

# AvMed

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

**Directions:** The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested:** (select ONE drug below)

**Nexletol™** (bempedoic acid)

**Nexlizet™** (bempedoic acid/ezetimibe)

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member AvMed #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Name/Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Authorization: 6 months**

**Section I. Diagnosis:** (select one below)

**Established Atherosclerotic Cardiovascular Disease**

Member is 18 years of age or older

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- Member has Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by at least **ONE** of the following (**submit documentation**):
  - Acute Coronary Syndrome
  - History of myocardial infarction
  - Stable or unstable angina
  - Peripheral arterial disease presumed to be of atherosclerotic origin
  - Coronary artery disease
  - Member has undergone coronary or other arterial revascularization procedure in the past (e.g., percutaneous coronary intervention (PCI), angioplasty, coronary stent procedure or coronary bypass graft (CABG) surgery)
  - History of stroke
  - History of transient ischemic attack
- Member must meet **ONE** of the following:
  - Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks (**verified by pharmacy paid claims**):
    - High intensity statin therapy with atorvastatin (generic Lipitor)  $\geq 40$  mg daily
    - High intensity statin therapy rosuvastatin (generic Crestor)  $\geq 20$  mg daily
    - Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - Low intensity statin therapy (member unable to tolerate moderate intensity therapy)
  - Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains  $\geq 70$  mg/dL
- Please provide member's LDL levels below (**submit labs with request**):
  - LDL baseline:** \_\_\_\_\_ **LDL post-treatment:** \_\_\_\_\_
- Member must meet **ONE** of the following:
  - Member has had a **90-Day** trial of a PCSK9 inhibitor (e.g., Repatha<sup>®</sup> - requires prior authorization) and failed to reach LDL target goal (**documentation of PCSK9 inhibitor failure, including LDL labs after 90 days of therapy, MUST be provided**)
  - Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (e.g., Repatha<sup>®</sup> - requires prior authorization) (**documentation of life-threatening adverse reaction MUST be provided**)

**High risk for Cardiovascular Disease (CVD) event but WITHOUT established CVD**

- Member is 18 years of age or older
- Member is at high risk for a CVD event but without established CVD confirmed by at least **ONE** of the following (**submit documentation**):
  - Reynolds risk score  $> 30$  %
  - 10-year ASCVD risk score  $\geq 20$  %
  - Coronary artery calcium score  $> 300$  Agatston units
  - Member is between 40 and 75 years of age and has a diagnosis of Type 1 or 2 diabetes

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- Member must meet **ONE** of the following:
  - Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks (**verified by pharmacy paid claims**):
    - High intensity statin therapy with atorvastatin (generic Lipitor)  $\geq 40$  mg daily
    - High intensity statin therapy rosuvastatin (generic Crestor)  $\geq 20$  mg daily
    - Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - Low intensity statin therapy (member unable to tolerate moderate intensity therapy)
  - Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains  $\geq 70$  mg/dL
- Please provide member's LDL levels below (**submit labs with request**):
  - LDL baseline:** \_\_\_\_\_ **LDL post-treatment:** \_\_\_\_\_

**Heterozygous Familial Hypercholesterolemia (HeFH)**

- Member is 18 years of age or older
- Member has heterozygous familial hypercholesterolemia (HeFH) as confirmed by the **ONE** of the following (**submit documentation**):
  - Member has an untreated low-density lipoprotein cholesterol (LDL-C)  $\geq 190$  mg/dL (prior to treatment with antihyperlipidemic therapy)
  - Member has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
  - Member has been diagnosed with heterozygous familial hypercholesterolemia by meeting **ONE** of the following diagnostic criteria thresholds:
    - Dutch Lipid Network criteria score was  $> 5$
    - Simone Broome criteria met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia
- Member must meet **ONE** of the following:
  - Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks (**verified by pharmacy paid claims**):
    - High intensity statin therapy with atorvastatin (generic Lipitor)  $\geq 40$  mg daily
    - High intensity statin therapy rosuvastatin (generic Crestor)  $\geq 20$  mg daily
    - Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - Low intensity statin therapy (member unable to tolerate moderate intensity therapy)
  - Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains  $\geq 70$  mg/dL

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- Please provide member's LDL levels below (**submit labs with request**):
  - LDL baseline:** \_\_\_\_\_ **LDL post-treatment:** \_\_\_\_\_
- Member must meet **ONE** of the following:
  - Member has had a **90-Day** trial of a PCSK9 inhibitor (e.g., Repatha® - requires prior authorization) and failed to reach LDL target goal (**documentation of PCSK9 inhibitor failure, including LDL labs after 90 days of therapy, MUST be provided**)
  - Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (e.g., Repatha® - requires prior authorization) (**documentation of life-threatening adverse reaction MUST be provided**)

**Section II. For members with contraindication or intolerance to statin therapy**

- Select below if the member is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks); Please provide previously attempted statin name, strength & therapy initiation date below:
  - Drug Name:** \_\_\_\_\_ **Strength:** \_\_\_\_\_ **Date started:** \_\_\_\_\_
  - Drug Name:** \_\_\_\_\_ **Strength:** \_\_\_\_\_ **Date started:** \_\_\_\_\_
- Member is unable to tolerate statin therapy due to the occurrence of at least **ONE** of the following symptoms (**submit documentation**):
  - Myalgia (muscle symptoms without CK elevations)
  - Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)
  - Member has experienced rhabdomyolysis or muscle symptoms with CK elevations > 10 times upper limit of normal
  - Member has a labeled contraindication to **ALL** statins as documented in medical records
- Re-initiation of statin therapy has been attempted and failed

**Reauthorization: 12 months.** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Provider must submit documentation of positive clinical response to therapy (e.g., reduction in LDL-C levels)
- Provider must document member's LDL levels below (**submit labs with request**):
  - LDL baseline:** \_\_\_\_\_ **LDL post-treatment:** \_\_\_\_\_
- Member is compliant with therapy (**verified by pharmacy paid claims**)

***\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\****  
***\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\****