Sentara Health Plans

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

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Abecma (idecabtagene vicleucel) (Q2055)

Diagnosis - Relapsed or Refractory Multiple Myeloma

NCD: Chimeric Antigen Receptor (CAR) T-cell therapy

Dosing: Single dose of 300-460 million autologous CAR-positive viable T-cells

Exclusion Criteria

- Prior CAR-T Therapy
- Prior allogeneic hematopoietic step cell transplantation (HSCT)
- Clinically active systemic infection

Authorization Criteria

- Confirmed diagnosis of relapsed or refractory multiple myeloma confirmed by one of the following:
  - Serum M-protein ≥ 1.0 g/dL
  - Urine M-protein ≥ 200 mg/24 h
  - Serum free light chain (FLC) assay: involved FLC ratio level ≥ 10 mg/dL (provided serum FLC ratio is abnormal)
- Member must have received at least two or more prior lines of therapy including the following:
  - a proteasome inhibitor (e.g., bortezomib)
  - an immunomodulatory agent (e.g., lenalidomide, thalidomide)
  - an anti-CD38 antibody (e.g., daratumumab, isatuximab)
- The disease must be refractory to the last regimen (as noted above)
- Attestation of the use of lymphodepleting chemotherapy regimen of cyclophosphamide and fludarabine prior to administration of Abecma
- Attestation of administration of acetaminophen and an H1-antihistamine prior to infusion
- Confirmation of the availability of tocilizumab prior to infusion
- Attestation that prophylactic use of dexamethasone or other systemic corticosteroids has not been used

Authorization Length

- One Time Authorization for date of service

References:

1. Abecma. Package Insert. Bristol Myers Squibb. 2021

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Actemra (tocilizumab) (J3262)

Diagnosis - Cytokine Release Syndrome (CRS)

Age: 2 years and older

Dosing:

- <30kg: 12mg/kg
- ≥30kg: 8mg/kg

Exclusion Criteria

- Prior CAR-T Therapy
- Prior allogeneic hematopoietic stem cell transplantation (HSCT)
- Clinically active systemic infection

Authorization Criteria

- Member has been approved for chimeric antigen receptor (CAR) T cell therapy

Authorization Length

- 4 doses per lifetime based on CAR-T therapy dates of service

Diagnosis - Rheumatoid Arthritis

Age: 2 years and older

Dosing: 4 mg/kg once every 4 weeks; may be increased to 8 mg/kg once every 4 weeks based on clinical response (maximum dose: 800mg/dose)

Exclusion Criteria: None

Initial Authorization Criteria

- Trial and failure of one of the following DMARD therapies:
    - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment

- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length: 12 months

Diagnosis – Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Age: 2 years and older

Dosing:

- <30kg: 10mg/kg/dose every 4 weeks
- ≥30kg: 8mg/kg/dose every 4 weeks (maximum dose: 800mg/dose)

Exclusion Criteria: None

Authorization Criteria

- Trial and failure of one of the following DMARD therapies
  - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Authorization Length: 12 months

Diagnosis - Systemic Juvenile Idiopathic Arthritis (SJIA)

Age: 2 – 17 years of age

Dosing:

- <30kg: 12mg/kg every 2 weeks
- ≥30kg: 8mg/kg/dose every 2 weeks (maximum dose: 800mg/dose)

Exclusion Criteria: None

Initial Authorization Criteria

- Member must have confirmed disease as defined by one of the following:
  - ≥5 active joint with fever for ≥2 weeks
  - ≥2 active joints with fever for ≥5 days in combination with prednisone 0.5mg/kg/day
- Fever>38°C or 100.4°F for ≥2 weeks
- Member is between 2-17 years of age
- Trial and failure of NSAIDs **and** high dose corticosteroids for ≥3 months

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References: Actemra. Package Insert. Genentech. 2022. Clinical Practice Guidelines (rheumatology.org)

Actimmune® (interferon gamma-1b) (J9216)

Diagnosis - Chronic Granulomatous Disease (CGD)

Ages: All ages

Dosing:

- BSA ≤0.5m2: 1.5 mcg/kg/dose three times weekly
- BSA >0.5m2: 50mcg/m^2 three times weekly

Exclusion Criteria

- None

Authorization Criteria

- Confirmation of disease by one of the following diagnostic results:
- Nitroblue tetrazolium test (Negative)
- Dihydrorhodamine test (DHR+ neutrophils < 95%)
- Genetic analysis or immunoblot positive for p22phox p40phox, p47phox, p67phox, or gp91phox

Authorization Length

- 12 months

Diagnosis - Severe Malignant Osteopetrosis

Dosing:

- BSA ≤0.5m2: 1.5 mcg/kg/dose three times weekly
- BSA >0.5m2: 50mcg/m^2 three times weekly

Exclusion Criteria

- None

Authorization Criteria

- Confirmation of disease by one of the following diagnostic results:
- X-ray or increased liver function tests
- Decreased RBC and WBC counts

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- Growth retardation
- Deafness/sensorineural hearing loss

Authorization Length

- 12 months

References:

1. Actimmune. Package Insert. Horizon Therapeutics. 2021

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Adakveo® (crizanlizumab-tmca) Injection (J0791/C9053)

Diagnosis - Vaso-occlusive crises (VOC)

Age: 16 years and older

Dosing: 5mg/kg IV at week 0, week 2 and every 4 weeks thereafter

Exclusion Criteria

- None

Initial Authorization Criteria

- Confirmed medical history or diagnosis of Sickle Cell Disease has been confirmed by one of the following:
  - HbSS
  - HbSC
  - HbSB0-thalassemia
  - HbSB+-thalassemia
- Member has experienced at least 2 vaso-occlusive crises (VOCs) within the preceding 12 months as determined by medical documentation with ICD codes.

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment as evidenced by a decrease in the number of vasco-occlusive crises since starting Adakveo
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References:

1. Adakeo. Package Insert. Novartis. 2021

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Adasuve (loxapine aerosol powder breath activated, inhaled) (J2062)

Diagnosis: Acute Agitation Associated with Schizophrenia or Bipolar I Disorder

Age: ≥ 18 years of age

Initial Dosing: 10mg administered by oral inhalation (only a single dose within a 24-hour period)

Exclusion Criteria:

- Current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchospasm
- Acute respiratory symptoms/signs (e.g. wheezing)
- Current use of medication to treat airways disease, such as asthma or COPD
- History of bronchospasm following ADASUVE treatment

Initial Authorization Criteria:

- Prescribed by or in consultation with a psychiatrist or mental health specialist
- Member has a diagnosis of acute agitation associated with schizophrenia or bipolar I disorder
- Member suffers from "Psychomotor agitation" as defined in DSM-V as "excessive motor activity associated with a feeling of inner tension"
- Documentation that member experiences agitation, often manifesting behaviors that interfere with their care (e.g., threatening behaviors, escalating or urgently distressing behavior, self-exhausting behavior), leading clinicians to the use of rapidly absorbed antipsychotic medications to achieve immediate control of the agitation
- Adasuve is part of the REMS Program to mitigate the risk of bronchospasm (loxapine must be administered only in an enrolled healthcare facility)

Initial Authorization Length: 12 Months

Reauthorization Length: 12 Months

Reauthorization Criteria:

- Member continues to meet criteria in the initial authorization section

References: Adasuve. Package Insert. Alexza Pharmaceuticals. 2022

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Adcetris (Brentuximab vedotin) (J9042)

No prior authorization required for oncology purposes

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Adstiladrin® (nadofaragene firadenovec-vncg) (J9029)

Diagnosis - Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors

Age: 18 years of age and older

Dosing: Four (4) 20-mL single dose vials (single dose) every 3 months

Exclusion Criteria

- None

Initial Authorization Criteria

- Member has a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors
- Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components)
- Requested medication will be used as a single agent in therapy, for intravesical instillation only

Initial Authorization Length

- 3 months (1 treatment)

Reauthorization Criteria

- Member has experienced disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Member has experienced an absence of unacceptable toxicity from the drug (e.g., disseminated adenovirus infection)

Reauthorization Length

- 6 months (2 treatments)

References:

1. Adstiladrin. Package Insert. Ferring Pharmaceuticals. 2023

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Adzynma (ADAMTS13 recombinant-krhn) (C9399, J3590)

Diagnosis – Prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

Age: 18 years of age and older

Dosing: Prophylaxis – 40 units/kg/dose every other week (may increase to weekly), On-Demand – 40IU/kg on day 1, 20 IU/kg on day 2, 15 IU/kg on day 3 and beyond until 2 days after the acute event has ended

Exclusion Criteria

- None

Initial Authorization Criteria

- Member has confirmed diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) due to inherited ADAMTS13 deficiency defined by all the following:
    - Submission of molecular genetic testing, documenting biallelic pathogenic variants in the ADAMTS13 gene located on chromosome 9q34
    - An ADAMTS13 activity of < 10 % as measured by the fluorescent resonance energy transfer-von Willebrand factor73 (FRETS-VWF73) assay (Note: Patients currently receiving prophylactic plasma infusion therapy that is clearly documented in current treatment regimen may exceed 10% ADAMTS13 activity at start of therapy)
    - Laboratory documentation confirms that anti-ADAMTS13 IgG inhibitory autoantibodies are NOT present
- **For Prophylactic Therapy Only**
    - Member has a past medical history recording the member having at least one TTP event or is currently receiving prophylactic plasma infusion therapy
- **For On-Demand Therapy Only**
    - Member is at current risk for disease exacerbation.
    - The authorization will provide a sufficient quantity in order for the patient to have a cumulative amount of medication on-hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization.

Initial Authorization Length

- 6 months (Prophylaxis)
- 3 months (On-Demand)

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Reauthorization Criteria

- Member has experienced response to treatment as determined by prescriber
- Member has not developed neutralizing antibodies to ADAMTS13
- **For Prophylactic Therapy Only**
    - Member has responded to an acute TTP event with therapy as evidenced by improvement in thrombocytopenia or in microangiopathic hemolytic anemia

Reauthorization Length

- 12 months (Prophylaxis)
- 3 months (On-Demand)

References:

1. Adzynma. Package Insert. Takeda Pharmaceuticals. 2023

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Aduhelm (aducanumab) IV (J0172)

The Health Plan follows the National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)

References:

1. Medicare Coverage Database

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Aldurazyme® (laronidate) IV Solution (J1931)

Diagnosis – Mucopolysaccharidosis I (MPS I) (Hurler syndrome, Hurler-Scheie, and Scheie forms)

Age: 6 months of age and older

Dosing: 0.58 mg/kg once weekly (dose should be rounded up to the nearest whole vial)

Exclusion Criteria

- None

Initial Authorization Criteria

- Member has a definitive diagnosis of MPS I confirmed by one of the following:
  - Detection of biallelic pathogenic mutations in the IDUA gene by molecular genetic testing
  - Fibroblast or leukocyte alpha-L-iduronidase (IDUA) enzyme activity level of less than 10% of the lower limit of the normal range of the measuring laboratory
- Member has diagnosis of one of the following:
  - Diagnosis of Hurler (severe) or Hurler-Scheie (attenuated) forms of disease
  - Diagnosis of Scheie (attenuated) form of disease with moderate to severe symptoms

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References:

1. Aldurazyme. Package Insert. BioMarin Pharmaceutical. 2023

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Aliqopa (copanlisib) IV (J999/C9399)

Diagnosis – Relapsed Follicular Lymphoma

Note: Bayer announced that, following discussions with the U.S. Food and Drug Administration (FDA), it will work with the FDA on a voluntary withdrawal of the Aliqopa® (copanlisib) U.S. New Drug Application for adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

Age: 18 years of age and older

Dosing: 60mg IV Infusions on days 1, 8, and 15 of a 28 day cycle

Exclusion Criteria

- None

Authorization Criteria

- Confirmation of diagnosis
- Member has received at least 2 prior systemic therapies

Authorization Length

- 28 day cycle

References:

1. Aliqopa. Package Insert. Bayer HealthCare Pharmaceuticals. 2023

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Alpha Proteinase Inhibitors

Aralast NP® (J0256)
Glassia™ (J0257)
Prolastin-C® (J0256)
Zemaira® (J0256)

Diagnosis – Alpha-Antitrypsin Deficiency with Emphysema

Age: 18 years of age and older

Dosing: All Alpha Proteinase Inhibitors: 60mg/kg body weight once weekly

Exclusion Criteria

- None

Initial Authorization Criteria

- Member has a diagnosis of congenital alpha-antitrypsin deficiency with emphysema
- Provider must specify the member's AAT phenotype deficiency:
- PiZ
- PiZ (null)
- Pi (null, null)
- PiMZ
- PIMS
- Member has clinical evidence of progressive panacinar emphysema
- Member has a documented rate of decline of FEV1 between 30-65%
- Serum AAT level must be submitted and be one of the following:
- <11 mmols/L
- <80 mg/dL if measured by radial immunodiffusion
- <50 mg/dL if measured by nephelometry

Initial Authorization Length

- 12 months

Re-Authorization Criteria

- Member must be compliant on medication

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- Member must have demonstrated improvement in the past 3 months
- Serum AAT level must be monitored

Re-Authorization Length

- 12 months

References:

1) Aralast NP. Package Insert. Takeda. 2023
2) Glassia. Package Insert. Takeda. 2023
3) Prolastin-C. Package Insert. Grifols Therapeutics. 2020
4) Zemaira. Package Insert. CSL Behring. 2022

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Alymsys (Bevacizumab-maly) (C9142)

No prior authorization required for oncology purposes

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Ambisome (amphotericin B liposome) (J0289)

Diagnosis:

- Cryptococcal meningitis in patients with HIV
- Febrile neutropenic patients with presumed fungal infection
- Systemic infections caused by Aspergillus sp, Candida sp, and/or Cryptococcus sp
- Visceral leishmaniasis

Age: NA

Initial Dosing: Diagnosis dependent

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an infectious disease and/or transplant specialist
- Member must have an FDA approved diagnosis
- Member has tried and failed conventional amphotericin B deoxycholate therapy OR renal impairment OR unacceptable toxicity precludes the use of the doxycholate formulation AND if applicable to the diagnosis, the member has also tried and failed fluocytosine, voriconazole, posaconazole, or caspofungin

Initial Authorization Length: 3 months

Reauthorization Dosing: Diagnosis dependent

Reauthorization Criteria:

- Provider attests that renal function is being monitored and no preclusions due to toxicity have been observed
- Documentation submitted to show that the member's condition has improved or stabilized, or that continued therapy is otherwise medically necessary and the benefits outweigh the risks

Reauthorization Length: 3 months

References: Ambisome. Package Insert. Gilead Sciences. 2020

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Amvuttra® (vutrisiran) SQ (J3490)

Diagnosis: Polyneuropathy of Hereditary Transthyretin-Mediated Amloidosis

Age: 18 years and older

Initial Dosing: 25 mg administered by subcutaneous injection once every 3 months

Required Premedication:

- Members should be premedicated with corticosteroid (e.g. dexamethasone 10mg or equivalent), acetaminophen (500mg), intravenous H1 blocker (e.g. diphenhydramine 50mg or equivalent), and intravenous H2 blocker

Exclusion Criteria:

- Hereditary Transthyretin Amyloidosis Agents are considered experimental, investigational or unproven for any other use including the following
    - History of liver transplant
    - Treatment of cardiomyopathy hATTR in absence of polyneuropathy symptoms
    - Severe renal impairment or end-stage renal disease
    - Moderate or severe hepatic impairment
    - New York Heart Association (NYHA) class III or IV heart failure
    - Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.)
    - Concurrent use of Tegsedi™ (inotersen), tafamidis, or diflunisal

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy **or** familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:
    - Documented genetic mutation of a pathogenic TTR variant
    - Confirmation of amyloid deposits on tissue biopsy
- Provider attests the member has documentation of the following:
    - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)
    - Clinical exam finding of abnormal nerve conduction study or neurological examination results
- Provider attests the member has one of the following:

  - A baseline polyneuropathy disability (PND) score ≤ IIIb
  - Has a baseline FAP Stage 1 or 2 **(stage 1=ambulatory, stage 2=ambulatory with assistance)**
- Provider attests the member has not received a liver transplant

Initial Authorization Length: 6 months

Reauthorization Dosing:

- **<100 kg:** 0.3 mg/kg every 3 weeks by intravenous infusion
- **≥100 kg**: 30mg every 3 weeks by intravenous infusion

Reauthorization Criteria:

- Member has previously received treatment with the requested medication
- Provider attests to all the following:
  - Member continues to have a polyneuropathy disability (PND) score ≤ IIIb
  - Member continues to have FAP Stage 1 or 2
  - Member has experienced a positive clinical response to the medication (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression)

Reauthorization Length: 6 months

References: Amvuttra. Package Insert. Alnylam Pharmaceuticals. 2023

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Anktiva (Nogapendekin Alfa Inbakicept) (J9030)

No prior authorization required for oncology purposes

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Aranesp (Epogen, Procrit) (J0885 [non-ESRD], Q4081 [ESRD])

No prior authorization required for oncology purposes

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Asparlas (Calaspargase Pegol-mknl) (J9118)

No prior authorization required for oncology purposes

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Aucatzyl (obecabtagene autoleucel) (J3590)

Diagnosis – Relapsed or Refractory B-cell Precursor Acute Lymphoblastic Lymphoma (ALL)

Age: 18 years of age and older

Dosing: Aucatzyl contains a total recommended dose of 410 x 10^6 CD19 CAR-positive viable T cells supplied in 3 to 5 infusion bag.

Exclusion Criteria

- NA

Initial Authorization Criteria

- Must be prescribed by or in consultation with an oncologist and the administrating healthcare facility has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member must have relapsed or refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)
- Member must not have received prior CAR-T therapy
- Member must meet one of the following criteria:
    - Member has not previously received anti-CD19 therapy (e.g., blinatumomab)
    - Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member must not have a clinically significant active systemic infection or inflammatory disorder
- Member must not have received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines or clinical practice
- Provider attests medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Bone marrow blast percentage has been assessed and the laboratory documentation has been provide to meet one of the following:

  - Bone Marrow Blast > 20%: Day 1 infusion with a dose of 10×10^6; Day 10 (±2 days) 100×10^6 Dose and 300×10^6 Dose
  - Bone Marrow Blast ≤ 20%: Day 1 infusion with a dose of 100×10^6; Day 10 (±2 days) 10×10^6 Dose and 300×10^6 Dose
- Member either have Philadelphia Chromosome (Ph)-Positive disease with prior therapy that includes a tyrosine kinase inhibitor OR have Philadelphia Chromosome (Ph)-Negative disease

Initial Authorization Length

- One treatment (dose) per lifetime

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Aucatzyl. Package Insert. Autolus. 2024

Avastin (Bevacizumab) (J9035)

- If used for Macular Degeneration, see *Macular Degeneration Drugs*
  - No prior authorization required for oncology purposes

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Bavencio (Avelumab) (J9023)

No prior authorization required for oncology purposes

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Beleodaq (belinostat) IV (J3380)

Diagnosis – Relapsed or refractory peripheral T-cell lymphoma (PTCL)

Age: 18 years of age and older

Dosing: 1,000 mg/m2 daily on days 1 to 5 every 21 days until disease progression or unacceptable toxicity

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Beleodaq. Package Insert. Cenexi Laboratories. 2023

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Benlysta® (belimumab) (J-0490)

Diagnosis – Systemic Lupus Erythematosus (SLE)

Age: 5 years of age and older

Dosing: 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter

Exclusion Criteria

- None

Initial Authorization Criteria

- Member is autoantibody positive (e.g., ANA, anti-ds-DNA, anti-SM)
- Member must have tried all the following standard therapies:
  - Corticosteroids
  - Immunosuppressive/Cytotoxic Agents

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member has an absence of intolerable side effects such as serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, or serious infusion reactions

Reauthorization Length

- 12 months

References: Benlysta. Package Insert. GSK. 2022

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Berinert® IV (C1 Esterase Inhibitor Human) (J0597)

Diagnosis – Hereditary Angioedema (HAE)

Age: All ages

Dosing (Treatment): 20 units/kg

Exclusion Criteria

- None

Initial Authorization Criteria

- Member has one of the following:
  - History of moderate to severe cutaneous or abdominal attacks (debilitating cutaneous/gastrointestinal symptoms)
  - Mild to severe airway swelling attacks of HAE (laryngeal/pharyngeal/tongue swelling)
- Confirmation the patient is avoiding the following possible Triggers for HAE attacked
  - Helicobacter pylori infections (confirmed by lab test)
  - Estrogen-containing oral contraceptive agents OR hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors
- Member must have diagnosis of HAE I, HAE II or HAE III defined below:
- HAE I
  - Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test)
  - Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
  - Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
  - Family history of HAE **OR** Normal C1Q Level
- HAE II
  - Normal to elevated C1-INH antigenic level
  - Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
  - Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
- HAE III

- Normal C1-INH antigenic level)
- Normal C4 level
- Normal C1-INH functional level
- Member has a known HAE causing C1-INH mutation **OR** family history of HAE

Initial Authorization Length: 12 Months

Reauthorization Criteria

- Significant improvement in severity and duration of attacks have been achieved and sustained
- Absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References: Berinert. Package Insert. CSL Behring. 2021

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Beqvez (fidanacogene elaparvovec-dzkt) (J3590)

Diagnosis - Moderately Severe or Severe congenital Factor IX deficiency

Age: 18 years of age and older

Dosing: The recommended dose of Beqvez is a single-dose intravenous infusion of 5 × 10^11 vector genomes per kg (vg/kg) of body weight

Exclusion Criteria

- Members with any of the following:
  - Positive test for antibodies to AAVRh74var after testing for pre-existing neutralizing antibodies
  - Factor IX (FIX) positive test (≥0.6 Bethesda Units [BU]) or a prior history for factor IX inhibitor
  - Serological HIV-1 or HIV-2 infection with CD4+ cell count <200 mm3 or viral load ≥20 copies/mL

Initial Authorization Criteria

- Medication has been prescribed by, or in consultation with, a specialist in hematology or treating a patient population with Hemophilia B
- Member does not have prior hemophilia AAV-vector based gene therapy
- Diagnosis of moderate-to-severe factor IX deficiency as defined by both of the following:
- ≤ 2% of normal circulating factor IX (must be confirmed by blood coagulation testing)
- Requiring continuous routine FIX prophylaxis (defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks) as documented in the medical records), for at least 2 months having at least 150 days of exposure prior to treatment with the requested medication, unless there is a detailed and fully documented contraindication or intolerance
- Member must have one of the following:
- Current or historical life-threatening hemorrhage
- Repeated, serious spontaneous bleeding episodes (past medical history record outlining the following: intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life-threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding)
- Currently using Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis)
- Factor IX activity will be monitored periodically (e.g. weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled

Last Updated: 03/28/25

Note: Members will continue to require exogenous Factor IX until response to Beqvez occurs

- Member will have baseline liver function assessed prior to and after therapy according to the monitoring schedule outlined in the product labeling with corticosteroids administered in response to elevations

Initial Authorization Length

- 30 days

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Beqvez. Package Insert. Pfizer. 2024

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Blenrep (Belantamab Mafodotin) (J9037)

No prior authorization required for oncology purposes

Last Updated: 03/28/25

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Blincyto (Blinatumomab) (J9039)

No prior authorization required for oncology purposes

Last Updated: 03/28/25

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Breyanzi (liscoabtagene maraleucel) IV (Q2054)

Diagnosis: B-Cell Lymphoma

Age: 18 years of age and older

Dosing (Treatment): Diagnosis dependent; One infusion only

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has NOT received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member does NOT have a clinically significant active systemic infection or inflammatory disorder
- Member has NOT received prior CAR-T therapy
- Member does NOT have primary central nervous system lymphoma
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member must meet ONE of the following criteria:
    - Member has NOT received prior anti-CD19 therapy, (e.g., tafasitamab)
    - Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- Member must meet ONE of the following diagnosis and corresponding treatment failure requirements:
    - Member has a diagnosis of diffuse large B cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma; high-grade B-cell lymphoma; primary mediastinal B-cell lymphoma (PMBCL); follicular lymphoma Grade 3B with one of the following
        - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin)
        - Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin)

and are NOT eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
    - Relapsed or refractory disease after two or more lines of systemic therapy
- Member has a diagnosis of Grade 1-2 follicular lymphoma
    - Disease is relapsed, refractory, or progressive after two (2) or more prior lines of therapy

Diagnosis: Chronic or Small Lymphocytic Lymphoma (CLL/SLL)

Age: 18 years of age and older

Dosing (Treatment): Diagnosis dependent; One infusion only

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has NOT received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member does NOT have a clinically significant active systemic infection or inflammatory disorder
- Member has NOT received prior CAR-T therapy
- Member does NOT have primary central nervous system lymphoma
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member must meet ONE of the following criteria:
    - Member has NOT received prior anti-CD19 therapy, (e.g., tafasitamab)
    - Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- Member has a diagnosis chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Requested medication will be used for relapsed or refractory disease
- Member has received at least 2 prior lines of therapy including BOTH of the following:
    - Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib)
    - B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax)

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Diagnosis: Mantle Cell Lymphoma (MCL)

Age: 18 years of age and older

Dosing (Treatment): Diagnosis dependent; One infusion only

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has NOT received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member does NOT have a clinically significant active systemic infection or inflammatory disorder
- Member has NOT received prior CAR-T therapy
- Member does NOT have primary central nervous system lymphoma
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member must meet ONE of the following criteria:
    - Member has NOT received prior anti-CD19 therapy, (e.g., tafasitamab)
    - Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- Member has a confirmed diagnosis of Mantle Cell Lymphoma, determined to be relapsed or refractory
- Requested medication will be used for relapsed or refractory disease
- Member must have received previous systemic therapy with BOTH of the following:
    - Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
    - Second systemic therapy (e.g., rituximab-based immunochemotherapy)

Initial Authorization Length

- One time only

Reauthorization Criteria

Last Updated: 03/28/25

- Reauthorization is not allowed

References: Breyanzi. Package Insert. Bristol Myers Squibb. 2024

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Brineura™ (cerliponase alfa) (J3590, C9399)

Diagnosis – Neuronal ceroid lipofuscinosis type 2

Age: 3 years of age and older

Dosing (Treatment): 300mg once every other week given by intraventricular (ICV) infusion

Exclusion Criteria

- Member does not have acute intraventricular access device-related complications (i.e. leakage, device failure, or device-related infection) or a ventriculoperitoneal shunt

Initial Authorization Criteria

- Member must have a documented diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency and Jansky-Bielschowski disease
- Diagnosis of CLN2 must have been confirmed by TPP1 deficiency or the detection of pathogenic mutations in each allele of the TPP1 gene (also known as the CLN2 gene)
- Member is symptomatic

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Member is not experiencing an FDA-labeled limitation of use or toxicity
- Provider must attest that ambulation loss has slowed from baseline

Reauthorization Length

- 12 months

References: Brineura. Package Insert. BioMarin. 2020

Last Updated: 03/28/25

Sentara Health Plans

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Briumvi™ (ublituximab) Injection (J3590, C9399)

Diagnosis – Relapsing Multiple Sclerosis

Age: 18 years of age and older

Dosing: 150mg IV infusion on day 1, followed by 450mg once 2 weeks later, then 450mg every 24 weeks beginning 24 weeks after the first dose

Exclusion Criteria

- Active hepatitis B virus infection

Initial Authorization Criteria

- Member must have one of the following confirmed forms of multiple sclerosis (MS):
  - Relapsing-remitting MS (RRMS)
  - Active Secondary-progressive MS (SPMS)
  - Clinically Isolated Syndrome (CIS)
- Member has tried and failed one previous disease modifying therapies for multiple sclerosis
- Prescriber must attest to all the following
  - Testing for quantitative serum immunoglobulins prior to initiation of therapy
  - Medication will NOT be given concurrently with live vaccines
  - Member has had at least one medically documented clinical relapse with the previous 12 months.
  - Member does not have concurrent use of other MS disease modifying agents

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects
- Member does not have concurrent use of other MS disease modifying therapies

Reauthorization Length

- 12 months

Last Updated: 03/28/25

References: Briumvi. Package Insert. TG Therapeutics. 2022

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Botox (onabotulinumtoxinA) (J0585)

Dysport

Xeomin (J0588)

MyoBloc

The Health Plan follows the below LCDs:

LCD L33458 “Chemodenervation”
LCD L34635 “Botulinum Toxin Type A & Type B”

References:

1. Medicare Coverage Database

Last Updated: 03/28/25

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Cabazitaxel (J9064)

No prior authorization required for oncology purposes

Last Updated: 03/28/25

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Carvykti (ciltacabtagene autoleucel) (J9999/C9399)

Diagnosis – Relapsed or Refractory Multiple Myeloma

Age: 18 years of age and older

Dosing: 1 dose of up to 100 million autologous CAR-positive viable T-cells (supplied as an infusion bag in a metal cassette)

Exclusion Criteria

- NA

Initial Authorization Criteria

- Must be prescribed by or in consultation with an oncologist and the administrating healthcare facility has enrolled in the Carvykti™ REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member must not have received prior CAR-T therapy
- Member must not have received prior allogeneic hematopoietic stem cell transplantation (HSCT) within 6 months of therapy
- Member must not have a clinically significant active systemic infection or inflammatory disorder
- Member must not have received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus
- (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to
- collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines or clinical practice
- Provider attests Carvykti™ will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member does not have known central nervous system involvement, including a history or presence of
- clinically relevant pathology, with myeloma
- Member does not have active or a history of plasma cell leukemia
- Member has an ECOG performance status of 0-1
- Member must have relapsed or refractory multiple myeloma and received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent

- Member must be refractory to lenolidomide

Initial Authorization Length

- One treatment (dose) per lifetime

Reauthorization Criteria

- NA

Reauthorization Length

- NA

1. References: Carvykti. Package Insert. Janssen Biotech. 2024

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Casgevy (exagamglogene autotemcel) (J3590/C9399)

Diagnosis – Sickle Cell Disease (SCD) in patients 12 years of age or older with recurrent vaso-occlusive crises (VOCs)

Age: 12 years of age and older

Dosing: 3 × 106 CD34+ cells per kg of body weight

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has a diagnosis of sickle cell disease (SCD) as confirmed by the BOTH of the following:
- Genetic panel confirming one of the following genotypes: βS/βS, βS/β0, βS/β+ (documentation required identifying biallelic HBB pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing)
- Medical chart notes detailing history of sickle cell disease (this will include documented history of crises as noted below)
- Provider must submit chart notes which contain detailed patient history and document ALL the following:
- Two or more episodes of severe vaso-occlusive crisis (VOC) events during each of the 2 years prior to consideration for treatment [severe VOC is defined as an occurrence of at least one of the following: acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions, acute chest syndrome, priapism lasting > 2 hours and requiring a visit to a medical facility, or splenic sequestration]
- Interval treatment history demonstrating inadequate control to a least hydroxyurea and ONE of the following therapies approved to prevent complications of SCD, or reduce VOCs:
    - Endari
    - Adakveo
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis) **[NOTE: Casgevy should not be used in patients with active HIV-1, HIV-2, HBV or HCV]**
- All other therapies for crises (e.g., Endari® (glutamine), Adakveo® (crizanlizumab), hydroxyurea) and anemia (e.g., Oxbryta® (voxelotor)) will be discontinued

Last Updated: 03/28/25

- Member does NOT have a history or confirmed diagnosis of Hereditary Persistence of Fetal Hemoglobin, or a fetal hemoglobin level (HbF) > 15% irrespective of concomitant treatment with HbF inducing treatments such as hydroxyurea
- Member has been screened and found negative for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus 1 &2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Member does NOT have advanced liver disease [Alanine transaminase (ALT) >3 × the upper limit of normal (ULN) or direct bilirubin value >2.5 × ULN; Baseline prothrombin time (PT) (international normalized ratio [INR]) >1.5 × ULN; History of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on liver biopsy]
- For members 12 to 16 years of age, a transcranial doppler (TCD) ultrasonography has been performed at baseline demonstrating a normal TCD velocity (time-averaged mean of the maximum velocity [TAMMV] <170 cm/sec in the middle cerebral artery (MCA) and the internal carotid artery [NOTE: members with a history of abnormal TCD (TAMMV ≥200 cm/sec) for subjects 12 to 18 excluded from service authorization]
- Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of exagamglogene autotemcel
- Females of childbearing potential and males capable of fathering a child must use effective method of contraception from start of mobilization through at least 6 months after administration of exagamglogene autotemcel
- Member is of sufficient weight to at least accept the minimum number of cells required to initiate the manufacturing process
- Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)
- Member will receive periodic life-long monitoring for hematological malignancies
- Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has NOT had prior HSCT or other gene therapy
- Member has not received other gene therapies to treat sickle cell disease [e.g., Lyfgenia® (lovotibeglogene autotemcel)]
- Provider must submit an assessment documenting a Karnofsky performance status of ≥ 80%
- Member does NOT have availability of a willing 10/10 HLA-matched sibling donor

Initial Authorization Length

- One treatment (dose) per lifetime

Reauthorization Criteria

- NA

Reauthorization Length

- NA

2. References: Casgevy. Package Insert. Vertex. 2022

Caverject (alprostadil injection) (J0270)

Diagnosis – Erectile Dysfunction

Age: NA

Dosing: Patient-specific titration required

Exclusion Criteria

- Medical problems that predispose to priapism, such as sickle cell anemia or sickle cell trait, multiple myeloma, or leukemia
- Treatment of erectile dysfunction in men with fibrotic conditions of the penis, sucha as anatomical deformation, angulation, cavernosal fibrosis, or Peyronie's disease
- Men with penile implants

Initial Authorization Criteria

- Confirmed diagnosis of erectile dysfunction due to vasculogenic, psychogenic, neurogenic, or mixed etiology
- Member has been assessed and is healthy enough for sexual activity, without any underlying, precluding cardiovascular status
- Member has been assessed and no known to have cavernosal venous leakage
- Alprostadil dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling and will not exceed > 60 mcg

Initial Authorization Length: 12 months

Reauthorization Criteria

- The member has reported at least a partial response to administration with alprostadil
- Member has not developed penile angulation or cavernosal fibrosis

Reauthorization Length: 12 months

References: Caverject. Package Insert. Pfizer. 2023

Last Updated: 03/28/25

Sentara Health Plans

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Cimzia™ Lyophilized IV (certolizumab) (J0717)

Diagnosis – Crohn's Disease

Age: 18 years of age and older

Dosing:

- **Loading**: 400mg at weeks 0, 2, 4
- **Maintenance**: 400mg every 4 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Confirmed diagnosis of Crohn's disease
- Trial and failure of budesonide or high dose (40-60mg prednisone) steroids
- Trial and failure of 1 DMARD therapy
    - Methotrexate, sulfasalazine, azathioprine, leflunomide, auranofin, hydroxychloroquine, OTHER as clinically appropriate

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length

- 12 months

Diagnosis – Psoriatic Arthritis and Rheumatoid Arthritis

Age: 18 years of age and older

Dosing:

- **Loading**: 400mg at weeks 0, 2, 4

- **Maintenance**: 200mg every 2 weeks or 400mg every 4 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Confirmed diagnosis of one of psoriatic arthritis or rheumatoid arthritis
- Trial and failure of 1 DMARD therapy
    - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length

- 12 months

Diagnosis – Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

Age: 18 years of age and older

Dosing:

- **Loading**: 400mg at weeks 0, 2, 4
- **Maintenance**: 200mg every 2 weeks or 400mg every 4 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with a Rheumatologist
- Confirmed diagnosis of one of the above
- Trial and failure of 1 NSAID (naproxen, meloxicam, ibuprofen, etc)

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length

- 12 months

Diagnosis – Chronic Plaque Psoriasis (Moderate-to-Severe)

Age: 18 years of age and older

Dosing:

- **≤ 90 kg**: 400mg at weeks 0, 2, 4 followed by 200mg every 2 weeks
- **>90 kg:** 400mg every 2 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by, or in consultation, with a dermatologist
- Confirmed diagnosis of Plaque Psoriasis
- Trial and failure of one of the following
    - UV Light therapy (NB UV-B, PUVA)
    - Oral Alternative System Therapy (acitretin, methotrexate, cyclosporine)

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length

- 12 months

References: Cimzia. Package Insert. UCB. 2022. https://rheumatology.org/clinical-practice-guidelines

Sentara Health Plans

AvMed Health
Medicare Part B Drug Policy
(April – June 2025)

Cinqair® IV (reslizumab) (J2786)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have not been established and will not be permitted. In the event a member has an active Dupixent®, Fasenra®, Xolair® and/or Nucala® authorization on file, all subsequent requests will not be approved.

Diagnosis – Asthma (Eosinophilic Phenotype)

Age: 18 years of age and older

Dosing: 3mg/kg once every 4 weeks IV over 20-50 minutes

Exclusion Criteria: NA

Initial Authorization Criteria

- Confirmed diagnosis of asthma with eosinophilic phenotype
- Attestation that member is currently using or has a contraindication or intolerance with one of the following medications:
    - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
    - One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)) Long-acting inhaled beta-2 agonist (LABA)

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy as indicated by one of the following:
    - Reduction in the frequency or severity of symptoms or exacerbations
    - Reduction in the daily maintenance oral corticosteroid dose
    - Reduction in the number of rescued medications
    - Reduction in the number of hospitalizations or emergency room visits
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length: 12 months

References: Cinqair. Package Insert. Teva. 2020

Last Updated: 03/28/25

Cinqair® IV (reslizumab) (J2786)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have not been established and will not be permitted. In the event a member has an active Dupixent®, Fasenra®, Xolair® and/or Nucala® authorization on file, all subsequent requests will not be approved.

Diagnosis – Asthma (Eosinophilic Phenotype)

Age: 18 years of age and older

Dosing: 3mg/kg once every 4 weeks IV over 20-50 minutes

Exclusion Criteria: NA

Initial Authorization Criteria

- Confirmed diagnosis of asthma with eosinophilic phenotype
- Attestation that member is currently using or has a contraindication or intolerance with one of the following medications:
    - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
    - One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)) Long-acting inhaled beta-2 agonist (LABA)

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy as indicated by one of the following:
    - Reduction in the frequency or severity of symptoms or exacerbations
    - Reduction in the daily maintenance oral corticosteroid dose
    - Reduction in the number of rescued medications
    - Reduction in the number of hospitalizations or emergency room visits
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length: 12 months

References: Cinqair. Package Insert. Teva. 2020

Continuous Glucose Monitors & Supplies

Preferred Products:

- Dexcom Systems including G6 and G7
- Freestyle Libre Systems including Libre2 and Libre3

Criteria:

- The Health Plan follows LCD L33822: Glucose Monitors

How to Request Coverage Determination:

A coverage determination is a decision made by our plan (not the pharmacy). To ask for a coverage determination, fill out the Coverage Determination Form.

Submission:

- Coverage Determination forms can be submitted to:

Express Scripts
Attn: Medicare Reviews
PO Box 66571
St. Louis, MO 63166-6571
Fax: 877-251-5896

You can also request a coverage determination through electronic PA. Click here for more information on how to submit a Medicare Coverage Determination through electronic method.

References: Medicare Coverage Database

Crysvita (burosumab-twza) Injection (J3590)

Diagnosis – X-Linked Hypophosphatemia

Age: 6 months of age and older

Dosing:

- **Pediatrics** (weight based):
  Note: Doses may be increased up to approximately 2 mg/kg (maximum 90 mg) every 2 weeks to achieve normal serum phosphorus
  - **<10 kg:** 1 mg/kg rounded to the nearest 1 mg every 2 weeks
  - **≥10 kg:** 0.8 mg/kg rounded to the nearest 10 mg up to a maximum of 90 mg every 2 weeks
- **Adults**:
  - 1 mg/kg rounded to the nearest 10 mg up to a maximum of 90 mg every 4 weeks

Exclusion Criteria

- Coadministration of oral phosphates and/or active vitamin D analogs
- Serum phosphorus levels within or above the normal range for age
- Severe renal impairment or end stage renal disease

Initial Authorization Criteria

- Must be prescribed by or in consultation with a nephrologist or endocrinologist or specialist experienced in the treatment of metabolic bone disorders
- Member must have documented diagnosis of X-linked Hypophosphatemia (XLH) confirmed by one of the following:
  1. Serum fibroblast growth factor-23 (FGF23) level > 30 pg/ml
  2. Genetic Testing: Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the member
- Member must meet one of the following criteria:
  1. Member's epiphyseal plates have **NOT** fused AND member has tried and failed or has experienced an intolerable life endangering adverse event (e.g. anaphylaxis) with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra) *OR*
     Note: Failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent
  2. Member meets **all** the following:
     - Member's epiphyseal plates have fused

  - Member is experiencing clinical signs and symptoms of the disease (e.g. limited mobility, musculoskeletal pain, or bone fractures)
  - Member has tried and failed or has experienced an intolerable life endangering adverse event (e.g. anaphylaxis) with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra) OR
    Note: Failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent
- Member's baseline fasting serum phosphorus level demonstrates current hypophosphatemia, defined as a phosphate level below the lower limit of the normal reference range for the member's age

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member continues to meet the initial criteria
- Member has experienced normalization of serum phosphate while on therapy
- Member has experienced a positive clinical response to Crysvita therapy (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain)

Reauthorization Length

- 6 months

Diagnosis – Tumor-Induced Osteomalacia

Age: 2 years of age and older

Dosing:
Note: In all patient populations, dose may be increased up to 2 mg/kg not to exceed 180mg every 2 weeks

- **Pediatrics**: 0.4 mg/kg rounded to the nearest 10 mg every 2 weeks
- **Adults:** 0.5 mg/kg every 4 weeks

Exclusion Criteria

- Coadministration of oral phosphates and/or active vitamin D analogs
- Serum phosphorus levels within or above the normal range for age
- Severe renal impairment or end stage renal disease

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Initial Authorization Criteria

- Must be prescribed by or in consultation with an oncologist, endocrinologist, or specialist experienced in the treatment of tumor-induced osteomalacia (TIO)
- Member has a diagnosis of fibroblast growth factor 23 (FGF-23)-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors (PMT) that cannot be curatively resected or localized
- Diagnosis of TIO associated with PMT has been confirmed and other causes of FGF-23 elevations, such as X-linked hypophosphatemia, autosomal dominant or recessive hypophosphatemic rickets, or Fanconi Syndrome have been ruled out
- Member has tried and failed or has experienced an intolerable life endangering adverse event (e.g. anaphylaxis) with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra) OR
  Note: Failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent
- Member's baseline fasting serum phosphorus level demonstrates current hypophosphatemia, defined as a phosphate level below the lower limit of the normal reference range for the member's age
- A baseline bone biopsy has been performed and osteoid volume/bone volume and osteoid thickness have been noted
- Crysvita will be discontinued if member undergoes additional treatment of the underlying tumor, such as radiation therapy or surgical excision; Crysvita dose will be adjusted for re-initiation according to
- phosphate levels after treatment is completed

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member continues to meet the initial criteria
- Current bone biopsy documents a decrease in osteoid volume/bone volume (OV/BV) and osteoid thickness, or maintenance of OV/BV and osteoid thickness below baseline level, since last approval of Crysvita
- Member has experienced normalization of serum phosphate while on therapy
- Member has experienced a positive clinical response to Crysvita therapy (e.g., radiographic evidence of healing of bone lesions, reduction of fractures, reduction of generalized bone pain)

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- Member is **NOT** experiencing any contraindications to therapy, including hyperphosphatemia or progression of neoplasm

Reauthorization Length

- 6 months

References: Crysvita. Package Insert. Kyowa Kirin. 2023

Dalvance (dalbavancin) (J0875)

Diagnosis – Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Age: NA

Dosing: Age and Weight based

Exclusion Criteria: NA

Initial Authorization Criteria

- Member must have a diagnosis of ABSSSI
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents one of the following:
    - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication to vancomycin
    - Staphylococcus aureus with reduced susceptibility to vancomycin [vancomycin-intermediate Staphylococcus aureus (VISA), or vancomycin-resistant Staphlyococcus aureus (VRSA)

Continuation of Therapy Following Inpatient Administration:

- Must be prescribed by or in consultation with an infectious disease specialist
- Only for administration in the Sentara/other health system infusion center (not for use in the hospital or emergency department)
- Only for patients discharged from a Sentara hospital/other qualified hospital
- Drug must be administered in the Sentara/other health system infusion center within 48 hours of discharge
- Use limited to the following:
    - Drug abuse patients
    - Physician does not want the patient to have a PICC line

Initial Authorization Length

- One Day

Reauthorization Criteria

- NA

Reauthorization Length

- NA

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References: Dalvance. Package Insert. Allergan. 2021

Darazalex (Daratumumab) (J9145)

No prior authorization required for oncology purposes

Darazalex Faspro (Daratumumab and Hyaluronidase) (J9144)

No prior authorization required for oncology purposes

Dextenza (dexamethasone intracanalicular ophthalmic insert) (J1096)

The Health Plan follows L38792 Local Coverage Determination (LCD) Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza)

References: Medicare Coverage Database

Doxorubicin Liposomal (Doxil,Lipodox) (Q2049, Q2050)

No prior authorization required for oncology purposes

Duchenne Muscular Dystrophy (DMD) Medications

Amondys 45 (casimersen) IV (J1426)
Exondys 51™ (eteplirsen) IV (J1428/C9484)
Viltepso (viltolarsen) IV (J1427)
Vyondys 53™ (golodirsen) IV (J1429)

Diagnosis – Duchenne Muscular Dystrophy (DMD)

Age: Drug dependent

- **Amondys 45/Exondys 51**: 7 years of age and older if requesting Exondys 51 or Amondys 45
- **Viltepso**: All ages
- **Vyondys 53**: 6 years of age and older

Dosing: 30mg/kg administered once weekly as a 35-60 minute IV infusion

Exclusion Criteria

- NA

Initial Authorization Criteria

- Must be prescribed by or in consultation with a specialist with expertise in the diagnosis of DMD
- Confirmed diagnosis of DMD
- Submit genetic testing confirming the mutation of the DMD gene is amenable to exon 51 skipping for Exondys 51 approval or exon 53 skipping for Vyondys 53 approval
- Member will not take the requested medication with any other RNA antisense agent (e.g., drisapersen) or any other gene therapy
- Dosing for DMD must be in accordance with the United States Food and Drug Administration (FDA) approved labeling; (see dosing above)
- Member is currently stabilized on ONE of the following and will continue to take along with the requested medication:
    - Deflazacort (Emflaza)
    - Prednisone
    - Prednisolone
- **For Exondys 51 and Vyondys 53:** The provider has documented the results of a 6 minute walk test at baseline

- Provider must submit baseline dystropin level (documentation submitted)
- Provider must submit current weight (documentation submitted)

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Documentation supports positive response to therapy (must meet all the following):
  - Increase in dystrophin level
  - Improved 6-minute walking test
  - Improvement in respiratory or muscle strength
- Member's current weight must be noted (chart notes documenting weight must be provided)

Reauthorization Length

- 6 months

References: Vyondys. Package Insert. Sarepta Therapeutics. 2021; Exondys. Package Insert. Sarepta Therapeutics. 2022; Amondys. Package Insert. Sarepta Therapeutics. 2021; Viltepso. Package Insert. NS Pharma. 2021

Durysta (bimatoprost) (J7351)

Diagnosis – Open Angle Glaucoma or Ocular Hypertension

Age: 18 years and older

Dosing: One implant per eye per lifetime

Exclusion Criteria:

- Active or suspected ocular or periocular infection
- Diagnosis of corneal endothelial cell dystrophy
- History of corneal transplantation or endothelial cell transplant
- Absent or ruptured posterior lens capsule
- Hypersensitivity to bimatoprost or to any other component of Durysta

Initial Authorization Criteria

- Medication must be prescribed by or in consultation with an ophthalmologist
- Member has a diagnosis of open angle glaucoma or ocular hypertension
- Member has an intolerance or insufficient response to at least two trials of IOP reducing eye drop agents (combination therapy should be used if warranted) from two different medication classes
    - One trial must be a prostaglandin analog
- The affected eye has not received prior treatment with Durysta (bimatoprost)

Initial Authorization Length

- One time implant only; 1 billable unit = 1 mcg; 1 implant = 10 mcg

Reauthorization Criteria

- Reauthorization is not permitted

References: Durysta. Package Insert. Allergan. 2020

Duopa (carbidopa and levodopa) Enteral Suspension (J7340)

Diagnosis – Parkinson's Disease Motor Fluctuations

Age: ≥18 years and older

Dosing: One cassette per day administered over 16 hours

Exclusion Criteria: Concomitant use with nonselective monoamine oxidase (MAO) inhibitors (i.e. phenelzine, tranylcypromine)

Initial Authorization Criteria

- Member must be using therapy via a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) or naso-jejunal tube
- Member experiences a wearing "off" phenomenon that cannot be managed by increasing the dose of oral levodopa

Initial Authorization Length

- 12 months

Reauthorization Criteria

- There is a confirmation of improvement or stabilization in clinical signs and symptoms of disease

Reauthorization Length

- 12 months

References: Duopa. Package Insert. Smiths Medical ASD. 2022

Elaprase® (idursulfase) (IV Infusion Only) (J1743)

Diagnosis – Mucopolysaccharidosis II (Hunter syndrome)

Age: 5 years of age and older

Dosing: 0.5mg/kg every 7 days (patient weight must be provided with the request)

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has absence of severe cognitive impairment
- Patient has a diagnosis of Hunter disease (also referred to as **Mucopolysaccharidosis II; MPS II)**
- Diagnosis of Hunter disease has been confirmed by **ONE** of the following:
    1. Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase;
    2. Detection of pathogenic mutations in the IDS gene by molecular genetic testing

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Absence of unacceptable toxicity from the drug. Examples of toxicity may include:
    - Severe hypersensitivity including anaphylactic and anaphylactoid reactions
    - Antibody development
    - Serious adverse reaction
    - Acute respiratory complication
    - Acute cardiorespiratory failure
- Member does not have progressive/irreversible severe cognitive impairment
- Member has demonstrated beneficial response to therapy compared to pretreatment

Reauthorization Length

- 6 months

References: Elaprase. Package Insert. Shire Human Genetic Therapies, Inc. 2021

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Elfabrio (pegunigalsidase alfa-iwxj) (IV Infusion) (J2508)

Diagnosis – Fabry's Disease

Age: 18 years of age and older

Dosing: 1mg/kg every 2 weeks

Exclusion Criteria

- Medication will NOT be used in combination with Galafold® (migalastat) or Fabrazyme® (agalsidase beta
- Member does NOT have any of the following contraindications to therapy:
  - Absence of demonstrable Fabry disease-related tissue pathology or clinical symptoms
  - Chronic kidney disease stages 3 to 5
  - History of renal dialysis
  - History of renal transplantation
  - Severe myocardial fibrosis defined as ≥ 2 late-enhancement positive ventricular segments
  - End-stage Fabry disease or other comorbidities with a life expectancy of < 1 year

Initial Authorization Criteria

- Prescribed by or in consultation with a cardiologist, nephrologist or specialist in genetics or metabolic disorders
- Member has a diagnosis of Fabry disease confirmed by at least ONE of the following:
  1. Biological males: plasma and/or leucocyte alpha galactosidase activity (by activity assay) less than lower limit of normal (submit labs; LLN in plasma = 3.2 nmol/hr/mL, LLN in leucocytes = 32 nmol/hr/mg/protein)
  2. Biological females: pathogenic variant in one of the Fabry disease GLA genes (submit documentation)
- Member has at least ONE of the following symptoms or physical findings attributable to Fabry disease (chart notes must be submitted for documentation):
  1. Burning pain in the extremities (acroparesthesias)
  2. Cutaneous vascular lesions (angiokeratomas)
  3. Corneal verticillata (whorls)
  4. Decreased sweating (anhidrosis or hypohidrosis)
  5. Personal history of exercise, heat, or cold intolerance
  6. Personal or family history of kidney failure
- Member's baseline urinary globotriaosylceramide (GL-3) concentration is > 1.5 times the upper limit of normal (submit labs)
- Provider has submitted member's current plasma globotriaosylsphingosine (lyso-Gb-3) level

Initial Authorization Length

- 6 months

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Reauthorization Criteria

- Absence of unacceptable toxicity from the drug. Examples of toxicity may include:
- Member has experienced a positive clinical response to treatment as defined by a reduction or stabilization in at least ONE of the following as compared to pre-treatment baseline (check all that apply; submit labs)
    - Plasma or urinary globotriaosylceramide (GL-3)
    - Plasma globotriaosylsphingosine (lyso-Gb3)
    - GL-3 inclusions per kidney biopsy

Reauthorization Length

- 12 months

References: Elfabrio. Package Insert. Chiesi Pharmaceuticals. 2024

Elrexflo (Elranatamab-bcmm) (J9999, C9165)

No prior authorization required for oncology purposes

Elzonris (tagraxofusp-erzs) IV (J9269)

Diagnosis – Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

Age: NA

Dosing: Age/weight based dosing

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Member has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1
- Medication will be used as monotherapy
- At initial therapy, member has a baseline serum albumin of 3.2 g/dL or higher

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

Reauthorization Length

- 12 months

References: Elzonris. Package Insert. Stemline Therapeutics. 2022

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Empliciti (Elotuzumab) (J9176)

No prior authorization required for oncology purposes

Enhertu (Fam-trastuzumab deruxtecan-nxki) (J9358)

No prior authorization required for oncology purposes

Entyvio® (vedolizumab) IV (J3380)

Diagnosis – Crohn's Disease or Ulcerative Colitis

Age: 18 years of age and older

Dosing:

- **Loading**: 300mg at weeks 0, 2, and 6
- **Maintenance**: Every 8 weeks (discontinue if no benefit by week 14)

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with a Gastroenterologist
- Confirmed diagnosis of one of the above diagnoses
- Trial and failure of one of the following:
  - Budesonide 9mg
  - High dose steroids (40-60mg prednisone)
- Trial and failure of 1 DMARD therapy
  - Methotrexate, sulfasalazine, azathioprine, 6-mercaptopurine

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member demonstrates a positive clinical response to therapy
- Member has not developed any contraindications to other significant adverse effects

Reauthorization Length

- 12 months

References: Entyvio. Package Insert. Takeda. 2023

Evenity® (romosozumab) Injection (J3111)

Diagnosis – Postmenopausal Osteoporosis

Age: 18 years of age and older

Dosing: Two (2) consecutive injections (105mg each) for a total dose of 210mg once monthly (12 visits MAX)

Exclusion Criteria

- Hypocalcemia

Initial Authorization Criteria

- Member must have tried and failed, or is intolerant, to other available osteoporosis therapies (i.e. denosumab, teriparatide, zoledronate)
- **Diagnostic Criteria:**
  - Confirmation the member has a diagnosis of high-risk fracture through one of the following:
    - Presence of fragility fractures (hip or spine) in the absence of other metabolic bone disorders
    - T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip
    - T-score between -1 and -2.5 and increased risk using FRAX country-specific thresholds
    - T-score between -1 and -2.5 with a fragility fracture of the proximal humerus, pelvis, or possibly distal forearm
  - **One of the below criteria must be met:**
    - Member is postmenopausal
    - Prescriber has attested that the requested agent is medically appropriate for the member's gender
  - **One of the below criteria must be met**:
    - BMD T-score ≤ -2.5 based on BMD measurements from one of the following:
      - Lumbar Spine (at least two vertebral bodies)
      - Hip (femoral neck, total hip)
      - Radius (one-third radius site)
    - History of one of the following resulting from minimal trauma within the past 5 years
      - Vertebral compression fracture
      - Fracture of the hip
      - Fracture of the distal radius
      - Fracture of the pelvis

- Fracture of the proximal humerus
- Both of the following:
  - BMD T-score between -1 and -2.5 as noted from the above sites
  - FRAX 10-year fracture probability of major osteoporotic fracture ≥20% OR hip fracture ≥3%

- **Safety Criteria**
  - The patient does not have any FDA-labeled contraindications to the requested agent
  - Presence of a thrombotic event (e.g., DVT, PE)
  - Dose would not exceed FDA-approved dosing of two consecutive subcutaneous injections (105 mg each) for a total dose of 210 mg once monthly.
  - Individual will not use Evenity (romosozumab-aqqg) in combination with any of the following:
    - Prolia® (denosumab)
    - Bisphosphonates
    - Evista® (raloxifene)
    - Miacalcin®/ Fortical® (calcitonin nasal spray)
    - Reclast® (zoledronic acid
    - Forteo® (teriparatide)
    - Tymlos® (abaloparatide)
  - The total duration of treatment with Evenity (romosozumab-aqqg) has not exceeded 12 months in lifetime
- Within the last year no documentation of heart attack, stroke, or other major cardiovascular event

Initial Authorization Length

- Lifetime

Definitions of Bone Denisty	
Normal	T-score ≥ -1.0
Low Bone mass (Osteopenia)	T-score between -1.0 and -2.5
Osteoperosis	T-score ≤ -2.5

References: Evenity. Package Insert. Amgen. 2020

Epkinly (Epcoritamab-bysp) (J9321)

No prior authorization required for oncology purposes

Epoetin Alfa (Epogen, Procrit) (J0885 [non-ESRD], Q4081 [ESRD])

No prior authorization required for oncology purposes

Erbitux (Cetuximab) (J9055)

No prior authorization required for oncology purposes

Erwinase (Asparaginase Erwinia Chrysanthemi) (J9019)

No prior authorization required for oncology purposes

Fetroja (cefiderocol) (J0699)

Diagnosis – Hospital-Associated Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia

Age: 18 years of age and older

Dosing: Based on CrCl

Exclusion Criteria: NA

Initial Authorization Criteria:

- Lab cultures from current hospital admission or office visit have been collected in the last (7) days and show sensitivity to Fetroja
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents HAP/VAP is caused by susceptible strains of these aerobic gram-negative bacilli: A. baumannii complex, E. coli, E. cloacae complex, K. pneumoniae, P. aeruginosa, and S. marcescens.

Continuation of Therapy Following Inpatient Administration:

- Member has been on Fetroja >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Fetroja

Initial Authorization Length: 14 Days

References: Fetroja. Package Insert. Shionogi & Co. 2021

Fabrazyme® (agalsidase beta) IV Infusion (J0180)

Exclusion Criteria: *Well characterized benign GLS polymorphisms; absence of demonstrable Fabry disease-related tissue pathology or clinical symptoms; development of ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV); current hemodialysis therapy; history of renal transplantation; persistent life-threatening or severe infusion reactions that do not respond to prophylaxis (e.g., anaphylaxis); end-stage Fabry disease or other comorbidities with a life expectancy of <1 year.*

Diagnosis – Fabry Disease (AKA Anderson-Fabry Disease)

Age: 2 years of age and older

Dosing: 1mg/kg infused every 2 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with a specialist in genetics, specialist in metabolic disorders, cardiologist, or nephrologist
- Member must have a confirmed diagnosis by one of the following:
    - **For males:** α-GAL A enzyme activity <1.5nmol/mL in plasma or <4nmol/hr/mL in isolated leukocytes AND documentation of disease-causing mutation in GLA gene located on Xq22.1
    - **For females:** documentation of disease-causing mutation in GLA gene located on Xq22.1 (lab must be submitted) AND documentation of clinically significant organ involvement (i.e., symptomatic cardiac disease, renal impairment, TIA or stroke history) must be submitted; symptoms must not be attributable to any other causes
- Member must be taking appropriate prophylaxis/treatment medications for the following:
    - **Renal:** Current pharmacy claims for ACE inhibitor or angiotensin receptor blocker (ARB) therapy must be noted for members with proteinuria
    - **Neurological:** Members with history of TIA or thrombotic stroke must have current pharmacy claims for antiplatelet therapy (i.e. clopidogrel, aspirin, prasugrel; etc.)
    - **Cardiac:** Pharmacy claims for ACE-I, calcium channel blocker, ARB, or antiplatelet therapy must be noted if member has documented valvular insufficiency, shortened PR interval, diastolic dysfunction, resting bradycardia or <EF
        - Current pharmacy claims for statin or other hyperlipidemia therapy must be noted for treatment of elevated lipids

  - **Pulmonary:** Pharmacy claims for bronchodilator therapy must be noted for members with pulmonary symptoms
- **Acroparathesia Monitoring:** Pharmacy claims for gabapentin, carbamazepine, topiramate, oxcarbazepine, phenytoin or other anticonvulsant therapy must be noted for acroparesthesia treatment

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Prescribed by or in consultation with a specialist in genetics, specialist in metabolic disorders, cardiologist, or nephrologist
- Review current plasma globotriaosylceramide (GL-3) level for a decrease from baseline level
- Review current plasma or urinary sediment lyso-Gb3 level for a decrease from baseline level
- Current IgG anti-agalsidase antibody titer must be submitted
- Chart notes and labs for all criteria listed must be submitted to document clinical improvement or stabilization in member's renal, cardiac, cerebrovascular, pulmonary function and pain levels from baseline
- Member must be taking appropriate prophylaxis/treatment medications for member's renal, cardiac, cerebrovascular, pulmonary function and pain levels if applicable from baseline

Reauthorization Length

- 6 months

References: Fabrazyme. Package Insert. Genzyme. 2023

Fasenra (benralizumab) (J0517)

Diagnosis - Asthma

Age: 6 years of age and older

Dosing: Age and weight dosing

Exclusion Criteria:

- Not for treatment of other eosinophilic conditions
- Not for relief of acute bronchospasm or status asthmaticus

Initial Authorization Criteria

- Prescribed by, or in consultation, with an allergist, immunologist, or pulmonologist
- Must have a peripheral blood eosinophil count ≥150 cells per microliter within the previous 6 weeks **Note**: Results must have been in the previous 6 weeks and prior to any treatment with an biologic indicated for asthma
- Must meet **both** the following criteria:
    1. Member has received combination therapy with an inhaled corticosteroid with an inhaled LABA, inhaled LAMA, oral leukotriene receptor antagonist, or oral theophylline
    2. Member's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by one of the following:
        - Member experienced one or more asthma exacerbation requiring treatment with systemic corticosteroids in the previous year
        - Member experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year
        - Member has a FEV1 less than 80% predicted (90% for adolescents)
        - Member has an FEV1/FVC less than 0.80 (0.90 for adolescents)
        - Member's asthma worsens upon tapering of oral corticosteroid therapy
- Member must not be using the medication concomitantly with other biologics indicated for asthma (i.e. Cinqair, Dupixent, Nucala, Tezspire, Xolair, etc)

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member has responded to therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy
- Member must still be receiving therapy with an inhaled corticosteroid concomitantly

Reauthorization Length

- 12 months

Diagnosis – Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Age: 18 years of age and older

Dosing: 30 mg every 4 weeks for the first 3 doses followed by once every 8 weeks thereafter

Exclusion Criteria: NA

Initial Authorization Criteria

- Prescribed by, or in consultation, with an allergist, immunologist, rheumatologist, or pulmonologist
- Must have a peripheral blood eosinophil count ≥150 cells per microliter within the previous 6 weeks
  Note: Results must have been in the previous 6 weeks and prior to any treatment with an anti-IL 5 medication
- Must have active, non-severe disease

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member has responded to therapy as determined by the prescribing physician

Reauthorization Length

- 12 months

Firazyr® (icatibant or sajazir) (J1744)

Diagnosis - Hereditary Angioedema (HAE)

Age: 18 years of age and older

Dosing: 1mg/kg infused every 2 weeks

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by, or in consultation, with an allergist, immunologist, or pulmonologist
- Member has a history of one of the following:
    1. Moderate to severe cutaneous or abdominal attacks
    2. Mild to severe airway swelling attacks of HAE (i.e. debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)
    3. Attestation the member is avoiding triggers for HAE attacks (i.e. estrogen-containing oral contraceptive agents OR hormone replacement therapy, antihypertensive agents containing ACE inhibitors, etc)

Member must have ONE of the following classes of HAE

HAE I

- Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test)
- Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
- One of the following:
    - Member has a family history of HAE
    - Normal C1q level

HAE II

- Normal to elevated C1-INH antigenic level
- Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)

HAE III

- Normal C1-INH antigenic level)
- Normal C4 level
- Normal C1-INH functional level
- One of the following:
    - Member has a known HAE causing C1-INH mutation (i.e., mutation of coagulation factor XII gene)
    - Member has a family history of HAE

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Significant improvement in severity and duration of attacks have been achieved and sustained
- Absence of unacceptable toxicity from the drug. (examples of unacceptable toxicity include hypersensitivity reactions)

Reauthorization Length

- 12 months

Fuzeon (enfuvirtide) (J1324)

Diagnosis – HIV-1 Infection

Age: ≥6 years of age

Dosing: Age and Weight based

Exclusion Criteria: NA

Initial Authorization Criteria:

- Failure of ≥ 12 weeks of antiretroviral therapy which includes 2 nucleoside analogue reverse transcriptase inhibitors and 1 drug from one of the following classes: an integrase strand transfer inhibitor, a nonnucleoside analogue reverse transcriptase inhibitor, or a boosted protease inhibitor
- Laboratory documentation provided showing current (within the past 30 days) HIV ribonucleic acid viral load ≥ 200 copies/mL
- Enfuvirtide will be concurrently used with additional antiretroviral agents to which the member is susceptible [at least two additional active antiretroviral agents]
- Dose does not exceed 180 mg per day [90 mg subcutaneous twice daily]

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Currently receiving medication (documentation supports that member is currently receiving Enfuvirtide for HIV-1 infection and has received this medication for at least 30 days)
- Member is responding positively to therapy
- Dose does not exceed 180 mg per day [90 mg subcutaneous twice daily]

Reauthorization Length

- 12 months

References: Fuzeon. Package Insert. Genetech. 2019

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Gamifant® (empalumab-lzsg) (J9210)

Diagnosis - Primary (familial) hemophagocytic lymphohistocytosis (HLH)

Age: 18 years of age and older

Dosing: 1 mg/kg as an intravenous infusion over 1 hour twice per week

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescriber must be one of the following or in consultation a hematologist, oncologist, or specialist in HLH
- Member must have a diagnosis of primary (familial) HLFL as confirmed by an FDA-approved genetic test
- Member meets five of the following criteria:
    - Persistent fever >101.3°F
    - Splenomegaly
    - Cytopenia defined by at least 2 of the following:
        i. Hemoglobin <9 g/dL (or <10 g/dL in infants)
        ii. Platelets <100 x 10^9/L
        iii. Neutrophils <1 x 10^9/L
    - Hypertriglyceridemia (fasting triglycerides ≥265 mg/dL) and/or hypofibrinogenemia (fibrinogen ≤1.5 g.L)
    - Hemophagocytosis in the bone marrow, spleen, or lymph nodes with no evidence of malignancy
    - Ferritin ≥500 mcg/L
    - High plasma concentration of soluble CD25 with level ≥2400 U/mL
- Prescriber has attached chart notes documenting member's intolerance to conventional therapy with etoposide, methotrexate, anti-thympocyte globulin, or cyclosporine
- Member has NOT previously had a stem cell transplant
- Member is a candidate for stem cell transplant and emapalumab is being used as part of induction therapy or maintenance phase of stem cell transplant, which will be discontinued at initiation phase of

stem cell transplant.
Note: Provider must provide the date of the stem cell transplant

- Medication will NOT be used for the treatment of secondary or acquired HLH

Initial Authorization Length

- 3 months or until initiation phase of stem cell transplantation

Reauthorization Criteria

- Member does not have evidence of unacceptable toxicity and has documentation of improvement in at least 3 clinical markers (i.e. platelet count, neutrophil count, ferritin, fibrinogen, etc)
- Member continues to require treatment with emapalumab as part of induction/maintenance phase of stem cell transplant; emapalumab will be discontinued at initiation phase of stem cell transplant.
  Note: Provider must provide the date of the stem cell transplant

Reauthorization Length

- 3 months

References: Gamafant. Package Insert. Patheon Italia. 2022

Givlaari™ (givosiran) (J0223)

Diagnosis - Acute Hepatic Porphyria (ICD-10 E80.21 or E80.29)

Age: 18 years of age and older

Dosing: 2.5 mg/kg once monthly by subcutaneous injection

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescriber must be one of the following or in consultation with a hepatologist, hematologist, oncologist, or specialist in treatment of acute hepatic porphyria
- Member has a clinical diagnosis of acute hepatic porphyria associated with one of the following:
  Note: A diagnosis of non-acute/chronic cutaneous porphyria is excluded from coverage
    - Acute intermittent porphyria (AIP)
    - Variegate Porphyria (VP)
    - Hereditary coproporphyria (HCP)
    - ALA dehydratase deficient porphyria (ADP)
    - Other ***(must send literature to support safety and efficacy for off-label diagnosis/dosing)***
- Diagnosis of AIP, HCP, VP, or ADP above is based on the member having at least ONE of the following clinical features (please note all symptoms present):
    - Gastrointestinal: abdominal pain, vomiting, constipation, diarrhea
    - Neurologic: pain extremities (back), Paresis, mental symptoms, respiratory paralysis
    - Cardiovascular: Tachycardia, systemic arterial hypertension
- Member has had elevated urinary or plasma PBG (porphobilinogen) and ALA (delta-aminolevulinic acid) levels within the previous year (please submit recent levels of ALA OR PBG)
- Member has a history of at least two documented porphyria attacks within the past 6 months
- Member must have one of the following:
    - Requirement of hospitalization (ICD E80.21 OR E80.29) that included IV hemin (J1640)
    - Urgent healthcare visit (ICD E80.21 OR E80.29) that included IV hemin (J1640)
    - Treatment with IV hemin monthly at home within the last 6 months from date of the request
    - Treatment with IV hemin due to severe CNS involvement including one of the following

symptoms associated with porphyria attack: Hallucination or Seizures

- Member will avoid concomitant use with CYP1A2 or CYP2D6 substrates (pharmacy claims will be verified), for which minimal concentration changes may lead to serious or life-threatening toxicities (e.g., clozapine, amitriptyline, theophylline, verapamil, clomipramine, clonidine, etc.)
- Member will avoid known triggers of porphyria attacks (i.e., alcohol, smoking, exogenous hormones, hypocaloric diet/fasting, certain medications such as barbiturates, hydantoins, sulfa-antibiotics, anti-epileptics, etc.)
- Members currently receiving prophylactic intravenous hemin (J1640) therapy will discontinue hemin within 3 to 6 months of initiation with givosiran
- Member has not received or is awaiting liver transplant

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member has absence of unacceptable toxicity from the drug (i.e anaphylactic reactions, severe hepatic toxicity, severe renal toxicity, severe injection site reactions, etc.)
- Member has had positive clinical response to givosiran as evidenced by a decrease in the frequency of acute porphyria attacks, and/or hospitalizations/urgent care visits, and/or a decreased requirement of hemin intravenous infusions (ICD E80.21 OR E80.29 at ER visits will be verified with last approval)
- Member has a reduction of or normalization of biochemical markers (i.e., ALA, PBG) compared to baseline (submit current lab results for documentation)
- Member will not use givosiran in combination with prophylactic intravenous hemin therapy
- Member has not received a liver transplant

Reauthorization Length

- 6 months

References: Givlaari. Package Insert. Alnylam Pharmaceuticals. 2023

Halaven (Eribulin) (J9179)

No prior authorization required for oncology purposes

Hemgenix (etranacogene dezaparvovec-drlb) (J411)

Diagnosis - Moderately Severe or Severe congenital Factor IX deficiency

Age: 18 years of age and older

Dosing: 1 infusion per lifetime: The dose of Hemgenix is 2 x 10^13 genome copies (gc) per kilogram (kg) of body weight (or 2 mL/kg body weight) administered as an intravenous infusion

Exclusion Criteria

- NA

Initial Authorization Criteria

- Medication has been prescribed by, or in consultation with, a specialist in hematology or treating a patient population with Hemophilia B
- Member does not have any of the following:
- Prior hemophilia AAV-vector based gene therapy
- Negative test for Factor IX inhibitor titers
- Diagnosis of Factor IX deficiency as defined by both of the following:
    - ≤ 2% of normal circulating factor IX (must be confirmed by blood coagulation testing)
    - Requiring continuous routine FIX prophylaxis (defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks) as documented in the medical records), unless there is a detailed and fully documented contraindication or intolerance
- Condition must satisfy one of the following:
    - Current or historical life-threatening hemorrhage
    - Repeated, serious spontaneous bleeding episodes (past medical history record outlining the following: intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life-threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding)
    - Currently using Factor IX prophylaxis therapy
- Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled.
- Member will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from etranacogene dezaparvovec treatment

- Member must have a baseline anti-AAV5 antibody titer of ≤ 1:678 measured by ELISA
- Member will have baseline liver function assessed prior to and after therapy, weekly, for at least 3 months
- Member has been screened for active infection with hepatitis B virus (HBV) or hepatitis C virus (HCV)
- Member has been screened for human immunodeficiency virus (HIV), and if positive, must be therapeutically managed with anti-viral therapy

Initial Authorization Length

- 30 days

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Hemgenix. Package Insert. CSL Behring. 2022

Hemophilia Factors

Listed below are the following HCPCS codes covered by The Health Plan.

HCPCS CODE	Description
J7180	Corifact: Factor XIII (antihemophilic factor, human)
J7182	Novoeight: Factor VIII, antihemophilic factor, recombinant
J7183	Wilate: Injection, Von Willebrand factor complex
J7185	Xyntha: Injection, factor VIII (antihemophilic factor, recombinant) per IU
J7186	Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII I.U. Alphanate®
J7187	Injection, Von Willebrand factor complex (Humate-P), per IU, VWF:RCO
J7188	Obizur (antihemophilic Factor VIII (Recombinant), Porcine Sequence
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 microgram
J7190	Factor VIII (antihemophilic factor [human]) per IU Alphanate®, Koate-DVI®, Monoclate-P®, Hemofil M®
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified Helixate FS®, Recombinate®, Refacto®, Kogenate FS®, Advate®
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU AlphaNine SD®, Mononine®
J7194	Factor IX, complex, per IU Proplex T®, Bebulin VH®, Profilnine SD®
J7195	Factor IX (antihemophilic factor, recombinant) per IU BeneFIX®
J7198	Factor VIII (Autoplex T, Feiba VH)
J7199	Hemophilia clotting factor, not otherwise classified
J7200	Rixubis® (factor IX, antihemophilic factor, recombinant)
J7201	Alprolix® (factor IX, Fc fusion protein, recombinant)
J7202	Idelvion® (factor IX, albumin fusion protein, recombinant)
J7203	Rebinyn® (factor IX, glycopegylated antihemophilic factor, recombinant)
J7204	Espercot® (factor VIII, glycopegylated-exei antihemophilic factor, recombinant)
J7205	Eloctate® (factor VIII, Fc fusion protein, recombinant)
J7207	Adynovate® (factor VIII, pegylated antihemophilic factor, recombinant)
J7208	Jivi® (factor VIII, pegylated-aucl antihemophilic factor, recombinant)
J7209	Nuwiq® (factor VIII, antihemophilic factor, recombinant)
J7210	Afstyla® (factor VIII, antihemophilic factor, recombinant)
J7211	Kovaltry® (factor VIII, antihemophilic factor, recombinant)
J7212	Sevenfact® (factor VIIa, antihemophilic factor, recombinant)

Request Must Be For One Of the Following:

- **Hemophilia A – Factor VIII Disease**

- **Hemophila B – Factor IX Disease**
- **Von Willebrand Disease**

Hyaluronate Acids

Euflexxa (J7323)
Synvisc/Synvisc-One (J7325)
Durolane (J7318)
Gel-One (J7326)
Gel-Syn (J7328)
Genvisc 850 (J7320/Q9980)
Hyalgan (J7321)
Hymovis (J7322/C9471)
Orthovisc (J7324)
Monovisc (J7327)
Supartz/FX (J7321)
SynoJoynt (J7331)
Triluron (J7332)
Trivisc (J7329)
Visco-3 (J7321)

1. Step Therapy Required. Please see Part B Step Therapy Document: Step Therapy Requirements for Sentara Medicare Outpatient (Part B) Medications (sitecorecontenthub.cloud)
    - Member must have tried one of the preferred products prior to approval of a non-preferred product
2. In addition the step therapy requirements, The Health Plan follows LCD L39260 "Hyaluronic Acid Injections for Knee Osteoarthritis"

References: Medicare Coverage Database

Hympavzi (marstacimab-hncq) (J3590)

Diagnosis – Hemophilia A or B

Age: 12 years of age and older

Dosing:

- 150 mg/mL in a single-dose prefilled syringe/pen once weekly

Exclusion Criteria

- Concomitant use with Hemlibra (emicizumab-kxwh) in those with hemophilia A as prophylactic therapy or other clotting factor replacement products

Initial Authorization Criteria

- **Hemophilia A:**
  - Member must meet the following conditions (documentation required):
    - Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing
    - A level of severe hemophilia A is documented by a factor VIII activity level <1 IU/dL (in the absence of exogenous factor VIII)
    - Member has been tested and found negative for active factor VIII inhibitors (i.e. results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) has been performed within the past 30 days and submitted) and member is not receiving a bypassing agent (e.g., Feiba, Sevenfact)
    - Member has not received prior gene therapy for hemophilia A.
    - Member meets one of the following:
      - Member has a history of life-threatening hemorrhage requiring on-demand use of Factor VIII therapy
      - Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor VIII therapy was required for these serious spontaneous bleeding episodes.
- **Hemophilia B:**
  - Member must meet the following conditions (documentation required):
    - Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing

  - A level of moderately severe to severe hemophilia B is documented by a factor IX activity less than or equal to 2 IU/dL (in the absence of exogenous factor IX)
  - Member has been tested and found negative for active factor IX inhibitors (i.e. results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) has been performed within the past 30 days and submitted) and member is not receiving a bypassing agent (e.g., Feiba, Sevenfact)
  - Member has not received prior gene therapy for hemophilia B.
  - Member meets one of the following:
    - Member has a history of life-threatening hemorrhage requiring on-demand use of Factor IX therapy
    - Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes.
- **For all diagnosis**:
  - Provider attests the member will be initiated on the requested medication at 150mg once weekly AND weighs greater than or equal to 35kg.
  - Member must have baseline negative pregnancy test prior to initiation of therapy if natal female of reproductive potential.

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced an absence of unacceptable toxicity from the drug
- Member has experienced disease response as indicated by improvement in member's symptoms as noted by the provider.
- If titration to 300mg once weekly dosing is medically necessary, all the following must be met (documentation required):
  - Member must be greater than or equal to 50kg
  - Control of bleeding events has been inadequate (defined as quantitative assessment of two or more bleeding events while on maintenance therapy at the lower dose of 150mg in the past six months)
  - Member has been fully adherent to maintenance therapy for at least six months at the lower dose

Reauthorization Length: 12 months

Ilaris (canakinumab) (J0638)

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

Diagnosis - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

Age: ≥2 years of age and older

Dosing based on weight:

- **40 kg**: Starting dosage is 150 mg subcutaneously every 4 weeks. The dosage can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
- **≤ 40 kg:** Starting dosage is 2 mg/kg subcutaneously every 4 weeks. The dosage can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.4mg/kg up to 300mg every 4 weeks

Exclusion Criteria

- Patient is not on concurrent treatment with a TNF inhibitor or other biologic response modifier **Examples**: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Must be prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of TRAPS
- Individual has TRAPS with genetic confirmation of the diagnosis (TNFRSF1A gene mutation)
- Chart notes documenting chronic or recurrent disease with six (6) flares within a 12-month time frame
- Labs document CRP >10mg/L

Initial Authorization Length: 6 months

Reauthorization Criteria

- Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- Member is receiving ongoing monitoring for presence of tuberculosis (TB) or other active infections
- Member has experienced disease response as indicated by improvement in member's symptoms from baseline AND improvement of CRP and SAA serum levels (both levels are <10 mg/L)

Reauthorization Length: 12 months

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Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Diagnosis - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Age: ≥2 years of age and older

Dosing based on weight:

- **40 kg**: Starting dosage is 150 mg subcutaneously every 4 weeks. The dosage can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
- **≤ 40 kg:** Starting dosage is 2 mg/kg subcutaneously every 4 weeks. The dosage can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.4mg/kg up to 300mg every 4 weeks

Exclusion Criteria

- Patient is not on concurrent treatment with any a TNF inhibitor or other biologic response modifier **Examples**: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of HIDS/MKD
- Test result submitted genetic MVK/enzymatic (MKD)
- Member has a history of > 3 febrile acute flares within a 6-month period and not receiving prophylactic treatment
- Labs document CRP >10mg/L

Initial Authorization Length: 6 months

Reauthorization Criteria

- Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- Member is receiving ongoing monitoring for presence of tuberculosis (TB) or other active infections
- Member has experienced disease response as indicated by improvement in member's symptoms from baseline AND improvement of CRP and SAA serum levels (both levels are <10 mg/L)

Reauthorization Length: 12 months

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Familial Mediterranean Fever (FMF)

Diagnosis - Familial Mediterranean Fever (FMF)

Age: ≥2 years of age and older

Dosing based on weight:

- **40 kg**: Starting dosage is 150 mg subcutaneously every 4 weeks. The dosage can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
- **≤ 40 kg:** Starting dosage is 2 mg/kg subcutaneously every 4 weeks. The dosage can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.4mg/kg up to 300mg every 4 weeks

Exclusion Criteria

- Patient is not on concurrent treatment with any a TNF inhibitor or other biologic response modifier **Examples**: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of FMF
- Type 1 disease characterized by:
- Recurrent and short episodes of inflammation and serositis
- Average of at least 1 documented acute FMF attack per month during the previous 6 months and lasting approximately 12 to 72 hours
- Documented a trial and failure colchicine
- Max children: 2mg/day
- Max Adult: 3mg/day
- Active Type 1 FMF disease with genetic confirmation of the diagnosis (MEFV gene exon 10 mutation) (De Baenedetti 2018)
- Currently active disease defined by
- > CRP 10 mg/L
- Presence fever and Serositis/Arthritis

Initial Authorization Length

- 6 months

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Reauthorization Criteria

- Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- Member is receiving ongoing monitoring for presence of tuberculosis (TB) or other active infections
- Member has experienced disease response as indicated by improvement in member's symptoms from baseline AND improvement of CRP and SAA serum levels (both levels are <10 mg/L)

Reauthorization Length

- 12 months

Cryopyrin-Associated Periodic Syndromes (CAPS)

Diagnosis - Cryopyrin-Associated Periodic Syndromes (CAPS)

Age: 4 years of age and older

Dosing based on weight:

- **≥15 kg and <40 kg**: : 2 mg/kg subcutaneously, every 8 weeks
  Note: Dose may be increased to 3 mg/kg for pediatric patients 15kg – 40kg with inadequate response
- **>40 kg**: 150 mg subcutaneously every 8 weeks

Exclusion Criteria

- Patient is not on concurrent treatment with any a TNF inhibitor or other biologic response modifier
  Examples: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Prescribed by or in consultation with a rheumatologist or immunologist with expertise in the diagnosis of CAPS
- Patient has documented moderate to severe rash
- Patient has documented elevated serum levels (baseline labs must be submitted):
  - C-Reactive (CRP)
  - Serum Amyloid A (SAA)
- Member meets one of the below criteria:
  - Presence of a pathogenic/likely pathogenic NLRP3 gene variant
  - Presence of a frequent NLRP3 gene variant of uncertain significance
  - No presence of one of the NLRP3 gene variants, but has two or more of the following:
    - Urticarial rash
    - Cold/stress-triggered flares
    - Chronic aseptic meningitis
    - Neurosensorial hearing loss
    - Skeletal abnormalities (epiphyseal overgrowth/frontal bossing)
  - Muckle-Wells Syndrome or Familial Cold Autoinflammatory Syndrome with noted mutation in the CIAS1/NLRP3 gene

Initial Authorization Length

- 6 months

Reauthorization Criteria

- Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- Member is receiving ongoing monitoring for presence of tuberculosis (TB) or other active infections
- Member has experienced disease response as indicated by improvement in member's symptoms from baseline AND improvement of CRP and SAA serum levels (both levels are <10 mg/L)
- Current progress notes stating rash is absent to minimal are submitted

Reauthorization Length

- 12 months

Systemic Juvenile Idiopathic Arthritis (sJIA)

Diagnosis - Systemic Juvenile Idiopathic Arthritis (sJIA)

Age: 2 - 17 years of age

Dosing based on weight:

- **≥7.5 kg**: 4mg/kg SQ every 4 week (max dose of 300mg)

Exclusion Criteria

- Patient is not on concurrent treatment with any a TNF inhibitor or other biologic response modifier **Examples**: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Member must has had persistent sJIA activity for a minimum of six (6) months
- MD must provide date of diagnosis
- Member must have trial and failure of both NSAIDs and corticosteroids
- One of the following within the last 3 months of this request:
- Member must have had ≥ 5 active joints with concomitant fever for at least 2 weeks
- Member must have had > 2 active joints with concomitant fever for at least 5 days and trial of prednisone or equivalent dosed at 0.5mg/kg/day or 30mg/day
- Member must have had CRP (>15 mg/L) within the last 2 months of this year
- Member must have had ESR (>45mm/hr) within the last 2 months of this year
- Member must have had fever > 38°C or 100.4°F for at least 2 weeks within the last 2 months of this request

Initial Authorization Length

- 3 months

Reauthorization Criteria

- Documentation of both of the following:
    - Decrease in ESR <30 mg/L
    - ESR <13mm/h

- Number of swollen joints has decreased

Reauthorization Length

- 12 months

Adult Onset Still's Disease (AOSD)

Diagnosis - Adult Onset Still's Disease (AOSD)

Age: 18 - 75 years of age

Dosing: 4 mg/kg every 4 weeks (maximum: 300 mg/dose).

Exclusion Criteria

- Patient is not on concurrent treatment with any a TNF inhibitor or other biologic response modifier **Examples**: Acetmra®, Cimzia®, Cosentyx®, Dupixent®, Enbrel®, Humira®, Nucala®, Orencia®, Rinvoq®, Simponi®, Skyrizi®, Stelara®, Taltz®, Tremfya®, Xolair®

Initial Authorization Criteria

- Member must meet two of the following without the presence of infection, malignancy, or other rheumatic disease (vasculitis):
- Fever >39 °C, lasting 1 week or longer
- Arthralgia or arthritis, lasting 2 weeks or longer
- Typical nonpruritic salmon-colored rash
- Leukocytosis >10,000/mm3 with >80% polymorphonuclear cells
- Disease activity based on DAS28 of ≥3.2 at screening
- Member must have had CRP (>15 mg/L) within the last 2 months of this year
- Member must have had ESR (>45mm/hr) within the last 2 months of this year
- At least 4 painful and 4 swollen joints at least 2 weeks within the last 3 months of this request
- Trial and failure of corticosteroids as first line of therapy
- Member must have a trial and failure of methotrexate

Initial Authorization Length

- 3 months

Reauthorization Criteria

- Documentation of both of the following:
    - Decrease in ESR <30 mg/L
    - ESR <13mm/h
- Number of swollen joints has decreased

- DAS28 has decreased to <2.6

Reauthorization Length

- 12 months

References: Ilaris. Package Insert. Novartis Pharmaceutical Corporation. 2023

Ilumya (tildrakizumab-asmn) (J3245)

Diagnosis - Moderate to Severe Chronic Plaque Psoriasis

Age: 18 years and older

Dosing: Subcutaneous 100mg at weeks 0, 4, and then every 12 weeks

Exclusion Criteria

- The Health Plan considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has NOT been established and will NOT be permitted.

Initial Authorization Criteria

- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- Trial and failure of either:
    - Phototherapy (defined by UV Light therapy: NB UV-B, PUVA)
    - Alternative Systemic Therapy (defined by acitretin, methotrexate, or cyclosporine)

Initial Authorization Length

- Lifetime

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Ilumya. Package Insert. Sun Pharmaceuticals. 2023

Imdelltra (Tarlatamab)

No prior authorization required for oncology purposes

Imfinzi (Durvalumab) (J9173)

No prior authorization required for oncology purposes

Immune Globulin Intravenous (IVIG)

Immune Globulin (Human) – Hyaluronidase (Hyqvia) (J1575)
Immune Globulin (Human) IM (Gamastan S/D and Gamastan) (J1460, J1560)
Immune Globulin (Human) IV (Bivigam) (J1556)
Immune Globulin (Human) IV (Carimune Nanofiltered and Gammagard S/D IGA < 1MCG/ML) (J1566)
Immune Globulin (Human) IV (Flebogamma Dif) (J1572)
Immune Globulin (Human) IV (Gammaplex) (J1557)
Immune Globulin (Human) IV (Octagam) (J1568)
Immune Globulin (Human) IV (Privigen) (J1459)
Immune Globulin (Human) IV or SQ (Gammagard Liquid) (J1569)
Immune Globulin (Human) IV or SQ (Gammaked or Gamunex-C) (J1561)
Immune Globulin (Human) IV or SQ (Gamunex-C) (J1561)
Immune Globulin (Human) SQ (HIzentra) (J1559)
Immune Globulin (Human) SQ (Cuvitru) (J1555)
Immune Globulin (Human) IV (Asceniv) (J1554)

Covered Indications, Limitations, and/or Medical Necessity

- Subcutaneous Immunoglobulin (SCIG)
  - L35093 Immune Globulin outlines the covered indications for which SCIG treatment is acceptable
    Note: SCIG for off-label conditions cannot be recommended at this time. Currently, SCIG therapy is FDA-approved for use in the treatment of PI diseases only; with the exception of one SCIG product that is also approved for maintenance therapy in CIDP
- Intravenous Immunoglobulin (IVIG)
  - L34580 Intravenous Immunoglobulin (IVIG) outlines the covered indications, both labeled and off-label, for which IVIG treatment is acceptable.
    - Coverage requirements that are and are not explicitly listed in this document will be required to meet the *Documentation Requirements* section set forth in the Local Coverage Determination

Infliximab

Rheumatoid Arthritis and Psoriatic Arthritis

Drugs Included:

Inflectra (Q5103)
Remicade (J1745)
Renflexis (Q5104)
Zymfentra (J1748)

Note: There is no preference for Infliximab product on the Medicare LOB.

Covered Indications, Limitations, and/or Medical Necessity

- L35677 Infliximab outlines the covered indications, both labeled and off-label, for which all infliximab treatments are acceptable.
    - Coverage requirements that are and are not explicitly listed in this document will be required to meet the *Documentation Requirements* section set forth in the Local Coverage Determination

Iron Homeostasis (Feraheme (Q0138), Injectafer (J1439), Monoferric (J1437))

Iron-Deficiency Anemia

Diagnosis – Iron Deficiency Anemia

Age: NA

Dosing: Weight based dosing

Exclusion Criteria: NA

Initial Authorization Criteria

- Submit the following labs collected within the last 30 days: serum ferritin (iron) AND total iron binding capacity (TIBC) OR transferrin saturation (TSAT%).
  Note: TSAT % = (Serum iron / TIBC) x 100%
- Labs show member's TSAT <20%

Initial Authorization Length: 2 months

Reauthorization Criteria

- NA

Reauthorization Length

- NA

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Moderate-to-Severe Restless Leg Syndrome (RLS)

Diagnosis – Moderate-to-Severe Restless Leg Syndrome (RLS)

Age: 18 years of age or older

Dosing: Weight based dosing

Exclusion Criteria: NA

Initial Authorization Criteria

- Submit the following labs collected within the last 30 days: serum ferritin (iron) AND total iron binding capacity (TIBC) **OR** transferrin saturation (TSAT%).
  Note: TSAT % = (Serum iron / TIBC) x 100%
- Member has trial and unsatisfactory response, intolerance or contraindication to oral iron administration
- Lab documentation shows member's TSAT <20% after trial of an oral iron supplement

Initial Authorization Length: 2 months

Reauthorization Criteria

- NA

Reauthorization Length

- NA

Cancer and Chemotherapy-Induced Anemia

Diagnosis – Cancer and Chemotherapy-Induced Anemia

Age: 18 years of age or older

Dosing: Weight based dosing

Exclusion Criteria: NA

Initial Authorization Criteria

- Submit the following labs collected within the last 30 days: serum ferritin (iron) **AND** total iron binding capacity (TIBC) **OR** transferrin saturation (TSAT%).
  Note: TSAT % = (Serum iron / TIBC) x 100%
- Member has functional iron deficiency and must meet **ONE** of the following:
  - Member has a TSAT < 50% with the goal of avoiding allogenic transfusion
  - Member has a TSAT <50% and requested medication will be used in combination with erythropoiesis-stimulating agents (ESAs)

Initial Authorization Length: 2 months

Reauthorization Criteria

- NA

Reauthorization Length

- NA

Jemperli (Dostarlimab-gxly) (J9272)

No prior authorization required for oncology purposes

Jevtana (Cabazitaxel) (J9043)

No prior authorization required for oncology purposes

Kadcyla (Ado-Trastuzumab) (J9354)

No prior authorization required for oncology purposes

Kalbitor (ecallantide) (J1290)

Diagnosis - Hereditary Angioedema (HAE)

Age: ≥12 years of age

Dosing: 30 mg (3 mL), administered subcutaneously in three 10 mg (1 mL) injections. If an attack persists, an additional dose of 30 mg may be administered within a 24-hour period

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by, or in consultation, with an allergist, immunologist, or pulmonologist
- Member has a history of one of the following:
  - Moderate to severe cutaneous or abdominal attacks
  - Mild to severe airway swelling attacks of HAE (i.e. debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)
  - Confirmation the member is avoiding the following possible triggers for HAE attacks (i.e. estrogen-containing oral contraceptive agents, hormone replacement therapy, antihypertensive agents containing ACE-inhibitors, etc)

Member must have ONE of the following classes of HAE

HAE I

- Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test)
- Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
- One of the following:
  - Member has a family history of HAE
  - Normal C1q level

HAE II

- Normal to elevated C1-INH antigenic level
- Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the

laboratory performing the test)

HAE III

- Normal C1-INH antigenic level)
- Normal C4 level
- Normal C1-INH functional level
- One of the following:
    - Member has a known HAE causing C1-INH mutation (i.e., mutation of coagulation factor XII gene)
    - Member has a family history of HAE

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Significant improvement in severity and duration of attacks have been achieved and sustained
- Absence of unacceptable toxicity from the drug. (examples of unacceptable toxicity include hypersensitivity reactions)

Reauthorization Length: 12 months

References: Kalbitor. Package Insert. Takeda Pharmaceuticals. 2021

Kepivance (palifermin) (J2425)

Diagnosis: Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Age: 18 years and older

Initial Dosing: Weight based dosing

Exclusion Criteria:

- Limitations of use: Safety and efficacy have not been established for nonhematologic malignancies. Palifermin is not recommended with conditioning regimens containing melphalan 200 mg/m2. Palifermin was not effective in decreasing the incidence of severe mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of allogeneic hematopoietic stem cell support.

Initial Authorization Criteria:

- Must be prescribed by or in consultation with an oncologist or transplant specialist
- Member has a hematologic malignancy (e.g., non-Hodgkin's lymphoma, Hodgkin's lymphoma, acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), chronic myelogenous leukemia, (CML), acute monocytic leukemia (AMoL) or multiple myeloma)
- Member is scheduled for autologous hematopoietic stem cell transplantation (autoHSCT)
- Member will undergo preparative regimen for autoHSCT which is expected to result in mucositis ≥ grade 3 in the majority of patients

Initial Authorization Length: One time authorization: 6 Total Doses [3 consecutive days before and 3 consecutive days after myelotoxic therapy]

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Kepivance. Package Insert. Swedish Orphan Biovitrum. 2021

Keytruda® (pembrolizumab) (J9271)

No prior authorization required for oncology purposes

Kebilidi (eladocagene exuparvovec-tneq) (J3590)

Diagnosis: Aromatic L-amino Acid Decarboxylase (AADC) Deficiency

Exclusion Criteria:

- Members who have not achieved skull maturity assessed by neuroimaging

Initial Authorization Criteria

- Must be prescribed by or in consultation with a neurologist
- Member must have a confirmed diagnosis of severe aromatic L-amino acid decarboxylase (AADC) deficiency as established by all the following (documentation required):
    - Genetic testing showing biallelic mutations in the DOPA decarboxylase (DDC) gene
    - Reduced levels of 5-hydroxyindoleacetic acid (5-HIAA), homovanilic acid (HVA), and 3-methoxy-4-hydroxyphenylglycol (MHPG)
    - High concentrations of 3-o-methyldopa (3-OMD), L-Dopa, and 5-OH tryptophan (5-HTP) in the cerebral spinal fluid (CSF)
    - Reduced aromatic L-amino acid decarboxylase (AADC) activity in the plasma
- Member must be experiencing persistent neurological defects (e.g., autonomic dysfunction, hypotonia, dystonia and other movement disorders, etc.) secondary to AADC deficiency despite standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitor, pyridoxine, or other forms of vitamin B6)
- Member must have achieved skull maturity as assessed by neuroimaging
- Member does not have pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency. Member has not received prior gene therapy
- Member must not have a baseline anti-AAV2 antibody titer above 1:1200 or >1 optical density value by enzyme-linked immunosorbent assay
- Member does not have any contraindications that would preclude surgical intraputaminal administration
- Member has tested negative for coronavirus disease of 2019 (COVID-19) a maximum of 72 hours prior to receiving gene therapy

Initial Authorization Length: One time only

References: Kibildi. Package Insert. PTC Therapeutics. 2024

Kimyrsa™ (oritavancin) (J2406)

Diagnosis: Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Age: 18 years and older

Initial Dosing: 1.2g as a single dose.

Exclusion Criteria:

- Use of intravenous unfractionated heparin sodium for 120 hours (5 days) after Kimyrsa administration

Initial Authorization Criteria

- Member must have a diagnosis of ABSSSI
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents one of the following:
    - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication to vancomycin
    - Staphylococcus aureus with reduced susceptibility to vancomycin [vancomycin-intermediate Staphylococcus aureus (VISA), or vancomycin-resistant Staphlyococcus aureus (VRSA)

Continuation of Therapy Following Inpatient Administration:

- Must be prescribed by or in consultation with an infectious disease specialist
- Only for administration in the Sentara/other health system infusion center (not for use in the hospital or emergency department)
- Only for patients discharged from a Sentara hospital/other qualified hospital
- Drug must be administered in the Sentara/other health system infusion center within 48 hours of discharge
- Use limited to the following:
    - Drug abuse patients
    - Physician does not want the patient to have a PICC line

Initial Authorization Length: 1 Day

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Reauthorization Length: NA

References: Kimyrsa. Package Insert. Melinta Therapeutics. 2021

Kisunla (donanemab-azbt) IV (J0175)

The Health Plan follows the National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)

References:

Medicare Coverage Database

Krystexxa™ (pegloticase) (J2507)

Diagnosis - Hyperuricemia

Age: ≥18 years of age

Dosing: 8 mg every 2 weeks

Exclusion Criteria: G6PD Deficiency

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a rheumatologist or nephrologist
- Member has baseline serum uric acid level ≥ 8 mg/dL
- Member has symptomatic hyperuricemia with the presence of ≥1 of the following:

1. ≥1 non-resolving subcutaneous tophus
2. 2 of more gout flares inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), or oral/injectable corticosteroids
3. Radiographic damage of any modality that is attributable to gout

- Member tried and failed a medically appropriate maximum dose of one of the following: (failure is defined by serum urate not being reduced to <6mg/dL despite therapy)

1. Allopurinol (maximally dosed at 400/800 mg/day)
2. Febuxostat

- Provider attests that antihistamines and corticosteroids are to be administered prior to infusion of Krystexxa
- Provider attests Kystexxa will NOT be prescribed for members with asymptomatic hyperuricemia or
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Provider attests medication must be used in combination with methotrexate unless clinically significant contraindication or therapy intolerance exists

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Must be prescribed by or in consultation with a rheumatologist or nephrologist
- Member has experienced an absence of unacceptable toxicity from the drug (e.g., anaphylaxis, hypersensitivity or infusion reactions, exacerbation of congestive heart failure)
- Medication must be used in combination with methotrexate unless clinically significant contraindication or therapy intolerance exists

- Provider attests that serum uric acid level is < 6 mg/dL prior to scheduled infusion
- Provider attests medication will be discontinued if serum uric acid levels increase to above 6 mg/dL on 2 consecutive lab tests

Reauthorization Length: 12 months

References: Krystexxa. Package Insert. Horizon Therapeutics. 2022

Kymriah (tisagenlecleucel) (Q2040)

B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

Diagnosis – B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

Age: 3-25 years of age

Dosing: 1 billable unit (1 infusion of up to 250 million car positive viable t-cells)

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member does not have an active infection or inflammatory disorder
- Member has not received live vaccines within 2 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member has not received prior CAR-T therapy
- Member has not received prior blinatumomab therapy
- Member has CD19-positive disease
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy)
- Member has a life expectancy > 12 weeks
- Member's disease is refractory or in second or later relapse defined as **ONE** of the following:
    - Second or greater bone marrow (BM) relapse
    - Any BM relapse after allogeneic stem cell transplantation (SCT)
    - Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy)
    - Chemo-refractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease)
    - Members with Philadelphia chromosome (Ph)-positive disease have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib, ponatinib, etc.)

  - Member is not eligible for allogeneic SCT
- Member has a performance status (Karnofsky/Lansky) ≥ 50

Initial Authorization Length: One time only

Reauthorization Criteria: NA

Reauthorization Length: NA

Large B-Cell Lymphoma

Diagnosis – Large B-Cell Lymphoma

Age: 18 years of age or older

Dosing: 3 billable units (1 infusion of up to 600 million car positive viable t-cells)

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member does not have an active infection or inflammatory disorder
- Member has not received live vaccines within 2 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member has not received prior CAR-T therapy
- Member has not received prior blinatumomab therapy
- Member has CD19-positive disease
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy)
- Member has a life expectancy > 12 weeks
- Member has one of the following aggressive B-cell non-Hodgkin lymphomas:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
  - High grade B-cell lymphoma
  - DLBCL arising from follicular lymphoma (TFL)
- Member's disease is relapsed or refractory, after two or more lines of systemic therapy, which included

an anthracycline and an anti-CD20 monoclonal antibody (i.e. rituximab) [unless tumor is CD20-negative], and is defined as one of the following:
    - Relapse after autologous hematopoietic stem cell transplantation (HSCT)
    - Refractory disease to the most recent therapy
- Member has an ECOG performance status of 0-1
- Member does not have primary central nervous system lymphoma

Initial Authorization Length: One time only

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Kymriah. Package Insert. Novartis Pharmaceuticals. 2022

Kyprolis (Carfilzomib) (J9047)

No prior authorization required for oncology purposes

Lamzede® (velmanase alfa-tycv) (J0217)

Diagnosis – Alpha Mannosidosis

Age: NA

Dosing:

- Approved for a maximum of 1 mg/kg (actual body weight) administered by intravenous infusion no more frequently than every week

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a geneticist or metabolic specialist
- Member has confirmed diagnosis of alpha mannosidosis
    - Alpha mannosidosis enzyme assay or genetic testing results supporting the diagnosis must be submitted
- Baseline age-appropriate values for at least one of the following have been documented:
    - 6-minute walk test (6-MWT)
    - 3-minute stair climb test (3-MSCT)
    - Pulmonary function tests (e.g., forced vital capacity)
    - Motor function test (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))

Initial Authorization Length: 12 months

- Member is currently receiving therapy with the requested agent
- The member is receiving benefit from therapy (e.g., improvement in 3-minute stair climbing test (3MSCT) from baseline, improvement in 6-minute walking test (6-MWT) from baseline, improvement in FVC, % predicted from baseline, reduction in serum or urine oligosaccharide concentration from baseline

Reauthorization Criteria:

Reauthorization Length: 12 months

References: Lamzede. Package Insert. Chiesi Farmaceutici. 2023

Lemtrada® (alemtuzumab) (J0202)

Diagnosis – Multiple Sclerois (MS)

Age: 18 years and older

Dosing:

- Year 1: 5 infusions (12mg daily for 5 consecutive days)
- Year 2: 3 infusions (12mg daily for 3 consecutive days)
- Year 3 and beyond: 3 infusions (12mg daily for 3 consecutive days) by medical necessity only

Exclusion Criteria:

- Active infection
- Human Immunodeficiency Virus (HIV)

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a neurologist
- Member has confirmed diagnosis of relapsing-remitting MS
- Member has had ≥1 medically documented clinical relapse within 12 months
- Provider is registered with Lemtrada® REMS program
- Member has tried and failed to at least two or more drugs indicated for the treatment of MS

Initial Authorization Length: 2 years

Reauthorization Criteria:

- Member's last Lemtrada® infusion was at least 12 months ago
- Member has had ≥1 medically documented clinical relapse within 12 months
- Provider is registered with Lemtrada® REMS program

Reauthorization Length: 12 months

References: Lemtrada. Package Insert. Genzyme. 2024

Leqembi (lecanemab) IV (J3590/C9399)

The Health Plan follows the National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)

References:

1. Medicare Coverage Database

Leqvio (inclisiran) (J1306)

Diagnosis – Primary Hyperlipidemia

Age: 18 years and older

Dosing: 284mg as a single injection, again at 3 months, then every 6 months thereafter

Exclusion Criteria: None

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a cardiologist, endocrinologist, or a lipid specialist
- Medication will be used as adjunct to a low-fat diet
- Member meets BOTH the following criteria:
    1. Member has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) unless member has been determined to be statin intolerant (chart note documentation required)
    2. Member has tried one high-intensity statin therapy above along with ezetimibe (as a single entity or as a combination product) for ≥ 8 continuous weeks unless member has been determined to be statin intolerant (chart note documentation required)
- Member's LDL-C level after this treatment regimen remains ≥100 mg/dL

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Provider attests member has experienced a positive clinical response to PCSK9 therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDLC), or apolipoprotein B levels) and continues to have need of requested medication

Reauthorization Length: 12 months

Diagnosis – Primary Hyperlipidemia

Age: 18 years and older

Dosing: 284mg as a single injection, again at 3 months, then every 6 months thereafter

Exclusion Criteria: None

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a cardiologist, endocrinologist, or a lipid specialist
- Medication will be used as adjunct to a low-fat diet
- Member meets BOTH the following criteria:
    1. Member has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) unless member has been determined to be statin intolerant (chart note documentation required)
    2. Member has tried one high-intensity statin therapy above along with ezetimibe (as a single entity or as a combination product) for ≥ 8 continuous weeks unless member has been determined to be statin intolerant (chart note documentation required)
- Member's LDL-C level after this treatment regimen remains ≥100 mg/dL

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Provider attests member has experienced a positive clinical response to PCSK9 therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDLC), or apolipoprotein B levels) and continues to have need of requested medication

Reauthorization Length: 12 months

References: Leqvio. Package Insert. Novartis. 2024

Libtayo (Cemiplimab-rwlc) (J9119)

No prior authorization required for oncology purposes

Luteinizing Hormone-Releasing Hormone (LHRH) Analogs

Leuprolide acetate (Lupron Depot) (J9217)
Goserelin acetate (Zoladex) (J7325)
Triptorelin pamoate (Trelstar) (J7318)
Histrelin acetate (Vantas) (J7326)
Leuprolide mesylate (Camcevi) (J1952)
Leuprolide acetate (Eligard) (J1950)
Leuprolide acetate (Fensolvi) (J1951)

1. The Health Plan follows LCD L39387 "Luteinizing Hormone-Releasing Hormone (LHRH) Analogs"

References: Medicare Coverage Database

Luxterna™ (voretigen neparvovec-rxy) (J3398)

Diagnosis – Retinal Dystrophy

Covered Indications, Limitations, and/or Medical Necessity

- L37863 Voretigene Neparvovec-rzyl (Luxturna®) outlines the covered indications, both labeled and off-label, for which all treatments are acceptable.
    - Coverage requirements that are and are not explicitly listed in this document will be required to meet the *Documentation Requirements* section set forth in the Local Coverage Determination

Lyfgenia (lovotibeglogene autotemcel) (J3590/C9399)

Diagnosis – Sickle Cell Disease (SCD) in patients 12 years of age or older with recurrent vaso-occlusive crises (VOCs)

Age: 12 years of age and older

Dosing: 3 × 106 CD34+ cells per kg of body weight

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has a diagnosis of sickle cell disease (SCD) as confirmed by the BOTH of the following:
- Genetic panel confirming one of the following genotypes: βS/βS, βS/β0, βS/β+ (documentation required identifying biallelic HBB pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing)
- Genetic panel confirming the member does NOT have more than two α-globin gene deletions, or carry the α-thalassemia trait, -α3.7/-α3.7
- Medical chart notes detailing history of sickle cell disease (this will include documented history of crises as noted below)
- Provider must submit chart notes which contain detailed patient history and document ALL the following:
- Two or more vaso-occlusive events/crises (VOE/VOC) in the previous year prior to initiating treatment in which date and outcome are documented within progress notes [VOE/VOC is defined as an occurrence of a visit to a medical facility for acute pain, acute chest syndrome, acute splenic sequestration, acute hepatic sequestration, priapism lasting > 2 hours AND necessitating subsequent interventions such as opioid pain management, non-steroidal anti-inflammatory drugs, RBC transfusion, etc.]
- Interval treatment history demonstrating inadequate control to a least hydroxyurea and ONE of the following therapies approved to prevent complications of SCD, or reduce VOCs:
    - Endari® (glutamine)
    - Adakveo® (crizanlizumab)
- ALL the following have been assessed, and confirmation is noted that the member does NOT have any of the following:

- Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI])
- Advanced liver disease, defined as one of the following:
    - Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value > 3 x the upper limit of normal (ULN)
    - Baseline prothrombin time or partial thromboplastin time >1.5 x ULN, suspected of arising from liver disease
    - MRI of the liver demonstrating clear evidence of cirrhosis
    - Liver biopsy shows any evidence of cirrhosis, bridging fibrosis, or significant active hepatitis
- MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)
- Member does NOT have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40
- Member does NOT have a history of untreated Moyamoya disease, or presence of Moyamoya disease that the provider believes will put the patient at risk of bleeding
- A transcranial doppler (TCD) ultrasonography has been performed at baseline demonstrating a normal TCD velocity (time-averaged mean of the maximum velocity [TAMMV] <170 cm/sec in the middle cerebral artery (MCA) and the internal carotid artery [NOTE: members with a history of abnormal TCD (TAMMV ≥200 cm/sec) excluded from service authorization; other history of severe cerebral vasculopathy, defined by any history of: overt ischemic or hemorrhagic stroke, occlusion or stenosis in the circle of Willis are also excluded]
- Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of lovotibeglogene autotemcel
- Females of childbearing potential and males capable of fathering a child must use effective method of contraception from start of mobilization through at least 6 months after administration of lovotibeglogene autotemcel
- Member is of sufficient weight to at least accept the minimum number of cells required to initiate the manufacturing process
- Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)
- Member will receive periodic life-long monitoring for hematological malignancies
- Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has NOT had prior HSCT or other gene therapy
- Member has NOT received other gene therapies to treat sickle cell disease [e.g., Casgevy™ (exagamglogene autotemcel)]

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- Provider must submit an assessment documenting a Karnofsky performance status of ≥60% for members ≥16 years of age, or a Lansky performance status of ≥60% for members <16 years of age
- Member does NOT have availability of a willing 10/10 HLA-matched sibling donor

Initial Authorization Length

- One treatment (dose) per lifetime

Reauthorization Criteria

- NA

Reauthorization Length

- NA

1. References: Lygenia. Package Insert. Bluebird Bio. 2022

Macular Degeneration Drugs

Drugs Included

Avastin® (bevacizumab) (J9035)
Beovu® (brolucizumab (J0179)
Byooviz (ranibizumab) (Q5124)
Cimerli (ranibizumab) (Q5128)
Eylea (afliberept) (J0178)
Eylea HD (afliberept) (J0177)
Lucentis (ranibizumab) (J2778)
Susvima (ranibizumab) (J2779)
Vabysmo (faricimab-svoa) (J2777)

Clinical Criteria for All Medications

- Member must have one of the below diagnoses:
  - Neovascular (wet) age-related macular degeneration (AMD)
  - Diabetic macular edema (DME)
  - Diabetic retinopathy (DR)
  - Macular edema following retinal vein occlusion (MEfRVO)
  - Neovascular glaucoma
- Other rare causes of choroidal neovascularization for ONE or more of the following:
  - Angioid streaks
  - Choroiditis (including, but not limited to histoplasmosis induced choroiditis)
  - Degenerative idiopathic myopia
  - Retinal dystrophies
  - Trauma
  - Pseudoxanthoma elasticum
  - Retinopathy of prematurity
  - Other: _____
- Indication of which eye(s) are being treated

Step Therapy Information:

1. Step Therapy Required for all medications other than Avastin/ Bevacizumab. Please see Part B Step Therapy Document: Step Therapy Requirements for Sentara Medicare Outpatient (Part B) Medications (sitecorecontenthub.cloud)

Drug Specific Information: The below lists the specific criteria required for each medication in addition to the above clinical criteria for all macular degeneration medications

Avastin/Bevacizumab

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 0.5mg once a month
- **Diabetic macular edema (DME):** 0.3mg once a month
- **Diabetic retinopathy (DR):** 0.3mg once a month
- **Macular edema following retinal vein occlusion (MEfRVO):** 0.5mg once a month

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: DME, DR, AMD, MEfRVO, mCNV

Initial Authorization Length: Indefinitely

Reauthorization Criteria: NA

Reauthorization Length: NA

Beovu

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 6 mg once per month (approximately every 25 – 31 days) for 3 months, followed by 6 mg once every 8 – 12 weeks
- **Diabetic macular edema (DME):** 6 mg every 6 weeks (approximately every 39 – 45 days) for 5 doses, followed by 6 mg once every 8 – 12 weeks
    - **Disease Activity Present (loss off <5 letters in BCVA score):** 6 mg once every 8 weeks
    - **No Disease Activity Present:** 6 mg once every 12 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: DME or AMD
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab

Initial Authorization Length: 3 months

Reauthorization Criteria:

- Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____
- Dosing is consistent with the above dosing based on disease activity

Reauthorization Length: Based on activity assessment

Byooviz

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD)**: 0.5 mg once a month
- **Macular edema following retinal vein occlusion (MEfRVO)**: 0.5 mg once a month
- **Myopic choroidal neovascularization (mCNV):** 0.5 mg once a month for up to 3 months; may retreat if necessary

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: AMD, MEfRVO, or mCNV
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____

Reauthorization Length: Based on activity assessment

Cimerli

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 0.5 mg once a month
- **Diabetic macular edema:** 0.3 mg once a month
- **Diabetic retinopathy:** 0.3mg once a month
- **Macular edema following retinal vein occlusion (MEfRVO)**: 0.5 mg once a month
- **Myopic choroidal neovascularization (mCNV):** 0.5 mg once a month for up to 3 months; may retreat if necessary

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: AMD, DME, DR, MEfRVO, or mCNV
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____

Reauthorization Length: Based on activity assessment

Eylea

Initial Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 2 mg (0.05 mL) once every 4 weeks for the first 12 weeks, followed by 2 mg (0.05 mL) once every 8 weeks
- **Diabetic macular edema:** 2 mg (0.05 mL) once every 4 weeks for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks
- **Diabetic retinopathy:** 2 mg (0.05 mL) once every 4 weeks for the first 5 injections, followed by 2
- mg (0.05 mL) once every 8 weeks
- **Macular edema following retinal vein occlusion (MEfRVO)**: 2 mg (0.05 mL) once every 4 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____

- Confirmation of diagnosis for one of the following: AMD, DME, DR, or MEfRVO
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab
- For **Diabetic Retinopathy**:
    - Provider has submitted member's baseline Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____

Initial Authorization Length: 12 months

Reauthorization Criteria:

- **AMD or DME**:
    - Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____
    - Dosing follows recommendations based on the below:
        - **No change in baseline**: 2 mg (0.05 mL) once every 8 weeks
        - **Increase in BCVA or increase presence of intraretinal or subretinal fluid or progression of pigment epithelial detachment**: 2 mg (0.05 mL) once every 4 weeks
- **DR w/ or w/o DME:**
    - Provider has submitted member's updated Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____
    - Dosing follows recommendations based on the below:
        - **Decreased DRSS or DRSS was 10**: 2 mg (0.05 mL) once every 8 weeks
        - **Increased DRSS or No change**: 2 mg (0.05 mL) once every 4 weeks

Reauthorization Length: Based on activity assessment

Eylea HD

Initial Dosing: Varies by diagnosis and request *see below*

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab
- Member has been diagnosed with ONE of the following labeled indications:
    - **Neovascular (wet) age-related macular degeneration (AMD):**
        - **Initial Dosing**: 8 mg once every 4 weeks for the first 3 doses, followed by **ONE** of the following (select requested dosing):
            - 8 mg once every 8 weeks q 8 mg once every 16 weeks

- **Off-label dose**: 8 mg every 4 weeks for 12 doses
  Provider please note: if this dose is selected, it will NOT be approved, please prescribe another medication that is FDA approved for the requested indication

- **Diabetic macular edema (DME):**
  - **Initial Dosing**: 8 mg once every 4 weeks for the first 3 doses, followed by ONE of the following (select requested dosing):
    - 8 mg once every 8 weeks
    - 8 mg once every 16 weeks
    - **Off-label dose**: 8 mg every 4 weeks for 12 doses
      Provider please note: if this dose is selected, it will NOT be approved, please prescribe another medication that is FDA approved for the requested indication
- **Diabetic retinopathy (DR) with and/or without DME**:
  - Provider has submitted baseline Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____
  - **Initial Dosing**: 8 mg once every 4 weeks for the first 3 doses, followed by ONE of the following (select requested dosing):
    - 8 mg once every 8 weeks
    - 8 mg once every 16 weeks
    - **Off-label dose**: 8 mg every 4 weeks for 12 doses
      Provider please note: if this dose is selected, it will NOT be approved, please prescribe another medication that is FDA approved for the requested indication

Initial Authorization Length: 12 months

Reauthorization Criteria:

- **Neovascular (wet) age-related macular degeneration (AMD):**
  - Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____
  - Dosing follows recommendations based on the below:
    - **No Change**: 8 mg once every 8 weeks
    - **Improvement**: 8 mg once every 16 weeks
- **Diabetic macular edema (DME):**
  - Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____
  - Dosing follows recommendations based on the below:
    - **No Change**: 8 mg once every 8 weeks
    - **Improvement**: 8 mg once every 16 weeks
- **Diabetic retinopathy (DR) with and/or without DME:**
  - Provider has submitted member's updated Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____
  - Dosing follows recommendations based on the below:

- **Decreased DRSS or DRSS was 10**: 8 mg once every 12 weeks
- **Increased DRSS or No change**: 8 mg once every 8 weeks

Lucentis

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 0.5 mg once a month
- **Diabetic macular edema:** 0.3 mg once a month
- **Diabetic retinopathy:** 0.3mg once a month
- **Macular edema following retinal vein occlusion (MEfRVO)**: 0.5 mg once a month
- **Myopic choroidal neovascularization (mCNV):** 0.5 mg once a month for up to 3 months; may retreat if necessary

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: AMD, DME, DR, MEfRVO, or mCNV
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____

Reauthorization Length: Based on activity assessment

Pavblu

Initial Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD**): 2 mg (0.05 mL) once every 4 weeks for the first 12 weeks, followed by 2 mg (0.05 mL) once every 8 weeks
- **Diabetic macular edema:** 2 mg (0.05 mL) once every 4 weeks for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks
- **Diabetic retinopathy:** 2 mg (0.05 mL) once every 4 weeks for the first 5 injections, followed by 2
- mg (0.05 mL) once every 8 weeks
- **Macular edema following retinal vein occlusion (MEfRVO)**: 2 mg (0.05 mL) once every 4 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for one of the following: AMD, DME, DR, or MEfRVO
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab
- For **Diabetic Retinopathy**:
    - Provider has submitted member's baseline Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____

Initial Authorization Length: 12 months

Reauthorization Criteria:

- **AMD or DME**:
    - Provider has submitted member's updated best corrected visual acuity (BCVA) score: _____
    - Dosing follows recommendations based on the below:
        - **No change in baseline**: 2 mg (0.05 mL) once every 8 weeks
        - **Increase in BCVA or increase presence of intraretinal or subretinal fluid or progression of pigment epithelial detachment**: 2 mg (0.05 mL) once every 4 weeks
- **DR w/ or w/o DME:**
    - Provider has submitted member's updated Diabetic Retinopathy Disease Severity Scale (DRSS) Level: _____
    - Dosing follows recommendations based on the below:
        - **Decreased DRSS or DRSS was 10**: 2 mg (0.05 mL) once every 8 weeks
        - **Increased DRSS or No change**: 2 mg (0.05 mL) once every 4 weeks

Reauthorization Length: Based on activity assessment

Susvimo

Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD)**: 2 mg via surgical administration every 6 months (1 single dose vial per eye per 6 months)
- **Diabetic Macular Edema (DME):** 2 mg via surgical administration every 6 months (1 single dose vial per eye per 6 months)

Exclusion Criteria: NA

Initial Authorization Criteria:
Note: Supplemental treatment to Susvimo is allowed with Lucentis only if ONE of the following are met: Decrease in visual acuity by half from the baseline visual acuity **OR** Increase of 150 µm or more in retinal thickness

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for AMD or DME
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab
- Provider attestation that the member does NOT have ocular or periocular infection or active intraocular inflammation or conjunctival scarring
- Provider attestation that Susvimo will NOT be used with other ophthalmic VEGF inhibitors (unless supplemental treatment was approved
    - Will be allowed with Lucentis only is one of the following are met:
        - Decrease in visual acuity by half from the baseline acuity
        - Increase of 15 µm or more in retinal thickness

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Medication has NOT caused toxicity to the eye (e.g., endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs)
- Member has experienced a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), and does not show loss of more than 20 letters in a BCVA (best corrected visual acuity)

Reauthorization Length: 12 months

Vabysmo

Initial Dosing:

- **Neovascular (wet) age-related macular degeneration (AMD)**: 6 mg once every 4 weeks for 4 doses, followed by one of the following dosing regimens:
    - Every 16 weeks
    - Every 12 weeks
    - Every 8 weeks
- **Diabetic Macular Edema (DME):** 6 mg once every 4 weeks for 6 doses, followed by 6 mg once every 8 weeks

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- **Macular Edema following Retinal Vein Occlusion (MEfRVO):** 6 mg once every 4 weeks for 6 months

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
- Confirmation of diagnosis for AMD, DME, or one of the following subtypes of RVO: Branch Retinal Vein Occlusion, Hemi-retinal vein occlusion, or Central retinal vein occlusion
- Member has tried and failed at least 30 days of therapy with Avastin or bevacizumab
- Provider attestation that Vabysmo will NOT be used with other ophthalmic VEGF inhibitors

Initial Authorization Length: 6 months

AMD Reauthorization Dosing :

- **No Change/Improvement in BCVA (compared to baseline after initial dosing regimen of every 4 weeks for 4 doses):** Every 16-week regimen
- **Decrease of >5 letters BCVA (compared to baseline on every 16 weeks regimen**): Every 12-week regimen
- **Decrease of >5 letters BCVA (compared to baseline on every 12-week regimen):** Every 8 week regimen

Reauthorization Criteria:
Note: Patients with loss of response to maintenance therapy administered at less frequent intervals may increase the dosing frequency in a stepwise manner until response is regained.

- **Early Reauthorization**: Patients with insufficient response during initial therapy
  - Provider has submitted member's baseline best corrected visual acuity (BCVA) score: _____
  - Provider has attested the patient has experienced an insufficient response to loading dose
- **All Other Reauthorization**:
  - Requested dosing follows the recommended *Reauthorization Dosing*
  - Medication has NOT caused toxicity to the eye (e.g., endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs)
  - Member has experienced a beneficial response to therapy (e.g., resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, improvement in the baseline best corrected visual acuity (BCVA))

Reauthorization Length: 6 months

Mepsevii® (vestronidase alpha-vjbk) (J1726)

Diagnosis: Mucopolysaccharidosis VII (MPS VII, Sly Syndrome)

Age: 5 months to 25 years

Initial Dosing: 4mg/kg every other week

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with an Endocrinologist or Geneticist
- Member must have diagnosis above confirmed through genetic testing or fibroblast glucuronidase enzyme assay using laboratory testing
- Member's current height and weight must be submitted
- Member's current normalized urine glycosaminoglycan levels must be submitted
- Member must have ≥2 of the following tests (chart notes must be included to confirm):
    - Current FVC
    - Baseline 6 minute walk time is attached (with date)
    - Visual acuity
    - BOT-2 fine motor precision scale
    - BOT-2 gross motor
    - Fatigue Pediatric Quality of Life Inventory (PedsQL) multidimensional fatigue scale

Initial Authorization Length: 12 months

Reauthorization Dosing: 4mg/kg every other week

Reauthorization Criteria:

- Member's current height and weight must be submitted
- Member's current normalized urine glycosaminoglycan levels must be submitted
- Member must have the previous tests completed upon initial approval (chart notes must be included to confirm):
    - Current FVC
    - Baseline 6 minute walk time is attached (with date)
    - Member's 6 minutes walk time must document usstained improvement from baseline
    - Visual acuity

- BOT-2 fine motor precision scale
- BOT-2 gross motor
- Fatigue Pediatric Quality of Life Inventory (PedsQL) multidimensional fatigue scale

Reauthorization Length: 12 months

References: Mepsevii. Package Insert. Ultragenyx Pharmaceutical. 2020

Muse (alprostadil suppository) (J0275)

Diagnosis – Erectile Dysfunction

Age: NA

Dosing: Patient-specific titration required

Exclusion Criteria

- Abnormal penile anatomy: MUSE is contraindicated in patients with urethral stricture, balanitis (inflammation/infection of the glans of the penis), severe hypospadias and curvature, and in patients with acute or chronic urethritis
- Sickle cell anemia or trait, thrombocythemia, polycythemia, multiple myeloma: MUSE is contraindicated in patients who are prone to venous thrombosis or who have a hyperviscosity syndrome and are therefore at increased risk of priapism (rigid erection lasting 6 or more hours)
- MUSE should not be used in men for whom sexual activity is inadvisable
- MUSE should not be used for sexual intercourse with a pregnant woman unless the couple uses a condom barrier

Initial Authorization Criteria

- Prescribed by or in consultation with a Urologist
- Confirmed diagnosis of erectile dysfunction due to vasculogenic, psychogenic, neurogenic, or mixed etiology
- Member has been assessed and is healthy enough for sexual activity, without any underlying, precluding cardiovascular status
- Member has been assessed and no known to have cavernosal venous leakage
- The member has had unsuccessful trials of phosphodiesterase-5 enzyme inhibitors taken by mouth, with **BOTH** sildenafil and tadalafil
- Alprostadil intraurethral pellet dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling and only two systems per 24-hour period

Initial Authorization Length: 12 months

Reauthorization Criteria

- The member has reported at least a partial response to administration with alprostadil
- Member has not developed penile angulation or cavernosal fibrosis

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Reauthorization Length: 12 months

References: MUSE. Package Insert. Meda Pharmaceuticals. 2017

Mvasi (Bevacizumab-awwb) (Q5107)

No prior authorization required for oncology purposes

Mylotarg (Gemtuzumab Ozogamicin) IV (J9203)

Newly Diagnosed CD33-positive Acute Myeloid Leukemia (AML)

Diagnosis – Newly Diagnosed CD33-positive Acute Myeloid Leukemia (AML)

Age: NA

Dosing: Age/weight based dosing

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has a diagnosis of newly diagnosed AML and meets all the following criteria:
  - Member is ≥1 month old
  - Member has CD33-positive disease
  - Any member with hyperleukocytosis (leukocyte count ≥30 Gi/L will undergo cytoreductive treatment prior to administration the requested medication
- If the member has *de novo* disease, the requested medication will be used in combination with daunorubicin and cytarabine

Authorization Length: Initial: 12 months; Reauthorization: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Mylotarg. Package Insert. Wyeth Pharmaceuticals. 2021

Relapsed or Refractory CD33-positive Acute Myeloid Leukemia (AML)

Diagnosis – Relapsed or Refractory CD33-positive Acute Myeloid Leukemia (AML)

Age: NA

Dosing: Age/weight based dosing

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has a diagnosis of newly diagnosed AML and meets all the following criteria:
  - Member is ≥ 2 years old
  - Member has CD33-positive disease
  - Any member with hyperleukocytosis (leukocyte count ≥30 Gi/L will undergo cytoreductive treatment prior to administration the requested medication
- The requested medication will be used as a single agent

Authorization Length: Initial: 12 months; Reauthorization: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Mylotarg. Package Insert. Wyeth Pharmaceuticals. 2021

Naglazyme® (galsulfase) IV Infusion (J1458)

Diagnosis: Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy Syndrome)

Age: 5 years and older

Initial Dosing: 1mg/kg once weekly

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a metabolic geneticist or other specialist in the treatment of this disease
- Member must have diagnosis above confirmed by **detection of pathogenic mutations in ARSB gene by molecular genetic test** OR all of the following:
    - Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes
    - Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency [MSD])
    - Member has an elevated urinary glycosaminoglycan (uGAG) level (i.e. dermatan sulfate or chondroitin sulfate) defined as being above the upper limit of normal by the reference laboratory
- Member's current weight must be submitted (must submit chart notes documenting member's current weight)
- Provider has attested to measuring one of the following at baseline:
    - Documented baseline 12-minute walk test (12-MWT)
    - 3-minute stair climb test
- Provider has attested to measuring baseline pulmonary function tests (e.g., FEV1, FVC; etc.)
- Provider has attested to measuring baseline lab value of urinary glycosaminoglycan (uGAG)

Initial Authorization Length: 6 months

Reauthorization Dosing: 1mg/kg once weekly

Reauthorization Criteria:

- Member continues to meet all initial authorization criteria

- Member's current weight must be noted (must submit chart notes documenting member's current weight)
- Member has absence of unacceptable toxicity from the drug, such as anaphylaxis or hypersensitivity reactions, immune-mediated reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions, spinal or cervical cord compression; etc.
- Member has had a clinically significant response to treatment since last approval as defined by improvement or stability from pre-treatment baseline by the following:
    - Provider has attested to improvement in or stability of pulmonary function testing
    - Provider has attested to improvement in or stability of 12-MWT or 3-minute stair climb test
    - Provider has attested to reduction in urinary glycosaminoglycan (uGAG) by ≥50% from baseline or maintenance of level at ≥50% below baseline

Reauthorization Length: 6 months

References: Naglazyme. PaBioMarin Pharmaceuticals. 2019

Neupogen (Filgrastim) (J1442)

No prior authorization required for oncology purposes

Niktimvo (axatilimab-csfr) IV Infusion (J9038)

Diagnosis: Chronic Graft versus Host Disease (cGVHD)

Age: 6 years and older

Initial Dosing: For patients weighing at least 40 kg, administer Niktimvo 0.3 mg/kg, up to a maximum dose of 35 mg, as an intravenous infusion over 30 minutes every 2 weeks until progression or unacceptable toxicity.

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with an oncologist, hematologist, or transplant specialty clinic
- Requested medication is being used for disease related to allogeneic hematopoietic stem cell transplantation
- Member must have a confirmed diagnosis of chronic graft versus host disease related to allogeneic hematopoietic stem cell transplantation
- Member's current weight must be submitted (must submit chart notes documenting member's current weight)
- Member must not have a histologic relapse of underlying cancer or post-transplant lymphoproliferative disease
- Member must not have a history of myositis
- Member must not have acute or chronic pancreatitis
- Member must have tried and failed two or more previous lines of systemic therapy for the treatment of cGVHD (i.e. corticosteroids, immunosuppressants) prior to approval
- Provider must attest the requested therapy will be used as a single agent or in combination with stable doses of systemic therapies for cGVHD which must include, but are not limited to, corticosteroids, calcineurin inhibitors, or mTOR inhibitors
- Member's current weight must be submitted (must submit chart notes documenting member's current

Initial Authorization Length: 6 months

Reauthorization Dosing: Same as initial authorization

Reauthorization Criteria:

- Member continues to meet all initial authorization criteria

- Member's current weight must be noted (must submit chart notes documenting member's current weight)
- Member has absence of unacceptable toxicity from the drug
- Provider has noted the member has responded positively to therapy as determined by the prescribing physician

Reauthorization Length: 12 months

References: Niktimvo. Package Insert. Syndax Pharmaceuticals. 2025

Nivestym (Filgrastim-aafi) (Q5110)

No prior authorization required for oncology purposes

Nucala® (mepolizumab) (J2182)

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, and/or Xolair® authorization on file, any subsequent requests for Nucala® will NOT be approved.

Diagnosis: Chronic rhinosinusitis with nasal polyps (CRSwNP)

Age: 18 years and older

Initial Dosing: 100mg administered once every 4 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an allergist, immunologist or otolaryngologist
- Member has a diagnosis of CRSwNP confirmed by the American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline (Update): Adult Sinusitis (AAO-HNSF 2015)/American Academy of Allergy Asthma & Immunology (AAAAI) with ONE of the following clinical procedures:
    - Anterior rhinoscopy
    - Nasal endoscopy
    - Computed tomography (CT)
- Documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of the following:
    - Mucosal inflammation AND at least **TWO** of the following:
        - Decreased sense of smell
        - Facial pressure, pain, fullness
        - Mucopurulent drainage
        - Nasal obstruction
- Member is currently being treated with medications in at least TWO of the following categories unless there is a contraindication or intolerance to these medications:
    - Nasal saline irrigation
    - Intranasal corticosteroids (e.g., fluticasone, budesonide, triamcinolone)
    - Leukotriene receptor antagonists (e.g., montelukast, zafirlukast, zileuton)
- Member is refractory, ineligible, or intolerant to ONE of the following:

  - Systemic corticosteroids
  - Sino-nasal surgery
- Member is requesting Nucala (mepolizumab) as add-on therapy to maintenance intranasal corticosteroid

Initial Authorization Length: 12 months

Reauthorization Dosing: 100mg administered once every 4 weeks

Reauthorization Criteria:

- Provider attests the member has experienced a positive clinical response to Nucala (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell)
- Provider attests to the decreased utilization of oral corticosteroids
- Member has been compliant on Nucala therapy and continues to receive therapy with an intranasal corticosteroid

Reauthorization Length: NA

References: Nucala. Package Insert. GlaxoSmithCline. 2023

Eosinophilic Granulomatosis Polyangiitis (EGPA)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, and/or Xolair® authorization on file, any subsequent requests for Nucala® will NOT be approved.

Diagnosis: Eosinophilic Granulomatosis Polyangiitis (EGPA)

Age: 18 years and older

Initial Dosing: 300mg administered as 3 separate 100mg injections once every 4 weeks

Exclusion Criteria: Therapy will not be approved if the member has a history of any of the following

- Organ/life threatening EGPA within 3 months prior to initiation
- Malignancy: current malignancy or previous history of cancer in remission for < 12 months
- Unstable cardiovascular disease: Ejection fraction < 20%, New York Heart Association Class III/IV failure, acute myocardial infarction diagnosed less than 3 months
- Unstable liver disease: Presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, cirrhosis, and known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones
- Rituximab within the past year; IVIG within the past 6 months; omalizumab within the past 4 months
- Pregnancy, breast-feeding, absence of contraception if female of child-bearing age

Initial Authorization Criteria:

- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Provider attests the member has a diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) > 6 months based on the history or presence of asthma
- Provider attests the member has eosinophil count of ≥150 cells/microliter at baseline
- Provider attests the member has **TWO** of the following:
    - A biopsy showing evidence of EGPA
    - Mono-or polyneuropathy
    - Pulmonary infiltrates, non-fixed on chest x-rays
    - Sino-nasal abnormality
    - Magnetic Resonance Imaging or Echocardiography of cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage (by bronchoalveloar lavage)

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- Palpable purpura
- Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)

- Member must have one of the following
  - **Relapsing disease**
    - Must have a history of at least one confirmed EGPA relapse requiring:
      - An increase in oral corticosteroids (OCS) dose
      - Initiation or increased dose of immunosuppressive therapy (e.g., cyclophosphamide, methotrexate, azathioprine or mycophenolate mofetil)
      - Hospitalization
      - Must have occurred > 12 weeks but < 2 years prior to initiation while receiving a dose of prednisone (or equivalent) of >7.5 milligram per day (mg/day) for at least 90 consecutive days.
  - **Refractory disease**
    - Must meet one of the following:
      - Failure to attain remission (Birmingham Vasculitis Activity Score (BVAS) =0) and OCS dose 15 mg/day prednisone), administered for at least 3 months.
      - Within 6 months prior to initiation, recurrence of symptoms of EGPA while tapering oral corticosteroids (OCS), occurring at any dose level ≥7.5 mg/day prednisone or equivalent taken for at least 90 consecutive days.

Initial Authorization Length: 12 months

Reauthorization Dosing: 300mg administered as 3 separate 100mg injections once every 4 weeks

Reauthorization Criteria:

- Provider attests the member meets ONE of the following:
  - Remission or improvement in the Birmingham Vasculitis Activity Score (BVAS) or prednisone/prednisolone daily dose of < 7.5mg
  - Decrease in maintenance dose of systemic corticosteroids, improvement in asthma symptoms or asthma exacerbations
  - Reduction of disease flares with tapering of corticosteroid therapy or immunotherapy

Reauthorization Length: NA

References: Nucala. Package Insert. GlaxoSmithCline. 2023

Hypereosinophilic Syndrome (HES)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, and/or Xolair® authorization on file, any subsequent requests for Nucala® will NOT be approved.

Diagnosis: Hypereosinophilic Syndrome (HES)

Age: 12 years and older

Initial Dosing: 300mg administered as 3 separate 100mg injections once every 4 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Allergist, Immunologist, Pulmonologist, or Rheumatologist
- Provider attests the member has a diagnosis of HES > 6 months or longer without any non-hematologic secondary cause (i.e. drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy)
- Provider attests the member has FIP1L1-PDGFRα-negative disease
- Provider attests the member has had two or more episodes of HES-related flares (worsening of clinical symptoms and/or worsening of blood eosinophil counts) requiring escalation of therapy in the past 12 months
- Member's HES-related flares occur spontaneously and did NOT occur within 4 weeks of a decrease in therapy
- Provider attests the member has been on a stable dose of HES therapy (such as oral corticosteroids, immunosuppressive agents and/or cytotoxic therapy) for the past 4 or more weeks
- Provider attests the member's blood eosinophil count is ≥ 1000 cells/microliter while taking stable doses of HES therapy

Initial Authorization Length: 12 months

Reauthorization Dosing: 300mg administered as 3 separate 100mg injections once every 4 weeks

Reauthorization Criteria:

- Provider attests the member has experienced a positive response to Nucala® therapy as determined by the prescriber (i.e. decreased number of flares, improved fatigue, reduced corticosteroid

requirements, and decreased eosinophil levels). Reduction of disease flares with tapering of corticosteroid therapy or immunotherapy

Reauthorization Length: NA

References: Nucala. Package Insert. GlaxoSmithCline. 2023

Severe Eosinophilic Asthma (SEA)

Note: The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, and/or Xolair® authorization on file, any subsequent requests for Nucala® will NOT be approved.

Diagnosis: Severe Eosinophilic Asthma (SEA)

Age: 6 years and older

Initial Dosing:

- **6 – 11 years old**: 40mg administered once every 4 weeks
- **12 years and older**: 100mg administered once every 4 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
- Member has above diagnosis as noted by one of the following:
  - Blood eosinophil count ≥150 cells/microliter at the initiation of treatment
  - Blood eosinophil count ≥300 cells/microliter in the past 12 months
- Clinical documentation that member is compliant with high-dose inhaled corticosteroids (ICS) and long-acting inhaled beta-2 agonists (LABA) for at least 90 days consecutively within the year of request and use of oral corticosteroids for exacerbation
- Provider must submit eosinophil blood count after a trial and failure of at least 90 days consecutively with high dose inhaled corticosteroids and long-acting inhaled beta-2 agonist. A failure of these medications is defined as a blood count > 150 cells/microliter (within 12 months)
- Has experienced ≥ 2 exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalizations)

Initial Authorization Length: 12 months

Reauthorization Dosing:

- **6 – 11 years old**: 40mg administered once every 4 weeks
- **12 years and older**: 100mg administered once every 4 weeks

Reauthorization Criteria:

- Provider attests the member has had a positive response to treatment based on the following:
  - Reduction in the frequency or severity of symptoms or exacerbations
  - Reduction in the daily maintenance oral corticosteroid dose
  - Reduction in the number of rescued medications
  - Reduction in the number of hospitalization or emergency room visits

Reauthorization Length: NA

References: Nucala. Package Insert. GlaxoSmithCline. 2023

Nuzyra IV (omadacycline) (J0121)

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Diagnosis: Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Age: 18 years and older

Initial Dosing:

- **Start Dose:** 200mg by intravenous infusion over 60 minutes OR 100mg by intravenous infusion over 30 minutes TWICE
- **Subsequent Doses**: 100mg by intravenous infusion over 30 minutes once daily

Exclusion Criteria: N/A

Initial Authorization Criteria

- Member must have a diagnosis of ABSSSI
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents one of the following:
    - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication to vancomycin
    - Staphylococcus aureus with reduced susceptibility to vancomycin [vancomycin-intermediate Staphylococcus aureus (VISA), or vancomycin-resistant Staphlyococcus aureus (VRSA)

Continuation of Therapy Following Inpatient Administration:

- Must be prescribed by or in consultation with an infectious disease specialist
- Only for administration in the Sentara/other health system infusion center (not for use in the hospital or emergency department)
- Only for patients discharged from a Sentara hospital/other qualified hospital
- Drug must be administered in the Sentara/other health system infusion center within 48 hours of discharge
- Use limited to the following:
    - Drug abuse patients
    - Physician does not want the patient to have a PICC line

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Nuzyra. Package Insert. Paratek Pharmaceuticals. 2021

Community-Acquired Bacteria Pneumonia (CABP) without Multi-Drug Resistant Organisms

Diagnosis: Community-Acquired Bacteria Pneumonia (CABP) without Multi-Drug Resistant Organisms

Age: 18 years and older

Initial Dosing:

- **Start Dose:** 200mg by intravenous infusion over 60 minutes OR 100mg by intravenous infusion over 30 minutes TWICE
- **Subsequent Doses**: 100mg by intravenous infusion over 30 minutes once daily

Exclusion Criteria: N/A

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
    - Lab culture must show sensitivity to Nuzyra

Continuation of Therapy Following Inpatient Administration:

- Member has been on Nuzyra >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Nuzyra

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Nuzyra. Package Insert. Paratek Pharmaceuticals. 2021

Ocrevus (ocrelizumab) Injection (J2350)

Ocrevus Zunovo (J3590)

Diagnosis: Primary Progressive Multiple Sclerosis (MS)

Age: 18 years and older

Initial Dosing:

- **Start Dose:** 300mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion
- **Subsequent Doses**: 600 mg intravenous infusion every 6 months

Exclusion Criteria:

- Active hepatitis B virus infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member has a confirmed diagnosis of Primary Progressive MS

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Ocrevus. Package Insert. Genetech. 2024

Relapsing-Remitting Multiple Sclerosis (MS)

Diagnosis: Relapsing-Remitting Multiple Sclerosis (MS)

Age: 18 years and older

Initial Dosing:

- **Start Dose:** 300mg intravenous infusion, followed two weeks later by a second 300mg intraventous infusion
- **Subsequent Doses**: 600mg intravenous infusion every 6 months

Exclusion Criteria:

- Active hepatitis B virus infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member has a confirmed diagnosis of Relapsing-Remitting MS
- Provider attests the member has had at least one medically documented clinical relapse within the previous 12 month

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Ocrevus. Package Insert. Genetech. 2024

Ohtuvayre (ensifentrine) (J7699)

Diagnosis – Chronic Obstructive Pulmonary Disease (COPD)

Age: 18 years of age and older

Dosing: 3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece

Exclusion Criteria

- NA

Initial Authorization Criteria

- Member has a diagnosis of moderate to severe Chronic Obstructive Pulmonary Disease (COPD) confirmed with spirometry demonstrating ONE of the following:
    - FEV1/FVC ratio <0.7 post-bronchodilation
    - Post-bronchodilator FEV1 % predicted of ≥ 30% and ≤ 80%
- Member is symptomatic confirmed by ONE of the clinical assessments
    - COPD Assessment Test (CAT) score > 10
    - Modified Medical Research Council (mMRC) dyspnea grade > 2
- Member has experienced ONE of the following:
    - At least two (2) exacerbations treated with short-acting bronchodilators and oral corticosteroids, with or without antibiotics in the past 12 months
    - At least one (1) exacerbation requiring hospitalization in the past 12 months θ Member has tried and failed at least ONE of the following dual or triple-maintenance therapies, unless there is a contraindication or intolerance to these medications, and must have been compliant with therapy for at least 90 consecutive days within year of the request:
        - Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
        - Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®), longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
- Member is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy for at least 90 consecutive days within year of the request:

  - Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
  - Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®), longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
- Member must continue to remain on dual or triple maintenance therapy while using Ohtuvayre™
- Medication will NOT be used in combination with an oral phosphodiesterase-4 (PDE4) inhibitor Daliresp® (roflumilast)

Initial Authorization Length

- 12 months

Reauthorization Criteria

- Member is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy for at least 90 consecutive days within year of the request:
  - Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
  - Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®), longacting beta agonist (LABA) (e.g., Advair HFA, Dulera ®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)

Reauthorization Length

- 12 months

References: Ohtuvayre. Package Insert. Verona Pharma 2024

Ophthalmic Corticosteroid Injections

Iluvien (fluocinolone acetonide intravitreal implant) (J7313)

Ozurdex (dexamethasone intravitreal implant) (J7312)

Xipere (triamcinolone acetonide injectable suspension) (C9092)

Note: Sentara considers the use of concomitant therapy with Dextenza®, Ozurdex®, Iluvien®, Retisert®, Xipere™, or Yutiq®, to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Dextenza®, Ozurdex®, Iluvien®, Retisert®, Xipere™, or Yutiq® authorization on file, all subsequent requests for an additional ophthalmic corticosteroid injection will NOT be approved.

Iluvien

Age: 18 years and older

Initial Dosing: One implant injected in affected eye every 36 months

Exclusion Criteria:

- Ocular or periocular infections
- Glaucoma

Initial Authorization Criteria:

- Member must have a diagnosis of Diabetic Macular Edema following BRVO or CRVO
- Member must have a previous course trial of corticosteroids and did not experience a significant rise in intraocular pressure
- Attestation that the member's best corrected visual acuity (BCVA) is measured at baseline and will be measured periodically during treatment

Initial Authorization Length: 1 implant per eye every 36 months; 1 box 0.19mg implants = 19 billable units

Reauthorization Dosing:

- Attestation the member has experienced disease response indicated by improvement of best corrected visual acuity (BCVA) score once compared to baseline
- Member has not experienced serious side effects related to toxicity (e.g. increased intraocular pressure, endophthalmitis, conjunctival hemorrhage)
- At least 36 months have passed since the last Iluvien intravitreal injection was administered

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Reauthorization Length: 1 implant per eye every 36 months; 1 box 0.19mg implants = 19 billable units

References: Iluvien. Package Insert. Alimera Sciences. 2016

Ozurdex

Age: 18 years and older

Initial Dosing: One implant injected in affected eye every 4 months

Exclusion Criteria:

- Ocular or periocular infections
- Glaucoma
- Torn or ruptured posterior lens capsule

Initial Authorization Criteria:

- Member must have a diagnosis of Diabetic Macular Edema following BRVO or CRVO, Diabetic Macular Edema (pseudophakic or phakic patients scheduled for cataract surgery), or non-infectious uveitis affecting the posterior segment of the eye
- Attestation that the member's best corrected visual acuity (BCVA) is measured at baseline and will be measured periodically during treatment

Initial Authorization Length: 1 implant per eye every 4 months; 1 implant = 7 billable units

Reauthorization Dosing:

- Attestation the member has experienced disease response indicated by improvement or stability of best corrected visual acuity (BCVA) score once compared to baseline
- Member has not experienced serious side effects related to toxicity (e.g. increased intraocular pressure, endophthalmitis, conjunctival hemorrhage)
- At least 4 months have passed since the last Ozurdex intravitreal injection was administered

Reauthorization Length: 1 implant per eye every 4 months; 1 implant = 7 billable units

References: Ozurdex. Package Insert. Abbvie. 2024

Xipere

Age: 18 years and older

Initial Dosing: 4 mg (0.1mL of the 40 mg/mL injectable suspension) injected in affected eye every 12 weeks = 36 billable units

Exclusion Criteria:

- Ocular or periocular infections

Initial Authorization Criteria:

- Member must have a diagnosis of macular edema associated with uveitis
- Attestation that the member's best corrected visual acuity (BCVA) is measured at baseline and will be measured periodically during treatment

Initial Authorization Length: 12 months

Reauthorization Dosing:

- Attestation the member has experienced disease response indicated by improvement or stability of best corrected visual acuity (BCVA) score once compared to baseline
- Member has not experienced serious side effects related to toxicity (e.g. increased intraocular pressure, endophthalmitis, conjunctival hemorrhage)
- At least 12 weeks have passed since the last Xipere intravitreal injection was administered

Reauthorization Length: 12 months

References: Xipere. Package Insert. Bausch & Lomb. 2022

Onpattro® (patisiran lipid complex) IV (J0222)

Diagnosis: Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis

Age: 18 years and older

Initial Dosing:

- **<100 kg:** 0.3 mg/kg every 3 weeks by intravenous infusion
- **≥100 kg**: 30mg every 3 weeks by intravenous infusion

Required Premedication:

- Members should be premedicated with corticosteroid (e.g. dexamethasone 10mg or equivalent), acetaminophen (500mg), intravenous H1 blocker (e.g. diphenhydramine 50mg or equivalent), and intravenous H2 blocker

Exclusion Criteria:

- Hereditary Transthyretin Amyloidosis Agents are considered experimental, investigational or unproven for any other use including the following
  - History of liver transplant
  - Treatment of cardiomyopathy hATTR in absence of polyneuropathy symptoms
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
  - New York Heart Association (NYHA) class III or IV heart failure
  - Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.)
  - Concurrent use of Tegsedi™ (inotersen), tafamidis, or diflunisal

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy **or** familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:
  - Documented genetic mutation of a pathogenic TTR variant
  - Confirmation of amyloid deposits on tissue biopsy
- Provider attests the member has documentation of the following:

  - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)
  - Clinical exam finding of abnormal nerve conduction study or neurological examination results
- Provider attests the member has one of the following:
  - A baseline polyneuropathy disability (PND) score ≤ IIIb
  - Has a baseline FAP Stage 1 or 2 **(stage 1=ambulatory, stage 2=ambulatory with assistance)**
- Provider attests the member has not received a liver transplant

Initial Authorization Length: 6 months

Reauthorization Dosing:

- **<100 kg:** 0.3 mg/kg every 3 weeks by intravenous infusion
- **≥100 kg**: 30mg every 3 weeks by intravenous infusion

Reauthorization Criteria:

- Member has previously received treatment with the requested medication
- Provider attests to all the following:
  - Member continues to have a polyneuropathy disability (PND) score ≤ IIIb
  - Member continues to have FAP Stage 1 or 2
  - Member has experienced a positive clinical response to the medication (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression)

Reauthorization Length: 6 months

References: Onpattro. Package Insert. Alnylam Pharmaceuticals. 2023

Orbactiv (oritavancin) (J2407)

Diagnosis: Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Age: 18 years and older

Initial Dosing: 1.2g as a single dose over 3 hours.

Exclusion Criteria:

- Use of intravenous unfractionated heparin sodium for 120 hours (5 days) after Orbactiv administration

Initial Authorization Criteria

- Member must have a diagnosis of ABSSSI
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents one of the following:
    - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication to vancomycin
    - Staphylococcus aureus with reduced susceptibility to vancomycin [vancomycin-intermediate Staphylococcus aureus (VISA), or vancomycin-resistant Staphylococcus aureus (VRSA)

Continuation of Therapy Following Inpatient Administration:

- Must be prescribed by or in consultation with an infectious disease specialist
- Only for administration in the Sentara/other health system infusion center (not for use in the hospital or emergency department)
- Only for patients discharged from a Sentara hospital/other qualified hospital
- Drug must be administered in the Sentara/other health system infusion center within 48 hours of discharge
- Use limited to the following:
    - Drug abuse patients
    - Physician does not want the patient to have a PICC line

Initial Authorization Length: 1 Day

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Reauthorization Length: NA

References: Orbactiv. Package Insert. Melinta Therapeutics. 2021

Orencia® (abatacept) IV Infusion Only (J0129)

Rheumatoid Arthritis

Psoriatic Arthritis

Juvenile Idiopathic Arthritis

Diagnosis: Juvenile Idiopathic Arthritis, Psoriatic Arthritis, and Rheumatoid Arthritis

Age: Varies based on disease state

Initial Dosing:

- **pJIA ≥6 years of age:**
  - **<75 kg:** 10 mg/kg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter
  - **≥75 to 100 kg:** 750 mg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter
  - **>100 kg:** 1000 mg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter
- **Adult RA and Adult PsA:**
  - **<60 kg:** 500mg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter
  - **60 to 100 kg:** 750 mg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter
  - **>100 kg:** 1000 mg intravenously 0, 2, and 4 weeks; then every 4 weeks thereafter

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with a Rheumatologist
- Provider attests the member has a moderate-to-severe diagnosis of pJIA, PsA, or RA
- Member has tried and failed one DMARD:

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Orencia. Package Insert. Bristol Meyers Squibb. 2023

Acute Graft Versus Host Disease

Diagnosis: Acute Graft Versus Host Disease (aGVHD)

Age: 2 years or older

Initial Dosing:

- **≤2 years of age:** 15 mg/kg as a 60-minute infusion on the day before transplantation, followed by a dose on Day 5, 14, and 2 after transplant
- **6 years and older:** 10 mg/kg (maximum dose 1000mg) as a 60-minute infusion on the day before transplantation, followed by a dose on Day 5, 14, and 2 after transplant

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member is undergoing a hematopoietic stem cell transplant (HSCT) from a matched or 1 allele-mismatched unrelated-donor
- Medication will be used for prophylaxis of acute graft versus host disease (aGVHD) (IV formulation only)
- Provider attestation the medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate
- Provider attestation the member will receive antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation and will continue for 6 months post-transplantation
- Provider attestation the member will be monitored for both EBV reactivation and cytomegalovirus (CMV) infection/reactivation

Initial Authorization Length: 4 doses only

Reauthorization Dosing: NA

Reauthorization Criteria: May not be renewed

References: Orencia. Package Insert. Bristol Meyers Squibb. 2023

Panhematin (hemin) (J1640)

Diagnosis: Acute Intermittent Porphyria; Attack

Age: ≥ 16 years of age

Initial Dosing: 1 to 4 mg/kg/day IV for 3 to 14 days; maximum: 6 mg/kg per 24 hours

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an obstetrics/genecology specialist
- Diagnosis of acute intermittent porphyria related to the menstrual cycle
- Documentation of elevation of urinary porphobilinogen (PBG) AND delta-aminolevulinic acid (ALA)
- Initial carbohydrate therapy has been documented to be inadequate
- Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling

Initial Authorization Length: 14 Days

Reauthorization Dosing: 1 to 4 mg/kg/day IV for 3 to 14 days; maximum: 6 mg/kg per 24 hours

Reauthorization Criteria:

- The member has previously been receiving Panhematin
- Documentation of positive clinical response to Panhematin (Effectiveness may be demonstrated by clinical improvement, or by a decrease in one or more of the following compounds in urine: ALA, PBG – porphobilinogen, Uroporphyrin, Coproporphyrin)
- Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling

References: Panhematin. Package Insert. Sagent Pharmaceuticals. 2020

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PiaSky (crovalimab-akkz) IV (J3590)

Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Age: 13 years or older who weigh at least 40 kg

Initial Dosing: Weight-based dosing applicable. Start with one loading dose administered by intravenous infusion, followed by 4 additional loading doses administered by subcutaneous injection. Then administer a maintenance dose every 4 weeks by subcutaneous injection.

- **Weight ≥ 40 kg to <100kg:**
  - **Loading Dose**: 1,000 mg IV on day 1 followed by 340 mg SQ on days 2, 8, 15, 22
  - **Maintenance Dose**: 680 mg SQ on day 29 and every 4 weeks thereafter
- **Weight ≥ 100 kg:**
  - **Loading Dose**: 1,500 mg IV on day 1 followed by 340 mg SQ on days 2, 8, 15, 22
  - **Maintenance Dose**: 1020 mg SQ on day 29 and every 4 weeks thereafter

Exclusion Criteria:

- Initiation during an unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Hematologist or Oncologist
- Prescriber must be enrolled in the Piasky Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have a confirmed diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 10% by flow cytometry testing
- Flow cytometry pathology report must demonstrate at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within 2 different cell lines from granulocytes, monocytes, and/or erythrocytes
- Member must have one of the following indications for therapy:
- Member is transfusion dependent as defined by having a transfusion within the last 12 months and one of the following:
  - Member's hemoglobin is less than or equal to 7g/dl
  - Member has symptoms of anemia and the hemoglobin is less than or equal to 9g/dl

- Member has high lactate dehydrogenase (LDH) level (defined as ≥ 1.5 times the upper limit of the normal range with clinical symptoms
- Presence of a thrombotic event (e.g., DVT, PE)
- Presence of organ damage secondary to chronic hemolysis
- Member is pregnant and benefit outweighs potential fetal risk

- Member does not have evidence of an active infection caused by encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis or Haemophilus influenzae)
- Medication will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, Soliris®, Ultomiris®, Empaveli®, Fabhalta®, Voydeya™)
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Member has **NOT** received a vaccination **at least two weeks prior** to the initiation of therapy with PiaSky® and documented the risks of delaying PiaSky® therapy outweigh the risks of developing an infection

Switch Therapy:

- PiaSky will be used as switch therapy and member meets all the following criteria:
  - Member is currently receiving treatment with eculizumab or ravulizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy
  - Provider attests administration of the IV loading dose will occur at the time of the next scheduled C5 inhibitor dose

Initial Authorization Length: 6 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug (i.e. meningococcal infections [septicemia and/or meningitis], infusion reactions, serious infections, etc.)
- Provider attests to a positive clinical response or stabilization as evidenced by any of the following while on Piasky therapy:
  - A decrease in LDH production from baseline
  - Stabilization of hemoglobin levels as supported by the following:
    - Member had a reduction in number of transfusions OR units of packed red cells transfused from baseline
    - Member maintained a hemoglobin concentration above 7g/dL OR maintained a hemoglobin concentration above 9g/dL if member had a baseline hemoglobin level above 7g/dL but below 9g/dL

- Member had a reduction in thrombotic events (e.g., DVT, PE)

Reauthorization Length: 6 months

References: Piasky. Package Insert. Genetech. 2024

Prevymis (letermovir) (J3490)

Cytomegalovirus (CMV), prophylaxis in HSCT

Diagnosis: Prophylaxis of Cytomegalovirus (CMV) infection and disease

Age: 18 years or older

Initial Dosing: 480 mg IV once daily through 200 days post-HSCT

Exclusion Criteria:

- Concomitant therapy with:
  - Pimozide
  - Ergot Alkaloids
  - Pitavastatin and simvastatin when co-administered with cyclosporine

Initial Authorization Criteria:

- Provider attestation to all the below:
  - Member is receiving this treatment for prophylaxis of cytomegalovirus (CMV) infection and disease
  - Provider attests the medication will be initiated between day 0 and day 28, before or after engraftment
  - Provider attests the member is not receiving the medication beyond 200 days post-transplant
  - Provider attests the member has a contraindication to therapy with oral Prevymis tablets and medical necessity to continue IV Prevymis therapy
- Member is a CMV-seropositive recipient [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)

Initial Authorization Length: 200 days of therapy

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Prevymis. Package Insert. Merck & Co. 2023

Cytomegalovirus (CMV), prophylaxis in kidney transplant

Diagnosis: Prophylaxis of Cytomegalovirus (CMV) infection and disease

Age: 18 years or older

Initial Dosing: 480 mg IV once daily through 200 days post-HSCT

Exclusion Criteria:

- Concomitant therapy with:
  - Pimozide
  - Ergot Alkaloids
  - Pitavastatin and simvastatin when co-administered with cyclosporine

Initial Authorization Criteria:

- Member will be receiving a kidney transplant
- Provider attestation to all the below:
  - Member is receiving this treatment for prophylaxis of cytomegalovirus (CMV) infection and disease
  - Provider attests the medication will be initiated between day 0 and day 7, before or after transplant
  - Provider attests the member is not receiving the medication beyond 200 days post-transplant
  - Provider attests the member has a contraindication to therapy with oral Prevymis tablets and medical necessity to continue IV Prevymis therapy
- Member is at high-risk for CMV disease [documentation recording kidney donor is CMV-seropositive, and the recipient (member) is CMV-seronegative (D+/R-)]

Initial Authorization Length: 200 days of therapy

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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References: Prevymis. Package Insert. Merck & Co. 2023

Prialt (ziconotide) (J2278)

Diagnosis: Refractory chronic pain secondary to intrathecal pain medication

Age: 18 years or older

Initial Dosing: 2.4 mcg/day (0.1 mcg/hr) and titrated to patient response
Note: Doses may be titrated upward by up to 2.4 mcg/day (0.1 mcg/hr) at intervals of no more than 2-3 times per week, up to a recommended maximum of 19.2 mcg/day (0.8 mcg/hr) by Day 21

Exclusion Criteria:

- Patients with a pre-existing history of psychosis with ziconotide
- Contraindications to the use of intrathecal analgesia include conditions such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF)

Initial Authorization Criteria:

- Prescribed by or in consultation with a pain management specialist
- Member meets one of the following:
    - Tried and failed other pain therapies including clonidine epidural and Duramorph epidural
    - History of prior and/or current narcotic abuse

Initial Authorization Length: 200 days of therapy

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Prialt. Package Insert. TerSera Therapeutics. 2023

Primaxin (cilastatin sodium/imipenem) IV (J0743)

Diagnosis:

- Lower Respiratory Tract Infections
- Urinary Tract Infections
- Intra-Abdominal Infections
- Gynecologic Infections
- Bacterial Septicemia
- Bone and Joint Infections
- Skin and Skin Structure Infections
- Endocarditis

Age: NA

Initial Dosing: Diagnosis, weight, and CrCl based

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected within the last 7 days
- Member must meet **ONE** of the following:
    - Trial and failure of one preferred oral **AND** IV antibiotic (e.g., amoxicillin, amoxicillin-clavulanate, cefazolin, cefdinir, cefepime, ceftriaxone, cephalexin, ciprofloxacin, clindamycin, dicloxacillin, doxycycline, ertapenem, fosfomycin, levofloxacin, linezolid, meropenem, nitrofurantoin, penicillin VK, piperacillin-tazobactam, and vancomycin)

Continuation of Therapy Following Inpatient Administration:

- Member has been on Primaxin >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Primaxin

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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References: Primaxin. Package Insert. Merck Sharp & Dohme. 2022

Prolia (denosumab) (J0897)

Age: ≥18 years or older

Exclusion Criteria:

- Hypocalcemia
- Pregnancy
- Concomitant use with Xgeva

Initial Authorization Criteria:

- Member must have one of the following FDA-approved indications:
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
    - Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
    - Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture, who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
    - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer.
    - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Initial Authorization Length: 12 months

Reauthorization Criteria:

- Member is currently receiving therapy with the requested medication AND for one of the FDA-approved indications listed in the *Initial Authorization Criteria* section
- Member has experienced clinical benefit from the requested medication

References: Prolia. Package Insert. Amgen Inc. 2024

Qalsody (tofersen) (C9157)

Diagnosis: Amyotrophic Lateral Sclerosis (ALS)

Age: ≥18 years or older

Initial Dosing: 100 mg (15 mL) per treatment for 3 doses administered at 14-day intervals, then every 28 days thereafter

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
- Member has weakness attributable to ALS confirmed by diagnostic testing (e.g., imaging, nerve conduction studies, laboratory results to support the diagnosis
- Documentation of genetic testing confirming the SOD1 mutation must be submitted

Initial Authorization Length: 12 months

Reauthorization Dosing: 100 mg (15 mL) every 28 days

Reauthorization Criteria:

- Member continues to meet the relevant indication-specific criteria in the *Initial Authorization Criteria* section
- Member has experienced clinical benefit from the requested medication

References: Qalsody. Package Insert. Biogen MA. 2023

Qutenza (capsaicin 8%) Patch (J7336)

Post-Herpetic Neuralgia

Diagnosis: Post-herpetic Neuralgia (PHN)

Age: ≥18 years or older

Initial Dosing: One patch to most painful area for 60 minutes; may apply up to 4 patches in a single application; may be repeated every 3 months

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member has a documented baseline Numerical Pain Rating Scale (NPRS) score
- Post-herpetic neuralgia has persisted for at least 6 months following healing of herpes zoster rash (i.e. crusting of the skin vesicles)
- Painful areas must not be located on the face, above scalp hairline, nor in proximity to mucous membranes
- Inadequate response, contraindication, or intolerance must be demonstrated to:
    - One tricyclic antidepressant (e.g. amitriptyline, nortriptyline, desipramine)
    - One gabapentinoid (e.g. pregabalin, gabapentin)

Initial Authorization Length: 3 months; Quantity Limit = 4 patches; 1120 billable units

Reauthorization Dosing: Same as initial.

Reauthorization Criteria:

- Member continues to meet the relevant indication-specific criteria in the *Initial Authorization Criteria* section
- There has been an absence of unacceptable toxicity from the medication (i.e. application site pain/burning, hypertension, decrease in sensory function
- Member has experienced an improvement in pain based on the Numberical Pain Rating Scale (NPRS) compared to baseline

Diabetic Peripheral Neuralgia

Diagnosis: Diabetic Peripheral Neuralgia (DPN)

Age: ≥18 years or older

Initial Dosing: One patch to feet for 30 minutes; may apply up to 4 patches in a single application; may be repeated every 3 months

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member has a documented baseline Numerical Pain Rating Scale (NPRS) score
- Member has painful, distal, symmetrical, sensorimotor polyneuropathy due to diabetes that has persisted for at least 1 year prior to screening
- All other causes of pain in the feet have been ruled out
- Inadequate response, contraindication, or intolerance must be demonstrated to:
    - One tricyclic antidepressant (e.g. amitriptyline, nortriptyline, desipramine)
    - One gabapentinoid (e.g. pregabalin, gabapentin)

Initial Authorization Length: 3 months; Quantity Limit = 4 patches; 1120 billable units

Reauthorization Dosing: Same as initial.

Reauthorization Criteria:

- Member continues to meet the relevant indication-specific criteria in the *Initial Authorization Criteria* section
- There has been an absence of unacceptable toxicity from the medication (i.e. application site pain/burning, hypertension, decrease in sensory function
- Member has experienced an improvement in pain based on the Numberical Pain Rating Scale (NPRS) compared to baseline

References: Qutenza. Package Insert. Averitas Pharma. 2023

AvMed Health Plans
Medicare Part B Drug Policy

Radicava (edaravone) IV (J1301)

Diagnosis: Amyotrophic Lateral Sclerosis (ALS)

Age: 18 years or older

Initial Dosing:

- **Initial Cycle:** 60 mg once daily for 14 days, followed by a 14-day drug-free period
- **Subsequent Cycles:** 60 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member has diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) per the EL Escorial
- Functionality retained on most activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised (ALSFRS-R) with the exception of dyspnea, orthopnea, and respiratory insufficiency which must be a score of 4)

ALSFRS-R Score For:	Score of 0	Score of 1	Score of 2	Score of 3	Score of 4
Speech Function	❑	❑	❑	❑	❑
Salivation Function	❑	❑	❑	❑	❑
Handwriting Function	❑	❑	❑	❑	❑
Cutting Food Function	❑	❑	❑	❑	❑
Dressing/Hygiene Function	❑	❑	❑	❑	❑
Turning in Bed Function	❑	❑	❑	❑	❑
Walking Function	❑	❑	❑	❑	❑
Climbing Stairs Function	❑	❑	❑	❑	❑
Dyspnea Function	❑	❑	❑	❑	❑
Orthopnea Function	❑	❑	❑	❑	❑
Respiratory Insufficiency Function	❑	❑	❑	❑	❑
Swallowing Function	❑	❑	❑	❑	❑

****Check the ALSFRS-R score that correlates to the patient for each of the following functions above****

-
- Member meets one of the following:
    - Tried and failed other pain therapies including clonidine epidural and Duramorph epidural
- Member has normal respiratory function confirmed by a % Forced Vital Capacity (%FVC) ≥80% at the start of treatment
- Provider attests the disease has been present two (2) years or less
- There has not been a history of spinal surgery after the onset of ALS
- Provider attests the medication will be used in combination with riluzole unless the patient has an FDA labeled contraindication or intolerance to riluzole

Initial Authorization Length: 6 months (86 doses over 180 days)

Reauthorization Dosing: 60 mg once daily for 10 days winin a 14-day period, followed by a 14-day drug-free period

Reauthorization Criteria:

- Provider attests to all the below:
    - Member is benefiting from therapy (e.g. slowing in the decline of functional abilities, and change in ALSFRS-R score has not changed -7 points from the last request)
    - Member has a normal respiratory function confirmed by % Forced Vital Capacity (%FVC) ≥70%
    - ALSFRS-R score for dyspnea, orthopnea, and respiratory insufficiency is 4
    - Medication will be used in combination with riluzole unless the patient has an FDA labeled contraindication or intolerance to riluzole

Reauthorization Length: 12 months (86 doses over 180 days)

References: Radicava. Package Insert. Mitsubishi Tanabe Pharma Corporation. 2022

Rebyota (fecal microbiota, live – jslm) (J1440)

Diagnosis: Recurrent Clostridium Difficile Infection Prophylaxis (CDI)

Age: 18 years or older

Initial Dosing: Rectal: 150 mL (contents of 1 bag) as a single dose, administered 24 to 72 hours after completion of C. difficile treatment regimen

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Infectious Disease Specialist or Gastroenterologist
- Member has a diagnosis of Clostridium difficile infection (CDI) confirmed by all the following:
  - Diarrhea (3 or more loose bowel movements within 24 hours or less)
  - Positive stool test for toxigenic C. difficile from a stool sample collected no more than 7 days prior
- This episode of CDI is at least 1 recurrent episode of CDI (> 2 total CDI episodes) in the past 6 months with previous treatment (e.g., vancomycin, fidaxomicin, including a pulsed vancomycin regimen)
- Requested medication will be used after antibiotic treatment for recurrent CDI (e.g., within 24 to 72 hours following the last dose of antibiotic treatment)
- Member is considered "high risk" for initial CDI defined by meeting at least ONE of the following:
  - Age ≥ 65 years
  - History of 1 or more CDI episodes within the previous six months
  - Compromised immunity
  - Documentation of hypervirulent strain (strains 027, 078, 244)
  - Clinically severe CDI (defined by a Zar score of ≥ 2 points):
    - Age > 60 years (1 point)
    - Body temperature > 38.3°C (1 point)
    - Albumin level 2.5 mg/dL (1 point)
    - Peripheral white blood cell count > 15,000 cells/mm3 within 48 hours (1 point)
    - Endoscopic evidence of pseudomembranous colitis (2 points)
    - Treatment in Intensive Care Unit (2 points)

Initial Authorization Length: One treatment per lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Rebyota. Package Insert. Ferring Pharmaceuticals. 2022

Recarbrio (Imipenem, Cilastatin, and Relebactam) (J0742)

Complicated Urinary Tract Infection or Pyelonephritis

Diagnosis – Complicated Urinary Tract Infection or Pyelonephritis

Age: 18 years of age or older

Initial Dosing:

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
    - Lab culture must show sensitivity to Recarbio
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin OR
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Initial Authorization Length: 7 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Reauthorization Length: NA

References: Recarbrio. Package Insert. Merck Sharp & Dohme. 2022

Complicated Intra-Abdominal Infections (cIAI)

Diagnosis – Complicated Intra-Abdominal Infections

Age: 18 years of age or older

Initial Dosing:

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
    - Lab culture must show sensitivity to Recarbio
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem OR
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Recarbrio >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Recarbrio

Initial Authorization Length: 7 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Recarbrio. Package Insert. Merck Sharp & Dohme. 2022

Releuko (Filgrastim-ayow) (Q5125)

No prior authorization required for oncology purposes

Retacrit (Epoetin alfa-epbx) (Q5105, Q5106)

No prior authorization required for oncology purposes

ESRD Members on Dialysis and CKD members not on dialysis

- The Health Plan follows LCD 39237 – Erythropoiesis Stimulating Agents for all non-oncologic requests

References:

1. Medicare Coverage Database

Rivfloza (nedosiran) (J3490)

Diagnosis – Primary Hyperoxaluria Type 1 (PH1) in patients 9 years of age or older

Age: 18 years or older

Dosing: 50kg or greater – 160mg once monthly; >50kg – 128mg once monthly

Exclusion Criteria: NA

Initial Authorization Criteria:

- Member ≥9 years of age
- Member has a definitive diagnosis of PH1 confirmed by biallelic pathogenic mutation in the alanine:glyoxalate aminotransferase (AGXT) gene as identified on molecular genetic testing
- Member has signs and symptoms attributed to PH1
- Member has ONE of the following:
  - Increased urinary oxalate excretion (i.e. greater than 0.7 mmol/1.73 m2 per day [90 mg/1.73 m^2 per day])
  - Increased urinary oxalate:creatinine ratio relative to normative values for age
- Member has eGFR ≥30 mL/min/1.73 m^2
- Member is not receiving hemodialysis

Initial Authorization Length: 6 months

Reauthorization Dosing: NA

Reauthorization Criteria:

- Member has experienced response to treatment as determined by prescriber

References: Rivfloza. Package Insert. Novo Nordisk. 2023

Rituximab IV (rituximab) (J9310/J9312)

Drugs Included:

Riabni™ (rituximab-arrx) (Q5123)
Rituxan® (rituximab) (J9312)
Ruxience™ (rituximab-pvvr) (Q5119)
Truxima® (rituximab-abbs) (Q5115)

The Health Plan follows LCD L35026 “Rituximab

References:

2. Medicare Coverage Database

Rituxan Hycela (rituximab and hyaluronidase) (J9311)

Chronic Lymphocytic Leukemia

Diagnosis: Chronic Lymphocytic Leukemia

Age: 18 years or older

Initial Dosing: Rituximab (1,600mg)/Hyaluronidase (26,800 units) (fixed dose) on day 1 of 28-day cycle in cycles 2 through 6 (in combination with fludarabine and cyclophosphamide)

Prescribing Information:

- All members must receive at least one full dose of intravenous rituximab (without experiencing severe adverse reactions) PRIOR to initiating treatment with subcutaneous rituximab/hyaluronidase.
- Members who do not tolerate a full IV dose should continue to receive IV rituximab in subsequent cycles.
- Members may be switched to subcutaneous rituximab/hyaluronidase injection AFTER a full IV dose has been successfully administered

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Oncologist
- Member has a confirmed diagnosis of chronic lymphocytic leukemia

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Diffuse Large B-Cell Lymphoma

Diagnosis: Diffuse Large B-Cell Lymphoma

Age: 18 years or older

Initial Dosing: Rituximab (1,400mg)/Hyaluronidase (23,400 units) (fixed dose) on day 1 of cycles 2 through 8 in combination with doxorubicin and cyclophosphamide, vincristine, and prednisone (CHOP)

Prescribing Information:

- All members must receive at least one full dose of intravenous rituximab (without experiencing severe adverse reactions) PRIOR to initiating treatment with subcutaneous rituximab/hyaluronidase.
- Members who do not tolerate a full IV dose should continue to receive IV rituximab in subsequent cycles.
- Members may be switched to subcutaneous rituximab/hyaluronidase injection AFTER a full IV dose has been successfully administered

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Oncologist
- Member has a confirmed diagnosis of diffuse large B-cell lymphoma

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Follicular Lymphoma

Diagnosis: Follicular Lymphoma

Age: 18 years or older

Initial Dosing:

- **Previously untreated:** Rituximab 1,400 mg/hyaluronidase 23,400 units (fixed dose) on day 1 of a 21-day cycle in cycles 2 through 8
- **Maintenance**: rituximab 1,400 mg/hyaluronidase 23,400 units (fixed dose) once every 8 weeks for 12 doses
- **Non-progressing disease following 6 to 8 cycles of first-line CVP chemotherapy**: Rituximab 1,400 mg/hyaluronidase 23,400 units (fixed dose) once weekly for 3 weeks (IV rituximab should be administered in week 1 for a total of 4 weeks of therapy) at 6-month intervals to a maximum of 16 doses.
- **Relapsed or refractory:** Rituximab 1,400 mg/hyaluronidase 23,400 units (fixed dose) once weekly for 3 weeks (IV rituximab should be administered in week 1) for a total of 4 weeks of therapy
- **Relapsed or refractory (retreatment**): Rituximab 1,400 mg/hyaluronidase 23,400 units (fixed dose) once weekly for 3 weeks (IV rituximab should be administered in week 1) for a total of 4 weeks of therapy

Prescribing Information:

- All members must receive at least one full dose of intravenous rituximab (without experiencing severe adverse reactions) PRIOR to initiating treatment with subcutaneous rituximab/hyaluronidase.
- Members who do not tolerate a full IV dose should continue to receive IV rituximab in subsequent cycles.
- Members may be switched to subcutaneous rituximab/hyaluronidase injection AFTER a full IV dose has been successfully administered

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Oncologist
- Member has a confirmed diagnosis of diffuse large B-cell lymphoma

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Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Rituxan Hycela. Package Insert. Genetech. 2021

Roctavian (valoctocogene roxaparvovec-rvox) (J1412)

Age: 18 years of age and older

Dosing: 1 infusion per lifetime: The dose of Roctavian is 2 x 10^13 genome copies (gc) per kilogram (kg) of body weight (or 2 mL/kg body weight) administered as an intravenous infusion = 44 vials

Exclusion Criteria

- Active infections, either acute or uncontrolled chronic
- Known significant hepatic fibrosis (stage 3 or 4), or cirrhosis
- Known hypersensitivity to mannitol

Initial Authorization Criteria

- Medication has been prescribed by, or in consultation with, a specialist in hematology or treating a patient population with Hemophilia A
- Member has a diagnosis of hemophilia A confirmed by a genetic panel (laboratory documentation required)
- Member has severe hemophilia A (congenital factor VIII deficiency) documented by a factor VIII activity level < 1 IU/dL (in the absence of exogenous factor VIII) (Assay results for activity level documentation required)
- Provider attests that any other bleeding disorder NOT related to hemophilia A has been ruled out
- Member must meet ONE of the following treatment scenarios:
    1. Member is on a stable dose of routine prophylaxis, regularly administered exogenous factor VIII for the prevention and control of bleeding for at least 12 months prior to the request of this treatment, as assessed and documented by prescriber, AND the member has been treated with factor VIII replacement therapy for a minimum of 150 exposure days
    2. Member is currently receiving chronic prophylactic Hemlibra® (emicizumab) therapy
- If the member has preexisting risk factors for hepatocellular carcinoma [e.g., patients with hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic

steatohepatitis (NASH), and advanced age], the provider will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration with Roctavian
- Post administration monitoring of patient serum ALT levels will be performed according to the monitoring schedule outlined in the product labeling with corticosteroids (or other immunosuppressive therapy) administered in response to elevations)
- Member has NOT received prior hemophilia AAV-vector–based gene therapy
- Member has is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA approved or CLIA-compliant test (laboratory documentation required)
- Member has been tested and found negative for active factor VIII inhibitors (i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) on 2 consecutive occasions at least one week apart within the past 12 months) and is NOT receiving a bypassing agent (e.g., Feiba)
- Provider documents a therapeutic plan to monitor the member's Factor VIII activity periodically, and discontinue routine prophylactic exogenous Factor VIII and any bispecific factor IXa- and factor X directed antibody therapy when activity levels >5 IU/dL)

Initial Authorization Length

- One treatment per lifetime. Coverage may NOT be renewed

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Roctavian. Package Insert. BioMarin Pharmaceutical. 2023

Rolvedon (Eflapegrastim-xnst) (J1449)

No prior authorization required for oncology purposes

Romidepsin IV

Non-lyophilized (J9318)
Lyophilized (J9319)

Diagnosis – Cutaneous T-Cell Lymphoma (CTCL) or Peripheral T-Cell Lymphoma (PTCL)

Age: 18 years of age and older

Dosing:

- **CTCL**: 14 mg/m2 days 1, 8, and 15 of a 28-day treatment cycle; repeat cycle as long as benefit continues and treatment is tolerated
- **PTCL**: 14 mg/m2 days 1, 8, and 15 of a 28-day treatment cycle for up to 6 cycles or until disease progression in patients with stable disease, partial response, or complete response or until disease progression or unacceptable toxicity

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has **ONE** of the following:
    - Diagnosis of CTCL and has tried with an inadequate response, intolerance, or contraindication to at least one prior therapy (e.g. retinoids, corticosteroids)
    - Diagnosis of PTCL and has tried with an inadequate response, intolerance, or contraindication to at least one prior therapy (e.g. conventional chemotherapy, stem cell transplant)

Authorization Length: Initial: 12 months; Reauthorization: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Romidepsin. Package Insert. Bristol Myers Squibb. 2021

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Ruconest (CI Inhibitor Recombinant) (J0596)

Diagnosis: Acute Attacks in Hereditary Angioedema

Age: 6 years or older

Initial Dosing:

- **<84 kg:** 50U per kg (Maximum 420 billable units per 28 days)
- **≥84 kg:** 4200 U (2 vials) (Maximum 420 billable units per 28 days)

Exclusion Criteria:

- History of immediate hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations

Initial Authorization Criteria:

- Prescribed by or in consultation with a specialist in Allergies, Immunology, Hematology, Pulmonology, or Medical Genetics
- Member has a history of one of the following:
  - Severe cutaneous episodes
  - Abdominal attacks (debilitating gastrointestinal symptoms)
  - Mild to severe airway swelling attacks of HAE (i.e. laryngeal/pharyngeal/tongue swelling)
- Confirmation the member is avoiding the following possible triggers for HAE attacks:
  - Helicobacter pylori infections
  - Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - Antihypertensive agents containing ACE-inhibitors
- **Member has ONE of the following clinical presentations consistent with HAE subtype, which is confirmed by repeat blood testing:**
  - **HAE I:**
    - Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test)
    - Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
    - Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **AND** one of the following:
      - Member has a family history of HAE

        - Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
    - **HAE II**:
        - Normal C1-INH antigenic level
        - Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
        - Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **AND** one of the following:
            - Member has a family history of HAE
            - Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
    - **HAE III:**
        - Normal C1-INH antigenic level
        - Normal C4 level
        - Normal C1-INH functional level
        - Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II
        - Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with one of the following:
            - Antifibrinolytic agent (i.e. tranexamic acid or aminocaproic
            - 17α- alkylated androgen (i.e. danazol)
            - Progestins (female patients only)
- Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene or kininogen-1
- Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g. cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) AND corticosteroids

Initial Authorization Length: 12 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member must continue to meet the criteria in section I & II.A - C.
- Significant improvement in severity and duration of attacks have been achieved and sustained

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions

References: Ruconest. Package Insert. Pharming Americas. 2020

Rybrevant (Amivantamab-vmjw) (J9061)

No prior authorization required for oncology purposes

Rylaze (Asparaginase Erwinia Chrysanthemi (Recombinant)-rywn) (J9021)

No prior authorization required for oncology purposes

Simponi Aria IV (golimumab) (J1602)

Moderate-to-Severe Active Rheumatoid Arthritis (RA)

Active Psoriatic Arthritis

Diagnosis: Moderate-to-Severe RA and Active Psoriatic Arthritis

Age: 2 years or older

Initial Dosing:

- **Moderate-to-Severe Rheumatoid Arthritis:** 2mg/kg at weeks 0, 4, and then every 8 weeks thereafter (in combination with methotrexate)
- **Active Psoriatic Arthritis**
  - **≥2 years and Adolescents**: 80 mg/m2/dose at weeks 0, 4, and then every 8 weeks thereafter
  - **18 years and older**: 2 mg/kg at weeks 0, 4, and then every 8 weeks

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Rheumatologist
- Trial and failure of at least one DMARD therapy:
  - Methotrexate
  - Hydroxychloroquine
  - Auranofin
  - Azathioprine
  - Leflunomide
  - Sulfasalazine

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Polyarticular Juvenile Idiopathic Arthritis

Diagnosis: Polyarticular Juvenile Idiopathic Arthritis

Age: ≥2 years or older

Initial Dosing: : 80 mg/m2/dose at weeks 0, 4, and then every 8 weeks thereafter

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Rheumatologist

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Active Ankylosing Spondylitis

Diagnosis: Active Ankylosing Spondylitis

Age: 18 years or older

Initial Dosing: 2 mg/kg at weeks 0, 4, and then every 8 weeks thereafter

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Rheumatologist
- Trial and failure of at least TWO NSAIDs

Initial Authorization Length: Lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Simpony Aria. Package Insert. Janssen. 2021

Simulect (basiliximab) (J0480)

Diagnosis: Kidney Transplant Rejection

Age: NA

Initial Dosing: Weight dependent

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Nephrologist and/or transplant specialist
- Member has received a kidney transplant
- Physician provided documentation that patient's prophylaxis therapy includes cyclosporine modified and corticosteroids
- Basiliximab dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling

Initial Authorization Length: 30 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

References: Simulect. Package Insert. Novartis Pharmaceuticals. 2020

Sivextro (tedizolid phosphate) (J3090)

Diagnosis: Acute bacterial skin and skin structure infections (ABSSSI)

Age: ≥ 12 years of age

Initial Dosing: 200 mg once daily for 6 days

Exclusion Criteria: NA

Initial Authorization Criteria:

- Provider must attest to diagnosis of acute bacterial skin and skin structure infection
- Submit lab cultures from current hospital admission or office visit collected within the last 7 days
- Culture must show that bacteria is sensitive to Sivextro or linezolid
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: penicillin VK, amoxicillin, amoxicillin-clavulanate, dicloxacillin, cephalexin, clindamycin, doxycycline, trimethoprim-sulfamethoxazole, and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: penicillin VK, amoxicillin, amoxicillin-clavulanate, dicloxacillin, cephalexin, clindamycin, doxycycline, trimethoprim-sulfamethoxazole, and linezolid
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: penicillin G, nafcillin, ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, vancomycin, daptomycin, clindamycin, and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: penicillin G, nafcillin, ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, vancomycin, daptomycin, clindamycin, and linezolid
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member is Currently on Sivextro >72 hours inpatient (progress notes must be submitted)
- Culture sensitivity results retrieved during admission shows resistance to all preferred antibiotics except for Sivextro (sensitive)

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Initial Authorization Length: 6 Days

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Sivextro. Package Insert. Merck Sharp & Dohme. 2023

Soliris (eculizumab) (J1300)

Diagnosis: Neuromyelitis Optica Spectrum Disorder (NMOSD)

Age: 18 years and older

Dosing: Max – 4 vials every 14 days

- IV Induction – 900 mg weekly for 4 doses
- Maintenance – 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

Dose Adjustments:

- Dosage adjustment for members receiving plasmapheresis or plasma exchange:
  - If most recent dose was ≥ 600 mg, administer 600 mg within 60 minutes after each plasmapheresis or plasma exchange
  - If most recent dose was 300 mg, administer 300 mg within 60 minutes after each plasmapheresis or plasma exchange
- Dose adjustment for members receiving fresh frozen plasma infusion:
  - If most recent dose was ≥ 300 mg, administer 300 mg within 60 minutes prior to each infusion of fresh frozen plasma

Exclusion Criteria:

- Unresolved meningococcal disease
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics
- Treatment with rituximab or mitoxantrone within the 3 months prior to Soliris® therapy
- Treatment with IVIG within 3 weeks prior to Soliris® therapy
- Use of greater than 20mg/day of oral glucocorticoids with or without other immunosuppressive therapy prior to treatment
- Concurrent treatment with disease-modifying therapies for multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab))

Initial Authorization Criteria:

- Prescribed by or in consultation with a nephrologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program

- Member must have a diagnosis of NMOSD confirmed by ALL the following:
  - Past Medical History of ONE of the following:
    - Optic neuritis
    - Acute myelitis
    - Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
    - Acute brainstem syndrome
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
  - Positive serologic test for anti-aquaporin-4 immunoglobulin (AQP4-IgG) antibodies (documentation submitted)
  - Diagnosis of multiple sclerosis or other diagnoses have been ruled out
- Member must meet ONE of the following [A historical relapse is defined as a new onset of neurologic symptoms or worsening of existing neurologic symptoms with an objective change on neurologic examination (clinical findings, magnetic resonance imaging findings, or both) that persist for more than 24 hours and/or the new onset of neurologic symptoms or worsening of existing neurologic symptoms that require treatment]:
  - Member has a history of at least one relapse during the previous 12 months prior to initiating Soliris
  - Member has a history of at least two relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris
- Medication will not be prescribed concurrently with with other complement inhibitor therapies (e.g., rvulizumab), IL-6 inhibitors (e.g., toclizumab), anti-CD20 directed antibody therapy (e.g., rituximab), or anti-CD19 directed antibody therapy (e.g., inebilizumab-cdon)
- Medication will not be used in combination with disease-modifying therapies for the treatment of multiple sclerosis (e.g., fingolimod, dimethyl fumorate, etc)
- Member does not have a systemic infection
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug

- Provider attests to a positive clinical response or stabilization while on therapy

Reauthorization Length: 6 months

Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Age: 18 years and older

Dosing: Max – 4 vials every 14 days

- IV Induction – 600 mg weekly for 4 doses
- Maintenance – 900 mg at week 5, then 900 mg every 2 weeks thereafter

Exclusion Criteria:

- Unresolved meningococcal disease
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics

Initial Authorization Criteria:

- Prescribed by or in consultation with a hematologist or nephrologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have a confirmed diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 10% by flow cytometry testing (documentation submitted)
- Flow cytometry pathology report must demonstrate at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within 2 different cell lines from granulocytes, monocytes, erythrocytes (must submit labs)
- Member must have ONE of the following indications for therapy:
    - Member is transfusion dependent as defined by having a transfusion within the last 12 months and ONE of the following:
        - Member's hemoglobin is less than or equal to 7 g/dL
        - Member has symptoms of anemia and the hemoglobin is less than or equal to 9 g/dL
    - Member has high lactate dehydrogenase (LDH) level (defined as ≥ 1.5 times the upper limit of the normal range with clinical symptoms)
    - Presence of a thrombotic event (e.g., DVT, PE)
    - Presence of organ damage secondary to chronic hemolysis
    - Presence of organ damage secondary to chronic hemolysis

  - Member is pregnant and potential benefit outweighs potential fetal risk
- Member does not have a systemic infection
- Medication will not be prescribed concurrently with another FDA approved product prescribed for the treatment of PNH (e.g., Bkemv, Epysqli, PiaSky, Ultomiris, Fabhalta, etc)
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug
- Provider attests to a positive clinical response or stabilization as evidenced by any of the following while on Soliris therapy:
  - Documentation of a recent (within 3 months) LDH level that shows a reduction from baseline
  - Documentation that the member has stabilized hemoglobin levels as supported by ONE of the following:
    - Member had a reduction in number of transfusions OR units of packed red cells transfused from baseline
    - Member maintained a hemoglobin concentration above 7 g/dL OR maintained a hemoglobin concentration above 9 g/dL if member had a baseline hemoglobin level above 7 g/dL but below 9 g/dL
  - Member had a reduction in thrombotic events (e.g., DVT, PE)

Reauthorization Length: 6 months

Diagnosis: Atypical Hemolytic Uremic Syndrome (aHUS)

Exclusion Criteria:

- Unresolved meningococcal disease

Initial Authorization Criteria:

- Prescribed by or in consultation with a Hematologist, Oncologist, or Nephrologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have a confirmed diagnosis or Atypical Hemolytic Uremic Syndrome (aHUS)
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level >10%)
- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out
- Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug induced malignant hypertension, HIV infection; etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency
- Documented baseline values of the following must be attested to by the provider: serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement
- Member does not have a systemic infection
- Will not be used in combination with other complement inhibitor therapy
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug
- Provider attests to a positive clinical response or stabilization as evidenced by any of the following while on Soliris therapy:
    - An increase in platelet count from baseline
    - Maintenance of normal platelet counts and LDH levels for at least 4 weeks
    - A 25% reduction in serum creatinine for a minimum of four weeks
    - Absence for at least 12 weeks of a decrease in platelet count of >25% from baseline, plasma exchange or plasma infusion, and new dialysis requirement

Reauthorization Length: 6 months

Diagnosis: Generalized Myasthenia Gravis

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Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies
- Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination
- Physician must have assessed and submitted a baseline Quantitative Myasthenia Gravis (QMG) score
- Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6
- Member has one of the following:
  - Member has tried and had an inadequate response to pyridostigmine
  - Member has an intolerance, hypersensitivity or contraindication to pyridostigmine
- Member has tried and failed at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
- Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- Member does not have a systemic infection
- Will not be used in combination with other complement inhibitor therapy
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug
- Member is receiving benefit from therapy

Reauthorization Length: 6 months

Diagnosis: Neuromyelitis Optica Spectrum Disorder (NMOSD)

Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have positive diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin (AQP4-IgG) antibodies
- Member exhibits one of the following core clinical characteristics of NMOSD:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- Will not be used in combination with other complement inhibitor therapy
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug
- Member is receiving benefit from therapy

Reauthorization Length: 6 months

Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a hematologist or neurologist
- Prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have positive diagnosis of PNH confirmed by detection of PNH clones of at least 10% by flow cytometry testing
- Flow cytometry pathology report must demonstrate at least two different glycosylphosphatidylinositol (GPI) protein deficiencies within two different cell lines from granulocytes, monocytes, erythrocytes
- Member is transfusion dependent as defined by having one of the following:
  - Member's hemoglobin is less than or equal to 7g/dL
  - Member has symptoms of anemia and the hemoglobin is less than or equal to 9g/dL
- Member has high lactate dehydrogenase (LDH) level defined as ≥1.5 times the upper limit of normal range with clinical symptoms
- Will not be used in combination with other medications for the same indication
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Soliris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug
- Member is receiving benefit from therapy

Reauthorization Length: 6 months

References: Soliris. Package Insert. Alexion Pharmaceuticals. 2024

Skyrizi IV (risankizumab-rzaa) (J2327)

Diagnosis: Crohn's Disease or Ulcerative Colitis

Age: ≥ 18 years of age

Initial Dosing: Induction dosing 600 – 1200mg, depending on diagnosis, at week 0, 4, and 8

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a gastroenterologist
- Confirmed diagnosis of moderately to severely active disease
- Member must have prior therapy with a corticosteroid or an immunomodulator

Initial Authorization Length: 2 months

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Skyrizi. Package Insert. AbbVie. 2024

Spevigo (spesolimab-sbzo) (J1747)

Diagnosis – Generalized Pustular Psoriasis (GPP) Flare

Age: 12 years of age or older and weighs at least 40 kg

Dosing: 900 mg dose [2 vials] at the beginning of each flare

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis
- Member has a known documented history of GPP (either relapsing [≥1 episode] or persistent [≥3 months] and is experiencing an acute, moderate-to-severe intensity disease flare
- Member is presenting with primary, sterile, macroscopically visible pustule on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)
- Diagnosis of GPP flare has been confirmed by documentation of at least ONE of the following:
- IL36RN, CARD14, or AP1S3 gene mutation
- Skin biopsy confirming presence of Kogoj's spongiform pustules
- Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]
- GPP flare of moderate-to-severe intensity (BSA ≥ 5% covered with erythema and the presence of fresh pustules, GPPPGA total score ≥ 3, GPPPGA pustulation sub score ≥ 2 (mild))
- Provider attestation of the following:
- Member will not receive live vaccine during or 16 weeks after treatment with the requested medication
- Member does not have an active infection, including clinically important localized infections
- Member is NOT on concurrent treatment with an IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib)
- Member will NOT use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus)
- Member does NOT have any of the following conditions:
    - Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome
    - Primary erythrodermic psoriasis vulgaris
    - Primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques
    - Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP)

Initial Authorization Length: Date of Service

Reauthorization Criteria

- Member is still experiencing persistent symptoms of an acute flare of GPP of moderate to severe intensity, as defined by BOTH of the following:
- Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of at least 2
- GPPGA pustulation sub score of at least 2 (i.e., moderate to very high-density pustules)
- Second infusion will take place no sooner than one week after the initial infusion

Reauthorization Length

- Date of service

Spravato (esketamine) (J3490)

Diagnosis – Treatment-Resistant Depression (TRD)/Major Depressive Disorder with Suicidal Ideation

Age: 18 years of age and older

Dosing:

- Weeks 1 to 4: Twice weekly: Day 1 starting dose: 56mg; Subsequent doses: 56mg or 84mg
- Weeks 5 to 8: Once weekly: 56mg or 84mg
- Week 9+: Every 2 weeks or once weekly: 56mg or 84mg

Exclusion Criteria

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation
- Intracerebral hemorrhage

Initial Authorization Criteria

- Spravato must be prescribed by or in consultation with a psychiatrist
- Provider attests the member is experiencing moderate to severe symptomology documented by a standardized rating scale that reliably measures depressive symptoms
- Member must have experienced clinical failure or intolerance with at least two (2) antidepressant therapies from at least two (2) different drug classes.
    - Attestation required (drug, dose, and duration along with the reason for discontinuation)
        i. Failures must be of adequate dose (maximally tolerated)
        ii. Failures must be of adequate duration (at least 6 weeks)
        iii. Adherent fills required (verified by pharmacy claims)
        iv. Failures must occur during current depressive episode
    - Antidepressant therapy would include any of the following classes:
        i. Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
        ii. Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine; etc.)
        iii. Bupropion
        iv. Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline; etc.)
        v. Mirtazapine

vi. Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine; etc.)
vii. Serotonin modulators (e.g., nefazodone, trazodone; etc.)

- Prescriber attests the member has been assessed for the risk for abuse of controlled substances (i.e., review of medical history, review of state prescription monitoring program (PMP)).

Initial Authorization Length: 3 months

Reauthorization Criteria

- Member must have sustained improvement/clinical response to Spravato defined by improvement from baseline scoring measured using the same scale submitted for initial approval.
  - Attestation of a recent scale with scoring (administered within the previous 30 days)

Reauthorization Length

- 6-months; Subsequent reauthorization: 12-months

Stelara (ustekinumab) (J3358)

Note: Members are approved for the requested medication under the medical benefit when given intravenously for induction dosing only**.** All maintenance doses administered subcutaneously should be approved under the member's pharmacy benefit using the coverage determination form found at Sentara Health Plans.

Diagnosis – Ulcerative Colitis or Crohn's Disease

Age: 18 years and older

Induction Dosing :

- ≤55 kg: 260 mg as single dose; 260 mg = 260 billable units
- >55 kg to 85 kg: 390 mg as single dose; 390 mg = 390 billable units
- >85 kg: 520 mg as single dose; 520 mg = 520 mg billable units

Exclusion Criteria: Sentara Health Plans considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has NOT been established and will NOT be permitted

Initial Authorization Criteria:

- Must be prescribed by or in consultation with a gastroenterologist
- Confirmed diagnosis of moderately to severely active disease
- Member must have prior therapy with a corticosteroid or an immunomodulator

Initial Authorization Length: 2 months

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Stelara. Package Insert. AbbVie. 2024

Sustol (Extended-Release Granistron) (SQ PFS) (J1627)

Diagnosis – Chemotherapy Associated Nausea and Vomiting

Age: NA

Dosing: Weight based dosing

Exclusion Criteria

- Sustol is NOT covered for breakthrough emesis, or repeat dosing in multi-day emetogenic chemotherapy regimens

Initial Authorization Criteria

- The member meets **ONE** of the following:
  - The member is receiving highly emetogenic chemotherapy (HEC) [e.g., any chemotherapy regimen that contains an anthracycline and cyclophosphamide; additionally, agents such as carboplatin with AUC≥4, carmustine with dose>250mg/m2, cisplatin, dacarbazine, doxorubicin with dose≥60mg/m2, epirubicin with dose≥90mg/m2].
  - The member is on moderate-low risk emetogenic chemotherapy **AND** has failed (defined as two or more documented episodes of vomiting) with palonosetron while receiving the current chemotherapy regimen.
- The requested therapy will administered subcutaneously by a healthcare provider, on Day 1 of chemotherapy; not more frequently than once every 7 days

Initial Authorization Length: 6 months

Reauthorization Criteria

- Member continues to meet the initial authorization criteria

Reauthorization Length

- 6-months

Sylvant (siltuximab) (J2860)

Diagnosis – Chemotherapy Associated Nausea and Vomiting

Age: Adults ≥ 18 years old

Dosing: 11 mg/kg every 3 weeks until treatment failure.

Exclusion Criteria

- Limitations of use: Siltuximab has not been studied in patients with MCD who are HIV positive or HHV-8 positive because in a nonclinical study, siltuximab did not bind to virally produced IL-6

Initial Authorization Criteria

- Prescribed by or in consultation with an oncologist, immunologist, and/or infectious disease specialist
- Attestation that Sylvant will be used as a single agent
- Documented diagnosis of Multicentric Castleman Disease
- Member is human immunodeficiency virus-negative and human herpesvirus-8-negative
- Member is currently free of all clinically significant infections and does not have evidence of organ failure
- Complete Blood Count (CBC) testing that documents all of the following prior to the first siltuximab dose:
    - Absolute neutrophil count greater than or equal to 1.0 x109/L
    - Platelet count greater than or equal to 75 x109/L
    - Hemoglobin that is less than or equal to 17g/dL
- The member will NOT receive any live vaccines while being treated with siltuximab
- Female patients must be advised of reproductive potential and counseled on the use of effective contraception during treatment with Sylvant and for 3 months after the last dose.

Initial Authorization Length: 6 months

Reauthorization Criteria

- No evidence of disease progression/treatment failure and the member has an absolute neutrophil count greater than or equal to1.0 x 109/L, a platelet count of greater than or equal to 50 x 109, and hemoglobin level less than 17g/dL

Reauthorization Length

- 6-months

Synagis (palivizumab) (90378)

Diagnosis – Respiratory Syncytial Virus, Prophylaxis

Age: Infants and Children ≤24 months

Dosing: Maximum 5 doses (dosed until March 31st)

Weight-based Dose	Dosage	Dispense Units
0 – 3.5 kg	≤ 53 mg	1 vial of 50 mg/0.5mL
3.6 –7 kg	54 – 105 mg	1 vial of 100 mg/1ml
7.1 – 10.3 kg	106.5 – 154.5 mg	1 vial of 50 mg/0.5mL and 1 vial of 100 mg/1mL
10.4 – 13.6 kg	156 – 205 mg	2 vials of 100 mg/1mL
13.7 – 16.93 g	205.5 – 254 mg	1 vial of 50 mg/0.5mL and 2 vials of 100 mg/1mL
17 – 20.3 kg	255 – 305 mg	3 vials of 100 mg/1mL

Additional Information

- Approval will be given for the current dosage and vial size(s). Throughout the RSV season, weight changes should be submitted on the Synagis request form when a different vial size(s) is/are required.
- Requests for doses exceeding the five (5) dose maximum or beyond the season end date will be denied
- As defined by The National Respiratory and Enteric Virus Surveillance System (NREVSS): RSV season is over when virology is < 10% for 2 consecutive weeks.
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV Hospitalization
- For all requests received after March 31st – If all below conditions are met, the request will be approved for an additional 1-month duration.
- For all requests received prior to November 1st – For members born between 32 to less than 35 weeks of gestation (without any significant medical conditions), if all below conditions are met, the request will only be approved for a maximum quantity of up to 3 doses.
- For requests to initiate treatment of Synagis prior to November 1st:
- Local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS) RSV Surveillance website **OR** recent surveillance data from a local/regional hospital (dated within < 14 days prior to the member's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality
- Member meets the stated criteria for their chronological and/or gestational age

- For requests to administer an additional dose of Synagis after March 31st:
- Member has NOT already received the maximum approvable five (5) doses of Synagis according to the member's chronological age, gestational age, and/or clinical situation
- Local virology data supplied from the National Respiratory & Enteric Virus Surveillance System (NREVSS): RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within < 14 days prior to the member's appointment) indicates an incidence of RSV greater than 10% (percent positive total antigen detection tests greater than 10%) for that locality

Exclusion Criteria

- NA

Initial Authorization Criteria

- **Preterm Infants without Chronic Lung Disease (CLD) of Prematurity or Congenital Heart Disease (CHD)**
- Patient must meet one of the following:
    - Infants without CLD or CHD born <28 weeks, 6 days and member's current age <12 months
    - Infants without CLD or CHD born between ≥ 29 weeks to 31 weeks, 6 days and member's current age ≤6 months at start of (RSV) season
- **Infants with Hemodynamically Significant Congenital Heart Disease (CHD)**
- Infants in the first year or second year of life who are undergoing cardiac transplant or cardiac bypass **DURING** the RSV season
  Note: For children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of Synagis should be considered after cardiac bypass or at the conclusion of extra-corporeal membrane oxygenation for infants and children younger than 24 months
- Infants < 12 months old at the start of RSV season with hemodynamically significant heart disease defined by ONE of the following:
    - Acyanotic CHD, receiving treatment for congestive heart failure (CHF) and requires cardiac surgery
    - Moderate to severe pulmonary hypertension (PH, PAH)
    - Cyanotic CHD and Synagis is recommended by a pediatric cardiologist

EXAMPLES OF SIGNIFICANT AND APPROVABLE CARDIAC CONDITIONS
Examples of significant hemodynamic cyanotic congenital heart disease:
Tetralogy of Fallot, Transportation of the great vessels, Ebstein's anomally, Tricuspid atresia, Total anomalous pulmonary venous return, Truncus arteriosus, Hypoplastic left heart syndrome

NON-APPROVABLE CARDIAC CONDITIONS	
Insignificant hemodynamic heart disease (and therefore are NOT approvable indications):	**Indications in which patients are NOT at an increased risk for RSV (and therefore are NOT approvable indications)**
Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus	• Lesions adequately corrected by surgery (unless the patient continues to require medications for CHF) • Mild cardiomyopathy who are NOT receiving medical therapy

- **Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder**
  - Infants <12 months old (first year life) with a neuromuscular disorder(s) or congenital pulmonary anomaly that impairs the ability to clear secretions from upper airway
  - Provider attests the member has one of the following:
    - Pulmonary malformation
    - Tracheoesophageal fistula
    - Upper airway conditions
    - Requires trachestomy
- **Immunocompromised Children**
  - Provider attests the infant or child <24 months of age is severely immunocompromised DURING the RSV season (i.e., receiving chemotherapy, undergoing solid organ or hematopoietic stem cell transplantation)
- **Children with Cystic Fibrosis**
  - Infants < 12 months old (first year of life) with Cystic Fibrosis with clinical evidence of CLD and/or nutritional compromise (e.g., requires total parenteral nutrition)
  - Infants with Cystic Fibrosis <24 months and >12 months (second year life) with manifestations of severe lung disease (e.g., previous history of hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest x-ray or CT scan that persist when stable or patient weight for length is less than the 10th percentile)

Initial Authorization Length

- 5 doses (dosed until March 31st)

Reauthorization Criteria

- NA

Reauthorization Length

- NA

References: Synagis. Package Insert. Sobi. 2021

Tecartus (Brexucabtagene autoleucel) IV (Q2053)

Diagnosis: B-Cell Lymphoma

Age: 18 years of age and older

Dosing (Treatment): Diagnosis dependent; One infusion only

Exclusion Criteria

- NA

Initial Authorization Criteria

- Healthcare facility has enrolled in the YESCARTA® & TECARTUS® REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member has NOT received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during treatment, and will not receive live vaccines until immune recovery following treatment
- Member does NOT have a clinically significant active systemic infection or inflammatory disorder
- Member has NOT received prior CAR-T therapy
- Member does NOT have primary central nervous system lymphoma
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Member must have an ECOG performance status of 0-1
- Member must also meet all diagnosis-specific criteria listed below:

Mantle Cell Lymphoma

- Member has not received prior allogeneic hematopoietic stem cell transplantation (HSCT)
- Member does not have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells or brain metastases
- Member has a confirmed diagnosis of Mantle Cell Lymphoma, determined to be relapsed or refractory

B-Cell Precursor Acute Lymphoblastic Leukemia

- Member has relapsed or refractory disease
- Member does not have CNS-3 disease or CNS-2 disease with neurological changes
- Member meets one of the following:
    - Member has not received prior anti-CD19 therapy(e.g. blinatumomab)
    - Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease
- Member's current state satisfies one of the following:
    - Member has Philadelphia chromosome (Ph)-positive disease refractory to tyrosine kinase inhibitors (TKIs) or intolerant to TKIs
    - Member has Philadelphia chromosome (Ph)-negative disease

References: Tecartus. Package Insert. Kite Pharma Inc. 2024

Tecelra (Afamitresgene Autoleucel) (C9399/J9999)

Diagnosis: Unresectable or Metastatic Synovial Sarcoma

Age: 18 years of age and older

Initial Dosing: The recommended dose is between 2.68 x 109 to 10 x 109 MAGE-A4 T cell receptor (TCR) positive T cells

Exclusion Criteria:

- Left ventricular ejection fraction (LVEF) less than 50%
- History of hypersensitivity to dimethyl sulfoxide (DMSO)
- Clinically significant active systemic infection
- Symptomatic brain metastases including leptomeningeal disease

Initial Authorization Criteria

- Must be prescribed by or in consultation with an oncologist and the administrating healthcare facility is trained in the management of cytokine release syndrome (CRS) and neurological toxicities
- Member must not have received any prior CAR-T therapy
- Member must not have received systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion
- Member must not have received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g. adequate renal and hepatic function)
- Member has been screened and found to be negative for Epstein Barr Virus (EBV), Cytomegalovirus (CMV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and any other infectious agents, if clinically indicated
- Member must be HIV-negative as confirmed by an HIV test prior to mobilization
  Note: Patients who have received Tecelra are likely to test false-positive on some commercial HIV nucleic acid tests for HIV due to the lentiviral vector used to make Tecelra having limited, short spans of genetic material which is identical to HIV
- Provider must attest the member will be monitored for secondary malignancies periodically after treatment
- Member has a diagnosis of unresectable or metastatic synovial sarcoma confirmed by the presence of a translocation between SYT on the X chromosome and SSX1, SSX2, or SSX4 on chromosome 18 (may be presented in the pathology report as t (X; 18))
- Member's condition has been confirmed to express the MAGE-A4 tumor antigen as determined by FDA-approved or cleared companion diagnostic device

- Member's condition has been confirmed to show positive for the HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, and HLA-A*02:06P allele
- Member's condition does NOT have HLA-A*02:05P in either allele (i.e., heterozygous or homozygous)
- Member has received one prior line of therapy with an anthracycline (e.g., doxorubicin) or ifosfamide
  Note: Members who have a contraindication or are intolerant to both anthracycline and ifosfamide must have previously received at least one systemic therapy

Initial Authorization Length: One time only

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Tecelra. Package Insert. Adaptimmune, LLC. 2024

Tecentriq/Tecentriq Hybreza (Atezolizumab) (J9022)

No prior authorization required for oncology purposes

Teflaro (ceftaroline fosamil) (J0712)

Diagnosis: Acute bacterial skin and skin structure infections (ABSSSI)

Age: NA

Initial Dosing: Age and weight based dosing

Exclusion Criteria:

- CAP with Pseudomonas risk, unless continuing from inpatient use

Initial Authorization Criteria

- Member must have a diagnosis of ABSSSI
- Must be prescribed by or in consultation with an infectious disease specialist
- Culture and sensitivity report documents one of the following:
    - Methicillin-resistant Staphylococcus aureus infection (MRSA) in a patient with an allergy or contraindication to vancomycin
    - Staphylococcus aureus with reduced susceptibility to vancomycin [vancomycin-intermediate Staphylococcus aureus (VISA), or vancomycin-resistant Staphlyococcus aureus (VRSA)

Continuation of Therapy Following Inpatient Administration:

- Must be prescribed by or in consultation with an infectious disease specialist
- Only for administration in the Sentara/other health system infusion center (not for use in the hospital or emergency department)
- Only for patients discharged from a Sentara hospital/other qualified hospital
- Drug must be administered in the Sentara/other health system infusion center within 48 hours of discharge
- Use limited to the following:
    - Drug abuse patients
    - Physician does not want the patient to have a PICC line

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Reauthorization Length: NA

References: Teflaro. Package Insert. Allergan. 2021

Community-acquired bacterial pneumonia (CABP) with MRSA risk

Diagnosis: Community-Acquired Bacterial Pneumonia (CABP) with MRSA risk

Age: NA

Initial Dosing: Age and weight based dosing

Exclusion Criteria:

- CAP with Pseudomonas risk, unless continuing from inpatient use

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected within the last 7 days
- Culture must show that bacteria is sensitive to Teflaro
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: amoxicillin, amoxicillin-clavulanate, dicloxacillin, doxycycline, azithromycin, cefdinir, cefpodoxime, levofloxacin, ciprofloxacin and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: amoxicillin, amoxicillin-clavulanate, dicloxacillin, doxycycline, azithromycin, cefdinir, cefpodoxime, levofloxacin, ciprofloxacin and linezolid
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, azithromycin, levofloxacin, and ciprofloxacin, vancomycin, and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, azithromycin, levofloxacin, and ciprofloxacin, vancomycin, and linezolid
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Teflaro >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Teflaro

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

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Reauthorization Criteria: NA

Reauthorization Length: NA

References: Teflaro. Package Insert. Allergan. 2021

Tegsedi (inotersen) (J3490)

Diagnosis: Hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy and Familial amyloid polyneuropathy (FAP)

Age: 18 years or older

Initial Dosing: 284 mg subcutaneous once weekly

Exclusion Criteria:

- History of acute glomerulonephritis caused by TEGSEDI
- Platelet count less than 100 x 10^9/L
- Hereditary Transthyretin Amyloidosis Agents are considered experimental, investigational or unproven for ANY other use including the following:
  - History of liver transplant; OR
  - History of acute glomerulonephritis caused by Tegsedi™; OR
  - Severe renal impairment or end-stage renal disease; OR
  - Moderate or severe hepatic impairment: OR
  - New York Heart Association (NYHA) class III or IV heart failure; OR
  - Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.), OR
  - Concurrent use of Onpattro® (patisiran), tafamidis or diflunisal

Initial Authorization Criteria:

- Medication must be prescribed by or in consultation with a neurologist
- Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy **or** familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:
  - Documented genetic mutation of a pathogenic TTR variant
  - Confirmation of amyloid deposits on tissue biopsy
- Member must be enrolled in the Tegsedi™ Risk Evaluation and Mitigation Strategy (REMS) program
- Prescriber must attest the patient is positive for **ALL** of the following:
  - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

- A baseline polyneuropathy disability (PND) score ≤ IIIb **OR** a baseline FAP Stage 1 or 2 **(stage 1=ambulatory, stage 2=ambulatory with assistance)**
- Member has not received a liver transplant
- Urinary protein to creatinine ratio (UPCR) is below 1000 mg/g
- The estimated glomerular filtration rate (eGFR) above 45 mL/minute/1.73 m^2

Initial Authorization Length: 6 months

Reauthorization Dosing: 284 mg subcutaneous once weekly

Reauthorization Criteria:

- Member has previously received treatment with Tegsedi™
- Tegsedi™ must have been prescribed by or in consultation with a neurologist
- Must have documentation of ONE of the following:
  - Member continues to have a polyneuropathy disability (PND) score ≤ IIIb or continues to have a FAP Stage 1 or 2
- Must have documentation that member has experienced a positive clinical response to Tegsedi™ (e.g., improved neurologic **impairment, motor function, quality of life, slowing of disease progression, etc.)**
- Must have absence of drug toxicity

Reauthorization Length: 6 months

References: Tegsedi. Package Insert. Janssen. 2021

Testosterone Replacement Therapy

Drugs Included:

Aveed (testosterone undecanoate) (J3145)
TestoPel (testosterone pellets) (11980/S0189)
Testosterone Cypionate (J1071)
Testosterone Enanthate (J3121)
Testosterone Undeconate (J3145)

The Health Plan follows L39086 Local Coverage Determination (LCD) Treatment of Males with Low Testosterone

References: Medicare Coverage Database

Tofidence (tocilizumab) (Q5133)

Step Therapy Requirements for ALL Indications

- Step Therapy Required. Please see Part B Step Therapy Document: Step Therapy Requirements for Sentara Medicare Outpatient (Part B) Medications (sitecorecontenthub.cloud)
    - Member must have tried one of the preferred products prior to approval of a non-preferred product

Diagnosis - Rheumatoid Arthritis

Age: 18 years and older

Dosing: 4 mg/kg once every 4 weeks; may be increased to 8 mg/kg once every 4 weeks based on clinical response (maximum dose: 800mg/dose)

Exclusion Criteria: None

Initial Authorization Criteria

- Trial and failure of one of the following DMARD therapies:
  Note: Tyenne may be used alone or with DMARDs.
    - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length: 12 months

Diagnosis – Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Age: 2 years and older

Dosing:

- <30kg: 10mg/kg/dose every 4 weeks
- ≥30kg: 8mg/kg/dose every 4 weeks

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Exclusion Criteria: None

Authorization Criteria

- Trial and failure of one of the following DMARD therapies
  Note: Tyenne may be used alone or with methotrexate only.
  - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Authorization Length: 12 months

Diagnosis - Systemic Juvenile Idiopathic Arthritis (SJIA)

Age: 2 years and older

Dosing:

- <30kg: 12mg/kg every 2 weeks
- ≥30kg: 8mg/kg/dose every 2 weeks

Exclusion Criteria: None

Initial Authorization Criteria

- Member must have confirmed disease as defined by one of the following:
  - ≥5 active joint with fever for ≥2 weeks
  - ≥2 active joints with fever for ≥5 days in combination with prednisone 0.5mg/kg/day
- Fever>38°C or 100.4°F for ≥2 weeks
- Member is between 2-17 years of age
- Trial and failure of NSAIDs **and/or** intra-articular glucocorticoids
- Trial and failure of non-biologic DMARD
  Note: Tofidence may be used alone or with methotrexate only.
  - Methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References: Tofidence. Package Insert. Biogen MA Inc. 2024. Clinical Practice Guidelines (rheumatology.org)

Tremfya (guselkumab) (J1628)

Note: Members are approved for the requested medication under the medical benefit for the purposes of induction for the ulcerative colitis indication only**.** All other doses beyond induction will be administered subcutaneously starting with 100mg at week 16, and every 8 weeks thereafter, or 200 mg at week 12 and every 4 weeks thereafter.

Diagnosis – Ulcerative Colitis

Age: 18 years and older

Dosing: 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8

Exclusion Criteria: None

Initial Authorization Criteria

- Trial and failure of one of the conventional therapies used for ulcerative colitis
    - Examples of conventional therapies include, but are not limited to, corticosteroids, immunosuppressants, etc.
- Provider attestation the member has moderately to severely active disease

Initial Authorization Length: 3 months

Reauthorization Criteria

- Members are approved for the requested medication under the medical benefit for the purposes of induction for the ulcerative colitis indication only
- All other doses beyond induction will be administered subcutaneously starting with 100mg at week 16, and every 8 weeks thereafter, or 200 mg at week 12 and every 4 weeks thereafter

Reauthorization Length: 12 months

References: Tremfya. Package Insert. Janssen Biotech. 2024.

Trogarzo IV (ibalizumab-uiyk) (J1746)

Diagnosis: Multidrug Resistant HIV Infection

Age: 18 years or older

Initial Dosing: Single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks administered as a diluted intravenous infusion (IV infusion) or undiluted intravenous push

Exclusion Criteria: NA

Initial Authorization Criteria:

- Diagnosis of HIV-1 infection
- Medication is being prescribed or in consultation with an Infectious Disease Specialist or a specialist in HIV treatment
- Member has been treated with antiviral therapy for at **least 6 months**
- Member has been identified to have multidrug resistant HIV-1 infection with documented resistance to at least **ONE** antiretroviral medication from at least **three (3)** of the following antiretroviral drug classes **(genotype/phenotype resistance testing results included)**:
  - Nucleoside Reverse Transcriptase Inhibitors
  - Non-Nucleoside Reverse Transcriptase Inhibitors
  - Protease Inhibitors
  - Entry Inhibitors
  - Integrase Inhibitors
- Member has a viral load greater than 1,000 copies/mL and must list Current Viral Load (recent lab work indicating viral load prior to initiating therapy must be included)
- Provider confirms ibalizumab will be used in conjunction with an optimized background regiment for antiretroviral therapy

Initial Authorization Length: 6 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Submission of documentation and/or lab work indicating patient has had a decrease in viral load since initiation of ibalizumab

- Must state patients viral load **after 6 months of treatment**
- Prescriber confirms member has continued an optimized background regimen during ibalizumab therapy

Reauthorization Length: 12 months

References: Trogarzo. Package Insert. Thera Technologies. 2019

Tyenne (tocilizumab-aazg) (Q5135)

Diagnosis – Giant Cell Arteritis

Age: 18 years and older

Dosing: The recommended dose is 6 mg per kg every 4 weeks in combination with a tapering course of glucocorticoids.

Exclusion Criteria: None

Initial Authorization Criteria

- Trial and failure of one of the following therapies:
  - 40mg of prednisolone daily for 4 weeks
  - 80mg of prednisolone daily if eye symptoms for 4 weeks

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length: 12 months

Diagnosis - Rheumatoid Arthritis

Age: 2 years and older

Dosing: 4 mg/kg once every 4 weeks; may be increased to 8 mg/kg once every 4 weeks based on clinical response (maximum dose: 800mg/dose)

Exclusion Criteria: None

Initial Authorization Criteria

- Trial and failure of one of the following DMARD therapies:
  - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Initial Authorization Length: 12 months

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Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length: 12 months

Diagnosis – Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Age: 2 years and older

Dosing:

- <30kg: 10mg/kg/dose every 4 weeks
- ≥30kg: 8mg/kg/dose every 4 weeks (maximum dose: 800mg/dose)

Exclusion Criteria: None

Authorization Criteria

- Trial and failure of one of the following DMARD therapies
    - Methotrexate, sulfasalazine, leflunomide, hydroxychloroquine

Authorization Length: 12 months

Diagnosis - Systemic Juvenile Idiopathic Arthritis (SJIA)

Age: 2 – 17 years of age

Dosing:

- <30kg: 12mg/kg every 2 weeks
- ≥30kg: 8mg/kg/dose every 2 weeks (maximum dose: 800mg/dose)

Exclusion Criteria: None

Initial Authorization Criteria

- Member must have confirmed disease as defined by one of the following:
    - ≥5 active joint with fever for ≥2 weeks

  - ≥2 active joints with fever for ≥5 days in combination with prednisone 0.5mg/kg/day
- Fever>38°C or 100.4°F for ≥2 weeks
- Member is between 2-17 years of age
- Trial and failure of NSAIDs **and** high dose corticosteroids for ≥3 months

Initial Authorization Length: 12 months

Reauthorization Criteria

- Member has experienced disease response with treatment
- Member has experienced an absence of unacceptable toxicity from the drug

Reauthorization Length

- 12 months

References: Tyenne. Fresenius Kabi USA. Package Insert. 2024

Tygacil (tigecycline) (J3243)

Diagnosis – Complicated Intra-Abdominal Infections

Age: 18 years of age or older

Initial Dosing:

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
  - Lab culture must show sensitivity to Recarbio
- Member must meet **ONE** of the following:
  - Trial and failure of all the following oral antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem OR
  - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Recarbrio >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Recarbrio

Initial Authorization Length: 7 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Recarbrio. Package Insert. Merck Sharp & Dohme. 2022

Tysabri (natalizumab) (J2323)

Multiple Sclerois

Diagnosis: Multiple Sclerosis

Age: 18 years or older

Initial Dosing: IV 300 mg infused over 1 hour every 4 weeks

Exclusion Criteria:

- Patients who have had or currently have PML

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Member has a confirmed diagnosis of relapsing-remitting MS
- Member has had at least **one** medically documented clinical relapse within 12 months
- Member is registered with the Tysabri® risk management program known as TOUCH
- Member has tried and failed at least one of the following agents or current **or** potential disease progression warrants the use of Tysbri:
    - Aubagio (teriflunomide)
    - Bafiertam (monomethyl fumarate)
    - Copaxone (glatiramer acetate)
    - Plegridy (peginterferon beta-1a)
    - Kesimpta (ofatumumab)
    - Mavenclad (cladribine)
    - Mayzent (siponimod)
    - Avonex (IFN beta-1b)
    - Extavia (IFN beta-1a)
    - Rebif (beta-1a)
    - Betaseron (IFN beta-1a)
    - Gilenya (fingolimod)
    - Tecfidera (dimethyl fumarate)
    - Vumerity (diroximel fumarate)
    - Zeposia (ozanimod)

Initial Authorization Length: Lifetime

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Tysabri. Package Insert. Biogen. 2023

Crohn's Disease

Diagnosis: Crohn's Disease

Age: 18 years or older

Initial Dosing: IV 300 mg infused over 1 hour every 4 weeks
Note: Discontinue if therapeutic benefit is not observed within initial 12 weeks of therapy

Exclusion Criteria:

- Patients who have had or currently have PML

Initial Authorization Criteria:

- Prescribed by or in consultation with a Gastroenterologist
- Member has a confirmed diagnosis of moderate-to-severe active Crohn's Disease with evidence of inflammation
- Member is registered with the Tysabri® risk management program known as CD TOUCH
- Member has tried and failed conventional therapies (i.e. budesonide or high dose steroids i.e prednisone 40-60mg)

Initial Authorization Length: Lifetime

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Tysabri. Package Insert. Biogen. 2023

Tzield (teplizumab) (J3590/C9399)

Diagnosis: Stage II Type I Diabetes

Age: 8 years or older

Initial Dosing:

- **Day 1**: 65 mcg/m2
- **Day 2**: 125 mcg/m2
- **Day 3**: 250 mcg/m2
- **Day 4**: 500 mcg/m2
- **Days 5 through 14**: 1,030 mcg/m2

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescribed by or in consultation with an Endocrinologist
- Member does not have any of the following:
  - Stage 1 or Stage 3 Type 1 Diabetes
  - Prior course of teplizumab
  - Received a live or live-attenuated vaccine within 8 weeks of starting treatment
  - Received an inactivated or mRNA vaccine within 2 weeks of starting treatment
  - Active infection
  - Lymphocyte count <1,000 lymphocytes/mcL
  - Absolute neutrophil count <1,500 neutrophils/mcL
- Member has at least one biologic relative with diagnosis of Type I Diabetes
- Member must be 18 years of age or older
- Member has a confirmed diagnosis of Stage 2 Type 1 diabetes defined by both of the following:
  - A) two of the following pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 (GAD) autoantibodies, Insulin autoantibody (IAA), Insulinoma-associated antigen 2 autoantibody (IA-2A), Zinc transporter 8 autoantibody (ZnT8A), Islet cell autoantibody (ICA)
  - B) Dysglycemia without overt hyperglycemia using oral glucose test defined by ONE of the following:
    - Fasting glucose 110-125mg/dL
    - 2-hour postprandial plasma glucose 140-199 mg/dL
    - An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL)

- Requested agent will be used as single agent therapy

Initial Authorization Length: One 14-Day Treatment only

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Tzield. Package Insert. Provention Bio. 2023

Ultomiris IV (ravulizumab-cwvz) (J1303)

Atypical Hemolytic Uremic Syndrome

Diagnosis: Atypical Hemolytic Uremic Syndrome

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Age: 1 month of age or older and has a weight of at least 5 kilograms

Initial Dosing:
Note: Members switching from eculizumab to Ultomiris should administer the loading dose of Ultomiris® 2 weeks after the last eculizumab infusion, and then administer maintenance doses once every 8 weeks, starting 2 weeks after loading dose administration as above

Indications	Body Weight Range (kg)	Loading Dose (mg)**	Maintenance Dose (mg) and Dosing Interval	
PNH and aHUS	5 to less than 10	600	300	Every 4 weeks
	10 to less than 20	600	600	
	20 to less than 30	900	2,100	Every 8 weeks
	30 to less than 40	1,200	2,700	
PNH, aHUS, and gMG	40 to less than 60	2,400	3,000	Every 8 weeks
	60 to less than 100	2,700	3,300	
	100 or greater	3,000	3,600	

Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Hematologist, Oncologist, or Nephrologist
- Prescriber must be enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have a confirmed diagnosis or Atypical Hemolytic Uremic Syndrom (aHUS)
- Thrombotic Thrombocytopenic Pupura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level >10%)
- Shinga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out

- Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug induced malignant hypertension, HIV infection; etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency
- Documented baseline values of the following must be attested to by the provider: serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement
- Member does not have a systemic infection
- Will not be used in combination with other complement inhibitor therapy (e.g., eculizumab)
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Ultomiris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Ultomiris® and documented the risks of delaying Ultomiris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.
- Provider attests to a positive clinical response or stabilization as evidenced by any of the following while on Ultomiris therapy:
    - An increase in platelet count from baseline
    - Maintenance of normal platelet counts and LDH levels for at least 4 weeks
    - A 25% reduction in serum creatinine for a minimum of four weeks
    - Absence for at least 12 weeks of a decrease in platelet count of >25% from baseline, plasma exchange or plasma infusion, and new dialysis requirement

Reauthorization Length: 6 months

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Diagnosis: Paroxysmal Nocturnal Hemoglobinuria

Age: 1 month of age or older and has a weight of at least 5 kilograms

Initial Dosing:
Note: Members switching from eculizumab to Ultomiris should administer the loading dose of Ultomiris® 2 weeks after the last eculizumab infusion, and then administer maintenance doses once every 8 weeks, starting 2 weeks after loading dose administration as above

Indications	Body Weight Range (kg)	Loading Dose (mg)**	Maintenance Dose (mg) and Dosing Interval	
PNH and aHUS	5 to less than 10	600	300	Every 4 weeks
	10 to less than 20	600	600	
	20 to less than 30	900	2,100	Every 8 weeks
	30 to less than 40	1,200	2,700	
PNH, aHUS, and gMG	40 to less than 60	2,400	3,000	Every 8 weeks
	60 to less than 100	2,700	3,300	
	100 or greater	3,000	3,600	

Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Hematologist or Oncologist
- Prescriber must be enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have a confirmed diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 10% by flow cytometry testing
- Flow cytometry pathology report must demonstrate at least 2 different glycosylphosphatidylinositol (GPI)
- Member must have one of the following indications for therapy:

- Member is transfusion dependent as defined by having a transfusion within the last 12 months and one of the following:
- Member's hemoglobin is less than or equal to 7g/dl **OR** one of the following:
    - Member has symptoms of anemia and the hemoglobin is less than or equal to 9g/dl
    - Member has high lactate dehydrogenase (LDH) level (defined as ≥ 1.5 times the upper limit of the normal range with clinical symptoms
    - Presence of a thrombotic event (e.g., DVT, PE)
    - Presence of organ damage secondary to chronic hemolysis
    - Presence of organ damage secondary to chronic hemolysis
    - Member is pregnant and potential benefit outweighs potential fetal risk
- Member does not have a systemic infection
- Will not be used in combination with other complement inhibitor therapy (e.g., eculizumab)
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Ultomiris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Ultomiris® and documented the risks of delaying Ultomiris therapy outweigh the risks of developing a meningococcal infection
- Medication will not be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, PiaSky®, Soliris®, Empaveli®, or Fabhalta®)

Initial Authorization Length: 6 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.
- Provider attests to a positive clinical response or stabilization as evidenced by any of the following while on Ultomiris therapy:
    - A decrease in LDH production from baseline
    - Stabilization of hemoglobin levels as supported by the following:
        - Member had a reduction in number of transfusions OR units of packed red cells transfused from baseline

- Member maintained a hemoglobin concentration above 7g/dL OR maintained a hemoglobin concentration above 9g/dL if member had a baseline hemoglobin level above 7g/dL but below 9g/dL
- Member had a reduction in thrombotic events (e.g., DVT, PE)

Reauthorization Length: 6 months

Generalized Myasthenia Gravis (gMG)

Diagnosis: Generalized Myasthenia Gravis

Age: 18 years or older

Initial Dosing:
Note: Members switching from eculizumab to Ultomiris should administer the loading dose of Ultomiris® 2 weeks after the last eculizumab infusion, and then administer maintenance doses once every 8 weeks, starting 2 weeks after loading dose administration as above

Indications	Body Weight Range (kg)	Loading Dose (mg)**	Maintenance Dose (mg) and Dosing Interval	
PNH and aHUS	5 to less than 10	600	300	Every 4 weeks
	10 to less than 20	600	600	
	20 to less than 30	900	2,100	Every 8 weeks
	30 to less than 40	1,200	2,700	
PNH, aHUS, and gMG	40 to less than 60	2,400	3,000	Every 8 weeks
	60 to less than 100	2,700	3,300	
	100 or greater	3,000	3,600	

Exclusion Criteria:

- Initiation in patients with unresolved serious Neisseria meningitidis infection

Initial Authorization Criteria:

- Prescribed by or in consultation with a Neurologist
- Prescriber must be enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies
- Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination
- Physician must have assessed and submitted a baseline Quantitative Myasthenia Gravis (QMG) score
- Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6

- Member has ONE of the following:
  - Member has tried and had an inadequate response to pyridostigmine
  - Member has an intolerance, hypersensitivity or contraindication to pyridostigmine
- Member must have ONE of the following:
  - Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
- Provider attests member has had an inadequate response, contraindication or intolerance to TWO of the following medications:
  - Vyvgart or Vyvgart Hytrulo
  - Rystiggo
- Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- Member does not have a systemic infection
- Will not be used in combination with other complement inhibitor therapy (e.g., eculizumab)
- Member must be administered a meningococcal vaccine at least two weeks prior to initiation of
- Ultomiris® therapy and revaccinated according to current medical guidelines for vaccine use **OR** the member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Ultomiris® and documented the risks of delaying Ultomiris therapy outweigh the risks of developing a meningococcal infection

Initial Authorization Length: 6 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member continues to meet the initial criteria
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.
- Member has demonstrated an improvement of at least 3 points from baseline in the Myasthenia Gravis Specific Activities of Daily Living scale (MG-ADL)
- Member has demonstrated an improvement of at least 5 points from baseline in the Quantitative Myasthenia Gravis (QMG)

Reauthorization Length: 6 months

References: Ultomiris. Package Insert. Alexion Pharmaceuticals. 2024

Xerava IV (eravacycline) (J0122)

Diagnosis: Complicated Intra-Abdominal Infections (cIAI)
(Only for patients who have limited or no alternative treatment options)

Age: 18 years or older

Initial Dosing: 1mg/kg by intravenous infusion over approximately 60 minutes every 12 hours for a total duration of 4 to 14 days

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
  - Lab culture must show sensitivity to Xerava
- Member must meet **ONE** of the following:
  - Trial and failure of all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem
  - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Xerava >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Xerava

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

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References: Xerava. Package Insert. Tetraphase Pharmaceuticals. 2021

Vabomere (meropenem and vaborbactam) (J2186)

Diagnosis – Complicated Urinary Tract Infection or Pyelonephritis

Age: 18 years of age or older

Initial Dosing: 4g every 8 hours in patients with eGFR ≥ 50 mL/min

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
    - Lab culture must show sensitivity to Vabomere
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin OR
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Vabomere >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Vabomere

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Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Vabomere. Package Insert. Melinta Therapeutics. 2023

Valstar (valrubicin) IV

Diagnosis – Carcinoma in situ (CIS) of the Urinary Bladder

Age: 18 years of age and older

Dosing: 800 mg administered intravesically once a week for six weeks; 4 billable units = 4 vials

Exclusion Criteria

- Perforated bladder or compromised bladder mucosa
- Concurrent urinary tract infections

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has a diagnosis of recurrent or persistent CIS of the urinary bladder and meet the following criteria:
    - Failure of intravesical BCG (bacillus Calmette- Guérin) treatment, unless contraindicated or clinically significant adverse effects are experienced
    - Cystectomy is not a therapeutic option as it would be associated with unacceptable morbidity or mortality

Authorization Length: One time authorization

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Valstar. Package Insert. Endo Pharmaceuticals. 2019

Vegzelma (Bevacizumab-adcd) (Q5129)

No prior authorization required for oncology purposes

Vibativ (telavancin) (J3095)

Diagnosis: Complicated skin and skin structure infections (cSSSI)

Age: ≥ 18 years of age

Initial Dosing: 10 mg/kg by IV infusion over 60 minutes every 24 hours for 7 to 14 days

Exclusion Criteria:

- Hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP)- Inpatient administration **(unless continuing from inpatient use)**
- Intravenous Unfractionated Heparin Sodium

Initial Authorization Criteria:

- Provider must attest to diagnosis of complicated skin and skin structure infection
- Submit lab cultures from current hospital admission or office visit collected within the last 7 days
- Culture must show that bacteria is sensitive to Vibativ or vancomycin
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: penicillin VK, amoxicillin, amoxicillin-clavulanate, dicloxacillin, cephalexin, clindamycin, doxycycline, trimethoprim-sulfamethoxazole, and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: penicillin VK, amoxicillin, amoxicillin-clavulanate, dicloxacillin, cephalexin, clindamycin, doxycycline, trimethoprim-sulfamethoxazole, and linezolid
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: penicillin G, nafcillin, ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, vancomycin, daptomycin, clindamycin, and linezolid
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: penicillin G, nafcillin, ampicillin, ampicillin-sulbactam, cefazolin, ceftriaxone, vancomycin, daptomycin, clindamycin, and linezolid
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member is Currently on Vibativ >72 hours inpatient (progress notes must be submitted)

- Culture sensitivity results retrieved during admission shows resistance to all preferred antibiotics except for Vibativ (sensitive)

Initial Authorization Length: 14 Days

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Vibativ. Package Insert. Cumberland Pharmaceuticals. 2023

Vyvgart (efgartigimod alfa-fcab)) (J9332)

Diagnosis: Generalized Myasthenia Gravis (gMG)

Exclusions:

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any active or clinically significant infections that has not been treated

Age: 18 years or older

Initial Dosing: The recommended dosage is 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) in cycles of once weekly injections for 4 weeks. Administer subsequent treatment cycles based on clinical evaluation; safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescriber by or in consultation with a neurologist
- Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies (lab test must be submitted)
- Member has a baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 5 (documentation required)
- Member has a baseline immunoglobulin G (IgG) level of at least 6 g/L (600 mg) (documentation required)
- Member has tried and failed or has an intolerance or contraindication to pyridostigmine
- Member has tried and failed or has an intolerance or contraindication to one of the following:
    - Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
    - Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
- Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)

- Member does NOT have an active infection, including clinically important localized infections
- Requested medication will NOT be administered with live-attenuated or live vaccines during treatment
- Medication will NOT be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, rozanolixizumab-noli, zilucoplan)

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member has NOT experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions)
- Member meets ONE of the following:
    - Member has demonstrated an improvement of at least 2 points in the MG-ADL total score from baseline sustained for at least 4 weeks (documentation required)
    - Member has demonstrated an improvement of at least 3 points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks (documentation required)
- Member requires continuous treatment, after initial beneficial response, due to new or worsening disease activity
  Note: A minimum of 50 days must have elapsed form the start of the previous treatment cycle

Reauthorization Length: 6 months

References: Vyvgart Hytrulo. Package Insert. Halozyme Therapeutics. 2024

Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) (J9334)

Diagnosis: Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Age: 18 years or older

Initial Dosing: The recommended dosage is 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) as once weekly injections

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescriber by or in consultation with a specialist for CIDP
- Member has progressive or relapsing and remitting CID for > 2 months (documentation required)
- Member was determined to have Probable or Definite CIDP according to EFNS/PNS 2010
- Member has decreased or absent deep tendon reflexes in upper or lower limbs
- Electrodiagnostic testing indicating demyelination must meet TWO of the following
    - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
    - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
    - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves
    - Reduced motor conduction velocity in at least 2 motor nerves
    - Prolonged distal motor latency in at least 2 motor nerves
    - Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
    - Prolonged F wave latency in at least 2 motor nerves
    - >30% amplitude reduction of the proximal negative peak CMAP relative to distal, excluding the posterior tibial nerve, if distal negative peak CMAP>20% of LLN, in two nerves, or in one nerve + >1 other demyelinating parameter in >1 other nerve
- Member has a baseline CIDP Disease Activity Status (CDAS) score ≥ 2 (documentation required)
- Member has tried and failed at least a 3-month trial of immunoglobulin (IG) or plasma exchange therapy (documentation required)
- Requested medication will NOT be used as maintenance therapy in combination with immunoglobulin or intravenous efgartigimod

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Reauthorization will follow the initial authorization criteria

Reauthorization Length: 12 months

Diagnosis: Generalized Myasthenia Gravis (gMG)

Exclusions:

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any active or clinically significant infections that has not been treated

Age: 18 years or older

Initial Dosing: The recommended dosage is 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) in cycles of once weekly injections for 4 weeks. Administer subsequent treatment cycles based on clinical evaluation; safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

Exclusion Criteria: NA

Initial Authorization Criteria:

- Prescriber by or in consultation with a neurologist
- Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies (lab test must be submitted)
- Member has a baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 5 (documentation required)
- Member has a baseline immunoglobulin G (IgG) level of at least 6 g/L (600 mg) (documentation required)
- Member has tried and failed or has an intolerance or contraindication to pyridostigmine
- Member has tried and failed or has an intolerance or contraindication to one of the following:

  - Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
- Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- Member does NOT have an active infection, including clinically important localized infections
- Requested medication will NOT be administered with live-attenuated or live vaccines during treatment
- Medication will NOT be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, rozanolixizumab-noli, zilucoplan)

Initial Authorization Length: 6 months

Reauthorization Criteria:

- Member has NOT experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions)
- Member meets ONE of the following:
  - Member has demonstrated an improvement of at least 2 points in the MG-ADL total score from baseline sustained for at least 4 weeks (documentation required)
  - Member has demonstrated an improvement of at least 3 points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks (documentation required)
- Member requires continuous treatment, after initial beneficial response, due to new or worsening disease activity
  Note: A minimum of 50 days must have elapsed form the start of the previous treatment cycle

Reauthorization Length: 6 months

References: Vyvgart Hytrulo. Package Insert. Halozyme Therapeutics. 2024

Vimizim IV (elosulfase alfa) (J1322)

Diagnosis: Mucopolysaccharidosis Type IVA (MPS IVA)

Age: 5 years or older

Initial Dosing: 2mg/kg once a week

Exclusion Criteria: NA

Prescribing Information:

- Due to high risk of anaphylaxis and infusion reactions, Vimizim® infusion should be administered ONLY by trained medical professionals and will NOT be approved for selfadministration or for administration by home healthcare providers

Initial Authorization Criteria:

- Prescriber by or in consultation with a metabolic geneticist or endocrinologist
- Member is at least 5 years of age
- Member has a diagnosis of mucopolysaccharidosis type IVA (MPS IVA) as verified by genetic testing
- Provider attests to documenting the below for the patient:
  - Current height and weight
  - Current FEV1
  - Current MVV
  - Current normalized urine keratin sulfate levels
  - Baseline 6 minute walk time of a distance of at least 30 meters

Initial Authorization Length: 24 Weeks

Reauthorization Dosing: 2mg/kg once a week

Reauthorization Criteria:

- Provider attests to a positive clinical response from baseline
- Provider attests to documenting the below for the patient:
  - Current height and weight
  - Current FEV1
  - Current MVV

- Current normalized urine keratin sulfate levels
- Baseline 6 minute walk time of a distance of at least 30 meters

Reauthorization Length: 12 months

References: Vimizim. Package Insert. BioMarin Pharmaceuticals. 2019

Vyxeos (liposomal daunorubicin and cytarabine) IV (J9153)

Diagnosis – Therapy-related acute myeloid leukemia (t-AML), acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

Age: NA

Dosing: Age/weight based dosing

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has a diagnosis of therapy-related acute myeloid leukemia (t-AML), acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

Authorization Length: Initial: 12 months; Reauthorization: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Beleodaq. Package Insert. Jazz Pharmaceuticals. 2022

Xgeva (denosumab) (J0897)

No prior authorization required for oncology purposes

Xolair (omalizumab) (J2357)

Moderate to Severe Persistent Asthma

Diagnosis: Moderate to Severe Persistent Asthma

Age: 6 years or older

Initial Dosing:

- **Maximum dosages will be based on a member weight of 150kg:**
  - 150mg every 4 weeks
  - 225mg every 2 weeks
  - 300mg every 2 weeks
  - 300mg every 4 weeks
  - 375mg every 2 weeks

Exclusion Criteria:

- The Health Plan considers the use of concomitant therapy with Cinqair, Dupixent, Fasenra, Nucala, Tezspire and Xolair to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair, Dupixent, Fasenra, Nucala or Tezspire authorization on file, all subsequent requests for Xolair will NOT be approved.

Initial Authorization Criteria:

- Member is at least 6 – 12 years of age and pretreatment IgE level of 30-1300 **OR**
- Member is 12 years of age and older pretreatment IgE level of 30-700
- Prescribed by or in consultation with an allergist or pulmonologist
- Member is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy within a year of request:
  - Medium to high-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))
- Member has experienced **ONE** of the following:

- More than 2 exacerbations requiring additional medical treatment (e.g., an increase in oral corticosteroid dose, emergency department, urgent care visits or hospitalizations) within the past 12 months
- Any prior intubation for an asthma exacerbation

Initial Authorization Length: 12 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member has experienced a sustained positive clinical response to Xolair ® therapy as demonstrated by at least ONE of the following
  - Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - Reduction in the dose of inhaled corticosteroids required to control asthma
  - Reduction in the use of oral corticosteroids to treat/prevent exacerbation
  - Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath or nocturnal awakenings
- Member is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications:
  - Medium to high-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol) Symbicort (budesonide/formoterol))

Reauthorization Length: 12 months

Chronic Idiopathic Urticaria

Diagnosis: Chronic Idiopathic Urticaria

Age: 12 years or older

Initial Dosing: 150 mg or 300 mg by subcutaneous injection every 4 weeks

Exclusion Criteria:

- The Health Plan considers the use of concomitant therapy with Cinqair, Dupixent, Fasenra, Nucala, Tezspire and Xolair to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair, Dupixent, Fasenra, Nucala or Tezspire authorization on file, all subsequent requests for Xolair will NOT be approved.

Initial Authorization Criteria:

- Prescribed by or in consultation with an allergist or pulmonologist
- Member has had a confirmed diagnosis of chronic idiopathic urticaria for at least 6 weeks with or without angioedema
- Member has failed ONE (1) of the following H1 antihistamines at 4 times the initial dose:
    - Cetirizine 20 mg – 40 mg QD
    - Desloratidine 10 – 20 mg QD
    - Fexofenadine 120 mg – 240 mg BID
    - Levocetirizine 10 mg – 20 mg QD
    - Loratadine 20 mg – 40 mg QD
- Member has remained symptomatic despite treatment with ALL of the following therapies:
    - Hydroxyzine 10 mg – 25 mg taken daily
    - Leukotriene Antagonist for at least 4 weeks (e.g., montelukast, zafirlukast)
    - H2 antihistamine, for treatment of acute exacerbations, for at least 5 days (e.g., famotidine, cimetidine)

Initial Authorization Length: 12 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member's disease status has been re-evaluated since the last authorization to confirm the member's condition warrants continued treatment

- Provider has attested the member's symptoms have improved (e.g., a decrease in the number of hives, a decrease in the size of hives, and improvement of itching)
- Symptoms returned when the Xolair® dose was tapered or withheld beyond the next dosing interval

Reauthorization Length: 12 months

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Diagnosis: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Age: 18 years or older

Initial Dosing:

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Bodyweight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

Exclusion Criteria:

- The Health Plan considers the use of concomitant therapy with Cinqair, Dupixent, Fasenra, Nucala, Tezspire and Xolair to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair,

Dupixent, Fasenra, Nucala or Tezspire authorization on file, all subsequent requests for Xolair will NOT be approved.

Initial Authorization Criteria:

- Prescribed by or in consultation with an allergist or pulmonologist
- Member has a pre-treatment IgE level of 30-1500
- Member has a diagnosis of CRSwNP confirmed by the American Academy of OtolaryngologyHead and Neck Surgery Clinical Practice Guideline (Update): Adult Sinusitis (AAO-HNSF 2015)/American Academy of Allergy Asthma & Immunology (AAAAI) with ONE of the following clinical procedures:
    - Anterior rhinoscopy
    - Nasal endoscopy
    - Computed tomography (CT)
- Documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of the following:
    - Mucosal inflammation AND at least two of the following
        - Decreased sense of smell
        - Facial pressure, pain, fullness
        - Mucopurulent drainage
        - Nasal obstruction
- Member is currently being treated with medications in at least two of the following categories unless there is a contraindication or intolerance to these medications and has been compliant with therapy:
    - Nasal saline irrigation
    - Intranasal corticosteroids (e.g., fluticasone, budesonide, triamcinolone)
    - Leukotriene receptor antagonists (e.g., montelukast, zafirlukast, zileuton)
- Member is refractory, ineligible or intolerant to ONE of the following:
    - Systemic corticosteroids
    - Sino-nasal surgery
- Member is requesting Xolair® (omalizumab) as add-on therapy to maintenance intranasal corticosteroids
- Member has had an unsuccessful 6-month trial of Dupixent® (dupilumab) OR Nucala® (mepolizumab)

Initial Authorization Length: 12 months

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria:

- Member has experienced a positive clinical response to Xolair® therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell)
- Member has decreased utilization of oral corticosteroids
- Member has been compliant on Xolair® therapy and continues to receive therapy with an intranasal corticosteroid

Reauthorization Length: 12 months

Yescarta (tisagenlecleucel) (J9999/Q2041)

Diagnosis: Large B-Cell Lymphoma

Age: 18 years or older

Initial Dosing: 150 mg or 300 mg by subcutaneous injection every 4 weeks

Exclusion Criteria:

- The Health Plan considers the use of concomitant therapy with Cinqair, Dupixent, Fasenra, Nucala, Tezspire and Xolair to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair, Dupixent, Fasenra, Nucala or Tezspire authorization on file, all subsequent requests for Xolair will NOT be approved.

Initial Authorization Criteria:

- Member does not have a clinically significant active systemic infection or inflammatory disorder
- Member has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Yescarta treatment, and will not receive live vaccines until immune recovery following treatment
- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- Prophylaxis for infection has been followed according to local guidelines
- Healthcare facility has enrolled in the Yescarta REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities
- Member does not have primary central nervous system lymphoma
- Member has NOT received prior CAR-T therapy
- Member did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT)
- Member has an ECOG performance status of 0-1
- Member has CD19-positive disease
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- Provider attests to all applicable clinical criteria in the diagnosis section below
    - **B-Cell Lymphoma:**

- **I.** Member has a diagnosis of large B-cell lymphone (LBCL) **AND** Member has refractory disease to first-line chemo-immunotherapy or relapse within 12 months of first-line chemo-immunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin)
- **II.** Member has AIDS-related large B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), DLBCL, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, or monomorphic posttransplant lymphoproliferative disorder (B-cell type) **AND** Medication will be used as additional therapy for members with intention to proceed to transplant who have partial response following second-line therapy for relapsed or refractory disease **OR** Medication will be used for treatment of disease that is in second or greater relapse
- **III.** Member has a diagnosis of Grade 1-2 follicular lymphoma **AND** Disease is relapsed, refractory, or progressive after two (2) or more prior lines of therapy

Initial Authorization Length: One time only

Reauthorization Dosing: *See Initial Dosing*

Reauthorization Criteria: NA

Reauthorization Length: NA

Yondelis (trabectedin) IV

Diagnosis – Soft Tissue Sarcoma or Ovarian Cancer

Age: 18 years of age and older

Dosing: Diagnosis and weight dependent

Exclusion Criteria

- NA

Initial Authorization Criteria

- Prescribed by or in consultation with an oncology specialist
- Member has **ONE** of the following:
    - Diagnosis of unresectable or metastatic soft tissue sarcoma (i.e. leiomyosarcoma, liposarcoma, and translocation-related sarcomas) AND trabectedin will be used as monotherapy following disease progression with an anthracycline-based chemotherapy, unless there is a contraindication or intolerance
    - Diagnosis of ovarian cancer AND trabectedin will be used in combination with doxorubicin liposomal AND disease is recurrent to recent platinum-based therapy [having achieved a response obtaining a platinum-free interval of 6 to 12 months]

Authorization Length: Initial: 12 months; Reauthorization: 12 months

Reauthorization Criteria

- Member is currently receiving the requested agent and member requires a continuation of therapy
- Must not be experiencing disease progression
- Member is not experiencing an FDA-labeled limitation of use or toxicity

References: Yondelis. Package Insert. Janssen Pharmaceuticals. 2020

Zarxio (filgrastim-sndz) (Q5101)

No prior authorization required for oncology purposes

Zemdri (plazomicin) (J0291)

Diagnosis – Complicated Urinary Tract Infection or Pyelonephritis

Age: 18 years of age or older

Initial Dosing: 15 mg/kg every 24 hours by IV over 30 minutes for patients with creatinine clearance greater than or equal to 90 mL/min; 10 mg/kg every 24 hours IV over 30 minutes for patients with creatinine clearance greater than or equal to 30 to less than 60; 10 mg/kg every 48 hours IV over 30 minutes for patients with creatinine clearance greater than or equal to 15 to less than 30

Exclusion Criteria: NA

Initial Authorization Criteria:

- Submit lab cultures from current hospital admission or office visit collected in the last (7) days
    - Lab culture must show sensitivity to Zemdri
- Member must meet **ONE** of the following:
    - Trial and failure of all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin OR
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following oral antibiotics: nitrofurantoin, cefdinir, cephalexin, amoxicillin, amoxicillin-clavulanate, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and fosfomycin
- Member must meet **ONE** of the following:
    - Trial and failure of all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
    - Cultures (retrieved from most recent office visit or current inpatient admission collected within the last 7 days) shows resistance to all the following IV antibiotics: ciprofloxacin, levofloxacin, ceftriaxone, cefazolin, cefepime, piperacillin-tazobactam, trimethoprim-sulfamethoxazole, gentamicin, tobramycin, amikacin, ertapenem, imipenem-cilastatin, and meropenem
- Provider must submit documentation of failed treatment options

Continuation of Therapy Following Inpatient Administration:

- Member has been on Zemdri >72 hours inpatient with progress notes submitted with the request
- Culture sensitivity results retrieved during admission shows resistance to all the preferred antibiotics except for Zemdri

Initial Authorization Length: 14 Days

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

References: Zemdri. Package Insert. Paratek Pharmaceuticals. 2021

Zinplava (bezlotoxumab) (J0565)

Diagnosis – Recurrent Clostridium Difficile Infection (rCDI)

Age: ≥ 1 year of age

Initial Dosing: 10 mg/kg as a single dose during antibacterial treatment for rCDI in conjunction with antibacterial treatment

Exclusion Criteria: NA

Initial Authorization Criteria:

- Must be prescribed by a gastroenterologist or infectious disease physician
- Must have diagnosis of Clostridium difficile
- Must submit positive stool test
- Must be used in conjunction with a standard of care antibiotic regimen for the treatment of CDI (i.e. oral vancomycin, oral fidaxomicin, or metronidazole)
- Must be at risk for recurrence in CDI with one of the following risk factors:
    - ≥65 years of age
    - Clinically severe CDI
        - WBC ≥15000 cells/mm3
        - Serum creatinine > 1.5mg/dL
        - Zar disease severity score of 2 or greater
            - 1 point for age ≥ 60, temperature > 100.9 degrees, albumin level 2.5 mg/dL, or peripheral white blood cell count greater than 15000 cells/mm3
            - 2 points for endoscopic evidence of psueomembranous colitis or intensive care unit status
        - History of previous CDI in the past 6 months
        - Immunosuppression or decreased immune function
        - Presence of hypervirulent strain of CDI (i.e. ribotype 27)

Initial Authorization Length: 30 days; 1 dose

Reauthorization Dosing: NA

Reauthorization Criteria: NA

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Reauthorization Length: NA

References: Zinplava. Package Insert. Merck Sharp & Dohme. 2023

Zirabev (Bevacizumab-bvzr) (Q5118)

No prior authorization required for oncology purposes

Zolgensma (onasemnogene abeparvovex-xioi) (J3399)

Diagnosis - Spinal Muscular Atrophy (SMA) – G12.0, G12.1

Age: ≤2 years of age

Initial Dosing: 1.1 × 1014 vector genomes (vg) per kg of body weight

Exclusion Criteria: NA

Initial Authorization Criteria:

NOTE: Zolgensma is not covered for any member included in a clinical trial for experimental therapy for SMA

- Prescriber must submit baseline documentation of one of the following:
  - Hammersmith Infant Neurological Exam (HINE) (infant to early childhood
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- Mutation or deletion of genes in chromosome 5q resulting in one of the following:
  - Homozygous gene deletion or mutation of SMN1 gene
  - Compound heterozygous mutation of SMN1 gene (deletion of SMN1 exon 7) (allele1) and mutation of SMN1 (allele2)
- Diagnosis of likely Type 1 SMA based on the results of SMA newborn screening
- Submission of medical records **(e.g., chart notes, laboratory values)** confirming that member has ≤ 2 copies of SMN2 gene
- Diagnosis of symptomatic SMA by a neurologist with expertise in the diagnosis of SMA
- For use in a neonatal member born prematurely, the full-term gestational age has been reached (fullterm gestational age – 40 weeks)
- One of the following
  - Six months of age or younger at the time of vector infusion
  - Over six months of age at the time of FDA approval on May 24, 2019, but less than 2 years of age at the time of vector infusion
- Previously established on nusinersen (Spinraza®) with a positive and stable clinical response (as evidenced by a Children's Hospital of Philadelphia Infant Test for Neuromuscular Disorders (CHOP INTEND) score of more than 40 points
- Member does not have advanced SMA at baseline (e.g., complete paralysis of limbs, invasive ventilator support (Tracheotomy with positive pressure), requirement of noninvasive ventilator support

averaging > 6 hours/day, and anti-AAV9)
- Submission of medical records, chart notes, laboratory values confirming member does not have advanced SMA as defined by the fact that member's most recent CHOP-INTEND score is ≥ 40
- Member is ≤ 13.5 kg
- Dose to be administered does not exceed one kit of Zolgensma® 1.1 x 1014 vector genomes (vg) per kg of body weight
- Member does not have either of the following
    - Invasive ventilation support (i.e., tracheotomy with positive pressure) or pulse oximetry < 95% saturation)
    - Use of noninvasive ventilator support averaging >6 hours/day
- Zolgensma® is prescribed by a neurologist with expertise in the treatment of SMA
- Member is not to receive routine concomitant SMN modifying therapy (e.g., Spinraza™) – ***any SMN modifying therapy will be terminated upon Zolgensma approval)***
- Physician submits the lab assessment for presence of anti-AAV9 antibodies and managed accordingly
- Physician attests that the member will not receive Zolgensma if the most recent pre-treatment antiAAV9 antibody titer is **above** 1:50
- Physician attests that member, while under the care of the physician, will be assessed by one of the following exam scales during subsequent office visits for a period not to exceed 3 years
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) scale during subsequent office visits while the member is 2 to 3 years of age or younger
    - Hammersmith Functional Motor Scale Expanded (HFMSE) during subsequent office visits while the member is 2 to 3 years of age or older
    - Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
- Physician would submit to Optima Health documentation, not more frequently than bi-annually, of follow-up member assessment(s) including, but not necessarily limited to, serial CHOP INTEND or HFMSE assessments while member is under the care of the physician
- Member will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and following receipt of Zolgensma® within accordance of the United States Food and Drug Administration (FDA) approved Zolgensma® labeling
- Member has never previously received Zolgensma® treatment in their lifetime
- If replacing Spinraza™ (nusinersen), Zolgensma® (onasemnogene) will not be prescribed concurrently as dual therapy or receive concomitant SMN modifying therapy
- Absence of the c.859G>C modification in exon 7 of SMN2 gene
- Lab values less than 30 days from time of request must be provided with form
- Documentation of baseline laboratory tests of the following to ensure no renal impairment, hepatic impairment or hematologic impairment is present in the following:
    - Platelet count within normal limits
    - Troponin-1 within normal limits

- Alanine aminotransferase/Aspartate aminotransferase (<2x upper limit of normal)
- Total bilirubin within normal limits
- Prothrombin time within normal limits
- Verify member does not have a contraindication or intolerant to corticosteroid therapy

Initial Authorization Length: One treatment per lifetime

Reauthorization Dosing: NA

Reauthorization Criteria: NA

Reauthorization Length: NA

Zulresso (brexanolone) (J3490)

Diagnosis - Moderate to severe Postpartum Depression (PPD)

Age: ≥18 years of age

Initial Dosing: 60-hour infusion per pregnancy; Member's ≤ 90kg: 5 vials

Exclusion Criteria: NA

Initial Authorization Criteria:

- Medication is prescribed by, or in consultation with a psychiatrist
- Member is diagnosed with moderate to severe postpartum depression supported by all the following:
  - Member meets DSM-5+ criteria for major depressive disorder (single or recurrent episode)
  - Member has a clinical diagnosis, made by a psychiatrist or other specialist in the field of psychiatry (e.g., PNP), of moderate to severe postpartum depression
  - Diagnosis and severity of depression is supported by a validated rating scale **(scale and date completed must be attached)**
  - Onset of symptoms occurred no earlier than the third trimester of pregnancy, no later than 4 months postpartum
- Member is 6 months or less postpartum
- Member must have experienced clinical failure with at least **one** oral antidepressant therapy and failure must meet the following criteria (must name medication):

  - Adequate dose (maximally tolerated)
  - Adequate duration (at least 6 weeks)
  - Adherent fills required (verified by pharmacy claims)
  - Failures must occur during current depressive episode
- Member does not have active psychosis or a history of bipolar disorder
- Healthcare facility, pharmacy, and patient are registered with the REMS program
- Member will be appropriately monitored for the duration of the infusion:
  - Healthcare provider will be available on site
  - Hypoxia monitoring using continuous pulse oximetry equipped with an alarm
  - Excessive sedation monitoring every two hours during planned, non-sleep periods
- Dose will not exceed 90 mcg/kg per hour over 60 hours (2.5 days) as follows:
  - 0 to 4 hours: Initiate with a dosage of 30 mcg/kg per hour
  - 4 to 24 hours: Increase dosage to 60 mcg/kg per hour
  - 24 to 52 hours: Increase dosage to 90 mcg/kg per hour (alternatively consider a dosage of 60 mcg/kg per hour for those who do not tolerate 90 mcg/kg per hour)
  - 52 to 56 hours: Decrease dosage to 60 mcg/kg per hour
  - 56 to 60 hours: Decrease dosage to 30 mcg/kg per hour

*****NOTE: Zulresso™ is considered not medically necessary when the above criteria is not met and investigational for all other uses.*****

Initial Authorization Length: One treatment per pregnancy

Reauthorization Dosing: NA

Reauthorization Criteria: NA