implantable defibrillator electrode
- 33273 - Repositioning of previously implanted subcutaneous implantable defibrillator electrode
- 93644 – EP eval of Subcutaneous ICD leads including DFT and programming and reprogramming of sensing and therapeutic parameters

- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VIII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] S. Al-Khatib, W. Stevenson, M. Ackerman , W. Bryant , D. Callans , A. Curtis , B. Deal , T. Dickfeld and et al, "2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death," *J Am Coll Cardiol,* vol. 72, no. 14, p. 1760, 2018.

[7] S. Cappelli, A. Olaru and E. De Maria, "The subcutaneous defibrillator: who stands to benefit," *E-Journal of Cardiology Practice ,* vol. 12, 2014.

[8] M. Maron, N. Steiger, A. Burrows and et al., "Evidence That Subcutaneous Implantable Cardioverter-Defibrillators Are Effective and Reliable in Hypertrophic Cardiomyopathy," *J Am Coll Cardiol,* vol. 6, no. 8, p. 1019–1021, 2020.

[9] E. Arbelo, A. Protonotarios , J. R. Gimeno , E. Arbustini , R. Barriales-Villa, C. Basso , C. R. Bezzina and et al., "2023 ESC Guidelines for the management of cardiomyopathies," *Eur Heart J,* pp. 3503-3626, 2023.

Cardio Policy

Ventricular Assist Device - Percutaneous and Permanent

POLICY NUMBER UM CARDIO_1390	**SUBJECT** Ventricular Assist Device - Percutaneous and Permanent		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24, 10/3/24	**APPROVAL DATE** October 4, 2024	**EFFECTIVE DATE** October 25, 2024	**COMMITTEE APPROVAL DATES** 02/12/20, 01/13/21, 11/09/21, 01/12/22, 01/11/23, 12/20/23, 01/10/24, 06/12/24, 10/4/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
    - Cardiologist note that prompted request
    - Heart Transplant team note
    - ECHO report
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

II. Purpose

Indications for determining medical necessity for the procedure of Ventricular Assist Device (VAD).

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Ventricular Assist Device

A. Patient Selection Criteria - Clinical Indicators of Advanced HF may include the following:

- Presence of advanced heart failure symptoms (HF) (New York Heart Association Functional Class III to IV) despite maximum guideline-directed medical therapy (GDMT) [6, 7]
- Not a candidate for cardiac transplantation at the time of Ventricular Assist Device (VAD) implant [6, 7]
- Intolerance of heart failure medications as per GDMT guidelines [6]
- Have a left ventricular ejection fraction (LVEF) ≤30% [6]
- Have demonstrated functional limitation with a peak oxygen consumption of < 14

mL/kg/min [6]
- Inotrope dependence [6]
- Frequent hospitalizations for HF in the past 12 months [6]
- Increasing need to escalate diuretics to maintain volume status, reaching daily furosemide equivalent dose >160 mg/d or use of supplemental metolazone therapy. [6]
- Refractory clinical congestion [6]
- Progressive deterioration in renal or hepatic function [6]
- Worsening right HF or secondary pulmonary hypertension [6]
- Low systolic blood pressure (SBP) ≤90 mm Hg [6]
- Cardiac cachexia [6]
- Persistent hyponatremia (serum sodium, <134 mEq/L)
- Refractory or recurrent ventricular arrhythmias; frequent ICD shocks [6]
- Increased predicted 1-year mortality (eg, >20%) according to HF survival models (eg, MAGGIC, SHFM) [6]

B. Bridge to transplantation (BTT) (AUC Score 8) [8]

- Device must be FDA-approved for bridge-to-transplant use and used according to labeling instructions
- Member is approved and listed as a candidate for heart transplantation or undergoing evaluation based on a decision for patient's candidacy by an interdisciplinary patient selection committee (including but not limited to medical doctors, nursing coordinators, social workers, nutritionists, etc.)
- Severe reductions in cardiac output or noncardiac co-morbidities that survival and successful cardiac transplantation are unlikely without mechanical circulatory support
- Impending cardiogenic shock despite inotropic support of intra-aortic balloon pump (±IABP) in presence of acute renal dysfunction (creatinine > 2.0) that is deemed secondary to insufficient renal blood flow and, is poorly responsive to inotropic support
- Pulmonary hypertension (PA systolic pressure > 60) that persists despite optimal medical and inotropic therapy

C. Bridge to Recovery (AUC Score 5) [8]

- Fatal low cardiac output in situations where recovery is possible or probable
- Acute myocardial infarction complicated by cardiogenic shock
- Acute myocarditis with shock [7]
- Acute cardiac failure following cardiac surgery
- Dilated cardiomyopathy with recent onset and non-ischemic etiology refractory to maximal GDMT [7]
- Post-cardiotomy shock in whom failure to wean from cardiopulmonary bypass [9]

D. Destination Therapy (DT) or Long-term device therapy (AUC Score 8) [8]

- Device must be FDA-approved for destination therapy use and used according to labeling instructions.
- Patients with one or more major contraindications to cardiac transplantation
- Dependence on intravenous inotropic support
- Peak oxygen consumption less than 12-14 mL/kg/min with cardiac limitation
- Class IV heart failure with expected mortality exceeding 50% in 1 year despite maximum GDMT

V. Contraindications for Ventricular Assist Device [6]

- Irreversible hepatic disease
- Irreversible renal disease

- Irreversible neurological disease
- Patient refusal of medical adherence that is necessary for post-operative recovery
- Severe psychosocial limitation
- Severely restricted pulmonary function
- Age greater than 80 years old for Destination Therapy (DT)
- Severe obesity with BMI >35 kg/m^2 [7] or malnutrition
- Musculoskeletal disease that impairs rehabilitation
- Active systemic infection or prolonged intubation
- Untreated/active malignancy with <2 years life expectancy [7]
- Severe peripheral vascular disease (PVD)
- Active substance use
- Impaired cognitive function
- Unstable psychiatric conditions
- Lack of social support
- Significant neurological dysfunction such as atherosclerotic vascular disease of carotid or vertebral systems and coagulation or hematologic disorders [7]
- Active pregnancy [7]

VI. Background

A. Definition

A ventricular assist device (VAD), also known as a mechanical circulatory support device, is an implantable mechanical pump that helps pump blood from the lower chambers of the heart (the ventricles) to the rest of the body. A VAD is used in people who have weakened hearts or have heart failure unresponsive to the guideline directed medical therapy.

The two basic types of VADs are: left ventricular assist device (LVAD) and a right ventricular assist device (RVAD). If both types are used at the same time, they may be called a biventricular assist device (BIVAD). The LVAD is the most common type of VAD. It helps the left ventricle pump blood to the aorta which is the main artery that carries oxygen-rich blood from the heart to your body.

RVAD usually used only for short-term support of the right ventricle after LVAD surgery or other heart surgery. An RVAD helps the right ventricle pump blood to the pulmonary artery, which carries blood to the lungs to pick up oxygen.

Current VADs have evolved with various designs for different placement and duration of use. [7]

- Percutaneous VAD (Impella and Tandem Heart) for short-term support
- Extracorporeal VAD (CentriMag and VA-ECMO) for short-term support
- Intrapericardial VAD (HeartMate 3) for long-tern support
- Intraventricular VAD (Jarvik 2000) for long-tern support
- Paracorporeal VAD (Berlin Excor) for both short and long-term in pediatrics

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner.

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

BTT:	Bridge to Transplantation
DT:	Destination Therapy
GDMT:	Guideline-directed medical therapy
LVEF:	Left ventricular ejection fraction
MAGGIC:	Meta-analysis Global Group in Chronic Heart Failure
PVD:	Peripheral vascular disease
SHFM:	Seattle Heart Failure model
VAD:	Ventricular assist device

VII. Coding and Standard

- **Primary codes**
  - 33979 – Insertion of ventricular assist device, implantable intracorporeal, single ventricle
  - 33980 – Removal of ventricular assist device, implantable intracorporeal, single ventricle
  - 33981 – Insertion of ventricular assist device, implantable intracorporeal, single ventricle
  - 33982 – Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
  - 33983 – Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
  - 33991 – Insertion of ventricular assist devices, percutaneous including radiological supervision and interpretation; arterial and venous access, with transseptal puncture
  - 33995 – Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
  - 33997 – Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VIII. References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

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[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

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Cardio Policy:

Wireless Pulmonary Artery Pressure Device Placement and Monitoring

POLICY NUMBER UM CARDIO_1402	**SUBJECT** Wireless Pulmonary Artery Pressure Device Placement and Monitoring		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 06/10/20, 06/14/21, 11/09/21, 08/10/22, 02/01/23, 01/10/24, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 06/10/20, 06/14/21, 11/09/21, 08/10/22, 02/01/23, 01/10/24, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
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I. PURPOSE

Indications for determining medical necessity for the implantation of a Wireless Invasive Pulmonary Artery Pressure Monitoring device and ongoing data collection.

II. DEFINITIONS

Patients with chronic congestive heart failure (CHF), who have been hospitalized for this diagnosis are at an increased risk of rehospitalization, regardless of their left ventricular ejection fraction (LVEF). Since 2011, several studies have demonstrated a reduction in CHF hospitalizations through the method of following patient's pulmonary artery pressure (PAP) as a predictor of an impending CHF exacerbation and subsequent hospitalization.

This is an implantable PAP monitoring device that allows a direct monitoring of the PAP via a sensor implanted in the PA. The sensor monitors changes in the PAPs and communicates via wireless to an external analyzer. This information is then uploaded to a web-based interface from which healthcare providers can track the results and manage patients.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.[6]

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in the major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. [5]

III. POLICY

Indications for approving a request for medical necessity are:

A. Patients with CHF of any LVEF type who have been hospitalized at least once over the prior year and still have Class III symptoms, and have been re-hospitalized with decreasing time intervals over the prior year, and have demonstrated chronically elevated mean PAP (greater than 30 mmHg) and PCWP greater than or equal to 20 mmHg by invasive means, or a PAS pressure greater than 40 mmHg by echocardiography measured in between acute exacerbations and within 30 days of the intended Wireless Pulmonary Artery Pressure device implant, despite documented compliance with maximally tolerated GDMT in conjunction with non-pharmacological adjuvant treatments (e.g. daily weights, dietary restrictions, VNS home visits) to prevent hospitalization for CHF. **(AUC Score 4)**[1,2,3,4]

B. Remote monitoring of the data is billable once per 30 days and must include at least once weekly downloads of pulmonary artery pressure recordings, interpretations(s), trend analysis, and report(s) by a physician or other qualified health care professional. **(AUC Score 4)**[1,2,3,4]

Limitations

A. The Wireless Pulmonary Artery Pressure Device System is contraindicated for patients with:
   1. an inability to take dual antiplatelet or anticoagulants for one-month post implant
   2. Have a GFR less than 25 cc/min or who are non-responsive to diuretic therapy or are on chronic renal replacement therapy
   3. Have a history of recurrent PE or DVT
   4. Have congenital heart disease
   5. Are likely to undergo heart transplantation or VAD placement within the next 6 months

B. The patient must be followed by a heart failure team within the health care facility.

C. Before a wireless pulmonary artery pressure device system can be implanted in a patient with heart failure the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[2,3,4,5]

D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request from Interventional Cardiologist/ Heart Failure

2. Echocardiogram and right heart catheterization reports

B. Primary codes appropriate for this service: Implantation of wireless PAP sensor monitor: 33289. For remote monitoring of an implantable wireless pulmonary artery pressure sensor monitor, use 93264
   1. Codes 93451 and 93568 are not to be used with 33289
   2. If 93264 is being billed, then physiologic monitoring codes i.e. 93297 can no longer be used

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. CardioMEMS HF System Post Approval Study; ClinicalTrials.gov Identifier: NCT02279888; Study Completion Date: February 3, 2020; https://clinicaltrials.gov/ct2/show/study/NCT02279888
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Cardio Policy
Percutaneous Closure of Patent Foramen Ovale (PFO)

POLICY NUMBER UM CARDIO_1417	**SUBJECT** Percutaneous Closure of Patent Foramen Ovale (PFO)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 5**
DATES COMMITTEE REVIEWED 11/11/20, 10/14/21, 11/09/21, 10/12/22, 09/13/23, 01/10/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 11/11/20, 10/14/21, 11/09/21, 10/12/22, 09/13/23, 01/10/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review
    - Medical notes from a Cardiologist and a Neurologist that indicate the need for the procedure and document that no other obvious etiology for the neurologic event has been discovered
    - A TEE report that documents the presence of the defect and addresses the suitability of the anatomy for the device placement
    - Results of diagnostic testing performed to rule out other causes of neurologic event, i.e. vascular disease, hypercoagulable state, occult atrial fibrillation, and consisting of at least a carotid duplex or CTA/MRA report, evidence of hematological workup, and evidence of heart rhythm monitoring.

II. Purpose

Indications for determining medical necessity for percutaneous closure of patent foramen ovale (PFO) for the secondary prevention of neurologic events.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications for Percutaneous Closure of a Patent Foramen Ovale

Percutaneous PFO closure is appropriate for patients with all of the following [6, 7]:

- a prior history of cryptogenic stroke or TIA
- ≤ 60 years of age
- TEE evidence of interatrial communication that is amenable to percutaneous closure

Limitations

- The existence of other stroke risk factors that would not be affected by device closure, such as but not limited to a cardiac source of embolism apart from PFO, rheumatic mitral stenosis, significant atherosclerosis of the carotid and intracranial circulation, protruding or mobile aortic plaque, coagulopathy, atrial fibrillation or flutter, or vasculitis involving the carotid circulation
- Presence of an inferior vena cava filter
- Elevated bleeding risk or coagulopathy that would prevent the use of dual anti-platelet therapy for six months, and aspirin indefinitely thereafter
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

V. Background

A. Abbreviations

CTA: computed tomographic angiography

MRA: magnetic resonance angiography

PFO: patent foramen ovale

TEE: transesophageal echocardiography/cardiograph

TIA: transient ischemic attack

B. Definitions

PFO is a congenital heart defect that allows for unnatural communication between the left and right sides of the heart at the level of the atria. One possible complication of this is that blood clots forming in the venous system have the opportunity to travel from the right side of the heart into the systemic circulation resulting in a paradoxical embolism that can cause neurologic events such as transient ischemic attack (TIA) and ischemic cerebrovascular accident (CVA or stroke) should it enter the cerebral circulation.

C. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. [1]

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

VI. Coding and Standards

- **Primary Codes**
  - 93580
- **Review**
  - Utilization Management Department

- **Final Approval**
    - Utilization Management Committee

References

[1] R. C. Hendel, B. D. Lindsay, J. M. Allen and et al., "ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force," *J Am Coll Cardiol,* vol. 71, no. 8, pp. 935-948, 2018.

[2] R. Hendel, M. Patel, J. Allen, J. Min, L. Shaw, M. Wolk, P. Douglas, C. Kramer, R. Stainback, S. Bailey, J. Doherty and R. Brindis, "Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force," *J Am Coll Cardiol,* vol. 61, no. 12, pp. 1305-17, March 2013.

[3] R. Bonow, P. Douglas, A. Buxton, D. Cohen, J. Curtis, E. Delong, J. J. Drozda, T. J. Ferguson, P. Heidenreich, R. Hendel, F. Masoudi, E. Peterson, A. Taylor and American College of Cardiology Foundation, "ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures," *Circulation,* vol. 124, no. 13, pp. 1483-502, Sept 2011.

[4] K. Fitch, S. J. Bernstein, M. D. Aguilar, B. Burnand, J. R. LaCalle, P. Lazaro, M. v. h. Loo, J. McDonnell, J. P. Vader and J. P. Kahan, The RAND/UCLA Appropriateness Method User's Manual, Santa Monica, CA: RAND Corporation, 2001.

[5] M. Patel, J. Spertus, R. Brindis, R. Hendel, P. Douglas, E. Perterson, M. Wolk, J. Allen , I. Raskin and American College of Cardiology Foundation, "ACCF proposed method for evaluating the appropriateness of cardiovascular imaging," *J Am Coll Cardiol,* vol. 46, no. 8, pp. 1606-13, Oct 2005.

[6] F. M. S. Collado, M.-F. Poulin, J. J. Murphy, H. Jneid and C. J. Kavinsky, "Patent Foramen Ovale Closure for Stroke Prevention and Other Disorders," *Journal of the American Heart Association,* vol. 7, 2018.

[7] D. M. Wiktor and J. D. Carroll, "The Case for Selective Patent Foramen Ovale Closure After Cryptogenic Stroke," *Advances in Interventional Cardiology,* vol. 11, 2018.

Cardio Policy:

Intervention on Adults with Congenital Heart Defects

POLICY NUMBER UM CARDIO_1418	**SUBJECT** Intervention on Adults with Congenital Heart Defects		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 12/09/20, 06/09/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24	**APPROVAL DATE** January 10, 2024	**EFFECTIVE DATE** January 26, 2024	**COMMITTEE APPROVAL DATES** 12/09/20, 06/09/21, 11/09/21, 07/13/22, 07/18/23, 01/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

I. PURPOSE

Indications for determining medical necessity for percutaneous and surgical therapeutic interventions for adults with congenital heart disease.

II. DEFINITIONS

Congenital heart defects (CHD) are diagnosed in 8-10 out of every 1,000 live births in the USA. Based on 2010 census data, the CDC estimates that there are currently more adults living with CHD than there are children living with CHD – a testament to improved treatments and lifespans. As such, adult cardiologists are becoming more and more likely to encounter patients with CHD who require maintenance, follow-up, and additional procedures later in life.

CHD can be broken down into five categories: shunt lesions, left-sided obstructive lesions, right-sided lesions, complex lesions, pulmonary, and coronary artery anomalies.

Shunt lesions allow for unnatural mixing of oxygenated and deoxygenated blood between the left and right circulatory systems such that a volume of blood from the higher-pressure region are transferred to that of the lower-pressure region, causing volume and pressure overload to the receiving circuit, and may result in deoxygenated blood entering the systemic circulation. They include septal defects of the atria and ventricles (ASD and VSD), atrioventricular septal defects (AVSD), anomalous connections between the pulmonary veins and right-sided venous return to the heart (partial anomalous pulmonary venous connections (PAPVC), and patent ductus arteriosus (PDA). The purpose of correction is to maintain separation of the systemic and pulmonary circulations and to correct the resulting pressure and volume overload on the receiving circuit.

Left-sided obstructive lesions include membranous occlusions of chambers, congenital valve stenoses, and coarctation of the aorta. Correction is essential to maintain forward cardiac output. Right-sided lesions involve a combination of isolated valve stenosis and regurgitation, as well as similar issues arising from Tetralogy of Fallot (TOF). Complex lesions involve transposition of the great arteries (TGA), and abnormalities involving single ventricles with double outlets and/or double inlets, where ongoing problems usually involve valve lesions, arrhythmias, and heart failure. Anomalous coronary arteries (ACA) involve an anomalous origin of the left and right coronary arteries along with an associated abnormal anatomical pathway whose course can result in restricted blood flow and myocardial ischemia. Surgical correction is necessary to prevent ischemia, infarction, and sudden cardiac death.

The diagnoses and procedures covered here have been limited to the more common ones encountered in clinical practice. It is recognized that more complex clinical situations and interventions exist, and such requests will be determined on a case-by-case basis by clinical reviewers.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost– effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Shunt Lesions

1. ASD
    a. In adults with isolated secundum ASD causing impaired functional capacity, right atrial and/or RV enlargement, and net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., pulmonary–systemic blood flow ratio [Qp:Qs] ≥1.5:1) without cyanosis at rest or during exercise, transcatheter or surgical closure to reduce RV volume and improve exercise tolerance is recommended, provided that systolic PA pressure is less than 50% of systolic systemic pressure and pulmonary vascular resistance is less than one third of the systemic vascular resistance **(AUC Score 8)**[1,2,5]
    b. Adults with primum ASD, sinus venosus defect or coronary sinus defect causing impaired functional capacity, right atrial and/or RV enlargement and net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1) without cyanosis at rest or during exercise, should be surgically repaired unless precluded by comorbidities, provided that systolic PA pressure is less than 50% of systemic pressure and pulmonary vascular resistance is less than one third of the systemic vascular resistance **(AUC Score 8)**[1,2,5]
    c. In asymptomatic adults with isolated secundum ASD, right atrial and RV enlargement, and net left-to right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1), without cyanosis at rest or during exercise, transcatheter or surgical closure is

reasonable to reduce RV volume and/or improve functional capacity, provided that systolic PA pressure is less than 50% of systemic pressure and pulmonary vascular resistance is less than one third systemic resistance **(AUC Score 7)**[1,2,5]

d. Surgical closure of a secundum ASD in adults is reasonable when a concomitant surgical procedure is being performed and there is a net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1) and right atrial and RV enlargement without cyanosis at rest or during exercise **(AUC Score 7)**[1,2,5]

e. Percutaneous or surgical closure may be considered for adults with ASD when net left-to-right shunt (Qp:Qs) is ≥1.5:1, PA systolic pressure is 50% or more of systemic arterial systolic pressure, and/or pulmonary vascular resistance is greater than one third of the systemic resistance **(AUC Score 6)**[1,2,5]

2. VSD

a. Adults with a VSD and evidence of left ventricular volume overload and hemodynamically significant shunts (Qp:Qs ≥1.5:1) should undergo VSD closure, if PA systolic pressure is less than 50% systemic and pulmonary vascular resistance is less than one third systemic **(AUC Score 8)**[1,5]

b. Surgical closure of perimembranous or supracristal VSD is reasonable in adults when there is worsening aortic regurgitation (AR) caused by VSD **(AUC Score 6)**[1,5]

c. Surgical closure of a VSD may be reasonable in adults with a history of IE caused by VSD, or in the presence of a net left-to-right shunt (Qp:Qs ≥1.5:1) when PA systolic pressure is 50% or more than systemic and/or pulmonary vascular resistance is greater than one third systemic **(AUC Score 5)**[1,5]

3. PAPVC

a. Surgical repair is recommended for patients with partial anomalous pulmonary venous connection when functional capacity is impaired and RV enlargement is present, there is a net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1), PA systolic pressure is less than 50% systemic pressure and pulmonary vascular resistance is less than one third of systemic resistance **(AUC Score 8)**[1,5]

b. Repair of partial anomalous pulmonary venous connection is recommended at the time of closure of a sinus venosus defect or ASD **(AUC Score 8)**[1,5]

c. Repair of a scimitar vein (hypoplastic lung drained by an APV into systemic vein- IVC) is recommended in adults when functional capacity is impaired, evidence of RV volume overload is present, there is a net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1), PA systolic pressure is less than 50% systemic pressure and pulmonary vascular resistance is less than one third systemic. **(AUC Score 8)**[1,3,5]

d. Surgery can be useful for right- or left-sided partial anomalous pulmonary venous connection in asymptomatic adults with RV volume overload, net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs ≥1.5:1), pulmonary pressures less than 50% systemic and pulmonary vascular resistance less than one third systemic **(AUC Score 6)**[1,5]

e. Surgery can be useful for repair of a scimitar vein in adults with evidence of RV volume overload, with Qp:Qs ≥1.5:1**(AUC Score 6)**[1,3,5]

4. Atrioventricular Septal Defect

a. Surgery for severe left atrioventricular valve regurgitation is recommended per GDMT indications for mitral regurgitation **(AUC Score 7)**[1,5]

b. Surgery for primary repair of atrioventricular septal defect or closure of residual shunts in adults with repaired atrioventricular septal defect is recommended when there is a net

left-to-right shunt (Qp:Qs ≥1.5:1), PA systolic pressure less than 50% systemic and pulmonary vascular resistance less than one third systemic **(AUC Score 7)[1,5]**

c. Surgery for primary repair of atrioventricular septal defect or closure of residual shunts in adults with repaired septal defect is recommended when there is a net left-to-right shunt (Qp:Qs ≥1.5:1), PA systolic pressure less than 50% systemic and pulmonary vascular resistance less than one third systemic **(AUC Score 7)[1,5]**

5. PDA

a. PDA closure in adults is recommended if left atrial or LV enlargement is present and attributable to PDA with net left-to-right shunt, PA systolic pressure less than 50% systemic and pulmonary vascular resistance less than one third systemic **(AUC Score 7)[1,4,5]**

b. PDA closure in adults may be considered in the presence of a net left-to-right shunt if PA systolic pressure is 50% or greater systemic, and/or pulmonary vascular resistance is greater than one third systemic **(AUC Score 5)[1,5]**

B. Left-Sided Obstructive Lesions

1. Surgical repair is indicated for adults with cor triatriatum sinister or congenital mitral stenosis for symptoms attributable to flow obstruction **(AUC Score 8)[1]**
2. Surgical intervention is recommended for adults with sub-aortic stenosis with a maximum gradient of 50 mmHg or more who have symptoms attributable to the obstructive lesion, or if the gradient is less than 50 mmHg in the presence of CHF, ischemic symptoms, or LV systolic dysfunction **(AUC Score 7)[1]**
3. In adults with bi-leaflet aortic valve stenosis and a non-calcified valve with no more than mild AI meeting indications for intervention per GDMT (see UM CARDIO_1095 Aortic Valve Replacement), it may be reasonable to treat with balloon valvuloplasty. **(AUC Score 5)[1]**

   Please refer to *UM CARDIO_1095 Aortic Valve Replacement* or *UM CARDIO_1295 Trans Catheter Aortic Valve Replacement* for such requests that are received for bi-leaflet AV patients.
4. Surgical repair is recommended for adults with supravalvular aortic stenosis and symptoms or decreased LV systolic function, regardless of gradient, if symptoms and LV pathology are attributable to the stenosis **(AUC Score 8)[1]**
5. Surgical repair or catheter-based stenting is recommended for adults with hypertension and significant (trans-obstructive gradient of 20 mmHg or more, measured by upper-lower extremity pressure differential, by echocardiography, or by cardiac catheterization) native or recurrent coarctation of the aorta **(AUC Score 8)[1]**

C. Right-Sided Lesions

1. Pulmonary Valve Pathology

a. In adults with moderate or severe valvular pulmonary stenosis and otherwise unexplained symptoms of HF, cyanosis from interatrial right-to-left communication, and/or exercise intolerance, balloon valvuloplasty is recommended **(AUC Score 8)[1,5]**

b. If balloon valvuloplasty has failed or is not feasible, then surgical repair is recommended **(AUC Score 8)[1,5]**

c. In symptomatic patients with moderate or greater PR resulting from treated isolated pulmonary stenosis, with RV dilation or RV dysfunction, pulmonary valve replacement is recommended **(AUC Score 7)[1,5]**

2. Double-Chamber Right Ventricle

a. Surgical repair for adults with double-chambered right ventricle and moderate or greater outflow obstruction is recommended in patients with otherwise unexplained symptoms of HF, cyanosis, or exercise limitation **(AUC Score 8)**[1,5]

3. Ebstein Anomaly

a. Surgical repair or reoperation for adults with Ebstein anomaly and significant TR is recommended when one or more of the following are present: HF symptoms, objective evidence of worsening exercise capacity, progressive RV systolic dysfunction by echocardiography or CMR **(AUC Score 8)**[1,5]

4. Tetralogy of Fallot

a. Pulmonary valve replacement (surgical or percutaneous) for relief of symptoms is recommended for patients with repaired TOF and moderate or greater PR with cardiovascular symptoms not otherwise explained **(AUC Score 8)**[1,5]

b. Pulmonary valve replacement (surgical or percutaneous) is reasonable for preservation of ventricular size and function in asymptomatic patients with repaired TOF and ventricular enlargement or dysfunction and moderate or greater PR **(AUC Score 6)**[1,5]

D. Anomalous Coronary Arteries

1. Surgery is recommended for anomalous origin of either the left or the right coronary artery from the opposite aortic sinus for symptoms or diagnostic evidence consistent with coronary ischemia attributable to the anomalous coronary artery **(AUC Score 8)**[1,5]
2. Surgery is reasonable for anomalous aortic origin of the left coronary artery from the right sinus in the absence of symptoms or ischemia, or if there is evidence of ventricular arrhythmia **(AUC Score 6)**[1,5]
3. Surgery is recommended for an anomalous left coronary artery that arises from the pulmonary artery **(AUC Score 8)**[1,5]
4. Surgery is recommended for an anomalous right coronary artery arising from the pulmonary artery if the patient is having symptoms that are attributed to the anomalous origin **(AUC Score 7)**[1,5]
5. Surgery is reasonable for an asymptomatic patient with an anomalous right coronary artery arising from the pulmonary artery if there is evidence of ventricular dysfunction or ischemia that is attributed to the anomalous origin **(AUC Score 6)**[1,5]

Limitations

A. Closure of shunt lesions should not be performed in adults with PA systolic pressure greater than two thirds systemic, pulmonary vascular resistance greater than two thirds systemic, and/or a net right-to-left shunt.

B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review

1. Progress notes from the cardiologist and (if indicated) cardiovascular surgeon
2. Reports from trans-thoracic and/or trans-esophageal echocardiograms, coronary/cardiac CTA, invasive cardiac catheterization, and CMR as applicable

B. Primary codes appropriate for this service:

1. Percutaneous closure of septal defect: atrial 93580; ventricular 93581 (both include a right heart cath procedure)
2. Surgical closure of septal defect - ASD: 33641, 33645, 33647; for VSD: 33647, 33660, 33665, 33670, 33675-7, 33681, 33684
3. PAPVC: 33724, 33726, 33730
4. PDA percutaneous closure: 93582; Surgical ligation: 33820, 33822, 33824; the following may be requested for surgical excision of coarctation with PDA: 33840, 33845
5. Cor Triatriatum surgical repair: 33732
6. Aortic valve – sub aortic membrane surgical resection: 33414-33416; Percutaneous balloon aortic valvuloplasty: 92986; Supravalvular stenosis: 33417
7. Percutaneous repair of Coarctation of the aorta: 33881; Surgical repair (may include PDA excision): 33840, 33845
8. Pulmonary valve percutaneous valvuloplasty: 92990; catheter-based replacement: 33477; Surgical intervention/replacement: 33470, 33471, 33474-33476, 33478
9. Pulmonary artery percutaneous interventions: 37236, 37237; Surgical interventions: 33917, 33920, 33922, 33924-3926Coronary artery anomalies: 33500-33507
10. Anomalous coronary artery surgical interventions: 33500-33507

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Karen K. Stout et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines J of American College of Cardiology; 73 (12) Apr 2019, pp e 81–192
2. Oster M, Bhatt A, Zaragoza-Macias E, et al. Interventional therapy versus medical therapy for secundum atrial septal defect: a systematic review (part 2) for the 2018 AHA/ACC guideline for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2018 Aug 9 [E-pub ahead of print].
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5. ACC Appropriate Use Criteria Methodology: 2018 Update. A Report of the American College of Cardiology Appropriate Use Criteria Task Force. Hendel et al. JACC VOL. 71, NO. 8, 2018.
6. NCQA UM 2023 Standards and Elements.

Cardio Policy
Ultrasound-Guided Vascular Access

POLICY NUMBER UM CARDIO_1453	**SUBJECT** Ultrasound-Guided Vascular Access	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 12/08/21, 12/14/22, 10/18/23, 01/10/24, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** March 29, 2024	**COMMITTEE APPROVAL DATES** 12/08/21, 12/14/22, 10/18/23, 01/10/24, 03/13/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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I. General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- Request for medical determination (the following items must be submitted for review)
    - Progress notes documenting the intent to perform a procedure necessitating access of the intravascular space and the medical necessity thereof.
- For reimbursement, a digital photographic image of the accessed vessel, including the needle and wire must be obtained for archiving.

II. Purpose

Indications for determining medical necessity for ultrasound-guided vascular access.

III. Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (Hendel, Lindsay, Allen, & et al., 2018; Hendel, et al., 2013; Bonow, et al., 2011; Fitch, et al., 2001; Patel, et al., 2005)

IV. Indications for Ultrasound Guided Vascular Access

The use of ultrasound-guided vascular access is recommended for procedures necessitating cannulation of any central or peripheral artery or vein as part of a diagnostic or interventional procedure. (Lamperti, et al., 2020)

V. Background

Overview

Attaining precise access to the intravascular space connotes the commencement of all invasive procedures involving the circulation, and failure to do so adeptly may have adverse consequences for the entire procedure. Assistance may be achieved by using an ultrasound-tipped needle that can locate the target blood vessel and allow it to be precisely cannulated to mitigate risks for the

remainder of the procedure. At present, the use of ultrasound guidance is recommended for all intravascular procedures to increase safety, improve first-time success, reduce total procedure time, and reduce the overall risk of complications.

AUC Score

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9
May be Appropriate Care- Median Score 4-6
Rarely Appropriate Care- Median Score 1-3

VI. Coding and Standards

- **Primary Codes**
  - 76937 – access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real-time ultrasound visualization of vascular needle entry, with permanent recording and reporting.
- **Review**
  - Utilization Management Department
- **Final Approval**
  - Utilization Management Committee

VII. References

[1] Bonow, R., Douglas, P., Buxton, A., Cohen, D., Curtis, J., Delong, E., . . . American College of Cardiology Foundation. (2011, Sept). ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation, 124*(13), 1483-502. doi:10.1161/CIR.0b013e31822935fc

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[6] Patel, M., Spertus, J., Brindis, R., Hendel, R., Douglas, P., Perterson, E., . . . American College of Cardiology Foundation. (2005, Oct). ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol, 46*(8), 1606-13. doi:10.1016/j.jacc.2005.08.030

Cardio Policy

Vascular Embolization or Occlusion

POLICY NUMBER UM CARDIO_1456	**SUBJECT** Vascular Embolization or Occlusion	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 01/12/22, 01/11/23, 01/10/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 01/12/22, 01/11/23, 01/10/24, 06/12/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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I. General information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.*
- To review a request for medical necessity, the following items must be submitted for review:
  - Provider notes that indicate the medical necessity for the service.
  - Non-Invasive vascular duplex/CTA/MRA and recent angiogram report(s)

II. Purpose

Indications for determining medical necessity for vascular embolization or occlusion.

III. Clinical reasoning

- All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use Criteria (AUC) scores, when available, are diligently listed alongside the criteria.
- This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5]

IV. Indications [6]

- Occlusion of congenital or acquired aneurysms, pseudoaneurysms, vascular malformations, and other vascular abnormalities that could potentially cause adverse health effects
- Devascularization of benign or nonneoplastic tissues that affect patient health, including, but not limited to:
  - Hypersplenism
  - Chemotherapy-induced thrombocytopenia
  - Uterine fibroids
  - Refractory renovascular hypertension
  - Proteinuria in end-stage kidney disease
  - Varicocele
  - Pelvic congestion syndrome
  - Prostatic artery embolization
  - Priapism
  - Ectopic pregnancy
- Flow redistribution to protect normal tissue or facilitate other medical treatment(s)
- Management of endoleaks, including but not limited to:

    - Direct sac puncture or collateral vessel embolization for type-II endoleaks
    - Intraoperative aneurysm sac embolization during stent graft placement to minimize the need for future reintervention.
- Treatment of acute or recurrent hemorrhage, including, but not limited to:
    - Hemoptysis
    - Gastrointestinal bleeding
    - Traumatic events
    - Surgical, or treatment-induced bleeding
    - Hemorrhagic neoplasms
- All of these indications may also be applicable in the pediatric population

V. Background

A. Definitions

Therapeutic embolization involves the placement of a device or substance to produce an intentional vessel occlusion; thereby inducing ischemia within a given tissue, redirecting bulk blood flow away from an area in which perfusion is undesirable, or preventing additional blood loss during a hemorrhagic event.

B. AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

C. Acronyms/Abbreviations

AUC	Appropriate use Criteria

VI.Coding and Standards

- **Primary Codes**
    - 37241, 37242, 37243, 37244
- **Related Codes**
- **Review**
    - Utilization Management Department
- **Final Approval**
    - Utilization Management Committee

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Cardio Policy:

FRACTIONAL FLOW RESERVE CT

POLICY NUMBER UM CARDIO_1457	SUBJECT FRACTIONAL FLOW RESERVE CT		DEPT/PROGRAM UM Dept	PAGE 1 OF 5
DATES COMMITTEE REVIEWED 02/14/24	APPROVAL DATE February 14, 2024	EFFECTIVE DATE February 23, 2024	COMMITTEE APPROVAL DATES 02/14/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Medicare, Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Fractional flow reserve computed tomography (FFR-CT).

II. DEFINITIONS

Fractional flow reserve computed tomography (FFR-CT) is a relatively new technology that estimates the effect of coronary arterial narrowing on blood flow, based upon the images acquired in a coronary computed tomography angiography study. Its role is to provide information that can more appropriately select patients requiring invasive coronary angiography.

History of FFR: Fractional Flow Reserve (FFR) is the ratio of baseline coronary flow to coronary flow during maximal hyperemia. Its use in the cardiac catheterization laboratory has successfully demonstrated utility in the quantitation of intracoronary flow dynamics secondary to lesional and microvasculature conditions. This technology has proven helpful in evaluating individual patients, with respect to prognostication of coronary artery disease and decisions regarding the appropriateness of coronary revascularization.[8-12]

Adaptation to CCTA: CCTA has shown utility in the evaluation of patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation,[13-16] as well as in low-risk emergency department scenarios.[17] Fractional flow reserve using CCTA seeks to provide an estimation of FFR by non-invasive methodology. Following assessment of quality CCTA images, in the appropriate subsets of patients with coronary stenoses, the technology makes mathematical assumptions to simulate maximal hyperemia and calculates an estimation of FFR (fractional flow reserve) for those coronary vessels with lesions, based upon the principles of fluid mechanics inherent to the Navier-Stokes Theorem.[18]

FFR-CT Results: Quantitative estimation of coronary lesional hemodynamic severity using FFR-CT might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization.

FFR-CT measurements appear reproducible,[19] with initial data demonstrating a strong correlation to invasive FFR, resulting in a high diagnostic performance.[20] Invasive FFR has excellent reproducibility[21] and a demonstrated track record of favorable outcomes when used in the selection of patients and vessels requiring PCI.[8,10-12] Evidence suggests that FFR-CT might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA[22] and that a negative FFR-CT in the evaluation of chest pain results in lower revascularization rates and lower cardiovascular death and MI at 1 year follow-up.[23] The FFR-CT data to date, however, provide no evidence showing that revascularization based upon FFR-CT improves clinical outcomes over invasive angiographic assessment. As a consequence of the above considerations, current revascularization guidelines do not advocate FFR-CT as a surrogate for invasive FFR, although, those guidelines refer to FFR-CT as an "emerging technology".[24]

III. POLICY

Indications for approving a request for medical necessity are:

A. Intermediate degrees of stenosis (40 - 90%) on coronary computerized tomographic angiography (CCTA) to guide decision making and help identify those patients who would benefit from revascularization[1]

B. Intermediate lesions in the above range and coronary calcification have made percentage stenosis interpretation difficult, thus could support approval of FFR-CT, in conjunction with the above criteria[2]

FFR-CT – ADDITIONAL INFORMATION[3,4]

None of the following clinical scenarios below apply, since FFR-CT either:

- Has not been adequately validated due to inapplicability of computational dynamics
- Due to problematic artifacts, and/or clinical circumstances
    - When patients have artifacts (heavy calcium) or body habitus (BMI > 35) that could interfere with the examination, the suitability for FFR-CT is at the discretion of the vendor who provides the FFR-CT service
    - Known ischemic coronary artery disease that has not been revascularized and there has been no change in patient status or in the CCTA images
- Recent myocardial infarction within 30 days[5]
- Prior coronary artery bypass graft surgery
- Complex congenital heart disease or ventricular septal defect (VSD) with pulmonary-to-systemic flow ratio > 1.4
- Metallic stents ≤ 3.0 mm in diameter in the coronary system
- Coronary lesions with a vessel diameter < 1.8 mm
- Severe wall motion abnormality on CCTA results

- Severe myocardial hypertrophy
- High risk indicators on stress test
- Coronary angiography within the past 90 days
- Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Recent Stress test (Imaging or Non – Imaging) report. Cardiac CT angiography if performed within 90days

B. Primary codes appropriate for this service: 75580 Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional. Reported once per CCTA when done on the same day.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

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Cardio Policy
Coronary Artery Calcium Scoring by Electron-Beam Tomography or Non-Contrast Coronary Computed Tomography

POLICY NUMBER UM CARDIO_1458	**SUBJECT** Coronary Artery Calcium Scoring by Electron-Beam Tomography or Non-Contrast Coronary Computed Tomography	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 8**
DATES COMMITTEE REVIEWED 03/13/24, 05/08/24	**APPROVAL DATE** May 08, 2024	**EFFECTIVE DATE** May 31, 2024	**COMMITTEE APPROVAL DATES** 03/13/24, 05/08/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL STATEMENT

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

PURPOSE

This guideline includes clinical criteria for coronary artery calcium scoring, by either EBCT or non-contrast CCT. CAC testing provides a quantitative assessment of coronary artery calcium content in Agatston units, as an adjunct to the estimation of global risk‡ for coronary or cardiovascular events over the next 10 years. A CAC Score > 0 is a highly specific feature of coronary atherosclerosis [5, 13].

CLINICAL REASONING

All criteria are either supported by Appropriate Use Scores or clinical reasoning that represents a standard of care that considers variables to deliver patient-centered care, supported by current guidelines endorsed by the American College of Cardiology and the American Heart Association. Care should always be determined on a case-by-case basis and reflect the best needs of the patient.

SPECIAL NOTE

See Legislative Requirements for specific mandates in: State of New Mexico and State of Texas

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POLICY: INDICATIONS FOR CORONARY ARTERY CALCIUM (CAC) TESTING

Patients, regardless of age, can be considered for CAC testing when there is well-documented evidence of one of the following [1, 2, 3, 4]:

- For asymptomatic patients, without known coronary disease, at intermediate global risk (7.5%-19.9%) (AUC 8)
- For asymptomatic patients, without known coronary disease, that are at either borderline global risk (5%-7.4%) (AUC 7) or estimated 10-year risk of less than 5%, but

are suspected to be at elevated ASCVD risk because of one or more major risk factor (listed below) not accounted for in global risk equations [1, 5, 6, 3, 7, 8, 9]:
    - Family history of premature ASCVD
    - Persistently elevated LDL-C > 160mg/dl or non-HDL-C > 190mg/dl
    - Chronic kidney disease
    - Metabolic syndrome
    - Conditions specific to women (e.g., pre-eclampsia, premature menopause) [9]
    - Inflammatory diseases (HIV, psoriasis, RA)
    - Ethnicity (e.g., South Asian ancestry)
    - Persistently elevated triglycerides (> 175mg/dl)
    - hsCRP > 2mg/L
    - Lp(a) levels > 50mg/dl
    - apoB > 130mg/dl
    - ABI < 0.9, 15
- For asymptomatic patients, without known coronary disease, where there is a need for alternative lipid-lowering strategies when statin therapy is contraindicated, due to adverse effects or patient reluctance [8, 7]
- CAC testing may be repeated indefinitely for re-assessment of the asymptomatic patient without known coronary disease after a minimum of 5 years until the calcium score breaches 400 or up to twice if the calcium score remains zero.

CODING AND STANDARDS

CPT Codes: 75571
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

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LEGISLATIVE REQUIREMENTS

STATE OF NEW MEXICO [11]

A. A group health plan, other than a small group health plan or a blanket health insurance policy or contract that is delivered, issued for delivery or renewed in this state shall provide coverage for eligible insureds to receive a heart artery calcium scan.
B. Coverage provided pursuant to this section shall:
    (1) be limited to the provision of a heart artery calcium scan to an eligible insured to be used as a clinical management tool;
    (2) be provided every five years if an eligible insured has previously received a heart artery calcium score of zero; and
    (3) not be required for future heart artery calcium scans if an eligible insured receives a heart artery calcium score greater than zero.

C. At its discretion or as required by law, an insurer may offer or refuse coverage for further cardiac testing or procedures for eligible insureds based upon the results of a heart artery calcium scan.
D. The provisions of this section do not apply to short-term travel, accident-only or limited or specified-disease policies, plans or certificates of health insurance.
E. As used in this section:
(1) "eligible insured" means an insured who:
(a) is a person between the ages of forty-five and sixty-five; and
(b) has an intermediate risk of developing coronary heart disease as determined by a health care provider based upon a score calculated from an evidence-based algorithm widely used in the medical community to assess a person's ten-year cardiovascular disease risk, including a score calculated using a pooled cohort equation;
(2) "health care provider" means a physician, physician assistant, nurse practitioner or other health care professional authorized to furnish health care services within the scope of the professional's license; and
(3) "heart artery calcium scan" means a computed tomography scan measuring coronary artery calcium for atherosclerosis and abnormal artery structure and function.

STATE OF TEXAS [12]

(a) A health benefit plan that provides coverage for screening medical procedures must provide the minimum coverage required by this section to each covered individual:
(1) who is:
(A) a male older than 45 years of age and younger than 76 years of age; or
(B) a female older than 55 years of age and younger than 76 years of age; and
(2) who:
(A) is diabetic; or
(B) has a risk of developing coronary heart disease, based on a score derived using the Framingham Heart Study coronary prediction algorithm, that is intermediate or higher.
(b) The minimum coverage required to be provided under this section is coverage of up to $200 for one of the following noninvasive screening tests for atherosclerosis and abnormal artery structure and function every five years, performed by a laboratory that is certified by a national organization recognized by the commissioner by rule for the purposes of this section:
(1) computed tomography (CT) scanning measuring coronary artery calcification; or
(2) ultrasonography measuring carotid intima-media thickness and plaque.

BACKGROUND

CAC testing is for cardiovascular risk assessment in individuals aged 40-75 years who have an intermediate (5-19.9%) 10-year ASCVD risk based upon the ACC/AHA pooled cohort risk

calculator. Documentation is required that the results of the study will affect decision making for preventative actions (i.e., statin therapy). CAC testing is a cardiovascular risk assessment tool, applicable only to the patient without known cardiovascular disease, for the purpose of primary prevention. It is not for the patient with suspected or known cardiovascular disease, coronary or otherwise, who already requires aggressive risk factor modification.

CAC score > 100 can also provide support for aspirin therapy and statin therapy [5, 14].

Calcium scores are used to help determine the use and dosage of statin therapy in patients with various risks of developing clinically symptomatic atherosclerotic disease. Once symptomatic coronary disease has been established or once the patient is considered high risk, the usefulness of calcium scoring falls away as patients should be on high dose therapy and the results of a calcium score would add no further benefit. If a patient is symptomatic, non-invasive or invasive testing should remain first line.

ǂ Global risk of CAD is defined as the probability of an asymptomatic patient without known CAD developing CAD, including myocardial infarction or CAD death, over a given period of time. Risk categories include:

- Low risk (<5%)
- Borderline risk (5% - 7.4%)
- Intermediate risk (7.5% to 19.9%)
- High risk (≥ 20%)

Links to Global Cardiovascular Risk Calculators

Risk Calculator	Website for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/

Abbreviations

ASCAD Atherosclerotic coronary artery disease

ASCVD	Atherosclerotic cardiovascular disease
CAC	Coronary artery calcium
CAD	Coronary artery disease
CCT	Cardiac computed tomography
EBCT	Electron beam computed tomography

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Cardio Policy
CT Heart
CT Heart Congenital (Not Including Coronary Arteries)

POLICY NUMBER UM CARDIO_1459	**SUBJECT** CT Heart		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 9**
DATES COMMITTEE REVIEWED 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** May 31, 2024	**COMMITTEE APPROVAL DATES** 03/13/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

PURPOSE

Indications for determining medical necessity for non-contrast cardiac computed tomography.

POLICY: INDICATIONS FOR HEART COMPUTED TOMOGRAPHY (CT)

Congenital Heart Disease [1, 2]

For all indications below, either CT or CMR can be performed:

- All congenital lesions: prior to planned repair and for change in clinical status and/or new concerning signs or symptoms

Patent Ductus Arteriosus

- routine surveillance (1-2 years) in a patient with postprocedural aortic obstruction (AUC 7)

Aortic Dilation

- routine surveillance (6-12 months) in a child with aortic sinus and/or ascending aortic dilation with increasing size (AUC 7)

Aortic Coarctation and Interrupted Aortic Arch:

- Routine surveillance (3–5 years) in a child or adult with mild aortic coarctation (AUC 7)
- Post procedure (surgical or catheter-based) routine surveillance (3–5 years) in an asymptomatic patient to evaluate for aortic arch aneurysms, in-stent stenosis, stent fracture, or endoleak (AUC 8)

Tetralogy of Fallot

- Post procedure routine surveillance (2–3 years) in a patient with valvular or ventricular dysfunction, right ventricular outflow tract obstruction, branch pulmonary artery stenosis, arrhythmias, or presence of an RV-to-PA conduit (AUC 7)

D-Loop Transposition of the Great Arteries:

- Post procedure routine surveillance (3–5 years) in an asymptomatic patient (AUC 7)
- Post procedure routine surveillance (1–2 years) in a patient with dilated aortic root with increasing size, or aortic regurgitation (AUC 7)
- Post procedure routine surveillance (3–12 months) in a patient with ≥moderate systemic AV valve regurgitation, systemic RV dysfunction, LVOT obstruction, or arrhythmias (AUC 7)

Congenitally Corrected Transposition of the Great Arteries:

- Unrepaired: routine surveillance (3–5 years) in an asymptomatic patient (AUC 7)
- Postoperative: routine surveillance (3–5 years) in an asymptomatic patient (AUC 7)
- Postoperative anatomic repair: routine surveillance (6–12 months) in a patient with valvular or ventricular dysfunction, right or left ventricular outflow tract obstruction, or presence of an RV-to-PA conduit (AUC 7)
- Postoperative physiological repair with VSD closure and/or LV-to-PA conduit: routine surveillance (3–12 months) in a patient with ≥moderate systemic AV valve regurgitation, systemic RV dysfunction, and/or LV-to-PA conduit dysfunction (AUC 7)

Truncus Arteriosus

- routine surveillance (1–2 years) in an asymptomatic child or adult with ≥ moderate truncal stenosis and/or regurgitation (AUC 7)
- Single-Ventricle Heart Disease (includes hypoplastic left heart syndrome, double-inlet LV, double-inlet RV, mitral atresia, tricuspid atresia, unbalanced A-V septal defect): postoperative routine surveillance (3-5 years) in an asymptomatic patient (AUC 7)

Cardiomyopathy [3]

- Quantification of myocardial (muscle) mass (CMR or CT) [4, 5, 6]
- Assessment of left ventricular systolic dysfunction when prior noninvasive imaging has been inadequate (AUC 7)
- Assessment of right ventricular morphology in suspected arrhythmogenic right ventricular cardiomyopathy (AUC 7) [7], based upon other findings such as [4]:
    - Nonsustained VT
    - Unexplained syncope
    - ECG abnormalities [6]
    - First-degree relative with positive genotype of ARVC (either, but CMR is superior to CT) [4, 6]

Valvular Heart Disease [8, 9]

- Characterization of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE, TEE, and/or fluoroscopy have been inadequate(AUC 7)

- Evaluation of RV systolic function in severe TR, including systolic and diastolic volumes, when TTE images are inadequate and CMR is not readily available
- Pulmonary hypertension in the absence of severe valvular disease [10]
- Evaluation of suspected infective endocarditis with moderate to high pretest probability (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inadequate
- Evaluation of suspected paravalvular infections when the anatomy cannot be clearly delineated by TTE and TEE

Evaluation of Intra- and Extra-cardiac Structures [3]

- Evaluation of cardiac mass, suspected tumor or thrombus, or cardiac source of emboli, when imaging with TTE and TEE have been inadequate (AUC 7)
- Re-evaluation of prior findings for interval change (i.e., reduction or resolution of atrial thrombus after anticoagulation (AUC 8), when a change in therapy is anticipated (AUC 7) [3, 11]
- Evaluation of pericardial anatomy (AUC 8), when TTE and/or TEE are inadequate or for better tissue characterization of a mass and detection of metastasis [CMR superior for physiologic assessment (constrictive versus restrictive) and tissue characterization, CT superior for calcium assessment] [4, 12, 13]

Electrophysiologic Procedure Planning [4, 7]

- Evaluation of pulmonary venous anatomy prior to radiofrequency ablation of atrial fibrillation and for follow-up when needed for evaluation of pulmonary vein stenosis (AUC 8)
- Non-invasive coronary vein mapping prior to placement of biventricular pacing leads (AUC 8)

Transcatheter Structural Intervention Planning

- Evaluation for transcatheter aortic valve replacement (TAVR) (AUC 9) [8, 14]
- When TTE and TEE cannot provide adequate imaging, CT imaging can be used for planning: robotic mitral valve repair, atrial septal defect closure, left atrial appendage closure, ventricular septal defect closure, endovascular grafts, and percutaneous pulmonic valve implantation [15]
- Evaluation for suitability of transcatheter mitral valve procedures, alone or in addition to TEE [16]

Aortic Pathology [8, 11, 3, 17, 18]

- CT, MR, or echo can be used for screening and follow-up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta in the following scenarios:
    - Evaluation of dilated aortic sinuses or ascending aorta identified by TTE (AUC 8)
    - Suspected acute aortic pathology, such as dissection (AUC 9)
    - Re-evaluation of known aortic dilation or aortic dissection with a change in clinical status or cardiac examination or when findings would alter management (AUC 8)
    - Screening first-degree relatives of individuals with a history of thoracic aortic aneurysm or dissection, or an associated high-risk mutation for thoracic aneurysm in common (AUC 7)
    - Screening second-degree relative of a patient with thoracic aortic aneurysm, when the first-degree relative has aortic dilation, aneurysm, or dissection
    - Six-month follow-up after initial finding of a dilated thoracic aorta, for assessment of rate of change (AUC 8)
    - Annual follow-up of enlarged thoracic aorta with size up to 4.4 cm
    - Biannual (twice/yr) follow-up of enlarged aortic root ≥ 4.5 cm or showing growth rate ≥ 0.5 cm/year
- Patients with Marfan syndrome may undergo annual imaging with CT, MRI or TTE, with increase to biannual (twice-yearly) when diameter ≥ 4.5 cm or when expansions is > 0.5 cm/yr (AUC 8)
- Patient with Turner syndrome should undergo initial imaging with CT, MRI, or TTE for evidence of dilatation of the ascending thoracic aorta. If imaging is normal and there are no risk factors for aortic dissection, repeat imaging should be performed every 5 - 10 years, or if otherwise indicated. If the aorta is enlarged, appropriate follow-up imaging should be done according to size, as above
- Evaluation of the aorta in the setting of a known or suspected connective tissue disease or genetic condition that predisposes to aortic aneurysm or dissection (i.e., Loeys-Dietz, Ehlers-Danlos), with re-evaluation at 6 months for rate of expansion. Complete evaluation with CMR from the cerebrovascular circulation to the pelvis is recommended with Loeys-Dietz syndrome.

CODING and STANDARDS

CPT Code: CPT Codes: 75572, 75573
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

- Cardiac computed tomography (Heart CT) images the cardiac chambers, great vessels, valves, myocardium, and pericardium to assess cardiac structure and function, particularly when echocardiography (transthoracic echocardiography and transesophageal echocardiography) cannot provide adequate information

- CT imaging can be used for assessment of:
    - Structures of the heart (e.g., chambers, valves, great vessels, masses), as in this guideline
    - Quantitative level of calcium in the walls of the coronary arteries, in the separate coronary artery calcium (CAC) scoring guideline

Abbreviations

ARVD/C	Arrhythmogenic right ventricular dysplasia/cardiomyopathy
CABG	Coronary artery bypass grafting surgery
CAD	Coronary artery disease
CCS	Coronary calcium score
CCT	Cardiac (heart) CT
CHD	Coronary heart disease
CMR	Cardiac magnetic resonance (imaging)
CT	Computed tomography
CTA	Computed tomography angiography
ECG	Electrocardiogram
EF	Ejection fraction
HF	Heart failure
LVOT	Left ventricular outflow tract
MI	Myocardial infarction
MPI	Myocardial perfusion Imaging or cardiac nuclear imaging
MR(I)	Magnetic resonance (imaging)
PA	Pulmonary artery
PCI	Percutaneous coronary intervention
PVML	Paravalvular mitral leak
RV	Right ventricle
SE	Stress echocardiogram
TAVR	Transcatheter aortic valve replacement
TMVR	Transcatheter mitral valve replacement
TR	Tricuspid regurgitation
TEE	Transesophageal echocardiography
TTE	Transthoracic echocardiography
VT	Ventricular tachycardia

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Cardio Policy
Right Heart Catheterization Only

POLICY NUMBER UM CARDIO_1460	**SUBJECT** Right Heart Catheterization Only		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 8**
DATES COMMITTEE REVIEWED 03/13/24, 06/12/24	**APPROVAL DATE** June 12, 2024	**EFFECTIVE DATE** June 28, 2024	**COMMITTEE APPROVAL DATES** 03/13/24, 06/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid, Medicare	

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GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

PURPOSE

Right heart catheterization is an invasive hemodynamic procedure used to evaluate right-sided cardiac pressures, calculate cardiac output, and pulmonary pressures. [1]

This guideline applies to patients with a stable clinical presentation, not to those with acute syndromes or acute valvular abnormalities.

In stable patients, preliminary evaluation with non-invasive cardiac testing is usually indicated prior to a recommendation for cardiac catheterization.

These guidelines **ONLY** covers procedures that include standalone right heart catheterization.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [2, 3, 4, 5, 6]

INDICATIONS FOR RIGHT CARDIAC CATHETERIZATION

Determining medical necessity

No prior heart Cath performed within the last 6 months

- Patients with known history of congestive heart failure **(AUC Score 7)**
- Patients with cardiomyopathy (EF less than 40%) with or without heart failure and or for re- evaluation due to change in clinical status or to guide therapy.

(AUC Score 7)

- Patients with known or suspected valvular heart disease **(AUC Score 8)**
- Patients with known or suspected intracardiac shunt **(AUC Score 8)**
- Patients with recent myocardial infarction in presence of LVEF less than 45% **(AUC Score 7)**
- Patients with worsening symptoms of pulmonary hypertension or is suspected to have Pulmonary Hypertension (Pulmonary Artery Systolic Pressure greater than 40 mm Hg) on echocardiogram. **(AUC Score 8)**
- Patients at least 6 months post-LVAD placement as a bridge to transplant in whom pulmonary hypertension existed (PVR greater than 2.5 Wood units) or mean PA pressure greater than 20 mmHg on RHC performed prior to LVAD implant **(AUC Score 8)**

Suspected or with known Constrictive or Effusive/Constrictive Pericarditis

After undergoing the following imaging tests: (no RIGHT heart cardiac catheterization within the last 6 months) **(AUC Score 7)**

- Transthoracic Echocardiogram
- Cardiac MRI or MRA
- Cardiac CT or CTA

CODINGS and STANDARDS

CPT Codes: 93451, 93503, 93530, 93593, 93594, 93598
NCQA Standards: UM 2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND

Heart catheterization is the passage of a thin flexible tube (catheter) into the right heart systems via veins (femoral vein, internal jugular vein, or antecubital vein), respectively, for the purposes of hemodynamic measurements, acquisition of blood samples from specific locations, and/or the injection of radiopaque medium for the purposes of visualizing vascular anatomy. Angiography is the passage of a catheter into the right side of the heart to diagnose chronic pulmonary disease or congenital heart diseases. [1]

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. [2]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. **Right Heart Failure** [7, 8, 9]
   Right heart failure is often a result of LV failure due to volume or pressure overload. Symptoms can include; chest pain, shortness of breath, palpitations, and increase in water retention causing peripheral/body edema.

   Other causes of right heart failure include:
   - Acute RVF
     - Volume overload from LHF or LVAD implant
     - Pressure overload from PE or hematological disorders (e.g., sickle cell disease, acute chest syndrome)
   - Chronic RHF
     - Pulmonary Hypertension (e.g., result from LHF)
     - Congenital Heart Disease (e.g., atrial or ventricular septal defects, Ebstein's anomaly)
     - Valvular insufficiency (e.g., pulmonary valve stenosis, tricuspid valve regurgitation)
     - Right ventricular myocardial disease (e.g., Right sided MI, amyloidosis, sarcoidosis, ARVD, cardiomyopathy)

2. **Congenital Heart Disease** [10, 11]
   Congenital heart disease is one cause of Right Ventricular Heart Failure. Congenital heart defects are malformations of the heart's valves, chambers, arteries, or veins that are present at birth. Common congenital heart defects that can lead to right ventricular heart failure include;
   - Atrial Septal Defect
   - Ebstein's Anomaly
   - I-Transposition of the great arteries
   - Pulmonary Valve Stenosis
   - Single Ventricle Defects (Hypoplastic Left Heart Syndrome, Pulmonary
   - Tetralogy of Fallot

3. **Hemodynamic parameters and pressure measurements** [1, 8]
   - Mean Right Atrial pressure
     - Normal: 1-5 mmHg
   - Mean pulmonary artery systolic and diastolic pressure
     - Normal systolic pressure: 15 to 30 mmHg
     - Normal diastolic pressure: 4 to 12 mmHg
   - Mean pulmonary artery pressure
     - mPAP Normal: 15mmHg
     - mPAP Abnormal: > 20 mmHg [12]

- Pulmonary capillary wedge pressure (PCWP)
    - PCWP Normal: 4 to 12 mmHg

NOTE: The above measured pressures can calculate cardiac output, cardiac index, pulmonary vascular resistance, systemic vascular resistance, stroke work index, right ventricular stroke work, PAPi.

- Pulmonary Vascular Resistance [12]
    - Normal upper limit: ≈2 Wood units (WU)
- Pulmonary Artery Pulsatility Index (PAPi) [13]
    - PAPi is the ratio between pulmonary artery pressure and right atrial pressure and is calculated using [(Systolic pulmonary artery pressure – diastolic pulmonary artery pressure) / right atrial pressure]
        - PAPi < 0.9: high sensitivity and specificity for right ventricular failure
        - PAPi < 1.85: high sensitivity a patient will experience right ventricular failure and require ventricular hemodynamic device support such as LVAD

4. **Constrictive Pericarditis** [14, 15]
   Constrictive Pericarditis is a condition in which granulation tissue develops in the pericardium over time resulting in the loss of the pericardial elasticity restricting ventricular filling. When ventricular filling is impeded throughout diastole the result is decreased end diastolic volume, decreased stroke volume, and decreased cardiac output.

   Cardiac catheterization may be considered to assess the hemodynamic pressures when other noninvasive imaging is inconclusive.

5. **Pulmonary Hypertension** [12, 13]
   Pulmonary hypertension is a progressive chronic disease caused by pulmonary vascular remodeling which overtime can lead to RHF and is associated with high rates of morbidity and mortality.

   Classification of PH is defined by having a mean pulmonary arterial pressure (mPAP) > 25 mmHg at rest [9]
   - mPAP ≥ 25 mmHg (pre and post capillary)
   - PCWP Precapillary ≤ 15 mmHg
   - PRV > 3 Wood Units

ACRONYMS / ABBREVIATIONS

ARVD	Arrhythmogenic right ventricular dysplasia
CCT	Cardiac computed tomography
CCTA	Coronary computed tomographic angiography

EF	Ejection fraction
LHF	Left heart failure
LVAD	Left ventricular assist device
MI	Myocardial Infarction
mPAP	Mean pulmonary arterial pressure
MRA	Magnetic resonance angiography
MRI	Magnetic resonance imaging
PA	Pulmonary artery
PAPi	Pulmonary Artery Pulsatility Index
PCWP	Pulmonary capillary wedge pressure
PE	Pulmonary Embolism
PH	Pulmonary hypertension
PVR	Pulmonary vascular resistance
RHC	Right heart catheterization
RHF	Right heart failure
RVSP	Right ventricular systolic pressure
RVF	Right ventricular failure

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Cardio Policy
Cardiac PET with CT for Attenuation

POLICY NUMBER UM CARDIO_1461	SUBJECT Cardiac PET with CT for Attenuation		DEPT/PROGRAM UM Dept	PAGE 1 OF 19
DATES COMMITTEE REVIEWED 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid, Medicare	

Table of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations, and CMS policies when applicable.

SPECIAL NOTE

A Heart PET scan for ischemic evaluation is indicated when all the criteria for MPI are met ***AND*** *there is likely to be equivocal imaging results because of BMI, large breasts or implants, mastectomy, chest wall deformity, pleural or pericardial effusion, or prior thoracic surgery or results of a prior MPI.* [1, 2] **(AUC Score 7)** [3]

Cardiac PET scanning, when used in conjunction with CT attenuation, includes evaluation of perfusion, function, viability, inflammation, anatomy, and risk stratification for cardiac-related events such as myocardial infarction and death. Maximum diagnostic accuracy of cardiac PET/CT is achieved when images are interpreted in conjunction with other relevant imaging, clinical information, and laboratory data.

CLINICAL REASONING

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. [1, 2, 3, 4, 5] .

INDICATIONS FOR HEART PET WITH CT FOR ATTENUATION [6, 7, 8]

- ***SUSPECTED CAD (When neither SE nor MPI have provided or are expected to provide optimal imaging)***
  Symptomatic patients without known CAD. No imaging stress test within the last 12 months. *The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the Diamond Forrester table in the Definitions section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to definitions) and utilized below.*
    - Less-likely anginal symptoms (AUC 4-6)
      - When a patient cannot walk a treadmill
      - When baseline EKG makes standard exercise test inaccurate (see Definitions section).
      - When a noncardiac explanation is provided for symptoms, no testing is required (AUC 8)
    - Likely Anginal Symptoms (typical angina)
      - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (AUC = 7). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
      - ≥ 50 year old (AUC 8)
- Repeat testing in a patient with new or worsening symptoms and negative result at least one year ago **AND** meets one of the criteria above
- **Asymptomatic patients without known CAD**
  - Previously unevaluated ECG evidence of possible myocardial ischemia including substantial ischemic ST segment or T wave abnormalities (see section in Background)
  - Previously unevaluated pathologic Q waves (see section in Background)
  - Unevaluated complete left bundle branch block **(AUC Score 8)** [9]

ABNORMAL CALCIUM SCORES (CAC) [6, 10, 11, 12, 13]

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months [14]
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months [14]
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior MPI done within the last 12 months

INCONCLUSIVE CAD EVALUATION AND OBSTRUCTIVE CAD REMAINS A CONCERN

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- Exercise stress ECG with low-risk Duke treadmill score (≥5), (see section in Background) but patient's current symptoms indicate increasing likelihood of disease
- Exercise stress ECG with an intermediate Duke treadmill **(AUC Score 8)** [9]
- Inconclusive/borderline coronary computed tomography angiography (CCTA) (e.g., 40 - 70% lesions) **(AUC Score 9)** [9]
- Cardiac PET stress-rest perfusion and metabolic activity study (with ^{18}F-FDG PET) is appropriate in patients with ischemic cardiomyopathy to determine myocardial viability prior to revascularization following an inconclusive SPECT [15, 6] **(AUC Score 9)** [9]
- Non-diagnostic exercise stress test with physical inability to achieve target heart rate (THR)
- An intermediate evaluation by prior stress imaging
- Coronary stenosis of unclear significance on previous coronary angiography [6] **(AUC Score 8)** [9]

FOLLOW-UP OF PATIENT'S POST CORONARY REVASCULARIZATION (PCI or CABG)

When neither SE nor MPI have provided, or are expected to provide, optimal imaging [6]

- **Asymptomatic, follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG), or percutaneous coronary intervention (PCI), (whichever is later), is appropriate only for patients with:
    - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
    - a history of silent ischemia or
    - a history of a prior left main stent

    OR

- For patients with high occupational risk (e.g.***,*** associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers***,*** and firefighters)

New, recurrent, or worsening symptoms post coronary revascularization *treated medically or by revascularization* is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. (AUC Score 8)

FOLLOW-UP OF KNOWN CAD [6]

When neither SE nor MPI have provided or are expected to provide optimal imaging

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or FFR ≤ 0.80 or significant stenosis in a major vessel (≥ 50% left main

coronary artery or ≥ 70% LAD, LCX, RCA)) over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

Unevaluated ACS

- Prior acute coronary syndrome (as documented in MD notes), without subsequent invasive or non-invasive coronary evaluation within the last 12 months
- Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has myocardial ischemia. No imaging stress test within the last 12 months
- The addition of Coronary CTA to the PETCT study may be considered for patients facing complex coronary interventions, suspected global myocardial ischemia, necessitating correlation between anatomy and perfusion [15] **(AUC Score 7)**

Heart Failure

- Newly diagnosed systolic heart failure or diastolic heart failure, *with reasonable suspicion of cardiac ischemia (prior events, risk factors*), unless invasive coronary angiography is immediately planned or adequate stress imaging has been done within the last 12 months [7, 16, 17] **(AUC Score 9)** [9]

Suboptimal Revascularization

- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (*no MPI diversion required*). [10]

Viability

- Reduced LVEF ≤ 50% requiring myocardial viability assessment to assist with decisions regarding coronary revascularization. (Diversion from PET not required when LVEF less than or equal to 40%) [16, 17, 18] **(AUC Score 9)** [9]

Ischemia and Nonobstructive Coronary Artery Disease (INOCA)

- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (no MPI diversion required).

Arrhythmias

- Ventricular arrhythmias
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not the immediately planned test [19]

- Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVC's (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed

Anti-arrhythmic Drug Therapy

- Prior Class IC antiarrhythmic drug
  - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide)
  - Annually for intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide)**)** [9]**(AUC Score 7)** [3]

Coronary Anomaly and Aneurism

- Assessment of hemodynamic significance of one of the following documented conditions: [20]
  - Anomalous coronary arteries [21]
  - Muscle bridging of coronary artery [6, 22]
- Coronary aneurysms in Kawasaki's disease [23] or due to atherosclerosis

Radiation

- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter [24]

Cardiac Sarcoidosis [25, 26, 27]
May be approved as a combination study with MPI for the evaluation and treatment of sarcoidosis. [28]

- Evaluation and therapy monitoring in patients with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR has not been performed
- Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion [27]
- Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy [27] **(AUC Score 9)** [9]
- Initial and follow-up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years

Infective Endocarditis

- In suspected infective endocarditis with moderate to high probability (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications [29, 30, 31]

Aortitis

- For diagnosis and surveillance of Aortitis, PET/CT or PET/MRI‡ hybrid imaging [32]

‡**NOTE:** If PET/MR study is requested, there is no specific CPT Code for this imaging study and a Health Plan review will be required.

PRIOR TO ELECTIVE NON-CARDIAC SURGERY

When neither SE nor MPI have provided or are expected to provide optimal imaging

- An intermediate or high-risk surgery with of one or more risk factors (see below), AND documentation of an inability to walk (or <4 METs) AND there has not been an imaging stress test within 1 year [33, 34, 35]
    - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL.
    - **Surgical Risk:**
        - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
        - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
        - **Low risk surgery**: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service [36]

POST CARDIAC TRANSPLANT

SE diversion not required [37]

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

Codings and Standards

CPT Codes: 78459, 78491, 78492, +78434, 78429, 78430, 78431, 78432, 78433, A9555, 93015, 93016, 93017, 93018, 78472
NCQA Standards: UM2
Applicable Lines of Business: Commercial, Exchange, Medicaid, Medicare

BACKGROUND [38, 39]

A PET study is a diagnostic test used to evaluate blood flow to the heart. During the test, a small amount of radioactive tracer is injected into a vein. A special camera, called a gamma camera, detects the radiation released by the tracer to produce computer images of the heart.

Combined with a medication, the test can help determine if there is adequate blood flow to the heart during activity versus at rest. The medication simulates exercise for patients unable to exercise on a treadmill or stationary cycle.

PET prefusion studies illustrate myocardial blood flow by demonstrating tracer uptake. PET metabolic evaluation studies are used to demonstrate inflammation produced by infiltrative disease such as sarcoidosis, but also enhance the detection of viable (hibernating) myocardium. Hybrid PET-CT scanning combines anatomical information with blood flow assessment and is useful for assessing viable myocardium, especially in CHF patients with global ischemia, or in patients with multivessel diffuse coronary artery disease as opposed to focal stenotic lesions.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. [1]

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

DEFINITIONS

1. Coronary application of PET includes evaluation of stable patients without known CAD, who fall into two categories [7, 8, 6]
    - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see websites for Global Cardiovascular Risk Calculators section).
    - **Symptomatic,** for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

2. The medical record should provide enough detail to establish the type of chest pain:
    a. **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine, or both.
    b. **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).

3. **Risk Factors for Coronary disease include (but not limited to)**: diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.
4. Beginning 2023, the classification terms for angina were updated within the ACC's Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to "Typical Angina", "Atypical Angina" and "Non-Anginal" symptoms, defined by the Diamond Forrester Table. We still provide this information for your reference: [10, 11, 9]

Diamond Forrester Table [40, 41]

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

- **Very Low:** < 5% pretest probability, usually not requiring stress evaluation
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High: > 90% pretest probability of CAD**

5. ECG Stress Test Alone versus Stress Testing with Imaging
Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate AND has an interpretable ECG for ischemia during exercise: [6]

- The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG [6]
- The patient who is under evaluation for exercise-induced arrhythmia
- The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
- For the evaluation of syncope or presyncope during exertion [42]

When exercise cannot be performed, pharmacologic stress can be considered.

6. Duke Exercise ECG Treadmill Score

   Calculates risk from ECG treadmill alone: [43]

   - Duke treadmill score (DTS) equation is:
     DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
   - The score ranges from - 25 to + 15 with values corresponding to low-risk (score of ≥ + 5), intermediate risk (scores ranging from - 10 to + 4), and high-risk (score of ≤ - 11) categories.

7. An uninterpretable baseline ECG includes: [7]

   - ST segment depression 1 mm or more (not for non-specific ST- T wave changes)
   - Ischemic looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
   - LVH with repolarization abnormalities, pre-excitation pattern such as WPW, ventricular paced rhythm, or left bundle branch block
   - Digitalis use with associated ST segment abnormalities

8. Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
   - > 40 ms (1 mm) wide
   - > 2 mm deep
   - > 25% of depth of QRS complex

9. Global Risk of Cardiovascular Disease
   - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. **High global risk by itself generally lacks scientific support as an indication for stress imaging.** There are rare exemptions, such as patients requiring I-C antiarrhythmic drugs who might require coronary risk stratification prior to initiation of the drug.
     - **CAD Risk—Low**
       10-year absolute coronary or cardiovascular risk less than 10%
     - **CAD Risk—Moderate**
       10-year absolute coronary or cardiovascular risk between 10% and 20%
     - **CAD Risk—High**
       10-year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* [44, 45, 46, 47, 48]

Risk Calculator	Websites for Online Calculator

Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

10. Definitions of Coronary Artery Disease [7, 8, 11]

    Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).

    - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
    - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
        - Suggested by percentage diameter stenosis ≥ 70% by angiography; intermediate lesions are 50 – 69% [6]
        - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross-sectional area on IVUS ≤ 6 square mm [7, 49]
        - FFR (fractional flow reserve) ≤ 0.80 for a major vessel [49]
        - Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
    - A major vessel would be a coronary vessel that would be amenable to revascularization if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
    - FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
    - Newer technology that estimates FFR from CCTA image is covered under the separate NIA Guideline for FFR-CT.

11. Anginal Equivalent [7, 42]

Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data, such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Most syncope per se is not an anginal equivalent.

ACRONYMS / ABBREVIATIONS

ADLs	Activities of daily living
BMI	Body mass index
CABG	Coronary artery bypass grafting
CAC	Coronary artery calcium
CAD	Coronary artery disease
CCTA	Coronary computed tomography angiography
CMR	Cardiac magnetic resonance imaging
CT(A)	Computed tomography (angiography)
DTS	Duke Treadmill Score
ECG	Electrocardiogram
FFR	Fractional flow reserve
IVUS	Intravascular ultrasound
LBBB	Left bundle-branch block
LVEF	Left ventricular ejection fraction
LVH	Left ventricular hypertrophy
MESA	Multi-Ethnic Study of Atherosclerosis
MET	Estimated metabolic equivalent of exercise
MI	Myocardial infarction
MPI	Myocardial perfusion imaging
MR(I)	Magnetic resonance (imaging)
PCI	Percutaneous coronary intervention
PET	Positron emission tomography
PFT	Pulmonary function test
PVCs	Premature ventricular contractions
SE	Stress echocardiography
TEE	Transesophageal echocardiography
THR	Target heart rate
TTE	Transthoracic echocardiography
VF	Ventricular fibrillation
VT	Ventricular tachycardia
WPW	Wolff-Parkinson-White

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Cardio Policy

Guideline Directed Medical Therapy (GDMT) – HEART FAILURE and CORONARY ARTERY DISEASE (CAD)

POLICY NUMBER UM CARDIO_1462	**SUBJECT** Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 9**
DATES COMMITTEE REVIEWED 05/08/24	**APPROVAL DATE** May 08, 2024	**EFFECTIVE DATE** May 31, 2024	**COMMITTEE APPROVAL DATES** 05/08/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. General Information

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

Heart failure with reduced ejection fraction (HFrEF) is a complex condition that can arise from multiple factors, including coronary artery disease, hypertension, myocardial infarction, valvular heart disease, and cardiomyopathies. These underlying conditions collectively impair the heart's ability to effectively pump blood, leading to a reduction in ejection fraction. Similarly, heart failure with preserved ejection fraction (HFpEF) presents with comparable symptoms but is distinguished by a left ventricular ejection fraction (LVEF) of 50% or higher.

Medical management is of utmost importance in addressing both HFrEF and HFpEF, aiming to alleviate symptoms, improve quality of life, and extend lifespan. Medications play a crucial role in reducing cardiac workload, enhancing cardiac function, and managing fluid overload. Before considering invasive procedures, the administration of medications is essential to stabilize the patient's condition, optimize cardiac function, and minimize the risks associated with such interventions.

Guideline-Directed Medical Therapy (GDMT) serves as the cornerstone of management for both heart failure and coronary artery disease (CAD). Evidence-based guidelines universally recommend GDMT for individuals diagnosed with CAD, particularly as a primary treatment for stable CAD and as a crucial component of secondary prevention following coronary revascularization procedures like percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). GDMT has been associated with a significant reduction in death rates and the risk of myocardial infarction (MI), and in some cases, its impact on mortality reduction may even surpass that of selecting a specific revascularization method. Notably, GDMT for CAD intersects with recommendations for heart failure management, emphasizing the importance of comprehensive and integrated care for individuals with these conditions.

II. Purpose

GDMT must be administered before further consideration of additional imaging and/or initial or additional procedures. This document outlines the requirements based on the current ACC and AHA recommendations.

III. Clinical Reasoning

The current ACC/AHA clinical practice guidelines have established the requirements for pharmacologic therapy considered for patients with chronic CAD and/or NYHA Class II-IV. When applicable, optimal GDMT shall focus on therapies with Class I recommendations that have demonstrated reductions in morbidity, mortality, and improvements in patient quality of life, unless specified. The beneficial effects of medications can become apparent within weeks of initiation. These drugs have additive effects and in most cases the effects are dose related. As a result, GDMT stipulates that all medications be initiated and then titrated to the maximal tolerated dose (or a target dose) as quickly as possible.

IV. Guideline Directed Medical Therapy (GDMT) for HFrEF (non-ischemic)

Documentation must be provided of <u>all</u> the following:

- **NYHA functional class (see definitions)**

- **The report of the last modality having measured the ejection fraction (EF)**
  - MUGA
  - Echocardiography
  - Left Ventriculogram
  - Nuclear stress test (SPECT)
  - Cardiac MRI
  - Cardiac CT
  - Cardiac PET

- **An up-to-date list of heart failure medications and their dosages (see definitions).** The following medications need to be addressed along with any intolerance or reason a medication cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
  - ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)
  - Beta blocker (bisoprolol, carvedilol, and metoprolol succinate
  - MRA
  - SGLT2 Inhibitor

- **Last vital signs measured while on medications**
  - Vital signs must be reasonably controlled (ie. BP <140/90mmHg, HR <100)

- **Documentation of Time since GDMT has been optimized:**
    - Patients diagnosed with non-ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT **for a period of 12 weeks** before moving forward with any additional testing or invasive/interventional procedures.

V. Guideline Directed Medical Therapy (GDMT) for HFrEF (Ischemic)

- **ISCHEMIC CARDIOMYOPATHY: In addition to the recommendations for GDMT in heart failure for non-ischemic cardiomyopathy (SEE ABOVE)**, those with suspected or known CAD should additionally document **all** of the following:

  - **The report of the last modality having demonstrated coronary disease**
    - Non-Invasive testing
    - Nuclear stress test (SPECT)
    - Stress Echocardiography
    - Coronary CTA
    - Cardiac PET scan
    - Cardiac MRI

  - Within the up-to-date list of medications and their dosages, as stated for heart failure in non-ischemic cardiomyopathy, **additional medications should document:**
    - Antiplatelet Therapy
    - Statin Therapy

  - Patients diagnosed with ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT for a period time before moving forward with any additional testing or invasive/interventional procedures.
    - The following time periods have been established post MI:
      - **Non-revascularized: 40 days**
      - **Revascularized: 12 weeks**

VI. Guideline Directed Medical Therapy (GDMT) for CAD with preserved ejection fraction

All of the following must be documented for GDMT:

- **Canadian Class for angina (see definitions) or description of ongoing symptoms despite medications**

- **The report of the last modality having demonstrated coronary disease**
  - Non-Invasive testing
  - Nuclear stress test (SPECT)
  - Stress Echocardiography
  - Coronary CTA
  - Cardiac PET scan

- Cardiac MRI

- **An up-to-date list of anti-anginal and risk modifying medications and their dosages (see definitions).** At least two of the following medications need to be addressed along with any intolerance or reason at least two medications cannot be titrated (when titration is indicated) to maximal dosing (ie… renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
  - ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)
  - Beta blocker if between 0- 3 years from MI (myocardial infarction)
  - Nitrates
  - Calcium channel blockers
  - Ranolazine

- **Last vital signs measured while on medications**
  - Vital signs must be reasonably controlled (ie. BP <140/90mmHg, HR <100)

- **Documentation of Time since GDMT has been optimized**

- **Exceptions for GDMT documentation:** The following **does not require** GDMT documentation:
  - Class I indications for revascularization inclusive of high-risk non-invasive testing, or prior invasive testing demonstrating high risk left main (LM) CAD and multivessel CAD associated with diabetes.

VII. Guideline Directed Medical Therapy (GDMT) for HFpEF

Heart Failure with preserved Ejection Fraction (HFpEF) is diagnosed clinically when the Left Ventricular Ejection Fraction (LVEF) is equal to or greater than 50%. It should be noted that HFpEF is not interchangeable with diastolic dysfunction, as the presence of diastolic dysfunction on echocardiogram lacks the specificity required for clinical diagnosis or condition. A comprehensive diagnostic evaluation is warranted to ascertain underlying etiologies that may mimic HFpEF. Following confirmation of HFpEF, therapeutic interventions should prioritize addressing comorbidities and adhering to guideline-directed medical therapy (GDMT) to optimize patient outcomes, including enhancing quality of life, reducing hospitalizations, and improving survival rates. This guideline is specifically dedicated to delineating the medical management strategies post-confirmation of HFpEF diagnosis (GDMT).

Documentation must be provided of **all** of the following:

- **NYHA functional class (see definitions)**

- **The report of the last modality having measured the Ejection Fraction**
  - MUGA
  - Echocardiography
  - Left Ventriculogram
  - Nuclear stress test (SPECT)
  - Cardiac MRI
  - Cardiac CT
  - Cardiac PET

- **Documentation that other conditions that mimic HFpEF have been considered**

- **An up-to-date list of heart failure medications and their dosages (see definitions).** The following medication needs to be addressed along with any intolerance or reason it cannot be

titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
    - SGLT2 Inhibitor

- **Last Vital signs measured while on medications**
    - Vital signs must be reasonably controlled (ie. BP <140/90mmHg)

- **Documentation of Time since GDMT has been optimized**

VIII. Background:

DEFINITIONS

- **Heart failure with reduced ejection fraction (HFrEF)** -- also known as systolic heart failure, occurs when the left ventricle of the heart is unable to pump blood efficiently. In this condition, the heart's pumping function is weakened, resulting in less blood being ejected into the body. HFrEF is characterized by a left ventricular ejection fraction (LVEF) of ≤40%. Patients with HFrEF may experience symptoms such as fatigue, shortness of breath, and fluid retention.
- **Heart failure with preserved ejection fraction (**HFpEF) occurs when the heart's main pumping chamber (left ventricle) has a normal or near-normal ejection fraction (EF). In HFpEF, the EF is ≥50%. As opposed to HFrEF, the hallmark of HFpEF is stiffening of the heart muscle, particularly in the left ventricle. This stiffness impairs the heart's ability to relax and fill with blood properly causing similar symptoms as HFrEF.
- **Guideline-Directed Medical Therapy (GDMT):** Evidence-based treatment regimens recommended by clinical practice guidelines for managing specific medical conditions. These guidelines are developed by expert panels and professional organizations to provide standardized, effective, and safe approaches to patient care. GDMT typically includes medications, lifestyle modifications, and other interventions that have demonstrated efficacy in improving patient outcomes. Evidence based pharmacologic therapies used in treatment of HFrEF have demonstrated a reduction in morbidity, mortality, and rate of hospitalization. Efficacious therapies used in HFpEF are directed towards the treatment of the underlying condition (e.g., HTN, AF) rather than on HR. Unless otherwise indicated, class 1 level of evidence will be used as the basis of the recommendations outlined in this document
- **American College of Cardiology/American Heart Association (ACC/AHA) Stages of HF:**
    1. Stage A: At high risk for HF but without structural heart disease or symptoms of HF.
    2. Stage B: Structural heart disease but without signs or symptoms of HF.
    3. Stage C: Structural heart disease with prior or current symptoms of HF.
    4. Stage D: Refractory HF requiring specialized interventions.
- **New York Heart Association (NYHA) Functional Classification:**
    1. Class I: No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.
    2. Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.
    3. Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF.
    4. Class IV: Unable to perform any physical activity without symptoms of HF, or symptoms of HF at rest.

Medications HFrEF:

Drug Class	Starting dose	Target dose
Beta-Blockers		
Bisoprolol	1.25 mg once daily	10 mg once daily
Carvedilol	3.125 mg twice daily	25 mg twice daily for weight <85 kg and 50 mg twice daily for weight ≥85 kg
Metoprolol succinate	12.5–25 mg daily	200 mg daily
ARNIs		
Sacubitril/valsartan	24/26 mg–49/51 mg twice daily	97/103 mg twice daily
ACEIs		
Captopril	6.25 mg 3× daily	50 mg 3× daily
Enalapril	2.5 mg twice daily	10–20 mg twice daily
Lisinopril	2.5–5 mg daily	20–40 mg daily
Ramipril	1.25 mg daily	10 mg daily
ARBs		
Candesartan	4–8 mg daily	32 mg daily
Losartan	25–50 mg daily	150 mg daily
Valsartan	40 mg twice daily	160 mg twice daily
Aldosterone antagonists		
Eplerenone	25 mg daily	50 mg daily
Spironolactone	12.5–25 mg daily	25–50 mg daily
SGLT2 inhibitors		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Vasodilators		
Hydralazine	25 mg 3× daily	75 mg 3× daily
Isosorbide Dinitrate	20 mg 3× daily	40 mg 3× daily
Fixed-dose combination	20 mg/37.5 mg (1 tab) 3× daily	2 tabs 3× daily

ACC = American College of Cardiology; ACEI = angiotensin-converting enzyme inhibitor; AHA = American Heart Association; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor-neprilysin inhibitor; GDMT = guideline-directed medical therapy; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; HFSA = Heart Failure Society of America; SGLT2 = sodium-glucose cotransporter-2.

Medications HFpEF

Drug Class	Starting dose	Target dose
SGLT2is		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Aldosterone antagonists		
Spironolactone	25 mg daily	50 mg daily
ARNIs		
Sacubitril/valsartan	24 mg/26 mg twice daily	97 mg/103 mg twice daily
ARBs		
Candesartan	4 mg to 8 mg daily	32 mg daily

ARB = angiotensin receptor blocker; ARNI = angiotensin receptor–neprilysin inhibitor; GDMT = guideline-directed medical therapy; HFpEF = heart failure with preserved ejection fraction; SGLT2 = sodium-glucose cotransporter-2.

- **The Canadian Cardiovascular Society (CCS)** provides a grading system for angina pectoris, which helps classify the severity of angina based on the patient's limitations during physical activity. Here are the four classes in the CCS angina grading scale:
  1. **Class I:** Patients experience angina only during strenuous or prolonged physical activity (such as walking or climbing stairs). Ordinary physical activity does not cause angina.
  2. **Class II:** Patients have slight limitation of ordinary activity. Angina occurs during vigorous physical activity, rapid walking, walking uphill, after meals, in cold or windy conditions, under emotional stress, or only during the few hours after awakening. They can still walk more than two blocks on level ground and climb more than one flight of ordinary stairs at a normal pace and in normal conditions.
  3. **Class III:** Patients experience marked limitation of ordinary physical activity. They can walk only one or two blocks on level ground and climb one flight of stairs at a normal pace and in normal conditions.
  4. **Class IV**: Patients have inability to carry on any physical activity without discomfort. Anginal symptoms may even be present at rest1.Non-Pharmacological Therapy – While not explicitly listed as a prerequisite in this guideline, it is still important to mention for the sake of completeness, other crucial facets of treatment.
- **Non-Pharmacological Therapy – While not explicitly listed as a prerequisite in this guideline, it is still important to mention for the sake of completeness, other crucial facets of treatment.**
  1. Smoking and alcohol cessation counseling.
  2. Weight management- restrict fluid intake if serum sodium is low; reduce weight if obese.
  3. Lifestyle modifications (e.g., diet, exercise program).

4. Limit dietary sodium intake (1500 mg/day for most patients with stage A and B HF; < 3g/day in patients with stage C and D HF).
5. Control diabetes mellitus (with DM- HbA1c level ≤ 6.5%) and hypertension (HTN- BP goal < 130/80 mm Hg).
6. Cardiac rehabilitation: patient evaluation and monitoring to support drug titration, monitor symptoms, improve health status, and increase exercise tolerance should continue after start of GDMT at least monthly for 3 months and every 3 months thereafter (more frequent follow up may be necessary for select patients).

IX. REFERENCES

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