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Medical Benefit Medication Prior Authorization Criteria

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These criteria apply to drugs given by a health care professional in a clinic, infusion center, or other setting.
These medication prior authorization criteria apply to Commercial members, State and Local Government members, Quartz BadgerCare Plus and/or Medicaid SSI members, and other persons whose Quartz benefits include coverage of drugs given by a health care provider (medical benefit).

July 1, 2025
Medical Benefit Drug
Prior Authorization Criteria

A medication prior authorization request may be started by members, providers, or designated representatives by fax, electronically on Quartz's website, telephone, mail. Or, for medical benefit medications, also by Health Link, Plan Link, MyQuartzTools, or electronic prior authorization (e-PA) within the electronic medical record. Electronic (e-PA) via Surescripts verifies member eligibility and member benefit information. Quartz sends back e-PA criteria questions to the provider staff which can be answered, and medical records can be attached to the request.

Quartz strongly recommends that the health care provider initiate the prior authorization request process on behalf of the member. This is because the health care provider will be able to include the medical history necessary for a timely decision to be made based on all of the relevant information, including any case specific circumstances that can be considered. Once a request and the supporting documentation have been submitted, a pharmacist or appropriate staff review the prior authorization criteria and exception requirements separately to make a coverage decision.

Abatacept (Orencia) Infusion
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0129	Abatacept infusion (Orencia)	Medical Benefit-Restricted	aGVHD: 4 doses	12 months

CRITERIA FOR COVERAGE FOR ALL DIAGNOSES:

- Trail and failure of abatacept self-injection (subcutaneous) or documented inability to self-administer abatacept injections.
- Diagnosis as listed.

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE PSORIATIC ARTHRITIS (PsA):

- Prescribed by or in consultation with a Dermatologist or Rheumatologist
- Symptoms presenting with at least one of the following: actively inflamed joints, axial disease, active skin/nail/scalp psoriasis involvement, dactylitis, or enthesitis.
- Failure/Intolerance/Contraindication to TWO of the following:
    - Adalimumab
    - Etanercept
    - Certolizumab
    - Golimumab
    - Risankizumab
    - Upadacitinib
    - Tofacitinib/Tofacitinib XR
    - Infliximab

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS (RA):

- Prescribed by or in consultation with a Rheumatologist.
- Documented failure with a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- Trial and failure, intolerance, contraindication to ≥ TWO of the following:
    - Adalimumab
    - Certolizumab
    - Etanercept
    - Upadacitinib
    - Tofacitinib/Tofacitinib XR
    - Infliximab
    - Golimumab

CRITERIA FOR COVERAGE OF JUVENILE IDIOPATHIC ARTHRITIS (JIA):

- Prescribed by or in consultation with a Rheumatologist.
- Documented failure with a 3-month trial and failure, intolerance, or contraindication to ONE of the following:

    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- Trial and failure, intolerance, or contraindication to ≥ TWO of the following:
    - Adalimumab
    - Etanercept
    - Tofacitinib/Tofacitinib XR
    - Infliximab

CRITERIA FOR COVERAGE FOR ACUTE GRAFT VERSUS HOST DISEASE (aGVHD):

- Prescribe by or in consultation with a Hematologist.
- Documentation of use of matched unrelated donor or 1-allelle mismatch donor
- Age > 2 years
- Infusion to be administered on Day 1, 5, 14, 28 post-transplant.

OR

- (Minnesota Plans Only) – Person has stage four metastatic cancer and abatacept is being used to treat cancer-related aGVHD

CRITERIA FOR QUANTITY EXCEPTIONS FOR aGVHD:

- Provision of published literature supporting the dose and/or frequency being requested after failure of an adequate trial of standardized dosing.

CONTINUATION OF COVERAGE CRITERIA (new to the plan/renewals):†

- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy including individual improvements in functional status related to therapeutic response.
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, clear skin, those with high supra-therapeutic trough levels, etc.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:

For information regarding coverage of abatacept on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com

Absolute contraindications to methotrexate are pregnancy, nursing, alcoholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate.

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

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P&T Revision Date: 10/15/2024
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Adamts13 recombinant-krhn (Adzynma)
Prior Authorization Criteria
DC-0127

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J7171	adamts13 recombinant-krhn (Adzynma)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Documented cTTP (congenital thrombotic thrombocytopenic purpura) diagnosis confirmed by both of the following:
  - Confirmed molecular genetic testing
  - ADAMTS13 activity<10%, as measured by the fluorescent resonance energy transfer-von Willebrand factor 73 (FRETS-VWF73) assay
- Person has not been diagnosed with any other TTP-like disorder (microangiopathic hemolytic anemia) including iTTP (immune medicate thrombocytopenia purpura)
- If requesting prophylactic therapy, history of at least one documented TTP event or currently receiving prophylactic therapy
- Prescribed by or in consultation with a hematologist, oncologist or similar specialist

CONTINUATION OF COVERAGE CRITERIA: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days.)

- Clinical documentation from the previous 12 months showing the person has had a positive clinical response to therapy (e.g. improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, strokes/transient ischemic attacks, clinical symptoms)

Guideline Note

Effective Date:	02/01/2025
P&T Approval Date:	01/01/2024
P&T Review Date:	10/2024

Revision History:

Date	Notes
01/07/2025	Revise J code

Aducanumab (Aduhelm)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Aducanumab (Aduhelm)	Medical Benefit-Restricted*	N/A	Initial: 6 months Renewal: 12 months

CRITERIA FOR COVERAGE (BADGERCARE ONLY):

- Diagnosis of Alzheimer's disease with mild cognitive impairment or dementia confirmed by all of the following:
  - Mini Mental State Exam (MMSE) score ≥24
  - Clinical Dementia Rating Global Score (CDR-GS) of 0.5 or 1
- Prescribed by or in consultation with a Neurologist, Geriatrician, Psychiatrist, or other Alzheimer's disease specialist
- Age 50 to 85 years
- Positive amyloid confirmed by a Positron Emission Tomography (PET) scan or Cerebral Spinal Fluid
- Person does not have any of the following:
  - Use of antiplatelet or anticoagulant drugs (except prophylactic aspirin)
  - History of advanced chronic heart failure, clinically significant conduction abnormalities, cerebrovascular abnormalities, bleeding disorder, clotting disorder, or brain hemorrhage
  - Diagnosis within the previous 12 months of stroke, transient Ischemic attack, unstable angina, myocardial infarction, unexplained loss of consciousness

CRITERIA FOR CONTINUATION OF THERAPY (BADGERCARE ONLY – 6 month and renewal):

- Magnetic Resonance Imaging (MRI) scans before the 7th and 12th dose confirming there are not amyloid-related imaging abnormalities (ARIA)
- Clinical documentation of a decrease in brain amyloid plaques
- Clinical documentation of a response to therapy such as slowed or stopped decline in CDR-GS, MMSE, or RBANS score
- Person does not have any of the following:
  - Use of antiplatelet or anticoagulant drugs (except prophylactic aspirin),
  - History of advanced chronic heart failure, clinically significant conduction abnormalities, cerebrovascular abnormalities, bleeding disorder, clotting disorder, or brain hemorrhage
  - Diagnosis within the previous 12 months: stroke, transient Ischemic attack, unstable angina, myocardial infarction, unexplained loss of consciousness

Note:
Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

***Excluded on some benefits. Please see your plan Summary Plan Document or Certificate of Coverage for details.**

Created: 05/22
Effective: 10/3/2022 Client Approval: P&T Approval: N/A

Afamelanotide (Scenesse)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J7352	Afamelanotide (Scenesse)	Medical Benefit-Restricted	None-implant every 2 months	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Erythropoietic Protoporphyria (EPP)
- Age ≥ 18 years
- History of phototoxic reactions due to free light exposure

CONTINUATION OF COVERAGE CRITERIA:*

- Initial criteria met AND Clinical documentation from the previous 12 months demonstrating objective improvements in pain control related to light exposure

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Created: 02/21
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Tecelra (afamitresgene autoleucel)
Prior Authorization Criteria
DC-0132

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9399, J9999	Tecelra (afamitresgene autoleucel)	Medical Benefit-Restricted	1 treatment	12 months

CRITERIA FOR COVERAGE:

- Patient is ≥16 years of age
- Diagnosis of unresectable or stage IV Synovial sarcoma
- Both of the following
    - Patient must be HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive
    - Patient does not have HLA-A*02:05P in either allele
- Presence of MAGE-A4 antigen as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)
- Patient must have progressed following ≥1 prior systemic chemotherapy
- Patient has never received Tecelra treatment in their lifetime

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE: Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Guideline Note:

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P&T Review Date:	04/21/2025

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Date	Notes
02/28/2025	Add orphan drug language

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Agalsidase Beta (Fabrazyme)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0180	Agalsidase Beta (Fabrazyme)	Medical Benefit-Restricted	1mg/kg IV infusion every two weeks	12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of Fabry Disease
- Person is 2 years of age or older
- Person has at least one of the following:
  - Detection of pathogenic mutations in the GLA gene by molecular genetic testing OR
  - Deficiency in alpha-galactosidase A (alpha-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS) OR
  - Significant clinical manifestations (e.g. neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillate)
- Will not be used in combination with other drugs used for Fabry Disease

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet the criteria for coverage

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Alemtuzumab (Lemtrada)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0202	Alemtuzumab (Lemtrada)	Medical Benefit-Restricted		12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Clinical documentation of a diagnosis of relapsing multiple sclerosis
- Drug prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis
- Failure (acute relapse or new lesion formation) while on higher efficacy oral disease modifying therapies (DMT - such as dimethyl fumarate, fingolimod, or cladribine (Mavenclad)
  OR
- Intolerance to, inability to take, or labeled contraindication to at least two oral DMTs
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Clinical assessment from the treating Neurologist from the previous 12 months documenting a relapsing form of multiple sclerosis and that the person is established on therapy
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

†Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

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Lenmeldy (Atidarsagene autotemcel)
Prior Authorization Criteria
DC-0126

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3391	Atidarsagene autotemcel (Lenmeldy)	Medical Benefit-Restricted	One dose	6 Months

CRITERIA FOR COVERAGE:

- Documented diagnosis of MLD (metachromatic leukodystrophy) with confirmed identification of two disease-causing ARSA (arylsulfatase A) alleles and ARSA activity below the normal range.
- Disease type as one of the following:
    - Pre-symptomatic late-infantile, defined as patients without neurological impairment (disease-related symptoms), with or without signs of the disease revealed by objective assessment (e.g. MRI)
    - Pre- or early symptomatic early-juvenile patients
        - Intelligence quotient ≥70
        - The ability to walk independently for ≥10 steps
    - Late-infantile with two or the following:
        - Age at onset of symptoms in the older sibling(s) ≤30 months
        - Two null (0) mutant ARSA alleles
        - Peripheral neuropathy at electroneurographic study
    - Early-juvenile
        - Age at onset of symptoms (in the subject or in the older sibling) between 30 months and 6 years
        - One null (0) and one residual (R) mutant ARSA allele(s)
        - Peripheral neuropathy at electroneurographic study
- Does not have evidence of HIV, Hepatitis C, Hepatitis B
- Does not have active neoplastic disease
- Does not have evidence of myelodysplastic syndrome or acute myelogenous leukemia
- Prescribed by or in consultation with a specialist knowledgeable in the management lysosomal storage disorders
- Does not have evidence of baseline organ dysfunction
- Has not undergone HSCT in the previous 6 months
- Has not undergone HSCT with evidence of residual cells of donor origin

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE: Medication must be billed to Forward Health under the pharmacy benefit. Refer to the Forward Health policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Guideline Note:

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Revision History:

Date	Notes
02/28/2025	Add high cost, orphan drug language
06/19/2025	Update HCPCS code based on quarterly updates

Alpha$_1$ Proteinase Inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaira) Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0257, J0256	Alpha-1 Proteinase inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaira)	Medical Benefit-Restricted	None	12 Months

CRITERIA FOR COVERAGE:

- Alpha-1 proteinase deficient (< 11 mcmol/L)
- Evidence of COPD (FEV_1 25% to 80% predicted) attributable to emphysema
- Person is no longer smoking
- Maximized COPD therapy based on GOLD guidelines

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet initial criteria for coverage

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Last Revised: 10/15/24 – Updated duration limit

Anti-Amyloid mAb For Alzheimer Disease
Prior Authorization Criteria
DC-101

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0175	Donanemab (Kisunla)	Medical Benefit - Restricted	N/A	6 months (Initial) 12 months (Renewal)
J0174	Lecanemab (Leqembi)	Medical Benefit - Restricted	N/A	

CRITERIA FOR COVERAGE:

- Diagnosis of one of the following based on the National Institute on Aging and the Alzheimer's Associated (NIA-AA) Criteria:
  - Mild cognitive impairment due to Alzheimer's disease
  - Mild dementia due to Alzheimer's disease
- Submission of medical records confirming the following:
  - Clinical Dementia Rating – sum of the boxes (CDR-SB) score of 0.5-9
- Submission of medical records confirming one of the following:
  - Mini-Mental State Examination (MMSE) score of 21 or greater
  - Montreal Cognitive Assessment (MoCA) score of ≥ 16
- Prescribed by or in consultation with a Neurologist, Geriatrician, Psychiatrist, or other Alzheimer's disease specialist
- Age 50 to 90 years
- Positive amyloid confirmed by ONE of the following:
  - Positron Emission Tomography (PET) scan
  - Lumbar puncture (Cerebral Spinal Fluid) confirming abnormalities suggestive of beta-amyloid accumulation such as presence of elevated phosphorylated tau (P-tau) protein and/or elevated total tau (T-tau) protein, reduced beta amyloid-42 (AB42) or a low AB42/AB40 ratio
  - All of the following:
    - A positive phosphorylated Tau217 blood test result
    - No history of chronic kidney disease (estimated glomerular filtration rate eGFR >60ml/min/1.73m2))
    - No history of a heart attack
- Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment
- Provider attests that evaluation of the patient's ApoE e4 carrier status has been performed prior to initiating treatment
- Other causes of symptoms have been ruled out (e.g. Lewy body dementia, Parkinson's disease, vitamin B12 deficiency, etc.)
- Provider will enroll patient in a registry [e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET)]
- Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm)
- Both of the following:
  - The patient is not currently taking an anticoagulant (e.g. warfarin, dabigatran)
  - The patient has no history of ischemic or hemorrhagic strokes involving the basal ganglia (lacunar) or

large areas of vascular territory

CRITERIA FOR CONTINUATION OF THERAPY (Renewal):

- Diagnosis of one of the following based on the National Institute on Aging and the Alzheimer's Associated (NIA-AA) Criteria:
  - Mild cognitive impairment due to Alzheimer's disease
  - Mild dementia due to Alzheimer's disease
- Submission of medical records confirming Clinical Dementia Rating – sum of the boxes (CDR-SB) score of 0.5-9Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th and 7th infusion treatment to show one of the following radiographic evidence of amyloid related imaging abnormalities (i.e, ARIA-E, ARIA-H):
  - Patient has mild radiographic severity of Aria – E on MRI and is asymptomatic
  - Patient has mild radiographic severity of Aria – E on MRI and has mild clinical symptoms
  - Patient has mild radiographic severity of Aria-H on MRI and is asymptomatic
  - ARIA (i.e. ARIA E, ARIA H) has not been observed on MRI
- Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm)

Note:
Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Guideline Note:

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Date	Notes
04/01/2025	Criteria/duration Revision

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Avacincaptad pegol (Izervay)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2782	Avacincaptad pegol (Izervay)	Medical Benefit-Restricted	None	None*

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
- Age ≥ 50 years

Created: 10/23
Effective: 10/1/24

Beremagene geperpavec-svdt (Vyjuvek)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
MISC	Beremagene geperpavec-svdt (Vyjuvek)	Medical Benefit-Restricted		6 months

*Approval limits of 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of dystrophic epidermolysis bullosa (DEB)
- Prescribed by or in consultation with a dermatologist.
- Patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.
- Medication is being used for the treatment of wounds.
- Patient is 6 months of age or older.
- Medication will be applied by a healthcare professional in either a healthcare professional setting (e.g., clinic) or the home setting.
- Wound(s) being treated meet all of the following criteria:
  - Adequate granulation tissue
  - Excellent vascularization
  - No evidence of active wound infection in the wound being treated.
  - No evidence or history of squamous cell carcinoma in the wound being treated.

CONTINUATION CRITERIA (NEW TO PLAN/RENEWAL):

- Documentation of positive clinical response (e.g., decrease in wound size, increase in granulation tissue, complete wound closure)
- Wound(s) being treated meet all of the following criteria:
  - Adequate granulation tissue
  - Excellent vascularization
  - No evidence of active wound infection in the wound being treated.
- No evidence or history of squamous cell carcinoma in the wound being treated.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- Medication must be billed to Forward Health under the pharmacy benefit. Refer to the Forward Health policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 10/23
Effective: 08/01/2024 Client Approval: P&T Approval: N/A

Betibeglogene Autotemcel (Zynteglo)
Prior Authorization Criteria
DC-0122

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J3393	Betibeglogene Autotemcel (Zynteglo)	Medical Benefit-Restricted	One treatment per lifetime	12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of transfusion-dependent beta-thalassemia as confirmed by the presence of a mutation at both alleles of the β-globin gene (i.e., β0/β0, β0/β+, β+/β+, β0/βE)
- One of the following:
  - Patient has a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs)
  - Patient requires 8 or more red blood cell (RBC) transfusions per year
- Patient is 4 years of age or older
- Provider attests that patient is clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT)
- Patient has obtained a negative test result for all the following prior to cell collection:
  - Hepatitis B virus (HBV)
  - Hepatitis C virus (HCV)
  - Human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2)
  - Human immunodeficiency virus (HIV)
- Patient is able to provide an adequate number of cells to meet the minimum recommended dose of 5 x 10^6 CD34+ cells/kg
- Patient does not have any of the following:
  - Severely elevated iron in the heart (e.g., patients with cardiac T2* less than 10 msec by MRI)
  - Advanced liver disease
  - MRI results of the liver demonstrating liver iron content greater than or equal to 15 mg/g (unless biopsy confirms absence of advanced disease)
- Both of the following:
  - Iron chelation therapy (e.g., deferoxamine, deferasirox) will be discontinued for at least 7 days prior to initiating myeloablative conditioning therapy
  - Prophylactic HIV anti-retroviral medications (e.g., Truvada, Descovy) or hydroxyurea will be discontinued for at least one month prior to mobilization (or for the expected duration for elimination of those medications)
- Prescribed by a stem cell transplant specialist OR hematologist
- Patient has never received Zynteglo treatment in their lifetime

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Guideline Note

Effective Date:	07/01/2025
P&T Approval Date:	01/2023
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
04/02/2025	Criteria update -prescriber type

References

1. Zynteglo Prescribing Information. Bluebird Bio, Inc. Somerville, MA. August 2022.
2. Galanello R and Origa R. Beta-thalassemia. Orphanet J Rare Dis. 2010 May 21;5:11. Available at: https://ojrd.biomedcentral.com/articles/10.1186/1750-1172-5-11. Accessed October 2022.
3. Locatelli F, Thompson AA, Kwiatkowski JL, et al. Betibeglogene Autotemcel Gene Therapy for Non-β(0)/β(0) Genotype β-Thalassemia. N Engl J Med. 2022 Feb 3;386(5):415-427. doi: 10.1056/NEJMoa2113206. Epub 2021 Dec 11.
4. Beaudoin FL, Richardson M, Synnott PG, et al. Betibeglogene Autotemcel for Beta Thalassemia: Effectiveness and Value; Final Evidence Report. Institute for Clinical and Economic Review, July 19, 2022. https://icer.org/beta-thalassemia-2022/#timeline
5. Per clinical consult with pediatric hematologist/oncologist. October 7, 2022.

Bezlotoxumab (Zinplava)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0565	Bezlotoxumab (Zinplava)	Medical Benefit-Restricted	None	One dose

*Limited to one dose given within 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of a current Clostridioides difficile (C diff) infection with a positive stool test from a recent stool sample
- History of one or more recurrent episodes (defined as recurrence of diarrhea and positive C diff test within 8 weeks after treatment of prior episode) of C diff

  OR
- First C diff infection and is high risk for recurrence because of one of the following; age 65 or older, immunocompromised state, or severe* C diff infection on presentation
- Prescribed by, or in consultation with, an Infectious Disease specialist or other specialist in the treatment of C diff infections
- On standard of care antibiotics for C diff (vancomycin or fidaxomicin)

OR

- (Minnesota Plans Only) – Person with stage four metastatic cancer and bezlotuxumab is being used to treat cancer therapy-related C. diff infection

IMPORTANT INFORATION:

Use of bezlotoxumab has only been evaluated as a one-time infusion; coverage for additional infusions is considered experimental and will not be covered.

*Severe infection defined as a Zar score of 2 or higher. The Zar score ranges from 1 to 8 and is based on the following factors: age > 60 yrs (1 point), body temperature > 38.3°C (100°F) (1 point), albumin level < 2.5 g per deciliter (1 point), peripheral WBC > 15,000 per cubic millimeter within 48 hours (1 point), endoscopic evidence of pseudomembranous colitis (2 points), and treatment in an ICU (2 points)

Created: 04/17
Effective: 06/03/2024 Client Approval: 06/04/21 P&T Approval: N/A

Botulinum toxin (Botox, Dysport, Myobloc, Xeomin, Daxxify)
Prior Authorization Criteria
DC-0130 and DB-0016

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0585, J0588, J0586, J0587, J0589	Botulinum toxin (Botox, Dysport, Myobloc, Xeomin, Daxxify)	Medical Benefit-Restricted	1 treatment every 12 weeks for migraine headaches	None

***Limited to 12 months for IL and MN plans**

CRITERIA FOR COVERAGE:

- Blepharospasm(involuntary movement of eyelids)
- Cervical Dystonia/Spasmodic Torticollis (involuntary contraction of neck muscles
    - Involuntary contractions of neck muscles
    - Sustained head torsion and/or tilt and limited range of motion in the neck
    - Persisting for six months or longer.
- Chronic anal fissure/tear unresponsive (e.g. nocturnal bleeding, pain) to an adequate trial of conservative therapeutic measures
- Chronic Migraine Headache Prevention
    - Suffers from chronic daily headaches (at least 15 days/month, over the last three months, where headaches last > 4 hours) that are not rebound due to medication overuse
    - Has failed trials of at least two preventative medications (i.e. anti-hypertensives, anti-convulsants, anti-depressants, CGRP agents, etc.)
    - Person is seen, and therapy has been approved by, a prescriber specializing in the medical management of migraine as part of a complete headache treatment plan (i.e. lifestyle modification)
- Cricopharyngeal spasm (spams of cricopharyngeal muscle around the esophagus)
- Congenital muscular torticollis**:** After six months of conservative treatment including physical therapy or stretching has failed/stagnated
- Esophageal Achalasia(dysfunction)**:** In persons who are unfit for definitive therapy such as pneumatic dilation (PD), laparoscopic Heller myotomy (LHM), or POEM (peroral esophageal myotomy)
- Essential hand tremor
- Focal upper extremity dystonia
- Gustatory hyperhidrosis (Frey's syndrome, facial hyperhidrosis) following parotid surgery
- Hemifacial Spasm (muscle twitching on one side of the face)
- Hyperhidrosis- **where excessive sweating is causing a persistent or chronic skin complication** (e.g., skin maceration, dermatitis, fungal infections). Botulinum toxin will not be approved to treat dermatitis as a medication side effect.
    - Primary axillary -After failure of at least two other treatment options including: topical treatments (e.g. aluminum salts) or oral agents (e.g. anticholinergics)
- Palmar/plantar: After failure of at least two other treatments including: topical treatments (e.g., aluminum salts), oral agents (e.g., anticholinergics) or iontophoresis
- Laryngeal dystonia (spasmodic dysphonia/tremor)
- Strabismus (eye misalignment)
- Orofacial dyskinesia (uncontrolled shaking, tics, tremors)

- Piriformis Syndrome causing significant functional impairment after a trial of other therapies has failed.
- Sialorrhea**:** When alternative treatments (e.g., anticholinergics or radiation to involved glands) failed or were not tolerated
- Spasticity from cerebral palsy or other central nervous system disease/disorder in addition to other treatment modalities such as physical therapy, or oral therapy
  -
- Thoracic Outlet Syndrome where symptoms have persisted for at least six months and paresthesia is present despite trial of alternative therapies (e.g. physical therapy, local anesthetics or corticosteroids).
- Torsion dystonia**:** Oral therapies failed or were not tolerated
- Oromandibular dystonia (muscle contractions of the lower face, jaw, and/or tongue; TMJ disorder muscle spasticity/pain) after trial of oral splits or failure of medication therapy
- Urinary incontinence
  - Detrusor sphincter dyssynergia (lack of coordination between detrusor muscle and urethral sphincter)– Persons with neurologic etiologies such as spinal cord injury or demyelinating diseases who have failed or cannot tolerate oral agents such as alpha-antagonists or anti-spasmodics.
  - Neurogenic detrusor overactivity (involuntary detrusor contractions) – Persons using clean intermittent self-catheterization who have incontinence and are unable to tolerate anticholinergics or a beta-3 agonist (e.g. Myrbetriq)
  - Overactive bladder- in persons who are refractory to behavioral modification and have tried and failed prior oral therapies such as anticholinergic medications (e.g solfenicin, oxybutynin) or a beta-3 agonist (e.g. Myrbetriq))

- (Minnesota plans only) – the person has stage four metastatic cancer and the requested drug is being used to treat chronic pain related to their cancer.

CRITERIA FOR REAPPROVAL/CONTINUATION OF THERAPY:†

- For members new to the plan: must have a listed diagnosis above and the prescriber must provide clinical documentation from the previous 12 months verifying the person is established on therapy.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS for MIGRAINE HEADACHES:

- Provider must document positive response to therapy (see above) and evidence of consistent (at least two successive occurrences) “wearing off” of therapeutic effect prior to the expected 3 month duration.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
See the Forward Health Diagnosis Code-Restricted Physician-Administered Drug List (Table 1)

IMPORTANT INFORMATION

- Prabotulinumtoxina-xvfs excluded from coverage as only FDA indication is cosmetic
- DaxibotulinumtoxinA-lanm will not be covered for cosmetic indications

TABLE 1
For BadgerCare+ members only-

Claims are covered for the following diagnosis codes:	
G114	HEREDITARY SPASTIC PARAPLEGIA
G2402	DRUG INDUCED ACUTE DYSTONIA
G2409	OTHER DRUG INDUCED DYSTONIA
G241	GENETIC TORSION DYSTONIA
G242	IDIOPATHIC NONFAMILIAL DYSTONIA
G243	SPASMODIC TORTICOLLIS
G245	BLEPHAROSPASM
G248	OTHER DYSTONIA
G2589	OTHER SPECIFIED EXTRAPYRAMIDAL AND MOVEMENT DISORDERS
G35	MULTIPLE SCLEROSIS
G512	MELKERSSON'S SYNDROME
G5131	CLONIC HEMIFACIAL SPASM, RIGHT
G5132	CLONIC HEMIFACIAL SPASM, LEFT
G5133	CLONIC HEMIFACIAL SPASM, BILATERAL
G5139	CLONIC HEMIFACIAL SPASM, UNSPECIFIED
G514	FACIAL MYOKYMIA
G518	OTHER DISORDERS OF FACIAL NERVE
G800	SPASTIC QUADRIPLEGIC CEREBRAL PALSY
G801	SPASTIC DIPLEGIC CEREBRAL PALSY
G802	SPASTIC HEMIPLEGIC CEREBRAL PALSY
G803	ATHETOID CEREBRAL PALSY
G804	ATAXIC CEREBRAL PALSY
G808	OTHER CEREBRAL PALSY
G8110	SPASTIC HEMIPLEGIA AFFECTING UNSPECIFIED SIDE
G8111	SPASTIC HEMIPLEGIA AFFECTING RIGHT DOMINANT SIDE
G8112	SPASTIC HEMIPLEGIA AFFECTING LEFT DOMINANT SIDE
G8113	SPASTIC HEMIPLEGIA AFFECTING RIGHT NONDOMINANT SIDE
G8114	SPASTIC HEMIPLEGIA AFFECTING LEFT NONDOMINANT SIDE
G8250	QUADRIPLEGIA, UNSPECIFIED
H02041	SPASTIC ENTROPION OF RIGHT UPPER EYELID
H02042	SPASTIC ENTROPION OF RIGHT LOWER EYELID
H02044	SPASTIC ENTROPION OF LEFT UPPER EYELID
H02045	SPASTIC ENTROPION OF LEFT LOWER EYELID
H02141	SPASTIC ECTROPION OF RIGHT UPPER EYELID
H02142	SPASTIC ECTROPION OF RIGHT LOWER EYELID
H02144	SPASTIC ECTROPION OF LEFT UPPER EYELID
H02145	SPASTIC ECTROPION OF LEFT LOWER EYELID
H4901	THIRD [OCULOMOTOR] NERVE PALSY, RIGHT EYE
H4902	THIRD [OCULOMOTOR] NERVE PALSY, LEFT EYE
H4903	THIRD [OCULOMOTOR] NERVE PALSY, BILATERAL
H4911	FOURTH [TROCHLEAR] NERVE PALSY, RIGHT EYE
H4912	FOURTH [TROCHLEAR] NERVE PALSY, LEFT EYE
H4913	FOURTH [TROCHLEAR] NERVE PALSY, BILATERAL
H4921	SIXTH [ABDUCENT] NERVE PALSY, RIGHT EYE
H4922	SIXTH [ABDUCENT] NERVE PALSY, LEFT EYE
H4923	SIXTH [ABDUCENT] NERVE PALSY, BILATERAL
H4931	TOTAL (EXTERNAL) OPHTHALMOPLEGIA, RIGHT EYE
H4932	TOTAL (EXTERNAL) OPHTHALMOPLEGIA, LEFT EYE
H4933	TOTAL (EXTERNAL) OPHTHALMOPLEGIA, BILATERAL
H4941	PROGRESSIVE EXTERNAL OPHTHALMOPLEGIA, RIGHT EYE
H4942	PROGRESSIVE EXTERNAL OPHTHALMOPLEGIA, LEFT EYE
H4943	PROGRESSIVE EXTERNAL OPHTHALMOPLEGIA, BILATERAL
H49881	OTHER PARALYTIC STRABISMUS, RIGHT EYE
H49882	OTHER PARALYTIC STRABISMUS, LEFT EYE
H49883	OTHER PARALYTIC STRABISMUS, BILATERAL
H499	UNSPECIFIED PARALYTIC STRABISMUS
H50011	MONOCULAR ESOTROPIA, RIGHT EYE
H50012	MONOCULAR ESOTROPIA, LEFT EYE
H50021	MONOCULAR ESOTROPIA WITH A PATTERN, RIGHT EYE
H50022	MONOCULAR ESOTROPIA WITH A PATTERN, LEFT EYE
H50031	MONOCULAR ESOTROPIA WITH V PATTERN, RIGHT EYE
H50032	MONOCULAR ESOTROPIA WITH V PATTERN, LEFT EYE
H50041	MONOCULAR ESOTROPIA WITH OTHER NONCOMITANCIES, RIGHT EYE
H50042	MONOCULAR ESOTROPIA WITH OTHER NONCOMITANCIES, LEFT EYE
H5005	ALTERNATING ESOTROPIA

H5006	ALTERNATING ESOTROPIA WITH A PATTERN
TABLE 1 (continued)	
H5007	ALTERNATING ESOTROPIA WITH V PATTERN
H5008	ALTERNATING ESOTROPIA WITH OTHER NONCOMITANCIES
H50111	MONOCULAR EXOTROPIA, RIGHT EYE
H50112	MONOCULAR EXOTROPIA, LEFT EYE
H50121	MONOCULAR EXOTROPIA WITH A PATTERN, RIGHT EYE
H50122	MONOCULAR EXOTROPIA WITH A PATTERN, LEFT EYE
H50131	MONOCULAR EXOTROPIA WITH V PATTERN, RIGHT EYE
H50132	MONOCULAR EXOTROPIA WITH V PATTERN, LEFT EYE
H50141	MONOCULAR EXOTROPIA WITH OTHER NONCOMITANCIES, RIGHT EYE
H50142	MONOCULAR EXOTROPIA WITH OTHER NONCOMITANCIES, LEFT EYE
H5015	ALTERNATING EXOTROPIA
H5016	ALTERNATING EXOTROPIA WITH A PATTERN
H5017	ALTERNATING EXOTROPIA WITH V PATTERN
H5018	ALTERNATING EXOTROPIA WITH OTHER NONCOMITANCIES
H5021	VERTICAL STRABISMUS, RIGHT EYE
H5022	VERTICAL STRABISMUS, LEFT EYE
H50311	INTERMITTENT MONOCULAR ESOTROPIA, RIGHT EYE
H50312	INTERMITTENT MONOCULAR ESOTROPIA, LEFT EYE
H5032	INTERMITTENT ALTERNATING ESOTROPIA
H50331	INTERMITTENT MONOCULAR EXOTROPIA, RIGHT EYE
H50332	INTERMITTENT MONOCULAR EXOTROPIA, LEFT EYE
H5034	INTERMITTENT ALTERNATING EXOTROPIA
H50411	CYCLOTROPIA, RIGHT EYE
H50412	CYCLOTROPIA, LEFT EYE
H5042	MONOFIXATION SYNDROME
H5043	ACCOMMODATIVE COMPONENT IN ESOTROPIA
H5051	ESOPHORIA
H5052	EXOPHORIA
H5053	VERTICAL HETEROPHORIA
H5054	CYCLOPHORIA
H5055	ALTERNATING HETEROPHORIA
H5060	MECHANICAL STRABISMUS, UNSPECIFIED
H50611	BROWN'S SHEATH SYNDROME, RIGHT EYE
H50612	BROWN'S SHEATH SYNDROME, LEFT EYE
H5069	OTHER MECHANICAL STRABISMUS
H50811	DUANE'S SYNDROME, RIGHT EYE
H50812	DUANE'S SYNDROME, LEFT EYE
H5089	OTHER SPECIFIED STRABISMUS
H509	UNSPECIFIED STRABISMUS
H510	PALSY (SPASM) OF CONJUGATE GAZE
H5111	CONVERGENCE INSUFFICIENCY
H5112	CONVERGENCE EXCESS
H5121	INTERNUCLEAR OPHTHALMOPLEGIA, RIGHT EYE
H5122	INTERNUCLEAR OPHTHALMOPLEGIA, LEFT EYE
H5123	INTERNUCLEAR OPHTHALMOPLEGIA, BILATERAL
H518	OTHER SPECIFIED DISORDERS OF BINOCULAR MOVEMENT
H519	UNSPECIFIED DISORDER OF BINOCULAR MOVEMENT
J385	LARYNGEAL SPASM
K117	DISTURBANCES OF SALIVARY SECRETION
K220	ACHALASIA OF CARDIA
L74510	PRIMARY FOCAL HYPERHIDROSIS, AXILLA
L74511	PRIMARY FOCAL HYPERHIDROSIS, FACE
L74512	PRIMARY FOCAL HYPERHIDROSIS, PALMS
L74513	PRIMARY FOCAL HYPERHIDROSIS, SOLES
L74519	PRIMARY FOCAL HYPERHIDROSIS, UNSPECIFIED
M6240	CONTRACTURE OF MUSCLE, UNSPECIFIED SITE
M62411	CONTRACTURE OF MUSCLE, RIGHT SHOULDER
M62412	CONTRACTURE OF MUSCLE, LEFT SHOULDER
M62421	CONTRACTURE OF MUSCLE, RIGHT UPPER ARM
M62422	CONTRACTURE OF MUSCLE, LEFT UPPER ARM
M62431	CONTRACTURE OF MUSCLE, RIGHT FOREARM
M62432	CONTRACTURE OF MUSCLE, LEFT FOREARM
M62441	CONTRACTURE OF MUSCLE, RIGHT HAND
M62442	CONTRACTURE OF MUSCLE, LEFT HAND

M62451	CONTRACTURE OF MUSCLE, RIGHT THIGH
M62452	CONTRACTURE OF MUSCLE, LEFT THIGH
M62461	CONTRACTURE OF MUSCLE, RIGHT LOWER LEG
M62462	CONTRACTURE OF MUSCLE, LEFT LOWER LEG
M62471	CONTRACTURE OF MUSCLE, RIGHT ANKLE AND FOOT
M62472	CONTRACTURE OF MUSCLE, LEFT ANKLE AND FOOT
TABLE 1 (continued)	
M6248	CONTRACTURE OF MUSCLE, OTHER SITE
M6249	CONTRACTURE OF MUSCLE, MULTIPLE SITES
M62831	MUSCLE SPASM OF CALF
M62838	OTHER MUSCLE SPASM
N310	UNINHIBITED NEUROPATHIC BLADDER, NOT ELSEWHERE CLASSIFIED
N311	REFLEX NEUROPATHIC BLADDER, NOT ELSEWHERE CLASSIFIED
N319	NEUROMUSCULAR DYSFUNCTION OF BLADDER, UNSPECIFIED
N3281	OVERACTIVE BLADDER
N3644	MUSCULAR DISORDERS OF URETHRA
N3941	URGE INCONTINENCE
N3946	MIXED INCONTINENCE
N39492	POSTURAL (URINARY) INCONTINENCE
G43001	MIGRAINE WITHOUT AURA, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43009	MIGRAINE WITHOUT AURA, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43011	MIGRAINE WITHOUT AURA, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43019	MIGRAINE WITHOUT AURA, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43101	MIGRAINE WITH AURA, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43109	MIGRAINE WITH AURA, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43111	MIGRAINE WITH AURA, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43119	MIGRAINE WITH AURA, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43401	HEMIPLEGIC MIGRAINE, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43409	HEMIPLEGIC MIGRAINE, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43411	HEMIPLEGIC MIGRAINE, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43419	HEMIPLEGIC MIGRAINE, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43501	PERSISTENT MIGRAINE AURA WITHOUT CEREBRAL INFARCTION, NOT INTRACTABLE, WITH STATUS
G43509	PERSISTENT MIGRAINE AURA WITHOUT CEREBRAL INFARCTION, NOT INTRACTABLE, WITHOUT STA
G43511	PERSISTENT MIGRAINE AURA WITHOUT CEREBRAL INFARCTION, INTRACTABLE, WITH STATUS MIGR
G43519	PERSISTENT MIGRAINE AURA WITHOUT CEREBRAL INFARCTION, INTRACTABLE, WITHOUT STATUS
G43601	PERSISTENT MIGRAINE AURA WITH CEREBRAL INFARCTION, NOT INTRACTABLE, WITH STATUS MIG
G43609	PERSISTENT MIGRAINE AURA WITH CEREBRAL INFARCTION, NOT INTRACTABLE, WITHOUT STATUS
G43611	PERSISTENT MIGRAINE AURA WITH CEREBRAL INFARCTION, INTRACTABLE, WITH STATUS MIGRAIN
G43619	PERSISTENT MIGRAINE AURA WITH CEREBRAL INFARCTION, INTRACTABLE, WITHOUT STATUS MIGR
G43701	CHRONIC MIGRAINE WITHOUT AURA, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43709	CHRONIC MIGRAINE WITHOUT AURA, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43711	CHRONIC MIGRAINE WITHOUT AURA, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43719	CHRONIC MIGRAINE WITHOUT AURA, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43801	OTHER MIGRAINE, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43809	OTHER MIGRAINE, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43811	OTHER MIGRAINE, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43819	OTHER MIGRAINE, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43901	MIGRAINE, UNSPECIFIED, NOT INTRACTABLE, WITH STATUS MIGRAINOSUS
G43909	MIGRAINE, UNSPECIFIED, NOT INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43911	MIGRAINE, UNSPECIFIED, INTRACTABLE, WITH STATUS MIGRAINOSUS
G43919	MIGRAINE, UNSPECIFIED, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS
G43B0	OPHTHALMOPLEGIC MIGRAINE, NOT INTRACTABLE
G43B1	OPHTHALMOPLEGIC MIGRAINE, INTRACTABLE

Guideline Note

Effective Date:	02/01/2025
P&T Approval Date:	01/2013
P&T Review Date:	07/2024

Revision History:

Date	Notes

01/07/2025	Add clarifying language for Oromandibular dystonia

Positive Allosteric Modulators of $GABA_A$ Receptors
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1632	Brexanolone (Zulresso)	Medical Benefit-Restricted	1 infusion	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of moderate to severe postpartum depression and symptoms began within the third trimester and/or no later than 12 weeks after delivery
- Postpartum within 9 months of delivery or pregnancy termination
- Person meets ONE of the following:
  - Documentation of potential risk of harm to self or others.

  OR
  - Documentation of severe impairment of activities of daily living (e.g. inability to care for self, requires supervision, impairments in social or occupational functioning) and/or impairing care of the infant due to depression.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Provider must provide a clinical reason and evidence-based clinical rationale for use of a dose outside of the quantity limit.

CONTINUATION OF COVERAGE CRITERIA (renewal):

- Initial criteria for coverage met

Created: 08/19
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Burosumab (Crysvita)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0584	Burosumab (Crysvita)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of X-linked hypophosphatemia
  - Age ≥ 1 year
  - Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated oral phosphate and vitamin D supplementation
  - Clinical documentation demonstrating evidence of rickets (children) or osteomalacia-associated bone disease (adults)

  OR
- Diagnosis of tumor-induced osteomalacia
  - Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated octreotide and oral phosphate plus vitamin D supplementation
  - Clinical documentation demonstrating evidence of rickets (children) or osteomalacia-associated bone disease (adults)

CONTINUATION OF COVERAGE CRITERIA:

- Initial criteria met Clinical documentation from the previous 12 months demonstrating objective improvements in skeletal quality from baseline**.**

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 05/18
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Cablivi (caplacizumab-yhdp)
Prior Authorization Criteria
DC-0136

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Day	Approval Limits*
C9047	Caplacizumab-yhdp (Cablivi)	Medical Benefit-Restricted	One vial (11mg)	Duration of outpatient plasma exchange

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Has a diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one ADAMST13 level below 20 percent
- Age ≥ 18 years
- Person has been receiving plasma exchange (PEX) and caplacizumab as an inpatient
- PEX will be continued on an outpatient basis

CRITERIA FOR DURATION EXCEPTIONS:

- Requests for coverage on the medical benefit after the person has completed PEX will be reviewed for Medical Necessity

CONTINUATION OF COVERAGE CRITERIA (renewal):

- Initial criteria met

Guideline Note

Effective Date:	04/01/2025
P&T Approval Date:	04/2019
P&T Review Date:	10/2024

Revision History:

Date	Notes
02/27/2024	Add policy number

Cabotegravir injection (Apretude)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0739	Cabotegravir injection (Apretude)	Medical Benefit-Restricted	One injection every 2 months	None

***Limited to 12 months for IL and MN plans**

CRITERIA FOR COVERAGE:

- Person has a high-risk of contracting HIV infection
- Person has renal disease or has had a decline in renal function due to use of tenofovir disoproxil fumarate oral OR
- Person unable to adhere to oral therapy PrEP regimen (tenofovir disoproxil fumarate OR tenofovir alafenamide)

CONTINUATION OF COVERAGE CRITERIA (renewal):†‡:

- The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing adherence to PrEP therapy requirements

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

‡Persons new to the plan must meet the initial criteria for coverage

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Provider must provide a clinical reason and evidence-based clinical rationale for use of a dose outside of the quantity limit.

Guideline Note:

Effective Date:	01/01/2025
P&T Approval Date:	05/17/2022
P&T Review Date:	10/15/2024

Revision History:

Date	Notes
12/10/2024	Update criteria name

Canakinumab (Ilaris)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0638	Canakinumab (Ilaris)	Medical Benefit-Restricted	None	None

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR CRYOPYRIN ASSOCIATED PERIODIC SYNDROMES (CAPS):

- Diagnosis of Cryopyrin-associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Familial Mediterranean Fever, tumor necrosis factor receptor-associated periodic syndrome or other periodic syndromes.
- Trial and failure, intolerance, or contraindication to anakinra (Kineret).

CRITERIA FOR COVERAGE FOR SYSTEMIC JUVENILE ARTHRITIS (SJIA) AND ADULT-ONSET STILL'S DISEASE:

- Prescribed by or in consultation with a Rheumatologist
- 3-month trial and failure, intolerance, or contraindication to at least ONE of the following; corticosteroids, methotrexate, or nonsteroidal anti-inflammatory drugs (NSAIDS)
- Trial and failure, intolerance, or contraindication to anakinra (Kineret).

CRITERIA FOR COVEARGE FOR GOUT:

- History of 3 or more gout flares in the previous 12 months
- Trial and failure, contraindication or intolerance to an adequate trial of colchicine
- Trial and failure, contraindication or intolerance to an adequate trial of a non-steroidal anti-inflammatory drug (NSAID)
- Trial and failure, contraindication or intolerance to systemic corticosteroids

CONTINUATION OF COVERAGE CRITERIA (new to plan):†

- Diagnosis of SJIA
- Prescriber provides clinical documentation from the previous 12 months showing a response to therapy (improvement or stable disease)

CONTINUATION OF COVERAGE CRITERIA (12-month renewal):

- Provider provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Created: 11/11
Effective: 05/01/2024 Client Approval: 06/04/21 P&T Approval: N/A

Cerliponase Alfa (Brineura)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0567	Cerliponase Alfa (Brineura)	Medical Benefit - Restricted	None	12 Months

CRITERIA FOR COVERAGE OF INITIAL USE:

- Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)
- Combined score of at least 3 on the CLN2 Clinical Rating Score

CRITERIA FOR CONTINUATION OF THERAPY/COVERAGE:

- Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)
- Age 3 years or older
- Individual is ambulatory (score of 1 or higher on the motor domain), which can include with assistance.

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 07/17
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Corticotropin Gel
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0800, J0801, J0802	Corticotropin Gel (Acthar Gel, Cortrophin Gel)	Medical Benefit-Restricted	N/A	Initial: 3 months Renewal: 12 months

*Initial and renewal approvals are limited to 12 months for IL and MN

CRITERIA FOR COVERAGE:

- Diagnosis of infantile spasm with electroencephalogram pattern consistent with hypsarthythmia
- Prescribed by, or in consultation with, a Neurologist
- Age < 2 years

OR

- FDA approved diagnosis with evidence-based supporting literature/guideline
- Trial and failure, contraindication, or intolerance to an adequate trial of preferred formulary medications appropriate for the condition

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Initial criteria for coverage is met
- Provider provides an evidence-based rationale for continued use and submits clinical documentation of evidence of patient response to therapy from the previous period.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:

For information regarding coverage of corticotropin gel on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 01/14
Effective: 11/01/2023 Client Approval: P&T Approval: N/A

Crizanlizumab-tmca (Adakveo)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/month	Approval Limits
J0791	Crizanlizumab-tmca (Adakveo)	Medical Benefit-Restricted	1 after loading dose	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of sickle cell disease with >1 vaso-occlusive crisis within the past 12 months, despite being on a stable hydroxyurea dose for at least 90 days, **OR** documentation is provided to show contraindication/intolerance to hydroxyurea
- Prescribed by, or in consultation with a Hematologist or other provider with experience in the treatment of sickle cell disease
- Person is 16 years or older
- Not used in combination with voxelotor (Oxbryta)

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- The prescriber provides an evidence-based rationale for using a dose/frequency outside of the quantity limit.

CONTINUATION CRITERIA (new to plan/12-month renewal):*

- Clinical documentation from the previous 12 months demonstrating a response to therapy such as:
    - Decreased frequency of sickle cell hospitalizations or urgent care visits
    - Decreased frequency of vaso-occlusive crisis
    - Reduction in use of pain medications
    - Improved quality of life (e.g. decreased pain, fewer missed day of work/school, increase in activities, etc.)

*Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Created: 02/20
Effective: 07/03/23 Client Approval: P&T Approval: N/A

PiaSky (crovalimab-akkz)
Prior Authorization Criteria
DC-0134

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1307	PiaSky (crovalimab-akkz)	Medical Benefit-Restricted	Single loading dose	12 months

CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Patient is 13 years of age or older
- Patient weighs at least 40 kg
- Trial and failure, contraindication, or intolerance to one of the following: i) Soliris (eculizumab) OR ii) Ultomiris (ravulizumab)
- Prescribed by or in consultation with a hematologist/oncologist

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Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	01/21/2025
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
02/17/2025	Revise J code

Daprodustat (Jesduvroq)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0889	Daprodustat (Jesduvroq)	Medical Benefit-Restricted	None	12 Months

CRITERIA FOR COVERAGE:

- Diagnosis of anemia due to chronic kidney disease (CKD)
- Age ≥18 years
- Person has been receiving dialysis for ≥4 months
- Patient is hyporesponsive to ESA therapy, defined as:
  - The need for >300 IU/kg per week of epoetin alfa

  OR
  - 1.5 mcg/kg per week of darbepoetin

Created: 10/23
Revised: 11/11/2024
Effective: 12/01/2024

P&T Revision Date: 10/15/2024
Last Revised: 11/11/2024 – update HCPCS code

Denosumab
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
Q5136	Denosumab-bbdz (Jubbonti, Wyost)	Medical Benefit - Restricted	None	None
J0897	Denosumab (Prolia, Xgeva)	Medical Benefit - Restricted	None	None

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE (Prolia):

- For the treatment of postmenopausal women who have **one of the following diagnoses and the associated criteria:**
  - T-score is less than or equal to -2.5 at the femoral neck, total hip , lumbar spine, or 33% (one-third) radius
    OR
  - low bone mass (T-score between -1.0 and -2.5 at femoral neck or lumbar spine)
    - 10 year probability of a hip fracture of at least 3%

    OR
    - 10 year probability of a major osteoporosis-related fracture of at least 20%

    OR
    - Fragility fracture of proximal humerus, pelvis, or distal forearm
  - No prior oral bisphosphonate trial is required for persons with very high fracture risk defined by at least one of the following:
    - Recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very low T-score (less than -3.0), very high FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%), high risk for falls, or history of injurious falls
  - For persons with high fracture risk (the absence of very high fracture risk), documentation of failure of an adequate trial (reduce BMD on therapy), intolerance to, or contraindication to oral bisphosphonate therapy is required
  - Not to be used at the same time in combination with anabolic agents

OR

- To increase bone mass in men with osteoporosis at high risk of for fractures (defined as history of osteoporotic fracture or multiple risk factors for fracture)
- Trial and failure, contraindication or intolerance to oral bisphosphonate therapy

OR

- Treatment of glucocorticoid-induced osteoporosis at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose equivalent to ≥7.5mg of prednisone for at least six months (high risk defined as osteoporotic fracture history, multiple risk factors for fracture)
- Trial and failure, contraindication or intolerance to bisphosphonate therapy

OR

- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Trial and failure, contraindication or intolerance to oral bisphosphonate therapy

OR

- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- Trial and failure, contraindication or intolerance to oral bisphosphonate therapy

*fracture risk to be assessed with FRAX score, number of osteoporosis related fractures, increased fall risk; indicators of higher fracture risk include: advanced age, glucocorticosteroids, very low T score, increased fall risk (many of these factors will reflect in the FRAX score; however, some risk factors are not incorporated, like number of fractures, time of fracture (recent), increased fall risk)

CRITERIA FOR COVERAGE (Xgeva):

- Diagnosis of one of the following: Prevention of skeletal-related events in patients with bone metastases from solid tumors, multiple myeloma, treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
- Documentation of one of the following: Intolerance to use of zoledronic acid, renal deterioration (an increase in serum creatinine >0.5 mg/dL over baseline in patients within 3 months following use of zoledronic acid, calculated CrCl <30ml/min, contraindication to zoledronic acid, person at high risk of toxicity to use of zoledronic acid including baseline renal function impairment (CrCl between 45-60 ml/min), diagnosis of myeloma with elevated light chains

OR

- For the treatment of giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity

OR

- (Minnesota plans only): person with stage four metastatic cancer and the requested drug is being used as supportive care for symptoms related to their cancer diagnosis

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuation therapy with the requested drug

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Important information:
Medications administered in the clinic are not included in the pharmacy benefit. They are covered by the medical benefit and must be procured by the clinic that is administering the medication.

Created: 10/13
Effective: 11/01/2024 Client Approval: 09/13/21 P&T Approval: N/A

Donislecel (Lantidra)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
MISC	Donislecel (Lantidra)	Medical Benefit-Restricted	None	One dose*

*Initial and renewal approvals limited to 12 months for IL and MN

CRITERIA FOR COVERAGE:

- Diagnosis of Type 1 Diabetes with duration of disease of 5 years or longer
- Prescribed by, or in consultation with, an Endocrinologist or other specialist in the treatment of type 1 diabetes
- Age 18–75 years
- Documentation showing recurrent, acute, and severe metabolic and potentially life-threatening complications requiring medical attention with one or more of the following over the previous 12 months:
  - Hyperglycemia
  - Hypoglycemia
  - Hypoglycemia unawareness associated with high risk of injury
  - Ketoacidosis
- Consistent failure of insulin-based management, defined as inability to achieve sufficient glycemic control (HbA1c >8%) or recurrent hypoglycemia unawareness, despite aggressive conventional therapy (usually including insulin pump), including all of the following:
  - Adjusting frequencies and amounts of insulin injected
  - Taking multiple blood glucose measurements on a daily basis
  - Modifying diet and exercise
  - Monitoring HbA1c levels
- Individual does not have any of the following:
  - Co-existing cardiac disease: myocardial infarction (within past six months), Heart failure, non-correctable coronary artery disease
  - Abnormal kidney or liver function or disease
  - C-peptide response to glucagon stimulation, any C-peptide >0.3 ng/mL (undetectable or very low levels of C-peptide)
  - Insulin requirement >0.7 IU/kg/day, HbA1c >12%

CONTINUATION OF COVERAGE CRITERIA (renewal/new to plan†):

- Individual has had ≤ 2 infusions of donislecel (Lantidra)
- One of the following:
  - Individual has not achieved independence from exogenous insulin within 1 year of the previous infusion
  - Individual is within 1 year of loss of independence from exogenous insulin after a previous infusion

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:

Use of donislecel (Lantidra) has only been evaluated as a maximum of three one-time infusions; coverage for additional infusions is considered experimental and will not be covered.

Created: 10/23
Effective: 01/01/2024 Client Approval: N/A P&T Approval: N/A

Soliris (eculizumab) and biosimilars
Prior Authorization Criteria
DC-0135

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1300, J1299 Q5139, Q5151, Q5152	Soliris (eculizumab) Bkemy (eculizumab), Epysqli (eculizumab)	Medical Benefit-Restricted	N/A	12 months

PNH CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- One of the following:
    - Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks
    - Prescribed medication is used for maintenance therapy and will not exceed 900 mg weekly at week 5, then 900 mg every 2 weeks thereafter
- Prescribed by or in consultation with a hematologist/oncologist

aHUS CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of atypical hemolytic uremic syndrome (aHUS)
- One of the following:
    - For patients 18 years of age and older: Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks
    - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter
    - For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS
- Prescribed by or in consultation with a hematologist or nephrologist

MG CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of generalized myasthenia gravis (gMG)
- Patient is anti-acetylcholine receptor (AChR) antibody positive
- One of the following:
    - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

    OR
    - Both of the following:
        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)
        - Trial and failure, contraindication, or intolerance to one of the following: Chronic plasmapheresis or plasma exchange (PE) or Intravenous immunoglobulin (IVIG)
- Trial and failure, contraindication, or intolerance to Vyvgart (efgartigimod)
- One of the following:
    - Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4

weeks
    - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter
- Prescribed by or in consultation with a neurologist

NMOSD CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- Patient is anti-aquaporin-4 (AQP4) antibody positive
- One of the following:
    - Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks
    - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter
- Prescribed by or in consultation with one of the following: neurologist or ophthalmologist

CRITERIA FOR COVERAGE (RENEWAL):

- Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions, increased in platelet counts) to therapy
- One of the following:
    - Prescribed medication is used for PNH maintenance therapy and will not exceed 900 mg every 2 weeks
    - Prescribed medication is used in an adult patient for aHUS maintenance therapy and will not exceed 1200 mg every 2 weeks
    - Prescribed medication is used in a pediatric patient for aHUS maintenance therapy and dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS
    - Prescribed medication is used for MG maintenance therapy and will not exceed 1200 mg every 2 weeks
    - Prescribed medication is used for NMOSD maintenance therapy and will not exceed 1200 mg every 2 weeks

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Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	05/2019
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
11/25/2024	New drug specific criteria, standardization
03/20/2025	Add Bkemy, Epysqli, new Soliris code

Edaravone (Radicava)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1301	Edaravone (Radicava)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria
- Prescribed by, or in consultation with, a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS)
- Age 20-75
- Independent living status (i.e., Japan ALS Severity Classification Grade 1 or 2)
- Score of ≥ 2 on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) (assessed and documented within the last 3 months)
- FVC % predicted ≥ 80% (assessed and documented within the last 3 months)
- Duration of disease from the first symptom of 2 years or less
- Current use of riluzole or documented contraindication/intolerance/lack of therapeutic effect of therapy

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):*

- Documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:

For information regarding coverage of edaravone on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 08/17
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Efgartigimod alfa (Vyvgart)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9332	Efgartigimod alfa (Vyvgart)	Medical Benefit Restricted	None	12 months
J9334	Efgartigimod-Hyaluronidase-qvfc (Vyvgart Hytrulo)	Medical Benefit Restricted	None	12 months

CRITERIA FOR COVERAGE (Myasthenia Gravis):

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
- Prescribed by, or in consultation with, a Neurologist
- Positive serologic test for anti-acetylcholine receptor (AChR) antibodies
- Baseline IgG level of at least 6g/L
- Initial Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 5
- Medical notes showing at least one of the following baseline measures: Quantitative Myasthenia Gravis (QMG) score within the past 12 months, number of immune globulin (IVIG) infusions, plasma exchange (PLEX) treatments or exacerbations/hospitalizations from within the past 12 months.
- Notes indicating that efgartigimod will not be used in combination with ongoing immune globulin (IVIG) infusions (does not apply to use of IVIG for treatment of acute myasthenic crisis).
- Trial and failure, intolerance, or contraindication of a six month trial of TWO immunosuppressive therapies (e.g. prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, rituximab).
    - If intolerance to one or more immunosuppressives, then prior 3 months trial and failure of IVIG OR prior use of and failure of at least 4 PLEX treatments.

CRITERIA FOR COVERAGE (Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)):

- Diagnosis of definite or probable CIDP
- Prescribed by, or in consultation with, a Neurologist
- Active disease with clinically meaningful symptoms on at least one CIDP clinical assessment tool such as INCAT (Inflammatory Neuropathy cause and treatment disability score), I-RODS (Inflammatory Rasch-built Overall Disability Scale), or mean grip strength.

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):*

- Initial criteria met.
- Prescriber provides clinical notes from the previous 12 months documenting response to therapy compared to baseline; such as improvement in symptoms/function (i.e. decrease in MG-ADL, QMG score, CIDP clinical assessment score), fewer disease exacerbations (i.e. decrease in hospitalizations, PLEX treatments, steroid dosing etc.).

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: 02/22
Effective: 10/01/2024

Kebilidi (eladocagene exuparvovec-tneq)
Prior Authorization Criteria
DC-0158

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
MISC	Kebilidi (eladocagene exuparvovec-tneq)	Medical Benefit-Restricted	Once per lifetime	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency
- Disease is confirmed by one of the following:
    - Molecular genetic testing confirms mutations in the DDC (DOPA decarboxylase) gene
    - CSF (cerebrospinal fluid) analysis showing a pattern of all of the following:
        - Reduced levels of 5-hydroxyindoleacetic acid (5-HIAA), homovanillic acid (HVA) and 3-methoxy-4- hydroxyphenylglycol (MHPG)
        - High concentrations of 3-O-methyldopa (3-OMD), L-Dopa, and 5- OH tryptophan (5-HTP)
        - Normal pterins (e.g., neopterin, biopterin)
    - Analysis of plasma showing reduced aromatic L-amino acid decarboxylase (AADC) activity
- Clinical signs and symptoms of the disease (e.g., hypotonia, oculogyric crises, developmental delays)
- Confirmation of skill maturity assessed by neuroimaging
- Prescribed by a provider in a medical treatment center with expertise in gene therapy
- Prescribed by one of the following:
    - Neurologist
    - Specialist with expertise in the diagnosis and management of aromatic L-amino acid decarboxylase (AADC) deficiency
- Patient has never received Kebilidi treatment in their lifetime

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication should be billed to Forward Health under the pharmacy benefit. Refer to the Forward Health policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.

Effective Date:	07/01/2025
P&T Approval Date:	04//15/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/25/2025	New criteria

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Elapegademase (Revcovi)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Elapegademase (Revcovi)	Medical Benefit-Restricted	None	12 Months

CRITERIA FOR COVERAGE:

- Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)
- Prescribed by, or in consultation with, an expert in the treatment of immune deficiencies

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):*

- The prescriber provides recent clinical documentation from the past 6 months of a trough plasma ADA activity ≥ 30 mmol/hr/L and a trough erythrocyte dAXP level below 0.02 mmol/L

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
For information regarding coverage of elapegademase on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 01/19
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Elivaldogene Autotemcel (Skysona)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
MISC	Elivaldogene Autotemcel (Skysona)	Medical Benefit-Restricted	One treatment per lifetime	3 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of early, active cerebral adrenoleukodystrophy (CALD) with all of the following:
  - Elevated very-long-chain fatty acid (VLCFA) values
  - Confirmed ABCD 1 mutation
  - Brain MRI demonstrating Loes score between 0.5 and 9
  - Gadolinium enhancement on MRI of demyelinating disease
  - NFS ≤ 1
- Prescribed by or in consultation with an Endocrinologist, Neurologist, Hematologist, Oncologist, or other expert in the treatment of early, active CALD
- Age between 4 and 17 years
- No prior history of hematopoietic stem cell transplantation (HSCT)
- No known or available HLA-matched family matched for HSCT and one of the following:
  - There is an unrelated matched donor, and risk of transplantation exceed risk of Skysona
  - There is no known unrelated matched donor

CRITERIA FOR DURATION EXCEPTION:

- The prescriber provides an evidence-based rationale for using a dosing regimen beyond the approval limit

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 01/23
Effective: 08/01/2024 Client Approval: P&T Approval:

Emapalumab (Gamifant)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J9210	Emapalumab (Gamifant)	Medical Benefit-Restricted	None	3 Months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Person diagnosed with primary hemophagocytic lymphohistiocytosis (HLH) defined as either:
  - Familial HLH caused by a gene mutation
    OR
  - HLH associated with an immunodeficiency syndrome (e.g. Griscelli syndrome)
    OR
  - Prescriber provides objective medical documentation and published evidence to support a clinical diagnosis of primary HLH
- Prescribed by, or in consultation with, a Hematologist, Oncologist or other specialty in treating HLH
- Documentation of active disease based on at least three of the following signs/symptoms:
  - Hemoglobin levels <90 g/L (in infants <4 weeks old, hemoglobin <100 g/L)
  - Platelets <100 × 109/L
  - Neutrophils <1.0 × 109/L
  - Elevated liver enzymes (i.e. 3-times the ULN for AST, ALT, GGT or LDH)
  - Fasting triglycerides ≥3.0 mmol/L or ≥265 mg/dL
  - Fibrinogen ≤1.5 g/L
  - Ferritin ≥500 mg/L
  - Elevated D-dimer
  - Splenomegaly and/or hepatomegaly
  - Neurologic symptoms (seizures, mental status changes, visual disturbances, ataxia)
- Current and ongoing treatment with dexamethasone unless contraindication or intolerance
- Treatment plan includes a hematopoietic stem cell transplantation (HSCT)
- Trial and failure, contraindication, or intolerance with at least two standard non-steroid HLH therapies (e.g. etoposide, alemtuzumab, antithymocyte globulin) in combination with a steroid medication unless contraindicated or not tolerated

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Initial criteria met.
- Medical documentation from the past 6 months to show both of the following: a 50% improvement in at least 3 signs/symptoms of active disease and that the treatment plan includes a HSCT or medical rationale is provided for why person is unable to undergo HSCT.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 05/19
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Eptinezumab-jjmr (Vyepti)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Year	Approval Limits
J3032	Eptinezumab-jjmr (Vyepti)	Medical Benefit-Restricted	Four infusions	12 months

CRITERIA FOR COVERAGE:

- Person has ≥ 4 migraine days per month with documentation that headaches are disabling (e.g. unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score, etc.)
- Age ≥ 18 years
- Trial and failure, intolerance, or contraindication to 2 generic preventive migraine medications (e.g. anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)
- Trial and failure, intolerance, or contraindication to ≥ 2 self-administered preventative CGRP inhibitors (e.g. erenumab (Aimovig), galcanezumab (Emgality))
- Drug is not being used in combination with another CGRP inhibitor preventative

CONTINUATION OF COVERAGE CRITERIA (renewal)†,‡:

- Clinical documentation from the previous 12 months showing a response to therapy (specific details regarding symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school, etc.).
- Drug is not being used in combination with another CGRP inhibitor preventative

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

‡ Persons new to plan must meet the initial criteria for coverage

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

Guideline Note:

Effective Date:	01/01/2025
P&T Approval Date:	05/2018
P&T Review Date:	10/15/2024

Revision History:

Date	Notes
12/10/2024	Update criteria name

Esketamine Nasal Inhalation (Spravato)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
G2082, G2083, S0013	Esketamine (Spravato)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of one of the following:
  - Major depressive disorder (MDD) with acute suicidal ideation or behavior (thoughts of self-harm with awareness they may die as a result and intends to act on those thoughts)
    OR
  - Treatment-resistant depression and at least one of the following:
    - Treatment was initiated during an inpatient hospitalization
      OR
    - Symptoms of depression continue despite an adequate trial (at or above minimum therapeutic dose for at least 4 weeks with 2 antidepressants
      OR
    - Symptoms of depression continue and there is documentation to show treatment limiting side effects with 2 antidepressants.

AND

- Medication is prescribed by, or in consultation with, a Psychiatrist
- Age ≥ 18 years
- Esketamine will be used in combination with an antidepressant medication

CRITERIA FOR CONTINUATION OF COVERAGE (new to plan/renewal):†

- Prescriber provides clinical documentation from the previous 12 months to show continued response and medical reasons to support treatment continuation.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:

Each treatment with esketamine nasal Inhalation must be supplied by a certified treatment center, supervised by a health care provider, and billed as part of the medical benefit.
The patient, facility and pharmacy must be enrolled in the Spravato Risk Evaluation Mitigation Strategy (REMS) Program

Created: 05/19
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Etranacogene dezaparvovec (Hemgenix)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J1411	Etranacogene dezaparvovec (Hemgenix)	Medical Benefit-Restricted	One infusion per lifetime	1 month

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of congenital hemophilia B
- Prescribed by, or in consultation with, a Hematologist or other specialist in the treatment of hemophilia B
- Age ≥ 18
- Current use of Factor IX prophylaxis therapy with a history of ≥ 150 previous exposure days of prophylaxis therapy
- One of the following is met:
  - Factor IX level less than 1 international unit (IU) / deciliter (dL)
  - Factor IX level is between 1 IU/dL and 5 IU/dL with
    - Current or historical life-threatening hemorrhage;

    OR
    - Repeated, serious spontaneous bleeding episodes
- Without evidence of any of the following:
  - History of factor IX inhibitor
  - Active inhibitors to factor IX
  - Active hepatitis c virus infection
  - Active hepatitis b virus infection
  - Current use of hepatitis B or C antiviral therapy
  - Uncontrolled HIV infection (e.g. HIV positive with CD4+ counts ≤200/µL)
  - Liver cirrhosis
  - Liver function testsǂ at least 2 times the upper limit of normal

ǂLiver function tests include aspartate transaminase (AST), Alanine transaminase (ALT), total bilirubin, and alkaline phosphatase (ALP).

CRITERIA FOR DURATION EXCEPTION:

- The prescriber provides an evidence-based rationale for using a dosing regimen beyond the approval limit

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 04/23
Effective: 08/01/24 Client Approval: P&T Approval: N/A

Evinacumab (Evkeeza)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1305	Evinacumab (Evkeeza)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of homozygous familial hypercholesteremia (HoFH) with either:
  - Clinical diagnosis (LDL-C > 500 mg/dL with xanthomas or family history of both parents with LDL-C levels > 250 mg/dL)

  OR
  - Genetic verification of HoFH
- Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders
- LDL-C level > 70 mg/dL
- Trial and failure, contraindication, or intolerance to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor unless there is genetic verification of receptor negative (null-null mutation) HoFH

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Diagnosis of homozygous familial hypercholesteremia (HoFH) with either:
  - Clinical diagnosis (LDL-C > 500 mg/dL with xanthomas or family history of both parents with LDL-C levels > 250 mg/dL)

  OR
  - Genetic verification of HoFH
- Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders
- Documentation of a clinically meaningful (≥ 10%) reduction in LDL-C from baseline

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Created: 05/21
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Exagamglogene autotemcel (Casgevy)
Prior Authorization Criteria
DC-0124

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3392	Exagamglogene autotemcel (Casgevy)	Medical Benefit-Restricted	None	Single dose

CRITERIA FOR COVERAGE FOR SICKLE CELL DISEASE:

- Age 12 years of age and older
- The person is eligible to undergo stem cell transplantation
- History of recurrent (at least two) severe vaso-occlusive crises in the last two years. Examples could include acute pain event requiring visit to a medical facility, and administration of pain medications or RBC transfusions, acute chest syndrome, priapism lasting >2 hours and requiring a visit to a medical facility, splenic sequestration
- No history of advanced liver disease
- No history of Moyamoya disease

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Guideline Note:

Effective Date:	01/01/2025
P&T Approval Date:	01/01/2024
P&T Review Date:	10/15/2024

Revision History:

Date	Notes
12/12/2024	Add J code

Fecal microbiota, live-jslm rectal suspension (Rebyota)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1440	Fecal microbiota, live-jslm rectal suspension (Rebyota)	Medical Benefit-Restricted	None	One dose

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE: All criteria must be met

- Diagnosis of at least 2 recurrent* episodes of Clostridioides difficile (C diff) infection (≥ 3 C diff infection episodes)
- Has a positive stool test for toxigenic C diff from a recent stool sample
- C diff infection is refractory to standard antibiotic therapy (vancomycin or fidaxomicin)
- Prescribed by, or in consultation with, an Infectious Disease specialist or Gastroenterologist
- Person is 18 years or older

*defined as recurrence of diarrhea and positive C diff test within 8 weeks after treatment of prior episode

CRITERIA FOR DURATION EXCEPTIONS:

- Person diagnosed with a recurrent* episode of C diff after previous treatment with fecal microbiota therapy

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Created: 07/23
Effective: 10/02/2023 Client Approval: P&T Approval: N/A

Fidanacogene elaparvovec-dzkt (Beqvez)
Prior Authorization Criteria
DC-0138

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9172, J1414	Fidanacogene elaparvovec-dzkt (Beqvez)	Medical Benefit-Restricted	None	1 per lifetime

CRITERIA FOR COVERAGE:

- Diagnosis of Hemophilia B (congenital Factor IX deficiency);
- One of the following:
    - Both of the following:
        - Diagnosis of severe hemophilia B
        - Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/mL)

    OR
    - All of the following:
        - Diagnosis of moderately severe hemophilia B
        - Documentation of endogenous Factor IX levels greater than or equal to 1% to less than or equal to 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL)
        - Patient has current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes
- Patient is currently using Factor IX prophylaxis therapy (e.g., BeneFIX, Ixinity, Rixubis, etc.) and will discontinue treatment after stable on Beqvez therapy;
- Both of the following:
    - Patient has been on prophylactic Factor IX replacement therapy for at least 6 months;
    - Patient has greater than 50 previous exposure days of treatment with a Factor IX agent;
- Patient is 18 years of age or older;
- Patient does not have any of the following:
    - Positive human immunodeficiency virus (HIV) test at screening that is not controlled with anti-viral therapy;
    - Active infection with hepatitis B or C virus;
    - Currently on antiviral treatment for hepatitis B or C;
    - Positive Factor IX inhibitor titer test prior to therapy;
    - History of Factor IX inhibitor;
    - Anti-AAVRh74var neutralizing antibodies (nAB);
- Provider attests that the following laboratory values have been checked prior to therapy and are less than two times the upper limit of normal: a) Alanine aminotransferase (ALT), b) Alkaline phosphatase (ALP), c) Aspartate aminotransferase (AST), d) Total bilirubin;
- Provider attests that hepatic ultrasound and elastography have been completed prior to therapy;
- Prescribed by a hematologist at a Hemophilia Treatment Center (HTC);
- Patient has never received any previous Hemophilia B gene therapy treatment in their lifetime (e.g., Hemgenix, Beqvez)

Guideline Note:

Effective Date:	01/01/2025
P&T Approval Date:	10/15/2024
P&T Review Date:	10/15/2024

Revision History:

Date	Notes
12/06/2024	Code update, add references

References

1. Beqvez Prescribing Information. Pfizer Inc. New York, NY. April 2024.

Vyalev (foscarbidopa and foslevodopa)
Prior Authorization Criteria
DC-0157

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J7356	Vyalev (foscarbidopa and foslevodopa)	Medical Benefit-Restricted	N/A	12 months

CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of Parkinson's Disease
- Patient is levodopa-responsive
- Patient is experiencing disabling "off" periods for a minimum of 2.5 hours/day
- Disabling "off" periods occur despite therapy with both of the following:
    - Oral levodopa-carbidopa
    - One drug from a different class of anti-Parkinson's disease therapy (e.g. entacapone, tolcapone, selegiline, rasagiline, pramipexole, ropinirole)
- Prescribed by or in consultation with a neurologist

CRITERIA FOR COVERAGE (RENEWAL):

- Documentation of positive clinical response (e.g. decreased in "off" time)

Effective Date:	07/01/2025
P&T Approval Date:	04/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
02/28/2025	New criteria

References

1. Vyalev Prescribing Information. AbbVie Inc. North Chicago, IL. October 2024.

Fosdenopterin (Nulibry)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
Misc code	Fosdenopterin (Nulibry)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of molybdenum cofactor deficiency (MoCD) Type A
- Prescribed or recommended by MoCD Type A specialist (e.g. genetics, pediatrics)

CRITERIA FOR CONTINUATION:

- Clinical documentation from an office visit from the previous 12 months showing response to therapy (e.g. continued use, tolerability, doses adjusted for weight, etc)
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:

- Fosdenopterin can administered at home but the medication and administration supplies should be billed and obtained under the medical benefit

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Created: 05/21
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Galsulfase (Naglazyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Cycle	Approval Limits
Galsulfase (Naglazyme)	Medical Benefit-Restricted		12 months

CRITERIA FOR COVERAGE:

- Diagnosis of mucopolysaccharidosis VI (MPS VI) (Maroteaux-Lamy syndrome) to improve walking and stair-climbing capacity

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:*

- Prescriber provides clinical documentation from the previous 12 months that the person has a diagnosis of mucopolysaccharidosis VI and has had improvement (or stable) in ambulation

*Continuation of therapy coverage will not be applied to persons who were not previously approved for coverage, whose therapy was initiated using a manufacturer sponsored free drug program, provider samples and/or vouchers.

Created: 2/22
Effective: 05/02/2022 Client Approval: P&T Approval:

Gaucher Disease
Prior Authorization Criteria
DC-0156

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1786	Cerezyme (imiglucerase)	Medical Benefit-Restricted	N/A	12 Months
J3060	Elelyso (taliglucerase alfa)	Medical Benefit-Restricted	N/A	12 Months
J3385	Vpriv (velaglucerase alfa)	Medical Benefit-Restricted	N/A	12 Months

CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of Type 1 Gaucher disease
- Patient has evidence of symptomatic disease (e.g., moderate to severe anemia [A}, thrombocytopenia [B], bone disease [C], hepatomegaly [D], or splenomegaly [D])
- One of the following:
    - Patient is 4 years of age or older (applies to Elelyso and VPRIV only)
    - Patient is 2 years of age or older (applies to Cerezyme only)

CRITERIA FOR COVERAGE (RENEWAL):

- Documentation of positive clinical response (e.g. decreased in symptoms of disease)

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- **CEREZYME** must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Endnotes

A. Goals of treatment with anemia are to increase hemoglobin to greater than or equal to 12.0 g/dL for males (greater than 12 years of age), and to greater than or equal to 11.0 g/dL for both children (less than or equal to 12 years of age) and females (greater than 12 years of age).
B. Moderate thrombocytopenia is defined as a platelet count of 60,000 to 120,000/microliter. A platelet count of 120,000/microliter to meet the criterion of thrombocytopenia is based on the upper end of the range that defines moderate thrombocytopenia.
C. In bone disease, the goal is to lessen or eliminate bone pain and prevent bone crises. Bone disease can be diagnosed using MRI, bone scan, and X-ray.
D. Hepatomegaly is defined as a liver mass of greater than 1.25 times normal value. Splenomegaly is defined as a splenic mass greater than the normal, and moderate splenomegaly is considered a spleen volume of greater than 5 and less than or equal to 15 times normal.

Effective Date:	07/01/2025
P&T Approval Date:	04/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
02/28/2025	New criteria

References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2022.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. May 2023.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. September 2021.
4. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004;41(4 Suppl 5):4-14.
5. Weinreb NJ, Aggio MC, Andersson HC, et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. Semin Hematol. 2004;41(suppl 5):15-22.
6. Weinreb N, Taylor J, Cox T, et al. A benchmark analysis of the achievement of therapeutic goals for type 1 Gaucher disease patients treated with imiglucerase. Am J Hematol. 2008;83:890-895.
7. Hollak CE, vom Dahl S, Aerts JM, et al. Force majeure: therapeutic measures in response to restricted supply of imiglucerase (Cerezyme) for patients with Gaucher disease. Blood Cells Mol Dis. 2010;44(1):41-7.

Givosiran (Givlaari)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0223	givosiran sodium (Givlaari)	Medical benefit-Restricted	None	Initial: 6 Months Renewal: 12 Months

CRITERIA FOR COVERAGE:

- Diagnosis of acute hepatic porphyria (AHP) (i.e. acute intermittent, variegate, hereditary coproporphyria or ALA dehydratase deficient) confirmed by appropriate laboratory testing (i.e. urine PBG, total porphyrins) or genetic testing
- Prescribed by, or in consultation with, a Hematologist, Hepatologist, or other provider with experience in the treatment of acute hepatic porphyria
- Age 18 years or older
- Active disease with at least 2 porphyria attacks requiring healthcare utilization within the past six months (i.e. IV hemin administration, hospitalizations) **OR** currently receiving prophylactic hemin to prevent porphyria attacks
- Individual has not had a liver transplant, does not have history of pancreatitis, and does not have an active virus infection (ex: hepatitis C, hepatitis B, etc.)
- Individual will not receive concomitant prophylactic hemin treatment

CONTINUATION CRITERIA (new to plan/ renewal):

- Initial criteria met and clinical documentation from the previous 12 months demonstrating a response to therapy such as:
    - Decreased number of porphyria hospitalizations
    - Significant reduction in hemin treatment days
    - Decrease in total number of porphyria attacks
    - Improvement in symptoms (ex: abdominal pain, nausea, vomiting, seizures, limb weakness, etc.)

*Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Created: 01/20
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Glucosidase Alfa Enzyme Therapies
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0221, J0220	Alglucosidase alfa (Lumizyme)	Medical Benefit-Restricted	None	None
J0219	Avalglucosidase alfa (Nexviazyme)	Medical Benefit-Restricted	None	None

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Covered for persons with a diagnosis of Pompe disease

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet initial criteria for coverage

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Created: 11/21
Effective: 07/03/23 Client Approval:5/23/23 P&T Approval: N/A

Golimumab infusion (Simponi Aria)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1602	Golimumab infusion (Simponi Aria)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE FOR ALL DIAGNOSES:

- Trial and failure of golimumab self-injection (subcutaneous) or documented inability to self-administer golimumab injections
- Diagnosis as listed

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS (RA):

- Prescribed by or in consultation with a Rheumatologist
- Documented failure with a 3-month trial, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)
  - Hydroxychloroquine
  - Leflunomide
  - Sulfasalazine

CRITERIA FOR COVERAGE OF MODERATE TO SEVERELY ACTIVE PSORIATIC ARTHRITIS (PsA)

- Prescribed by or in consultation with a Dermatologist or Rheumatologist
- Documentation of at least ONE of the following; actively inflamed joints, axial disease, active skin/nail/scalp psoriasis involvement, dactylitis, or enthesitis

CRITERIA FOR COVERAGE OF ANKLYOSING SPONDYLITIS (AS)

- Prescribed by or in consultation with a Rheumatologist
- 1-month trial and failure intolerance, or contraindication to scheduled prescription doses of two different nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen, nabumetone, diclofenac, etc.

CRITERIA FOR COVERAGE FOR ULCERATIVE COLITIS (UC):

- Prescribed by or in consultation with a Gastroenterologist
- High-risk disease as evidenced by ONE of the following:
  - Extensive colitis
  - Deep ulcers
  - Age < 40 years
  - High C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) labs
  - Steroid-requiring disease
  - History of hospitalization due to UC
  - C. difficile infection
  - CMV infection
- Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

(MN PLANS ONLY) CRITERIA FOR COVERAGE FOR CHECKPOINT INHIBITOR-INDUCED INFLAMMATORY ARTHRITIS

- Person with stage four metastatic cancer and golimumab is being used to treat checkpoint inhibitor-induced musculoskeletal inflammatory disease

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewals):†

- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy including individual improvements in functional status related to therapeutic response.
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, clear skin, those with high supra-therapeutic trough levels, etc.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
For information regarding coverage of golimumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

While the anti-TNF agents have been deemed safe in pregnancy, there are product specific differences. Certolizumab does not appear to cross the placenta and therefore, it may pose less risk to a fetus. For pregnant women established on anti-TNF therapy, therapy interruptions prior to delivery are recommended with infliximab (8-10 weeks prior) and adalimumab (4-5 weeks prior). For pregnant women established on anti-TNF therapy and requiring an adjustment to anti-TNF therapy, consideration will be given to use of certolizumab.

Absolute contraindications to methotrexate are pregnancy, nursing, alcoholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate.

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Inadequate Disease Control of UC/CD:
Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc) and/or recent endoscopy results demonstrating ongoing inflammation

Steroid Dependence:
-Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis
-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs
-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin
-endoscopy, colonoscopy, sigmoidoscopy

Ulcerative Colitis Disease Severity:
Based on the degree of presentation of the signs and symptoms and change in baseline inflammatory status
Moderate disease - more than four stools per day with minimal signs of toxicity, anemia, abdominal pain, low grade fever
Severe disease - more than six bloody stools per day, fever, tachycardia, anemia, elevated ESR or CRP

Crohn's Disease Classification:
Stricturing - narrowing of bowel that may cause bowel obstruction
Penetrating - fistulae may form between bowel and other structures
Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

1. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
2. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.
3. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.

Created: 10/23
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit, remove separate BadgerCare+ criteria

Tremfya (guselkumab)
Prior Authorization Criteria
DC-0161

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1628	Tremfya (guselkumab)	Medical Benefit-Restricted	3 doses	90 days

CRITERIA FOR COVERAGE CROHN'S DISEASE (INITIAL):

- Diagnosis of moderately to severely active Crohn's disease (CD)
- One of the following:
  - Frequent diarrhea and abdominal pain
  - At least 10% weight loss
  - Complications such as obstruction, fever, abdominal mass
  - Abnormal lab values (e.g., C-reactive protein [CRP])
  - CD Activity Index (CDAI) greater than 220
- Prescribed by or in consultation with a gastroenterologist
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
  - 6-mercaptopurine
  - Azathioprine
  - Corticosteroids
  - Methotrexate

CRITERIA FOR COVERAGE ULCERATIVE COLITIS (INITIAL):

- Diagnosis of moderately to severely active ulcerative colitis
- One of the following:
  - Greater than 6 stools per day
  - Frequent blood in the stools
  - Frequent urgency
  - Presence of ulcers
  - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
  - Dependent on, or refractory to, corticosteroids
- Prescribed by or in consultation with a gastroenterologist
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
  - 6-mercaptopurine
  - Azathioprine
  - Corticosteroids (e.g. prednisone)
  - Aminosalicylate (e.g. mesalamine, olsalazine, sulfasalazine)

CRITERIA FOR COVERAGE (RENEWAL):

- Clinical documentation from the previous 12 months showing the patient was started on therapy and needs to complete the part of the 3 dose loading series.

Effective Date:	07/01/2025
P&T Approval Date:	04//15/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/25/2025	New criteria

References

1. Tremfya Prescribing Information. Janssen Biotech, Inc. Horsham, PA. 2025.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

Hemophilia Factor Products
Prior Authorization Criteria
DC-0041

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
Factor XIII Products				
J7180, J7181	Corifact, Tretten	Medical Benefit-Restricted	None	None
Factor VIII Products				
J7182, J7185, J7188, J7190, J7192, J7204, J7205, J7207, J7208, J7209, J7210, J7211, J7214	Eloctate, Esperoct, Nuwiq, Afstyla, Adynovate, Recombinate, Kovaltry, Kogenate FS, Helixate FS, Advate, Koate, Hemofil, Xyntha, Novoeight, JIVI, Obizur, Altuviiio	Medical Benefit-Restricted	None	None
Factor IX Products				
J7193, J7194, J7195, J7200, J7201, J7202, J7203, J7213	Mononine, Profilnine, Ixinity, Benefix, Rixubis, Alprolix, Idelvion, Rebinyn	Medical Benefit-Restricted	None	None
Von Willebrand Factor Products				
J7179, J7183, J7186, J7187	Wilate, Alphanate, Humate-P, Vonvendi	Medical Benefit-Restricted	None	None
Factor VII Products				
J7189, J7212	NovoSeven RT, Sevenfact	Medical Benefit-Restricted	None	None
Factor X Products				
J7175	Coagadex	Medical Benefit-Restricted	None	None
Anti-Inhibitor Products				
J7198	Feiba NF	Medical Benefit-Restricted	None	None

* Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Medication must be provided from a preferred provider
  - UW Health Specialty Pharmacy 1-866-894-3784

CRITERIA FOR COVERAGE FOR ILLINOIS PPO/POS PLANS:

- Person is followed by a specialist in bleeding disorders or a bleeding disorders program

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to plan must meet initial criteria for coverage

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE: Medication should generally be billed to ForwardHealth under the pharmacy benefit. Criteria for Coverage:

- Medication is needed urgently (in less than 24 hours) can cannot be obtained under the pharmacy benefit within this time period.

OTHER INFORMATION:

For Hemlibra (emicizumab-kxwh) and Hympavzi (marstacimab-hncq), refer to pharmacy benefit.

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	02/2018
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/21/2025	Add note about Hympavzi, update Badgercare plus/Medicaid SSI language

Hereditary Angioedema Medications
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limit/Month	Approval Limits*
J0596, J0597, J0598, J0599	C1 esterase inhibitor (Berinert, Cinryze, Haegarda, Ruconest)	Medical benefit-Restricted	Hagegarda: Weight-based number of vials	Haegarda: 6 months All others: 12 months
J1290	Ecallantide (Kalbitor)	Medical benefit-Restricted	None	12 months
J1744	Icatibant (generic)	Medical benefit-Restricted	None	12 months
J0593	Lanadelumab (Takhzyro)	Medical benefit-Restricted	2	6 months

*Limited to 12 months for IL and MN plans

GENERAL CRITERIA FOR COVERAGE:

- Diagnosis of Hereditary Angioedema (HAE)
  - Low C4 AND low C1 inhibitor level or function

  OR
  - Normal C1 inhibitor level with a family history of HAE AND high dose antihistamines did not control symptoms
- Prescribed by, or in consultation with, an Allergist or other provider with experience in the treatment of HAE
- Discontinuation of any medications that may cause angioedema (e.g. ACE inhibitors, estrogens, ARBS)

CRITERIA FOR COVERAGE OF TREATMENT FOR ACUTE ATTACKS(Berinert, Ruconest, ecallantide, icatibant):

- General criteria met
- Requested product will not be used in combination with other approved treatments for acute attacks

CRITERIA FOR COVERAGE FOR LONG-TERM PREVENTION/PROPHYLAXIS (Haegarda, lanadelumab):

- General criteria met
- Requested product will not be used in combination with other approved HAE prevention treatments
- History of ≥ 2 attacks per month or person's symptoms are moderate to severe

CRITERIA FOR COVERAGE FOR LONG-TERM PREVENTION/PROPHYLAXIS (Cinryze):

- General criteria met
- Requested product will not be used in combination with other approved HAE prevention treatments
- History of ≥ 2 attacks per month or person's symptoms are moderate to severe
- Trial and failure (no reduction in frequency of attacks or severity of attacks) or intolerable side effects with Haegarda and lanadelumab
- Trial and failure (no reduction in frequency of attacks or severity of attacks), contraindication, or intolerable side effects with berotralstat

  OR
  - Age 6-12 years

Rytelo (imetelstat)
Prior Authorization Criteria
DC-0133

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0870	Rytelo (imetelstat)	Medical Benefit-Restricted		6 months (initial) 12 months (renewal)

CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of myelodysplastic syndrome;
- Disease is low to intermediate-1 risk [A];
- All of the following:
  - Hemoglobin less than 10 g/dL
  - Baseline absolute neutrophil count of 1.5 x 10^9 /L or greater
  - Baseline platelet count of 75 x 10^9 /L or greater
- Both of the following:
  - Patient does not have a confirmed mutation with deletion 5q [del(5q)]
  - Patient has not received prior treatment with Revlimid (lenalidomide) or hypomethylating agents (e.g., azacitidine, decitabine)
- Patient requires 4 or more red blood cell units over 8 weeks
- One of the following:
  - Previous treatment with an erythropoiesis stimulating agent shows no response
  - Previous treatment with an erythropoiesis stimulating agent shows loss of response
  - Patient is ineligible for treatment with an erythropoiesis stimulating agent

CRITERIA FOR COVERAGE (RENEWAL):

- Patient does not show evidence of progressive disease while on therapy

Endnotes

A. Disease was determined as low to intermediate-1 risk based on the International Prognostic Scoring System (IPSS). [1,4]

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	01/21/2025
P&T Review Date:	01/21/2025

Revision History:

Immune Globulin
Prior Authorization Criteria
DC-0045

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1551, J1552, J1554, J1556, J1569, J1566, J1561, J1559, J1575, J1568, J1599, J1459, J1558, J1460, J1572, J1557, J7799, J1555, J1560, J1576, MISC	Alyglo, Asceniv, Bivigam, Carimune NF, Cutaquig, Cuvitru, Flebogamma DIF, GamaSTAN, Gammagard, Gammagard S/D Less IgA, Gammaked, Gammaplex, Gamunex-C, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify, Yimmugo	Medical Benefit - Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Prescribed by or in consultation with a specialist in the treatment of the condition (ex: Immunologist, Hematologist, Neurologist, Nephrologist, etc.)
- Individual has a diagnosis from the following:
  - Birdshot retinochoroidopathy
  - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
  - Cytomegalovirus associated pneumonitis with organ transplant
  - Enteroviral meningoencephalitis
  - Graves ophthalmopathy
  - Guillain-Barre Syndrome (GBS)
  - Henoch-Schonlein purpura
  - IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
  - Kawasaki disease (KD)
  - Lambert-Eaton myasthenic syndrome (LEMS) with weakness (short course)
  - Lupus erythematosus (severe)
  - Multifocal Motor Neuropathy (MMN)
  - Myasthenic crisis
  - Necrotizing fasciitis
  - Pediatric acute-onset neuropsychiatric syndrome (PANS)
  - Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
  - Posttransfusion purpura
  - Rheumatoid Arthritis (severe)
  - Rotaviral enterocolitis
  - Solid organ transplantation, antibody mediated rejection
  - Stevens-Johnson Syndrome or toxic epidermal necrolysis
  - Still disease, Felty syndrome, macrophage activation syndrome
  - Transplant desensitization or waitlist desensitization

- Individual has a diagnosis with supporting labs, purpose, OR failure, intolerance, or contraindication to conventional therapies as listed in the following:
  - Autoimmune hemolytic anemia (AIHA)

    - Adjunctive to other therapies (ex: prednisone, rituximab) or when other therapies have failed
- Autoimmune uveitis
    - Refractory to corticosteroid or immunosuppressive therapy
- BK polyomavirus nephropathy in kidney transplant recipient
    - Inadequate response to reduction of maintenance immunosuppressive therapy
- Bone Marrow Transplantation (BMT)
    - For prevention of graft vs. host disease (GVHD) or prevention of infections
    - Confirmation of upcoming allogeneic BMT with IgG level <400mg/dL OR post-transplant allogeneic BMT within the past four months
- Bullous Pemphigoid (pemphigus vulgaris, pemphigus foliaceus, mucous-membrane pemphigoid, etc.)
    - Failure, intolerance, or contraindication to systemic corticosteroid or immunosuppressive agent (ex: doxycycline, azathioprine, mycophenolate, methotrexate)
        - Additional Information: Topical corticosteroid products may be used previously however a systemic agent is required prior to consideration of immune globulin
- Chronic lymphocytic leukemia (CLL)
    - Documented hypogammaglobulinemia (IgG <400 mg/dL) or history of bacterial infections associated with B-cell CLL
- Clostridioides (formerly Clostridium) difficile
    - Failure, intolerance, or contraindication to vancomycin and fidaxomicin
- Dermatomyositis or Polymyositis
    - Failure, intolerance, or contraindication to an immunosuppressive therapy (ex: corticosteroids, azathioprine, methotrexate, etc.)
- Human Immunodeficiency Virus (HIV)-associated
    - Thrombocytopenia with platelet counts <50,000
    - Prevention of infection in pediatric individuals with hypogammaglobulinemia (IgG <400mg/dL)
- Immune Thrombocytopenic Purpura (ITP)
    - Acute thrombocytopenic purpura with bleeding or severe documented platelet count (<30,000/ mm3)
    - Chronic thrombocytopenic purpura with failure, intolerance, or contraindication to corticosteroids or splenectomy
    - Fetal and neonatal alloimmune thrombocytopenia
- Juvenile idiopathic arthritis
    - Refractory a prior therapy (ex: IL-6 inhibitor)
- Lambert-Eaton myasthenic syndrome (LEMS) with refractory weakness, Chronic (see above for acute)
    - Refractory weakness for chronic, maintenance use requires diagnosis with previous failure, intolerance, or contraindication to immunomodulating therapy (ex: corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine)
- Multiple Sclerosis (relapsing forms)
    - Failure, intolerance, or contraindication to two prior therapies corticosteroids, plasmapheresis, disease modifying agents (ex: glatiramer, dimethyl fumarate, rebif, etc.)
- Multiple myeloma
    - History of recurrent, severe infections OR hypogammaglobulinemia (IgG <400 mg/dL)
- Myasthenia Gravis (MG, see section above for Myasthenia Crisis)
    - Refractory Myasthenia Gravis with 1.) failure, intolerance, or contraindication to two prior medications such as glucocorticoids and an immunomodulator therapy (ex: azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus) OR 2.) Immune globulin will be used as “bridge therapy” until more slowly acting immunotherapy takes effect

- Neuromyelitis Optica Spectrum Disorder (NMOSD)
  - Failure or intolerance to an adequate trial of at least one prior therapy such as glucocorticoids, plasma exchange, rituximab, etc.
  - Not to be used in combination with other biologic treatments for NMOSD (ex: satralizumab, eculizumab, inebilizumab, etc.)
- Polyarteritis nodosa (PAN)
  - Failure, intolerance, or contraindication to a prior therapy (ex: corticosteroids, cyclophosphamide, infliximab, rituximab)
- Post B-Cell Depleting Therapies (ex: rituximab, CAR-T Kymriah, etc.)
  - Hypogammaglobulinemia (IgG <400 mg/dL) and history of recurrent/severe bacterial infections associated with B-cell depletion
- Passive Immunity in select populations (product GamaSTAN and GamaSTAN S/D)
  - Hepatitis A - prophylaxis; postexposure within 14 days and/or prior to manifestation of disease
  - Measles - Within 6 days of exposure in unvaccinated person who has not previously had measles
    - Following Advisory Committee on Immunization Practices recommendations
  - Rubella - Post exposure prophylaxis in exposed pregnant individual
  - Varicella - For immunosuppressed individual when varicella zoster immune globulin is not available
- Primary Immunodeficiency (congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, severe combined immunodeficiency)
  - IgG value below normal OR normogammaglobulinemia with impaired specific antibody production OR history of recurrent infections
- Stiff person syndrome
  - Failure, intolerance, or contraindication to gamma amino butyric acid (GABAergic) medication (ex: benzodiazepines, baclofen, or combination of benzodiazepine with baclofen)
- Other indications not listed must be submitted with peer-reviewed medical literature to support the proven efficacy and safety of the requested use along with the clinical rationale to support medical necessity for use

CRITERIA FOR COVERAGE for ILLINOIS PLANS Specific to Primary Immunodeficiency:

- Diagnosis of Primary Immunodeficiency (congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, severe combined immunodeficiency)
- Other diagnoses see CRITERIA FOR COVERAGE sections above.

CRITERIA OF COVERAGE CRITERIA (12-month renewal or new member)

- Prescriber provides clinical documentation from the previous 12 months pertinent to an indication (listed in the sections above) for immune globulin and describes the person's response as stable disease or improvement with supporting lab results (examples: immune globulin levels, reduction in infections, platelet counts, C-reactive protein, improvement in functional status such as mobility or physical function, antibody titers, reduction in steroid use, etc.).
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Guideline Note:

Effective Date:	04/01/2025

P&T Approval Date:	01/2013
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
12/26/2024	Add Yimmugo

CRITERIA FOR QUANTITY EXCEPTIONS:

- Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit

CONTINUATION OF COVERAGE CRITERIA (new to plan):†

- Clinical documentation from the previous 12 months of a response with current therapy

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Clinical documentation from the previous 12 months of a response with current therapy

AND

- Lanadelumab: Clinical documentation supporting no attacks through the preceding 6 months

OR

- Haegarda: Confirmation there are no weight changes warranting different quantity limits

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: 01/18
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Date	Notes
11/25/2024	New criteria

References

1. Rytelo Prescribing Information. Catalent Indiana, LLC. Bloomington, IN. June 2024.
2. ClinicalTrials.gov. Study to Evaluate Imetelstat (GRN163L) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS). Available at: https://www.clinicaltrials.gov/study/NCT02598661?cond=NCT02598661&rank=1. Accessed July 28, 2024.
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4. Leukemia and Lymphoma Society: The International Prognostic Scoring System. Available at: https://www.lls.org/myelodysplastic-syndromes/diagnosis/international-prognostic-scoring-system. Accessed July 28, 2024.
5. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes v3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed July 29, 2024.

Inclisiran (Leqvio)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limit	Approval Limits
J1306	Inclisiran (Leqvio)	Medical Benefit-Restricted	Initial = 3 doses Renewal = 2 doses	12 months

QUARTZ COMMERCIAL CRITERIA FOR COVERAGE

- Diagnosis of Primary hyperlipidemia, Heterozygous Familial Hypercholesteremia, Homozygous Familial Hypercholesterolemia, OR established arteriosclerotic cardiovascular disease (ASCVD)*
- Prescribed by, or in consultation with, a specialist (e.g. Cardiologist, Endocrinologist, or Lipidologist-documentation required)
- Person has LDL-C ≥ 70 mg/dL while on maximally tolerated statin doses
- Failure of adequate trial of a self-administered PCSK9 inhibitor (e.g. evolocumab) or inability to self-administer an injection
- **For statin TOLERANT persons**
  - Adherent treatment with a high potency statin (ex. atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a minimum of 8 weeks duration
    OR
  - Adherent treatment with a maximally tolerated dose of any statin for a minimum of 8 weeks duration if the patient cannot tolerate a high potency statin
- **For statin INTOLERANT persons**
  - The person is considered "statin intolerant"† or has a contraindication to statin use such as active liver disease or persistently elevated serum transaminases

QUARTZ COMMERCIAL CONTINUATION OF COVERAGE CRITERIA:‡

- Clinical documentation from the previous 12 months demonstrating a reduction in LDL-C from baseline
- Continued adherent treatment to baseline lipid-lowering therapies

‡Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Symptoms not controlled on at least 12 weeks of a 'standard regimen' and rationale provided with published literature supporting why an alternative dosing regimen would be expected to be effective

QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
CRITERIA FOR COVERAGE of Clinical Atherosclerotic Cardiovascular Disease (ASCVD):

- Diagnosis of Clinical ASCVD which is supported by a history of one of the following:
  - The member has CAD, which is supported by a history of one of the following:
    - Myocardial infarction
    - Coronary revascularization
    - Angina pectoris
  - The member has a history of non-hemorrhagic stroke.
  - The member has symptomatic peripheral arterial disease as evidenced by one of the following:

- Intermittent claudication with an ABI of less than 0.85
- Peripheral arterial revascularization procedure or amputation due to atherosclerotic disease

- The member has taken a PCSK9 inhibitor drug concurrently with a maximized statin regimen for at least 3 continuous months with failure to reach an LDL less than or equal to 70 mg/dL.
- The member will continue to take the maximally tolerated dose of a statin during treatment with Leqvio.

QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI CRITERIA FOR COVERAGE of Heterozygous Familial Hypercholesterolemia (HeFH):

- Diagnosis of HeFH, as evidenced by clinical documentation that supports a definitive diagnosis of HeFH using either WHO criteria (Dutch Lipid Clinic Network clinical criteria with a score greater than 8) or Simon Broome diagnostic criteria.
- Prescribed by a specialist in cardiology or lipid management.
- The member's age is consistent with the FDA-approved product labeling for Leqvio.
- The member has taken a PCSK9 inhibitor drug concurrently with a maximized statin regimen for at least three continuous months with failure to reach an LDL less than or equal to 100 mg/dL.
- The member will continue to take the maximally tolerated dose of a statin during treatment with Leqvio.

QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI CRITERIA FOR CONTINUATION/RENEWAL for ASCVD:

- Diagnosis of clinical ASCVD and all of the following
  - Clinical documentation of LDL reduction of at least 30 percent from pre-treatment baseline or a decrease to 100 mg/dL or less.
  - Member has continued to take the maximized statin treatment regimen during treatment with Leqvio.

QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI CRITERIA FOR CONTINUATION/RENEWAL for HeFH:

- Diagnosis of clinical HeFH and all of the following
  - Clinical documentation of LDL reduction of at least 30 percent from pre-treatment baseline or a decrease to 130 mg/dL or less.
  - Member has continued to take the maximized statin treatment regimen during treatment with Leqvio.

DEFINITIONS:

*ASCVD refers to the following conditions: coronary heart disease such as myocardial infarction, angina, coronary artery stenosis >50%; cerebrovascular disease such as transient ischemic attack, ischemic stroke, or carotid artery stenosis > 50%; peripheral artery disease such as claudication; and aortic atherosclerotic disease such as abdominal aortic aneurysm and descending thoracic aneurysm.

†Statin intolerance is defined as the inability to tolerate at least 2 statins, with:

- one started at the lowest starting dose
- statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)
- symptoms or lab abnormalities reversed with statin discontinuation but returned with re-challenge of statins
- symptoms or lab abnormalities are not due to established predispositions such as drug interactions, significant changes in physical activity, or underlying muscle disease

A retrial of a statin may be requested prior to consideration of approval based on the information provided.

Guideline Note:

Effective Date:	01/01/2025
P&T Approval Date:	02/2022

Inebilizumab-cdon (Uplizna)
Prior Authorization Criteria
DC-0142

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1823	Inebilizumab-cdon (Uplizna)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- Patient is anti-aquaporin-4 (AQP4) antibody positive
- Prescribed by or in consultation with neurologist/ophthalmologist
- Trial and failure, contraindication, or intolerance to rituximab

CONTINUATION OF COVERGE CRITERIA*

- Prescriber provides clinical documentation from the previous 12 months that describes the person's response as stable disease or improvement seen on therapy (example: reduced number of relapses, reduced number of hospitalizations, etc.)

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	11/2020
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
12/23/2024	Standardization

References

1. Uplizna Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. July 2021.

Infused transthyretin (ATTR) amyloidosis treatments
Prior Authorization Criteria
DC-0089

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Month	Approval Limits*
J0222	Patisiran (Onpattro)	Medical Benefit-Restricted	None	Initial: 12 months Continuation: indefinite
J0225	Vutrisiran (Amvuttra)	Medical Benefit-Restricted	None	Initial: 12 months Continuation: indefinite

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE for Hereditary Transthyretin amyloidosis (hATTR) with polyneuropathy:

- Diagnosis confirmed with one of the following:
  - Bone scintigraphy
  - Endomyocardial biopsy
  - Genetic testing
- One of the following:
  - Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
  - Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
  - Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
  - Patient has a baseline Karnofsky Performance Status score greater than or equal to 60%
- Presence of clinical signs and symptoms of the disease (e.g. peripheral/autonomic neuropathy, ability to walk, quality of life)
- No history of liver transplant
- Prescribe by or in consultation with a Neurologist, Cardiologist, or other expert in hATTR
- Age 18 years or older
- Drug is not being used in combination another TTR-lowering agent (e.g. inotersen, patisiran, vutrisiran)Drug is not being used in combination with a TTR-stabilizing agent (e.g. diflunisal, tafamidis, tafamidis meglumine

CRITERIA FOR COVERAGE for Transthyretin Amyloidosis (ATTR) with cardiomyopathy (Amvuttra only):

- Diagnosis confirmed with one of the following:
  - Bone scintigraphy
  - Endomyocardial biopsy
- Evidence of cardiac involvement as assessed with transthoracic echocardiography, with an end diastolic interventricular septal wall thickness exceeding 12mm.
- One of the following:
  - One prior hospitalization for heart failure
  - Clinical evidence of heart failure with signs of volume overload or elevated intracardiac pressures warranting diuretic treatment
- Prescribed by, or in consultation with, a Neurologist, Cardiologist, or other expert in transthyretin-mediated amyloidosis (ATTR)
- Age 18 years or older
- Drug is not being used in combination another TTR-lowering agent (e.g. inotersen, patisiran, vutrisiran)

CRITERIA FOR CONTINUATION OF COVERAGE (new to plan):†

- Initial criteria met
- The prescriber must provide clinical documentation of the person's initial response to therapy (e.g. clinical manifestation stability/improvement) .

CRITERIA FOR CONTINUATION OF COVERAGE (annual renewal):†

- Clinical documentation for the previous 12 months of response to therapy or documentation of clinical stability

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Effective Date:	07/01/2025
P&T Approval Date:	01/2023
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
04/02/2025	Revise criteria for new indication

Infused Oncology Agents
Prior Authorization Criteria
DC-008

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J9061	Amivantamab (Rybrevant)	Medical Benefit-Restricted	None	Up to 12 months
J9038	Axatilimab-csfr (Niktimvo)	Medical Benefit Restricted	None	Up to 12 months
J9119	Cemiplimab (Libtayo)	Medical Benefit-Restricted	None	Up to 12 months
J9275	Cosibelimab (Unloxcyt)	Medical Benefit – Restricted	None	Up to 12 months
C9174	Datopotamab deruxtecan-dlnk (Datroway)	Medical Benefit-Restricted	None	Up to 12 months
MISC	Dinutuximab (Unituxin)	Medical Benefit – Restricted	None	Up to 12 months
J9173	Durvalumab (Imfinzi)	Medical Benefit-Restricted	None	Up to 12 months
J9176	Elotuzumab (Empliciti)	Medical Benefit-Restricted	None	Up to 12 months
J1323	Elranatamab-bcmm (Elrexfio)	Medical Benefit-Restricted	None	Up to 12 months
J9177	Enfortumab (Padcev)	Medical Benefit-Restricted	None	Up to 12 months
J9321	Epcoritamab (Epkinly)	Medical Benefit-Restricted	None	Up to 12 months
J9286	Glofitamab (Columvi)	Medical Benefit-Restricted	None	Up to 12 months
J9229	Inotuzumab ozogamicin (Besponsa)	Medical Benefit – Restricted	None	Up to 12 months
J9227	Isatuximab (Sarclisa)	Medical Benefit-Restricted	None	Up to 12 months
J9359	Loncastuximab (Zynlonta)	Medical Benefit-Restricted	None	Up to 12 months
J9223	Lurbinectedin (Zepzelca)	Medical Benefit-Restricted	None	Up to 12 months
J9353	Margetuximab (Margenza)	Medical Benefit-Restricted	None	Up to 12 months
J9248	Melphalan (Hepzato)	Medical Benefit Restricted	None	Up to 12 months
J9063	Mirvetuximab (Elahere)	Medical Benefit-Restricted	None	Up to 12 months
J9204	Mogamulizumab (Poteligeo)	Medical Benefit-Restricted	None	Up to 12 months

J9350	Mosunetuzumab-axgb (Lunsumio)	Medical Benefit-Restricted	None	Up to 12 months
J9313	Moxetumomab (Lumoxiti)	Medical Benefit-Restricted	None	6 months
J9029	Nadofaragene firadenovec-vncg (Adstiladrin)	Medical Benefit-Restricted	None	Up to 12 months
J9348	Naxitamab (Danyelza)	Medical Benefit-Restricted	None	Up to 12 months
J9295	Necitumumab (Portrazza)	Medical Benefit-Restricted	None	Up to 12 months
J9028	Nogapendekin alfa inbak-pmln (Anktiva)	Medical Benefit-Restricted	None	Up to 12 months
J9298	Nivolumab/relatlimab (Opdualag)	Medical Benefit-Restricted	None	Up to 12 months
J9271	Pembrolizumab (Keytruda)	Medical Benefit-Restricted	None	Up to 12 months
J9309	Polatuzumab Vedotin (Polivy)	Medical Benefit-Restricted	None	Up to 12 months
J9345	Retifanlimab-dlwr (Zynyz)	Medical Benefit-Restricted	None	Up to 12 months
J2860	Siltuximab (Sylvant)	Medical Benefit-Restricted	None	Up to 12 months
J9331	Sirolimus protein-bound (Fyarro)	Medical Benefit-Restricted	None	Up to 12 months
J0208	Sodium thiosulfate (Pedmark)	Medical Benefit-Restricted	None	Up to 12 months
J9349	Tafasitamab (Monjuvi)	Medical Benefit-Restricted	None	Up to 12 months
J9269	Tagraxofusp-erzs (Elzonris)	Medical Benefit-Restricted	None	Up to 12 months
J9325	Talimogene laherparepvec (Imlygic)	Medical Benefit Restricted	None	Up to 12 months
J9026	Tarlatamab-dlle (Imdelltra)	Medical Benefit Restricted	None	Up to 12 months
J3055	Talquetamab-tgvs (Talvey)	Medical Benefit-Restricted	None	Up to 12 months
J9274	Tebentafusp (Kimmtrak)	Medical Benefit-Restricted	None	Up to 12 months
J9380	Teclistamab-CQYV (Tecvayli)	Medical Benefit-Restricted	None	Up to 12 months
J9329	Tislelizumab-jsgr (Tevimbra)	Medical Benefit – Restricted	None	Up to 12 months
J9273	Tisotumab vedotin (Tivdak)	Medical Benefit-Restricted	None	Up to 12 months

J3263	Toripalimab-tpzi (Loqtorzi)	Medical Benefit – Restricted	None	Up to 12 months
J9352	Trabectedin (Yondelis)	Medical Benefit-Restricted	None	Up to 12 months
J9347	Tremelimumab-ACTL (Imjudo)	Medical Benefit-Restricted	None	Up to 12 months
J9276	Zanidatamab-hrii (Ziihera)	Medical Benefit – Restricted	None	Up to 12 months
J9382	Zenocutuzumab-Zbco (Bizengri)	Medical Benefit-Restricted	None	Up to 12 months
J1326	Zolbetuximab-clzb (Vyloy)	Medical Benefit-Restricted	None	Up to 12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Drug must be prescribed by, or in consultation with, an Oncologist, Hematologist, or other specialist in the treatment of malignancy
- The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the person presents with‡

OR

- The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person‡

OR

- **(Minnesota plans only) -** the requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the person* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person's specific condition

OR

- **(Illinois plans only) –** the requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the person* in the American Hospital Formulary Service Drug Information, Thompson Micromedex's Drug Dex, Elsevier Gold Standard's Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person's specific condition.

‡includes any relevant genetic testing, mutations, etc.

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):**

- Initial criteria for coverage met

**Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Guideline Note:

Effective Date:	07/01/2025

P&T Approval Date:	12/2018
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
04/01/2025	Add Bizengri, Datroway, remove J9022, J9308, A9606, J9299, A9513, A9607, J9228, A9590, J9272, J9144, J9145, J9047, J9118, J9037, J9023, J9022, J9024

Letermovir (Prevymis)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
Misc Code	Letermovir (Prevymis)	Medical Benefit-Restricted	None	1 Course (up to 200 days post-transplant

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Prescribed by, or in consultation with, a Hematologist, Oncologist, Infectious Disease, or Transplant specialist
- Covered for CMV prophylaxis in adults with one of the following:
  - Post allogenic hematopoietic stem cell transplant
  - Port kidney transplant
- Documentation of cytomegalovirus (CMV)-seropositive recipient (R+) or have a CMV positive donor (D+)
- Drug is initiated within the first:
  - Allogenic hematopoietic stem cell transplant: 28 days post-transplant
  - Kidney transplant: 7 days post-transplant
- Documentation that the person does not have active CMV infection (CMV PCR level over 250 IU/ml) and is not receiving preemptive treatment (ex. foscarnet)
- Person unable to tolerate/swallow the oral tablet form of letermovir

CONTINUATION OF COVERAGE CRITERIA (new to plan):†

- Persons new to coverage who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course (to a maximum of Day 200 post-transplant)
- Person unable to tolerate/swallow the oral tablet form of letermovir

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides an evidence-based clinical rationale for using a duration beyond 200 days post-transplant

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:

For information regarding coverage of letermovir on the prescription drug benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 12/17
Effective: 01/01/2024 Client Approval: N/A P&T Approval: N/A

Lifilecucel (Amtagvi)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
MISC (C9399, J9999)	Lifilecucel (Amtagvi)	Medical Benefit-Restricted	One time	Up to 6 months

CRITERIA FOR COVERAGE (BADGERCARE ONLY):

- Patient is ≥18 years of age
- Diagnosis of unresectable or Stage IV metastatic melanoma
- Patients must have progressed following ≥1 prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if *BRAF* V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor
- Patients must have an ECOG PS of 0 or 1
- Prescribed by or in consultation with an oncologist

Created: 06/2024
Effective: 10/01/2024

Lovotibeglogene autotemcel (Lyfgenia)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
MISC (C9399, J3590)	Lovotibeglogene autotemcel (Lyfgenia)	Medical Benefit-Restricted	1 dose/lifetime	6 months

CRITERIA FOR COVERAGE (BadgerCare only):

- Age 12 years of age and older
- The person is eligible to undergo stem cell transplantation
- History of at least four vaso-occlusive events requiring a medical evaluation in the last two years. Examples could include an episode of acute pain with no medically determined cause other than vaso-occlusion lasting more than two hours, acute chest syndrome, acute hepatic sequestration, and acute splenic sequestration
- No history of more than two α-globin gene deletions

Created: 01/24
Effective: 8/01/2024

Lumasiran (Oxlumo)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0224	Lumasiran (Oxlumo)	Medical Benefit-Restricted		Initial: 6 months Renewal: 12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of Primary Hyperoxaluria Type 1 confirmed by Genetic testing (AGXT mutation) or liver biopsy
- Prescribed by, or in consultation with, a Nephrologist, Urologist, or other related specialty
- Current use of, or history of trial and failure, contraindication, or intolerance to, pyridoxine (vitamin B6)
- No history of liver transplant

CONTINUATION OF COVERAGE CRITERIA:*

- Prescriber provided clinical documentation from the past 12 months of symptom or metabolic improvement from start of therapy

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer sponsored free drug program, provider samples, and/or vouchers.

Created: 01/21
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Luspatercept (Reblozyl)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Day	Approval Limits*
J0896	Luspatercept (Reblozyl)	Medical benefit-Restricted		Initial: 3 months Renewal: 12 months

*Initial and renewal authorizations limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR BETA THALASSEMIA:

- Diagnosis of transfusion-dependent Beta Thalassemia (confirmed by genetic testing) requiring at least 6 RBC units per 24 weeks, AND
- Prescribed by, or in consultation with, a Hematologist or other provider with experience in the treatment of beta thalassemia
- Age 18 years or older with no history of splenectomy
- No recent history of deep vein thrombosis (DVT) or stroke (within past six months)

CRITERIA FOR COVERAGE FOR OTHER FDA LABELED INDICATIONS:

- Prescribed by, or in consultation with a specialist in treatment of the requested diagnosis

CONTINUATION OF COVERAGE CRITERIA (3-month renewal):†

- Initial criteria met
- For treatment of Beta Thalassemia only, clinical documentation from the previous 3 month demonstrating at least a 33% reduction in RBC transfusions

CONTINUATION OF COVERAGE CRITERIA (new to plan/12-month renewal):†

- Initial criteria met and clinical documentation from the previous 12 months demonstrating stable disease (i.e. no increase in RBC transfusion requirements)

†Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Created: 02/20
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

IMPORTANT INFORMATION:
Use of nusinersen is considered experimental when used for other indications. Nusinersen has not been proven for use in SMA without chromosomal 5q mutations or deletions Despite the FDA-label for adult patients, limited data are available to support use at this time. Use of onasemnogene-abeparvovec-xioi (Zolgensma) in combination with nusinersen has not been fully evaluated in clinical trials for efficacy and safety and combination therapy is not covered at this time.

HINE= Hammersmith Infant Neurologic Exam (used in infants to early childhood)
HFSME=Hammersmith Functional Motor Scale Expanded
ULM=Upper Limb Module test (used in non-ambulatory patients)
CHOP INTEND= Children's hospital of Philadelphia Infant Test of Neuromuscular Disorders

Types of SMA and characteristics

Type	Number of copies of SMN2	Onset	Incidence
1	Two	Before 6 months	60%
2	Three or Four	6-18 months	27%
3	Three or Four	Early childhood	13%

Omvoh (mirikizumab-mrkz)
Prior Authorization Criteria
DC-0160

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9168	Omvoh (mirikizumab-mrkz)	Medical Benefit-Restricted	3 doses	90 days

CRITERIA FOR COVERAGE CROHN'S DISEASE (INITIAL):

- Diagnosis of moderately to severely active Crohn's disease (CD)
- One of the following:
  - Frequent diarrhea and abdominal pain
  - At least 10% weight loss
  - Complications such as obstruction, fever, abdominal mass
  - Abnormal lab values (e.g., C-reactive protein [CRP])
  - CD Activity Index (CDAI) greater than 220
- Prescribed by or in consultation with a gastroenterologist
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
  - 6-mercaptopurine
  - Azathioprine
  - Corticosteroids
  - Methotrexate
- Trial and failure, contraindication, or intolerance to TWO of the following:
    - One formulary adalimumab product
    - Skyrizi (risankizumab-rzaa)
    - One formulary ustekinumab product
    - Rinvoq (upadacitinib)
    - One inflixmab biosimilar
    - Cimzia (certolizumab pegol)

CRITERIA FOR COVERAGE ULCERATIVE COLITIS (INITIAL):

- Diagnosis of moderately to severely active ulcerative colitis
- One of the following:
  - Greater than 6 stools per day
  - Frequent blood in the stools
  - Frequent urgency
  - Presence of ulcers
  - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
  - Dependent on, or refractory to, corticosteroids
- Prescribed by or in consultation with a gastroenterologist
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
  - 6-mercaptopurine
  - Azathioprine
  - Corticosteroids (e.g. prednisone)
  - Aminosalicylate (e.g. mesalamine, olsalazine, sulfasalazine)

- Trial and failure, contraindication, or intolerance to TWO of the following:
    - One formulary adalimumab product
    - Skyrizi (risankizumab-rzaa)
    - One formulary ustekinumab product
    - Rinvoq (upadacitinib)
    - Xeljanz/Xeljanz XR (tofacitinib)
    - One infliximab biosimilar

CRITERIA FOR COVERAGE (RENEWAL):

- Clinical documentation from the previous 12 months showing the patient was started on therapy and needs to complete the part of the 3 dose loading series.

Effective Date:	07/01/2025
P&T Approval Date:	04//15/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/25/2025	New criteria

References

1. Omvoh prescribing information. Eli Lilly & Co. Indianapolis, IN. January 2025.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

Monoclonal Antibody Agents for Alzheimer's Disease
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0174	Lecanemab (Leqembi)	Medical Benefit-Restricted	N/A	12 months
MISC	Donanemab (Kisunla)	Medical Benefit-Restricted	N/A	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Alzheimer's disease with mild cognitive impairment or dementia confirmed by two of the following:
  - Mini Mental State Exam (MMSE) score ≥20
  - Global Clinical Dementia Rating(CDR) of 0.5 or 1.0
  - CDR Memory Box score of 0.5 or greater
  - Montreal Cognitive Assessment (MoCA) score of ≥ 16
- Prescribed by or in consultation with a Neurologist, Geriatrician, Psychiatrist, or other Alzheimer's disease specialist
- Age 50 to 90 years
- Positive amyloid confirmed by
  - Positron Emission Tomography (PET) scan

  OR
  - Lumbar puncture (Cerebral Spinal Fluid) confirming both of the following:
    - Presence of elevated phosphorylated tau (P-tau) protein and/or elevated total tau (T-tau) protein
    - Reduced beta amyloid-42 (AB42) or a low AB42/AB40 ratio
- Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment
- Other causes of symptoms are ruled out (e.g. Lewy body dementia, Parkinson's disease, vitamin B12 deficiency, etc.)
- Provider will enroll patient in a registry [e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET)]
- Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm)
- Person does not have any of the following:
  - Use of antiplatelet or antithrombotic drugs (except prophylactic aspirin or clopidogrel)
  - History of cerebrovascular abnormalities, bleeding disorder, clotting disorder, or brain hemorrhage
  - Diagnosis of stroke, seizures, transient Ischemic attack within the previous 12 months

CRITERIA FOR CONTINUATION OF THERAPY:

- Magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th and 7th infusion treatment
- Documentation showing two of the following:
  - Mini Mental State Exam (MMSE) score ≥20
  - Global Clinical Dementia Rating(CDR) of 0.5 or 1.0
  - CDR Memory Box score of 0.5 or greater
  - Montreal Cognitive Assessment (MoCA) score of ≥ 16
- Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm
- Clinical documentation of a decrease in brain amyloid plaques

- Clinical documentation showing One of the following:
  - Patient has mild radiographic severity of ARIA-E on MRI and one of the following:
    - Patient is asymptomatic
    - Patient has mild clinical symptoms
  - Patient has mild radiographic severity of Aria-H on MRI and is asymptomatic
  - ARIA (i.e., ARIA-E, ARIA-H) has not been observed on MRI

Note:
Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Created: 10/24
Effective: 1/1/2025

Natalizumab (Tysabri)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
Q5134	Natalizumab (Tyruko)	Medical Benefit-Restricted		12 months
J2323	Natalizumab (Tysabri)	Medical Benefit-Restricted		12 months

CRITERIA FOR COVERAGE FOR RELAPSING FORMS OF MULTIPLE SCLEROSIS:

- Diagnosis of relapsing multiple sclerosis (relapsing-remitting, active secondary progressive, relapsing-progressive)
  OR
- Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing clinically definite multiple sclerosis (e.g. ≥ 3 T2 white matter lesions or ≥ 2 enhancing lesions on MRI)
- Prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis
- Trial and failure (acute relapse or new lesion formation) while on higher efficacy oral disease modifying therapies (DMT - such as dimethyl fumarate, fingolimod, or cladribine (Mavenclad)
  OR
- Intolerance or contraindication to at least two oral DMTs

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE CROHN'S DISEASE:

- Prescribed by, or in consultation with, a Gastroenterologist
- High-risk individual (characteristics include: age <30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)
  OR
- Low-risk adult individual and ≥ ONE of the following:
  - 3-month trial and failure, intolerance, or contraindication to 2 conventional therapies (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease
- Trial and failure, intolerance, or contraindication to TWO of the following:
  - Adalimumab
  - Infliximab biosimilar
  - Certolizumab (Cimzia)
  - Risankizumab (Skyrizi)
  - Vedolizumab (Entyvio)
  - Ustekinumab (Stelara)

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy including individual improvements in functional status related to therapeutic response.

†Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

IMPORTANT INFORMATION:
Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Inadequate Disease Control of UC/CD:
Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc) and/or recent endoscopy results demonstrating ongoing inflammation

Steroid Dependence:
-Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis
-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs
-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin
-endoscopy, colonoscopy, sigmoidoscopy

Crohn's Disease Classification:
Stricturing - narrowing of bowel that may cause bowel obstruction
Penetrating - fistulae may form between bowel and other structures
Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

1. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
2. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.
3. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.

Created: 08/16
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Nusinersen (Spinraza)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Day	Approval Limits
J2326	Nusinersen (Spinraza)	Medical benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE: All criteria are met

- Diagnosis of Spinal muscle atrophy (SMA) based on genetic testing documenting 5q SMA (homozygous gene deletion or mutation) and having at least 2 copies of SMN2 gene.
- Prescribed by, or in consultation with, a Neurologist or other clinician with expertise in management and treatment of SMA
- Age < 18 years at initiation
- Medical records documentation provided to establish baseline level of function as appropriate for age and motor function (e.g. HINE, HFSME, ULM, or CHOP INTEND, based on age and motor ability). For patients diagnosed as a result of newborn screening or those that are pre-symptomatic, baseline assessment is still required.
- Not dependent upon invasive ventilation or tracheostomy or requires non-invasive ventilation for less than 16 hours per day (for naps and nighttime sleep)
- Has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy
- Not being used in combination with risdiplam (Evrysdi)

CONTINUATION OF COVERAGE CRITERIA*

Annual review (12 months):All criteria are met

- Patients that meet initial criteria above and are established on therapy
- Medical record documentation of clinically significant improvement in SMA-related symptoms (improvement, stabilization or decreased decline since previous approval). Documentation should include specific scale used based on age and motor function and comparison to baseline. Response is defined as improvement in more categories of motor milestones than worsening
    - For infants age <24 months, provision of CHOP-INTEND and HINE-2 evaluation to document motor status and efficacy of therapy
        - Response to therapy based on at least 2-point increase overall or at least one point increase from baseline
    - For HFSME, a change of 3 or more points from baseline is considered clinically meaningful.

    OR
    - Patient achieved and then maintained any new motor milestones from pretreatment baseline when they would otherwise be unexpected to do so.

* Continuation of therapy/coverage criteria may not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:

Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

IMPORTANT INFORMATION:
Use of nusinersen is considered experimental when used for other indications. Nusinersen has not been proven for use in SMA without chromosomal 5q mutations or deletions Despite the FDA-label for adult patients, limited data are available to support use at this time. Use of onasemnogene-abeparvovec-xioi (Zolgensma) in combination with nusinersen has not been fully evaluated in clinical trials for efficacy and safety and combination therapy is not covered at this time.

HINE= Hammersmith Infant Neurologic Exam (used in infants to early childhood)
HFSME=Hammersmith Functional Motor Scale Expanded
ULM=Upper Limb Module test (used in non-ambulatory patients)
CHOP INTEND= Children's hospital of Philadelphia Infant Test of Neuromuscular Disorders

Types of SMA and characteristics

Type	Number of copies of SMN2	Onset	Incidence
1	Two	Before 6 months	60%
2	Three or Four	6-18 months	27%
3	Three or Four	Early childhood	13%

Created: 03/17
Effective: 07/03/2023 Client Approval: 07/12/21 P&T Approval: N/A

Ocrelizumab (Ocrevus)
Prior Authorization Criteria
DC-0084

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2350	Ocrelizumab (Ocrevus)	Medical Benefit-Restricted		12 months
J2351	Ocrelizumab Hyaluronidase (Ocrevus Zunovo)	Medical Benefit-Restricted		12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR RELAPSING FORMS OF MULTIPLE SCLEROSIS:

- Diagnosis of relapsing multiple sclerosis (relapsing-remitting, active secondary progressive, relapsing-progressive)
  OR
- Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing clinically definite multiple sclerosis (e.g. ≥ 3 T2 white matter lesions or ≥ 2 enhancing lesions on MRI)
- Prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis
- Trial and failure (acute relapse or new lesion formation) while on higher efficacy oral disease modifying therapies (DMT - such as dimethyl fumarate, fingolimod, or cladribine (Mavenclad)
  OR
- Intolerance or contraindication to at least two oral DMTs

CRITERIA FOR COVERAGE FOR PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS:

- Diagnosis of a progressive form of multiple sclerosis
- Prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Clinical assessment from the treating Neurologist from the previous 12 months documenting a diagnosis of multiple sclerosis or Clinically Isolated Syndrome (CIS) and that the person is established on therapy

†Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	08/2016
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/21/2025	Update MISC code to J2351

Olipudase alfa (Xenpozyme)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0218	Olipudase alfa (Xenpozyme)	Medical Benefit Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of acid sphingomyelinase deficiency type B or type A/B with all of the following:
  - Diagnosis confirmed by enzyme assay or genetic testing
  - Spleen volume ≥ 5 multiples of normal
  - For age ≥ 18 years: diffusion capacity of the lungs for carbon monoxide (DLco) ≤70% of predicted normal
- Prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders
- Individual does not have any of the following:
  - History of major organ transplant
  - International normalized ratio (INR) >1.5
  - Require ventilatory support for >12 hours per day
  - Platelet count $<60 \times 10^3/\mu L$,
  - Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >250 IU/L or total bilirubin >1.5 mg/dL
  - Rapidly progressing neurologic abnormalities

CRITERIA FOR CONTINUATION/RENEWAL:*

- Clinical documentation from the previous 12 months showing objective disease improvement or stabilization (eg platelet count increase, spleen volume decrease, increased percent predicted diffusion capacity of the lungs for carbon monoxide, liver volume decrease)

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: xx/xx
Effective: 07/03/2023 Client Approval: P&T Approval: 11/15/2022

Omalizumab (Xolair)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2357	Omalizumab (Xolair)	Medical Benefit-Restricted	None	Initial: 6 months Renewal: 12 months

*Limited to 12 months for IL and MN plans without a Quartz pharmacy benefit

GENERAL CRITERIA FOR INITIAL COVERAGE:

- Initial six (6) months of therapy must be done in the clinic setting by a healthcare professional
- After the first 6 months of treatment, therapy must be transitioned to self-administration and the drug dispensed at the pharmacy as a take home drug, UNLESS one of the following are met:
  - Documentation of an allergic-type reaction to omalizumab while receiving in clinic
  - Clinical evaluation and deemed high risk for anaphylaxis by MD (ex. history of anaphylaxis to other drugs/foods)
- Diagnosis-specific criteria met

CRITERIA FOR COVERAGE FOR ASTHMA:

- Diagnosis of Moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)
- Age ≥6
- Serum IgE level ≥30 international units/mL
- Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)
- Person is a non-smoker or smoking cessation therapy has been recommended
- Not well controlled or poorly controlled asthma despite episodic use of systemic corticosteroids or at least 3 months of medium to high-dose inhaled corticosteroids (ICS) in combination with long acting beta2 agonist (LABA) or leukotriene modifiers

  OR
- Person with ≥ ONE adverse effects from medium to high dose ICS or long-term risks of adverse effects from high dose ICS or oral corticosteroids
  - Cataracts in patients > 40 years of age
  - Glaucoma
  - Recurrent thrush
  - Dysphonia
  - Growth inhibition, after evaluation by Endocrine Consult
  - Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

CRITERIA FOR COVERAGE FOR URTICARIA:

- Diagnosis of chronic (at least 3 months), refractory urticaria
- Trial and failure, intolerance, or contraindication to BOTH of the following:
  - Scheduled, high dose non-sedating antihistamines
  - ≥ one short course of corticosteroids

CRITERIA FOR COVERAGE FOR IMMUNOTHERAPY PROTOCOLS:

- Prescribed by Allergist

CRITERIA FOR COVERAGE FOR NASAL POLYPS:

- Diagnosis of chronic rhinosinusitis with nasal polyposis
- Prescribed by or in consultation with a specialist experienced in the treatment of nasal polyps (ex: Otolaryngologist, Allergist)
- At least eight weeks of moderate to severe nasal congestion/blockage/obstruction OR diminished sense of smell OR rhinorrhea
- No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation
- Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (ex: nasal polyp score five out of eight)
- ONE of the following:
    - Trial and inadequate response or intolerance to ≥ 2 nasal steroid sprays (i.e. failed two nasal sprays)
    - Trial and inadequate response or intolerance to an intramuscular (IM) steroid injection for polyps with one previous nasal spray
- ONE of the following:
    - Trial and inadequate response or intolerance to oral corticosteroids for nasal polyps
    - Prior surgery for nasal polyps greater than six months ago
- Will be used in combination with a nasal corticosteroid medication

CRITERIA FOR COVERAGE Ig-E MEDIATED FOOD ALLERGY:

- Diagnosis of IgE-mediated food allergy, as demonstrated by a clinical history of IgE mediated allergy to at least one or more foods with allergies confirmed by a positive skin prick test, allergen specific IgE (≥ 6 kUA/L), or oral food challenge
- History of severe allergic reaction following exposure to one or more foods
- Patient is 1 year of age or older
- Prescribed by or in consultation with an allergist or immunologist
- Drug used in conjunction with a diet that avoids food allergens
- Documentation of BOTH of the following:
    - Baseline total IgE ≥ 30 IU/mL and ≤ 1850 IU/mL
    - Drug is dosed based on serum IgE levels and body weight

CRITERIA FOR COVERAGE OF CHECKPOINT INHIBITOR-RELATED DERMATOLOGIC SIDE EFFECTS:
(Minnesota Plans Only) – Person with stage four metastatic cancer and omalizumab is requested to treat checkpoint inhibitor-related pruritis

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Documentation that person has experienced an allergic-type reaction to omalizumab or has had anaphylaxis to any agents (ex. food, drugs) in the past and requires continued use/observation in the clinic setting
- Prescriber provides clinical documentation from the previous 12 months there was clinical improvement from prior to initiating omalizumab

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
Omalizumab in combination with an IL-5 inhibitor will only be considered on a case-by-case basis if each individual agent with combination medium to high dose ICS/LABA did not control symptoms. Omalizumab in combination with tezepelumab has not been studied and coverage is not allowed except in extenuating circumstances.

Continuation of case-by-case approved IgE inhibitor and IL-5 inhibitor combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations

For information regarding coverage of omalizumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Table 1. Outcome Measure values for uncontrolled asthma

Measure	Not Well Controlled	Very Poorly Controlled
Baseline symptoms (outside of exacerbation)	> 2 days/week	Throughout the day
Nighttime awakening	1-3 times/week	≥ 4 times/week
Interference with normal activity	Some limitation	Extremely limited
Short acting beta agonist use for symptom control	> 2 days/week	Several times per day
FEV1	60-80% predicted or personal best	< 60% predicted or personal best
Asthma exacerbations requiring oral steroids ≥ 2 times in the past year	Yes	Yes
Asthma Control Test (ACT)	16-19	≤ 15

Created: 01/13
Revised: 10/15/2024
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P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Onasemnogene abeparvovec (Zolgensma)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Lifetime	Approval Limits/Lifetime*
J3399	Onasemnogene abeparvovec (Zolgensma)	Medical benefit-Restricted	1 (weight-based)	1 treatment

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:
- Diagnosis of spinal muscle atrophy (SMA) based on documentation of gene mutation analysis with bi-allelic SMN1 mutations (5q point mutation/deletion) and has no more than **3** copies of SMN2 gene.
- Prescribed by, or in consultation with, a Neurologist or other clinician with expertise in management and treatment of SMA
- Age < 2 years at administration
- Baseline antibody titers of anti AAV9 antibodies are ≤1:50 (based on ELISA), documented within one month prior to administration
- Does not have advanced SMA (e.g. permanent ventilatory dependence, complete limb paralysis, etc.)
- For infants established on nusinersen, will not continue nusinersen (Spinraza) post onasemnogene infusion (not studied)
- For infants established on risdiplam, will not continue risdiplam (Evrysdi) post- onasemnogene infusion (not studied)

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
- The prescriber provides an evidence-based clinical reason for utilizing an extended duration

CRITERIA FOR QUANTITY EXCEPTIONS:
- The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

IMPORTANT INFORMATION:
Use of onasemnogene abeparvovec in combination with nusinersen or risdiplam would be considered experimental at this time as it has not been fully evaluated. Despite the broad FDA-label for all SMA types, published data do not yet support broad use of therapy in all SMA types and ages.

For persons with 4 or more copies of the SMN2 gene or for other indications not listed, requests must be submitted with peer-reviewed medical literature to support the proven efficacy and safety of the requested use along with the clinical rationale to support medical necessity for use

Palifermin (Kepivance)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Cycle	Approval Limits
J2425	Palifermin (Kepivance)	Medical Benefit-Restricted	6	12 months

CRITERIA FOR COVERAGE:

- Prescribed by, or in consultation with, an Oncologist, Hematologist or other specialist in the treatment of malignancy.
- Persons at high risk for grade 3 or 4 mucositis associated with high dose chemotherapy and/or radiotherapy with hematologic malignancies requiring a hematopoietic stem cell transplant (HSCT).

CONTINUATION OF COVERAGE CRITERIA:*

- Initial criteria met

*Continuation of therapy coverage will not be applied to persons who were not previously approved for coverage, whose therapy was initiated using a manufacturer sponsored free drug program, provider samples and/or vouchers.

Created: 11/18
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Palivizumab (Synagis)
Prior Authorization Criteria
DC-0055

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Season	Approval Limits*
90378	Palivizumab (Synagis)	Medical Benefit-Restricted	5 doses	One season (November/April)

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Infant has not received nirsevimab-alip (Beyfortus) for RSV prevention
- At least one of the following:
  - Infants born at ≤ 29 weeks, 0 days gestation and less than 1 year old on start of RSV season (November) **OR**
  - Chronic lung disease of prematurity (defined as gestational age <32 weeks, 0 days at birth and required >21% oxygen for at least the first 28 days after birth)
    - In the first year of life for preterm infants as defined above
    - In the second year of life for infants who continue to require medical support (corticosteroids, diuretics, or oxygen) during the 6 months prior to season (since May of current year) **OR**
  - In the first year of life for infants with congenital heart disease with at least ONE of the following:
    - Congestive heart failure requiring medications
    - Moderate to severe pulmonary hypertension
    - Acyanotic heart disease requiring medications **OR**
  - For infants in the first year of life who have congenital airway abnormalities or severe neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough. **OR**
  - Infant less than 2 years of age and immunocompromised (i.e. SCID, HIV infection, solid organ or hematopoietic transplant or on chemotherapy) during RSV season **OR**
  - Infant less than 2 years of age and will undergo cardiac transplantation during RSV season

IMPORTANT INFORMATION:

- The RSV season in Wisconsin is typically from November to April but has extended into May and started earlier in October.
- Additional doses may appropriate during periods of atypical RSV inter-seasonal activity for eligible patients and in cases of inter-seasonal activity more than 5 doses consecutive doses is reasonable
- Treatment for a second RSV season will be evaluated on a case-by-case basis in situations not described above.
- The diagnosis of cystic fibrosis on newborn screening without other indications as noted above will not be covered.

Effective Date:	07/01/2025
P&T Approval Date:	01/2013
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
04/02/2025	Criteria Revision

References

1. Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.
2. Commitee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. Pediatrics. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. Pediatrics. 2010 Jul;126(1):e116-23.
4. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(34):920-925

Peanut Powder (Palforzia)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
Misc code	Peanut powder (Palforzia)	Medical Benefit-Restricted	One initial dose escalation kit	One time

*Limited to 12 months for IL and MN plans

CRITERIA FOR INITIAL COVERAGE:

- Prescribed by, or in consultation with, an Allergist/Immunologist
- Age 4 to 17 years
- Documentation of a systemic allergic reaction to peanuts (anaphylaxis, tongue/throat swelling, shortness of breath/wheezing the requires treatment, urticaria, angioedema, hypotension, and/or vomiting that occurs within 1-2 hours after ingestion of peanut)
- Documentation of a positive skin prick test (wheal diameter ≥ 3 mm) OR peanut specific IgE (≥ 0.35 kUA/L) within the past 12 months.
- Used in conjunction with a peanut-avoidance diet

CRITERIA FOR QUANTITY EXCEPTIONS:

- The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

CRITRERIA FOR DURATION EXCEPTIONS:

- The prescriber provides an evidence-based rationale for why drug cannot be given as described in the Dose and Administration section of the prescribing information.

CONTINUATION OF COVERAGE CRITERIA:

- Initial criteria met

IMPORTANT INFORMATION:

For information regarding coverage of peanut powder on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 06/20
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Pegcetacoplan (Syfovre)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2781	Pegcetacoplan (Syfovre)	Medical Benefit-Restricted	None	None*

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE: All criteria must be met

- Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
- Person is 60 years or older

Created: 07/23
Effective: 10/01/2024

Empaveli (pegcetacoplan)
Prior Authorization Criteria
DC-0129

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J7799	Empaveli (pegcetacoplan)	Medical Benefit-Restricted	N/A	12 months

PNH CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Prescribed medication dose will not exceed 1080mg twice weekly
- Prescribed by or in consultation with a hematologist/oncologist

CRITERIA FOR COVERAGE (RENEWAL):

- Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy
- Prescribed medication dose will not exceed 1080mg twice weekly

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Guideline Note:

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P&T Approval Date:	05/2019
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
11/25/2024	New drug specific criteria, standardization

References

1. Empaveli Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. February 2023.
2. Per clinical consultation with specialist, June 18, 2021.
3. Kulasekararaj AG., et al. “Ravulizumab (ALXN1210) vs Eculizumab in C5-Inhibitor–Experienced Adult Patients with PNH: the 302 Study.” Blood, vol. 133, no. 6, 2019, pp. 540–549.
4. Hillmen P, et al. “Pegcetacoplan versus Eculizumab in Paroxysmal Nocturnal Hemoglobinuria.” New England Journal of Medicine, vol. 384, no. 11, 2021, pp. 1028–1037.

Pegfilgrastim
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits/Fill	Approval Limits
Q5130	Pegfilgrastim-pbbk (Fylnetra)	Medical Benefit-Restricted	1	12 months
Q5127	Pegfilgrastim-fpgk (Stimufend)	Medical Benefit-Restricted	1	12 months
Q5120	Pegfilgrastim -bmez (Ziextenzo)	Medical Benefit Restricted	1	12 months
Not Covered				
Pegfilgrastim (Neulasta, Neulasta OnPro)				
Eflapegrastim (Rolvedon)				
Efbemalenograstim alfa-vuxw (Ryzneuta)				

CRITERIA FOR COVERAGE:

- Maximized trial and failure (e.g. febrile neutropenia or chemotherapy delayed), contraindication, or intolerance to preferred biosimilars including Fulphila, Nyvepria, and Udenyca

OR

- **(Minnesota plans only)** – the person has stage four metastatic cancer and the requested drug is being used as supportive care for their cancer treatment

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):

- Initial criteria for coverage met

IMPORTANT INFORMATION:

Fulphila (pegfilgrastim-jmdb), Nyvepria (pegfilgrastim-apgf), and Udenyca (pegfilgrastim-cbqv)) are all covered without prior authorization on the medical benefit.

For information regarding coverage of pegfilgrastim on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 08/12
Effective: 10/01/2024 Client Approval: 06/10/21 P&T Approval: N/A

Pegloticase (Krystexxa)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2507	Pegloticase (Krystexxa)	Medical Benefit - restricted	None	Initial: 6 months Renewal: 12 months

*Initial and renewal authorizations are limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of gout with
  - Serum uric acid level > 6.0 mg/dL
  - Frequent gout flares (≥ 2 flares/year) OR non-resolving subcutaneous tophi (≥1 tophi, gouty arthropathy defined clinically or radiographically as joint damage due to gout
- Prescribed by, or in consultation with, and monitored by a Rheumatologist
- Trial and failure of maximized doses, contraindication, or intolerance to both allopurinol and febuxostat
- Trial and failure, contraindication, or intolerance to colchicine or nonsteroidal anti-inflammatories (NSAIDs) and glucocorticoid use for acute attacks
- Documentation that the person does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency

CRITERIA FOR CONTINUATION OF THERAPY (new to plan/renewal)†

- Clinical documentation demonstrating the person has achieved and maintained a serum uric acid level < 6.0 mg/dL (most recent value must be within the previous 2 months)
- Clinical documentation from the previous 12 months demonstrating an objective reduction in gout symptoms such as reduction in tophi or number of acute attacks

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage by the plan whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Created: 11/18
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Pegunigalsidase alfa (Elfabrio)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2508	Pegunigalsidase alfa (Elfabrio)	Medical Benefit-Restricted	1mg/kg IV infusion every two weeks	12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE:

- Diagnosis of Fabry Disease
- Person has at least one of the following:
  - Detection of pathogenic mutations in the GLA gene by molecular genetic testing OR
  - Deficiency in alpha-galactosidase A (alpha-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS) OR
  - Significant clinical manifestations (e.g. neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillate)
- Will not be used in combination with other drugs used for Fabry Disease

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet the initial criteria for coverage

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plasminogen, human (Ryplazim)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2998	plasminogen, human (Ryplazim)	Medical Benefit Restricted	None	12 months

INITIAL CRITERIA FOR COVERAGE:

- Diagnosis of plasminogen deficiency type 1 or other FDA labeled indication
- Prescribed by, or in consultation with Hematologist or other specialist is the treatment of plasminogen deficiency
- Person with refractory symptomatic lesions

CRITERIA FOR CONTINUATION OF COVERAGE (new to plan/12-month renewal):

- Initiation criteria met.
- Prescriber provides clinical notes from the previous 12 months documenting response to therapy compared to baseline; such as decrease in lesion frequency or size of lesions.

Created: 02/22
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Pozelimab-bbfg (Veopoz)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9376	Pozelimab-bbfg (Veopoz)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of CHAPLE disease and confirmed CD55 loss-of function mutation by genetic testing
- Prescribed by, or in consultation with, a Hematologist, Gastroenterologist, or other provider who specializes in rare genetic hematologic diseases
- Age ≥ 1 year
- Pozelimab (Veopoz) will not be used in combination with Soliris

CONTINUATION OF COVERAGE CRITERIA:

- Documentation of a positive clinical response (e.g. improvement or no worsening in clinical symptoms, increase in or stabilization of albumin and IgG concentrations, increase in growth percentiles)

Created: 10/23
Effective: 04/01/2024 Client Approval: P&T Approval: N/A

Restricted Progesterone
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J1729	Hydroxyprogesterone compounded	Medical Benefit-Restricted	None	2nd trimester use: 6 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR WOMEN IN THE 2ND TRIMESTER:

- Documentation of a singleton pregnancy
- Documentation of a history of preterm birth

CRITERIA FOR COVERAGE FOR THE TREATMENT OF INFERTILITY (Illinois plans only):

- Quartz plan issued in the state of Illinois
- Infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m

CONTINUATION OF COVERAGE CRITERIA (new to plan):†

- Persons new to the plan who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Initial criteria met

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: 01/13
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Pulmonary Hypertension Drugs
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J1325	Epoprostenol (Veletri)	Medical Benefit-Restricted	None	12 months
Misc code	Selexipag (Uptravi)	Medical Benefit-Restricted	None	6 months
J3285	Treprostinil (generic version)	Medical Benefit-Restricted	None	12 months
Not Covered:				
Treprostinil (Remodulin)				

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE (all agents):
- Diagnosis of pulmonary arterial hypertension
- Prescribed by, or in consultation with, a Cardiologist or Pulmonologist

CRITERIA FOR COVERAGE (selexipag IV):
- General Criteria met
- Documented inability to swallow oral selexipag

CONTINUATION OF COVERAGE CRITERIA (renewal):†
- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet the initial criteria for coverage

IMPORTANT INFORMATION:
For information regarding coverage of pulmonary hypertension drugs on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 12/18
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Ultomiris (ravulizumab-cwvz)
Prior Authorization Criteria
DC-0137

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1303	**Ultomiris (ravulizumab-cwvz)**	Medical Benefit-Restricted	N/A	12 months

PNH CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Patient is one month of age and older
- Prescribed medication dose will not exceed the manufacturer recommended dose based on the patient's weight
- Prescribed by or in consultation with a hematologist/oncologist

aHUS CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of atypical hemolytic uremic syndrome (aHUS)
- Patient is one month of age and older
- Prescribed medication dose will not exceed the manufacturer recommended dose based on the patient's weight
- Prescribed by or in consultation with a hematologist/nephrologist

MG CRITERIA FOR COVERAGE (INITIAL):

- Diagnosis of generalized myasthenia gravis (MG)
- Patient is anti-acetylcholine receptor (AChR) antibody positive
- One of the following:
    - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

    OR

    - Both of the following:
        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)
        - Trial and failure, contraindication, or intolerance to one of the following: Chronic plasmapheresis or plasma exchange (PE) or Intravenous immunoglobulin (IVIG)
- Prescribed medication dose will not exceed the manufacturer recommended dose based on the patient's weight
- Prescribed by or in consultation with a neurologist

CRITERIA FOR COVERAGE (RENEWAL):

- Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy
- Prescribed medication dose will not exceed the manufacturer recommended dose based on the patient's weight

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	05/2019
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
11/25/2024	New drug specific criteria, standardization

References

1. Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. April 2022.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

Ryoncil (remestemcel-L-rknd)
Prior Authorization Criteria
DC-0159

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9399, J3590	Ryoncil (remestemcel-L-rknd)	Medical Benefit-Restricted	8 treatments	28 days

CRITERIA FOR COVERAGE (INITIAL):

- Age 2 months -17 years old
- Diagnosis of grade B-D aGVHD (acute graft vs. host disease) with symptoms involving skin, liver, and/or GI tract, except Grade B skin only
- Steroid refractory disease, progression within 3 days or no improvement within 7 days of consecutive steroid treatment
- Trial and failure of at least ONE NCCN supported second line therapy or medical reason to avoid all second line therapies
- High risk disease, defined as one of the following:
    - Skin stage 4
    - Lower gastrointestinal (GI) stage 3+
    - Liver stage 3+
    - Both of the following:
        - Skin stage 3
        - Lower GI or liver stage 2+
- Prescribed by (or in consultation with) an oncologist, hematologist, or bone marrow transplant (BMT) specialist

CRITERIA FOR COVERAGE (RENEWAL):

- One of the following:
    - Partial response to an initial course of treatment, defined as organ improvement of ≥1 stage without worsening of any other organ
    - Mixed response to an initial course of treatment, defined as improvement of at least one organ with worsening of another organ
    - Recurrence of acute graft vs. host disease after a complete response to an initial course of treatment

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE: Medication should be billed to Forward Health under the pharmacy benefit. Refer to the Forward Health policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Effective Date:	07/01/2025
P&T Approval Date:	04//15/2025
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/25/2025	New criteria

References

1. Ryoncil (remestemcel-L-rknd) suspension for intravenous infusion. Prescribing information. Mesoblast, Inc. 2025.
2. Macmillan ML, DeFor TE, Weisdorf DJ. What predicts high risk acute graft-versus-host disease (GVHD) at onset? Identification of those at highest risk by a novel acute GVHD risk score. *Br J Haematol.* 2012; 157(6): 732-741. https://doi.org/10.1111/j.1365-2141.2012.09114.x
3. MacMillan ML, et al. Biol Blood Marrow Transplant 2015;21:761-767; https://z.umn.edu/MNAcuteGVHDRiskScore
4. National Comprehensive Cancer Network. Hematopoietic Cell Transplant. (Version 1.2025). https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed March 26, 2025.

Reslizumab (Cinqair)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2786	Reslizumab (Cinqair)	Medical Benefit-Restricted		12 months

CRITERIA FOR COVERAGE:

- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm3 and other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out
- Prescribed by, or in consultation with, an asthma specialist (Allergist, Immunologist, Pulmonologist)
- Age ≥ 18 years
- Trial and failure, contraindication, or intolerance to at least one self-administered biologic therapies for eosinophilic asthma

AND

- Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent† ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier

  OR
- Patient has intolerance to medium to high dose inhaled corticosteroids. Exceptions based on adverse effects from high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids include:
  - Cataracts in patients > 40 years of age
  - Glaucoma
  - Recurrent thrush
  - Dysphonia
  - Growth inhibition, after evaluation by Endocrine Consult
  - Diagnosis of osteoporosis where treatment is resistant to FDA approved osteoporosis treatment

†Adherent treatment is defined as a medication possession ratio (MPR) ≥ 70% based on the previous 120 days of prescription claims (records will be required for approval)

CRITERIA FOR CONTINUATION (new to plan/renewal):‡

- The prescriber provides clinical documentation from the preceding 12 months showing a response to therapy

‡Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:

Il-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in extenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations).

Continuation of case-by-case approved IgE inhibitor, IL-5 inhibitor, or tezepelumab combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations or

hospitalizations.

Table 1. Outcome Measure values for uncontrolled asthma

Measure	Not Well Controlled	Very Poorly Controlled
Baseline symptoms (outside of exacerbation)	> 2 days/week	Throughout the day
Nighttime awakening	1-3 times/week	≥ 4 times/week
Interference with normal activity	Some limitation	Extremely limited
Short acting beta agonist use for symptom control	> 2 days/week	Several times per day
FEV1	60-80% predicted or personal best	< 60% predicted or personal best
Asthma exacerbations requiring oral steroids ≥ 2 times in the past year	Yes	Yes
Asthma Control Test (ACT)	16-19	≤ 15

Created: 04/23
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Restricted Medications with Miscellaneous Codes
Prior Authorization Criteria
DC-0152

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
MISC codes	Varies	Medical Benefit-Restricted	Varies	Up to 12 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE OF RESTRICTED MEDICATIONS BILLED WITH MISCELLANEOUS HCPCS CODES (NON-ONCOLOGY DIAGNOSES):†

- Used for a Food and Drug Administration (FDA) approved indication
- Failure of an adequate trial, intolerance, or contraindication to clinically appropriate covered alternatives for the person's diagnosis

OR

- **(Minnesota plans only) –** the requested drug is prescribed for a person with:
  - Emotional disturbance or mental illness and the prescriber provides written documentation that all equivalent covered drugs were considered, and it has been determined that the drug prescribed will best treat the person's condition.
    - For continuation of care: the person has been treated for 90 days prior to the change, the medication is working, and the prescriber documents the drug prescribed will best treat the person's condition.

    OR
  - Stage four metastatic cancer and prescribed drug is used for cancer related treatment including but not limited to: pain, constipation, nausea, or prevention/treatment of infection.

    OR
  - Pediatric acute-onset neuropsychiatric syndrome (PANS) or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)

OR

- **(Illinois plans only) –**
  - The requested FDA approved drug is being used for the long-term treatment of tick-borne disease.

    OR
  - The requested medication is for a mental health condition or substance use disorder under the mental and behavioral disorder chapter of the International Classification of Disease or is listed in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders:
    - If the medication is being used for substance use disorder, Determination should be based on criteria established by American Society of Addiction Medicine and should not be more restrictive than non-behavioral health or substance use disorder diagnosis
    - If the medication is being used for a mental health condition, apply the usual criteria at the beginning of the criteria set, making sure determination is not more restrictive than for non-behavioral health or substance use disorder

    OR
  - The requested drug is being used to treat pediatric acute-onset neuropsychiatric syndrome (PANS) or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)

CRITERIA FOR COVERAGE OF RESTRICTED ONCOLOGY MEDICATIONS BILLED WITH MISCELLANEOUS HCPCS CODES:†

- Prescribed by, or in consultation with, an Oncologist, Hematologist, or other provider specializing in the treatment of malignancy
- The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition of the person

OR

- The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person

OR

- **(Minnesota plans only) -** the requested drug is being used alone or in a combination regiment that is recommended for use in the specific condition of the person in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person's specific condition

OR

- **(Illinois plans only) –** the requested drug is being used alone or in a combination that is recommended for use in the specific condition of the person in the American Hospital Formulary Service Drug Information, Thompson Micromedex's Drug Dex, Elsevier Gold Standard's Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person's specific condition.

†Unless there are drug product specific prior authorization criteria (e.g. mepolizumab (Nucala®), daratumumab (Darzalex®), etc.), then the drug product specific criteria apply and must be met for coverage.

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):

- Initial criteria for coverage met

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	04/2017
P&T Review Date:	10/01/2024

Revision History:

Date	Notes
02/27/2025	Add policy number

Rethymic (allogeneic processed thymus tissue-agdc)
Prior Authorization Criteria
DC-0131

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9399, J3590	Rethymic (allogeneic processed thymus tissue-agdc)	Medical Benefit-Restricted	1 treatment	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of congenital athymia with confirmation from specialist (pediatric immunologist) and surgery conducted by surgeon with experience with Rethymic
- Age <18 years
- Dose limit*: maximum recommended dose is 22,000 mm2 of Rethymic per m2 of recipient's body surface area
- Absence of pre-existing cytomegalovirus infection
- Pre-procedure anti-human leukocyte antigen (HLA) antibody screening has been completed

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Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	01/21/2025
P&T Review Date:	01/21/2025

Revision History:

Date	Notes
11/12/2024	New criteria

References

1. IPD analytics. Rethymic (allogeneic processed thymus tissue -agdc) Published October 2021. Accessed November 2024.

Rilonacept (Arcalyst)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2793	Rilonacept (Arcalyst)	Medical Benefit-Restricted	Single loading dose	30 days

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES:

- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children ≥ age 12
- Prescribed by, or in consultation with, a Rheumatologist or Immunologist
- Trial and failure, contraindication, or intolerance to kineret (Anakinra)

CRITERIA FOR COVERAGE FOR PERICARDITIS:

- Diagnosis of symptomatic recurrent pericarditis (i.e. idiopathic or post-cardiac injury pericarditis)
- Prescribed by, or in consultation with, a Cardiologist

CRITERIA FOR QUANTITY/DURATION EXCEPTIONS:

- For ongoing CLINIC administration: Documentation of physical disability making self-injection at home unfeasible (e.g. debilitating arthritis of hands or neurologic disease affecting hands).

CONTINUATION OF COVERAGE CRITERIA (renewal):†

- Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

†Persons new to the plan must meet the initial criteria for coverage

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Created: 08/12
Effective: 08/01/2024 Client Approval: P&T Approval: N/A

Risankizumab (Skyrizi) Infusion
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J2327	Risankizumab infusion (Skyrizi)	Medical Benefit-Restricted	IBD: 3 infusions for loading dose (weeks 0, 4, 8)	3 months

*Limited to 12 months for IL and MN plans

QUARTZ COMMERCIAL CRITERIA FOR COVERAGE FOR CROHN'S DISEASE (CD):

- Diagnosis of moderate to severely active CD
- Prescribed by or in consultation with a Gastroenterologist
- Age ≥ 18 years
- High-risk individual (characteristics include: age <30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc.)
  OR
- Low-risk individual and AT LEAST ONE OF THE FOLLOWING:
  - 3-month trial and failure, intolerance, or contraindication to 1 conventional therapy (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease

QUARTZ COMMERCIAL/BADGERCARE CRITERIA FOR COVERAGE FOR ULCERATIVE COLITIS (UC):

- Diagnosis of moderate to severely active UC
- Prescribed by or in consultation with a Gastroenterologist
- Age ≥ 18 years High-risk individual (characteristics include extensive colitis, deep ulcers, age <40 at diagnosis, High CRP and ESR, steroid-requiring disease, history of hospitalization, C. difficile infection, CMV infection, etc.).
- Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

QUARTZ COMMERCIAL CRITERIA FOR QUANTITY EXCEPTIONS:

- For more than 3 IV loading doses
  - Provision of published literature supporting efficacy and safety of dosing regimen with greater than 3 loading doses
  - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies (when clinical lab available)

QUARTZ COMMERCIAL CONTINUATION OF COVERAGE CRITERIA (new to plan):†

- The prescriber must provide clinical documentation from the previous 3 months that the person has started infusion loading for Crohn's disease and needs to finish the loading regimen

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI CRITERIA FOR COVERAGE FOR CD:

- Diagnosis of Crohn's disease (CD)
- Prescribed by or in consultation with a Gastroenterologist
- The patient has taken adalimumab for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.
- Infusion indicated for 3 doses (week 0, week 4, and week 8)

IMPORTANT INFORMATION:
For information regarding coverage of risankizumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Inadequate Disease Control of UC/CD:
Worsening of baseline symptoms (i.e., bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc), extraintestinal manifestations (i.e., fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e., C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc) and/or recent endoscopy results demonstrating ongoing inflammation

Steroid Dependence:
-Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis
-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs
-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin
-endoscopy, colonoscopy, sigmoidoscopy

Crohn's Disease Classification:
Stricturing - narrowing of bowel that may cause bowel obstruction
Penetrating - fistulae may form between bowel and other structures
Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

1. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
2. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.

3. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.

Created: 10/23
Effective: 10/01/2024 Client Approval: 07/26/2022

Romiplostim (Nplate)
Prior Authorization Criteria
DC-0145

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2802	Romiplostim (Nplate)	Medical Benefit-Restricted	Acute radiation injury: 1 dose	12 months

CRITERIA FOR COVERAGE FOR IMMUNE THROMBOCYTOPENIA PURPURA (ITP):

- Diagnosis of chronic ITP with a platelet count < 50,000/mcL
- Prescribed by, or in consultation with, Hematology
- Trial and failure, intolerance, or contraindication to ≥ 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danazol, or splenectomy)

CRITERIA FOR COVERAGE FOR HEMATOPOIETIC RADIATION INJURY SYNDROME:

- Diagnosis of acute hematopoietic radiation injury syndrome
- Prescribed by, or in consultation with, Hematology

(MN PLANS ONLY) CRITERIA FOR COVERAGE FOR CANCER-RELATED THROMBOCYTPENIA:

- Person with stage four metastatic cancer and romiplostim is being used to treat cancer treatment-related low platelet counts

CRITERIA FOR QUANTITY EXCEPTIONS:

- The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

CONTINUATION OF COVERAGE CRITERIA (12 month):*

- Clinical documentation from the previous 12 months showing objective disease improvement or stabilization (eg platelet count increase

* Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Guideline Note:

Effective Date:	07/01/2025
P&T Approval Date:	03/2013
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/25/2025	Revise continuation criteria, remove old J code

Romosazumab-aqqg (Evenity)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3111	Romosozumab-aqqg (Evenity)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Total duration of treatment will not exceed 12 months over a person's lifetime
- Person has not had a myocardial infarction or stroke within the preceding year and consider the benefits versus the risks in people with other cardiovascular risk factors
- Will not be used in combination with anti-resorptive therapy
- For the treatment of postmenopausal women who have **one of the following**:
    - Diagnosis of osteoporosis with a T-score of less than or equal to -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius
    - At very high risk of fracture defined by **AT LEAST ONE** of the following:
        - Recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very low T-score (less than -3.0), high risk for falls, or history of injurious falls

OR

- Diagnosis of osteopenia with a T-score between -1.0 and -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius
- 10 year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20%
- At very high risk of fracture defined by **AT LEAST ONE** of the following**:**
    - Recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very high FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%), high risk for falls, or history of injurious falls

Fracture risk to be assessed with FRAX score, number of osteoporosis related fractures, increased fall risk; indicators of higher fracture risk include: advanced age, glucocorticosteroids, very low T score, increased fall risk (many of these factors will reflect in the FRAX score; however, some risk factors are not incorporated, like number of fractures, time of fracture (recent), increased fall risk

CRITERIA FOR A DURATION EXCEPTIONS:

- The prescriber provides an evidence-based clinical rationale for requesting a treatment duration outside of the FDA approved duration

CONTINUATION OF COVERAGE CRITERIA (new to plan):*

- Persons new to the plan who are established on therapy and need to complete the remainder of the current treatment course (up to 12 months total)

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Romosozumab is a clinic administered medication and is not covered under the prescription drug benefit.
Romosozumab should be billed under the medical benefit and must be supplied and administered by a medical provider.

Created: 09/19
Effective: 08/01/2024 Client Approval: P&T Approval: N/A

Rozanolixizumab-noli (Rystiggo)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9333	Rozanolixizumab-noli (Rystiggo)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of generalized Myasthenia Gravis (gMG) with all of the following:
  - Positive serological test for anti-acetylcholine receptor (AChR) OR anti-muscle-specific tyrosine kinase (MuSK) antibodies
  - MGFA clinical classification of Class II to IVa disease
- Prescribed by, or in consultation with, a Neurologist or other specialist in the treatment of Myasthenia Gravis
- Patient has an MG-ADL total score ≥3 (with ≥3 points from non-ocular symptoms)
- Trial and failure, intolerance, or contraindication of a six month trial of TWO immunosuppressive therapies (e.g. prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, rituximab).
  - If intolerance to one or more immunosuppressives, then prior 3 months trial and failure of IVIG OR prior use of and failure of at least 4 PLEX treatments.

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):*

- Initial criteria met.
- Prescriber provides clinical notes from the previous 12 months documenting response to therapy compared to baseline; such as improvement in symptoms/function (i.e. decrease in MG-ADL and/or QMG score), fewer disease exacerbations (i.e. decrease in hospitalizations, PLEX treatments, steroid dosing etc.).

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: 10/23
Effective: 05/01/2024 Client Approval: 07/12/21 P&T Approval: N/A

Sebelipase alfa (Kanuma)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2840	Sebelipase alfa (Kanuma)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Covered for persons with Lysosomal Acid Lipase (LAL) deficiency (Wolman disease or Cholesterol ester storage disease (CEST) confirmed by dried blood spot testing

AND

- Prescribed by, or in consultation with, a specialist in Genetics and Metabolism

AND

- Two separate elevated alanine aminotransferase levels ≥ 1.5 times the ULN

CONTINUATION OF THERAPY:*

- Clinical documentation from the previous 12 months demonstrating response to therapy such as improvements from baseline in liver function tests, cholesterol levels, or reductions in hepatic fat.

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Sebelipase alfa is a clinic administered medication and is not covered under the prescription drug benefit.

Created: 12/15
Effective: 07/03/23 Client Approval: P&T Approval: N/A

Spesolimab-sbzo (Spevigo)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J1747	Spesolimab-sbzo (Spevigo)	Medical Benefit Restricted	2- 900mg IV infusions	3 months

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR PUSTULAR PSORIASIS:

- Prescribed by Dermatologist
- Adult (age>18)
- Diagnosis of generalized pustular psoriasis with a flare of moderate to severe intensity
  - *GPPPGA total score/subscores demonstrating moderate to severe intensity*
  - *New/worsening pustules*
  - *>5% TBSA covered with erythema and pustules*
- Not used in combination with other systemic and topical medications for psoriasis

CRITERIA FOR COVERAGE FOR UNLISTED INDICATIONS (evaluated for medical necessity):

- **Consider the following items:**
  - Prescribed by an Expert/Specialist with experience in treated condition
  - Peer reviewed published evidence to support use of therapy in indication
  - Failure or intolerance or contraindication to standard of therapy for condition

CRITERIA FOR QUANTITY EXCEPTIONS

- No data on re-dosing of therapy beyond 2-initial doses

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- Prescriber provides an evidence-based rationale for using a extended treatment duration

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Created: 01/17/2023
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Sutimlimab (Enjaymo)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1302	Sutimlimab (Enjaymo)	Medical Benefit-Restricted	none	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of primary cold agglutinin disease (CAD)
- History of at least one blood transfusion within the previous six months
- Hemoglobin level ≤ 10 g/dL
- One or more symptoms associated with CAD (ex: anemia, acrocyanosis, etc.)
- Prior failure, intolerance, or contraindication to rituximab unless need for rapid acting therapy (ex: severe anemia, cardiac surgery, etc.)
- Not using in combination with rituximab

CONTINUATION OF COVERAGE CRITERIA:*

- Prescriber provides clinical documentation from the previous 12 months that describes the person's response as stable or improvement seen on therapy

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program and/or voucher

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Created: 05/22
Effective: 07/03/2023 Client Approval: P&T Approval: 5/17/2022

Systemic Lupus Erythematosus (SLE) treatments
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0490	Belimumab infusion (Benlysta)	Medical Benefit-Restricted	None	12 months
J0491	Anifrolumab (Saphnelo)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of auto-antibody positive moderate to severe SLE with or without lupus nephritis without severe central nervous system lupus
- Prescribed by, or in consultation with, a Rheumatologist or other expert in the treatment of SLE
- Trial and failure (symptoms persist), contraindication, or intolerance with ALL of the following; hydroxychloroquine, nonsteroidal anti-inflammatories (NSAIDS such as ibuprofen, naproxen, etc.), a steroid-sparing immunosuppressive such as azathioprine or methotrexate, and a short course of oral steroids.
- **Belimumab only -** Inability to self-administer weekly injection despite adequate teaching and interventions from a pharmacist or other health care providers

CRITERIA FOR CONTINUATION OF COVERAGE (new to plan/renewal):*

- Clinical documentation from the previous 12 months demonstrating benefits from therapy
- **Belimumab only** - Inability to self-administer weekly injection despite adequate teaching and interventions from a pharmacist or other health care providers

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:

For information regarding coverage of belimumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Created: 08/17

Effective: 05/01/2024 Client Approval: 11/26/21 P&T Approval: N/A

Teplizumab (Tzield)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9381	Teplizumab (Tzield)	Medical Benefit-Restricted		14 days

CRITERIA FOR COVERAGE:

- Diagnosis of Stage 2 type 1 diabetes with all the following:
  - Presence of two or more pancreatic islet autoantibodies†
  - Evidence of dysglycemia‡
- Prescribed by, or in consultation with, an Endocrinologist or other specialist in the treatment of Type 1 Diabetes
- Age≥8

†Pancreatic autoantibodies include: 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)

‡ Dysglycemia is defined by the American Diabetes Association as:

- A fasting plasma glucose between 100 mg/dL and 125 mg/dL (5.6–6.9 mmol/L)
- 2 hour post prandial plasma glucose between 140mg/dL and 199 mg/dL (7.8–11.0 mmol/L)
- A1C 5.7–6.4% (39–47 mmol/mol) or ≥10% increase in A1C

Created: 04/2023
Effective: 07/3/23 Client Approval: P&T Approval: N/A

Teprotumumab-trbw (Tepezza)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3241	Teprotumumab (Tepezza)	Medical Benefit-Restricted	8 Doses	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of thyroid-associated ophthalmopathy (Graves' orbitopathy) with moderate-to-severe symptoms such as:
  - Lid retraction ≥ 2 mm
  - Proptosis ≥ 3 mm
  - Intermittent diplopia
  - Clinical activity score (CAS) ≥ 4
- Medical or surgical reversal of hyperthyroidism
- Trial and failure, contraindication, or intolerance to an adequate 4-week trial of high-dose oral steroids (30-40 mg/day)

CONTINUATION OF COVERAGE CRITERIA (new to the plan):*

- Persons new to coverage who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- The prescriber provides published evidence to support the safety and efficacy of a treatment regimen beyond 8 doses.

* Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

Created: 10/20
Effective: 07/03/2023 Client Approval: P&T Approval: N/A

Testosterone
Prior Authorization Criteria
DC-0085

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J1071, J3121, J1072	Testosterone cypionate (Azmiro) and enanthate injections	Medical Benefit-Restricted	None	None
J3145	Testosterone extended-release injection (Aveed)	Medical Benefit-Restricted	None	None
S0189	Testosterone implant (Testopel)	Medical Benefit-Restricted	None	None
Misc. code	Testosterone injection (generics, Xyosted)	Medical Benefit-Restricted	None	None

*Limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE FOR TESTOSTERONE INJECTIONS (generic cypionate and enanthate):

- Diagnosis of gender dysphoria, transsexualism, or other gender identity diagnosis

OR

- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism
- Laboratory data demonstrating androgen deficiency†
- Documentation of symptoms other than decreased libido and/or other sexual dysfunction

OR

- (Minnesota Plans Only) – Person with stage four metastatic cancer and testosterone is being used to treat cancer-related side effects or hypogonadism

†Androgen deficiency is defined as a fasting, morning testosterone level (drawn between 7 and 10 AM or within 3 hours of waking for shift workers) below the lower limit of normal as defined by the laboratory reference range. A single low testosterone is not diagnostic for androgen deficiency and must be confirmed with a second fasting, morning testosterone level.

CRITERIA FOR COVERAGE FOR TESTOSTERONE INJECTIONS (Xyosted):

- Above criteria met
- Documented trial and failure, contraindication, or intolerance to a generic testosterone injection

CRITERIA FOR COVERAGE FOR TESTOSTERONE EXTENDED-RELEASE INJECTIONS AND IMPLANTS (Aveed, Testopel):

- Above criteria met
- Documented trial and failure, contraindication or intolerance to BOTH a topical testosterone and a non-extended-release injection formulation (generic cypionate or enanthate).

CONTINUATION OF COVERAGE CRITERIA (generic testosterone cypionate or enanthate):‡

- Persons new to coverage who are established on therapy or have been previously authorized by the plan will have coverage under their drug benefit for the remainder of the current treatment course.

CONTINUATION OF COVERAGE CRITERIA (Aveed, Testopel, Xyosted)

- Initial criteria for coverage met.

‡Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage but whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
For information regarding coverage of testosterone on the prescription drug benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com.

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	09/17/2017
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/21/2025	Add J1072 Testosterone cypionate (Azmiro)

Tezepelumab (Tezspire)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2356	Tezepelumab (Tezspire)	Medical Benefit-Restricted		12 months

GENERAL CRITERIA FOR COVERAGE:

- Prescribed by, or in consultation with, an asthma specialist (Allergist, Immunologist, Pulmonologist)
- Age ≥ 12 years
- Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent † ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier
  OR
- Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids include:
  - Cataracts in patients > 40 years of age
  - Glaucoma
  - Recurrent thrush
  - Dysphonia
  - Growth inhibition, after evaluation by Endocrine Consult
  - Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

†Adherent treatment is defined as a medication possession ratio (MPR) ≥ 70% based on the previous 120 days of prescription claims

CRITERIA FOR COVERAGE FOR EOSINOPHILIC ASTHMA:

- General criteria for coverage met
- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm3 and other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out
- Trial and failure, intolerance, or contraindication to at least two self-administered biologic therapies for eosinophilic asthma (i.e. dupilumab, benralizumab, mepolizumab)

CRITERIA FOR COVERAGE FOR ALLERGIC ASTHMA:

- General criteria for coverage met
- Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)
- Serum IgE level ≥30 international units/mL
- Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)
- Trial and failure, intolerance, or contraindication to at least one self-administered biologic therapy for allergic asthma (i.e. omalizumab)

CRITERIA FOR COVERAGE FOR SEVERE ASTHMA:

- General criteria for coverage met
- Diagnosis of severe asthma as defined by the GINA guidelines with ALL of the following:

- History of ≥ 2 asthma exacerbations requiring systemic corticosteroids within the past 12 months OR one asthma exacerbation requiring hospitalization in the past 12 months
- Asthma is non-eosinophilic (example: blood eosinophil counts of <150 cells/uL)
- Asthma is non-allergic (example: Serum IgE level <30 international units/mL, negative skin tests or in vitro reactivity to common aeroallergens)

CRITERIA FOR CONTINUATION (new to plan/renewal):‡

- The prescriber must provide clinical documentation from the preceding 12 months showing response to therapy

‡Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in extenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations).

Continuation of case-by-case approved IgE inhibitor, IL-5 inhibitor, or tezepelumab combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations.

Table 1. Outcome Measure values for uncontrolled asthma

Measure	Not Well Controlled	Very Poorly Controlled
Baseline symptoms (outside of exacerbation)	> 2 days/week	Throughout the day
Nighttime awakening	1-3 times/week	≥ 4 times/week
Interference with normal activity	Some limitation	Extremely limited
Short acting beta agonist use for symptom control	> 2 days/week	Several times per day
FEV1	60-80% predicted or personal best	< 60% predicted or personal best
Asthma exacerbations requiring oral steroids ≥ 2 times in the past year	Yes	Yes
Asthma Control Test (ACT)	16-19	≤ 15

Created: 04/23
Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Tildrakizumab (Ilumya)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3245	Tildrakizumab (Ilumya)	Medical Benefit - Restricted	#1 every 12 weeks	12 Months

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERE PLAQUE PSORIASIS:

- Prescribed by or in consultation with a Dermatologist
- Documentation of ONE of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement ≥ 3%
  - Debilitating palmer/plantar psoriasis or involvement in other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas
- Trial and failure, intolerance, or contraindication to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)
- Trial and failure, intolerance, or contraindication to risankizumab (Skyrizi)
- Trial and failure, intolerance, or contraindication to at least TWO of the following:
  - Adalimumab
  - Apremilast
  - Etanercept
  - Secukinumab
  - Infliximab biosimilar

CRITERIA FOR QUANTITY EXCEPTIONS

- Regimen based on FDA label (based on weight or response to therapy at lower dose) or published literature supporting the dose and/or frequency being requested after failure of an adequate trial of standardized dosing

CONTINUATION OF COVERAGE CRITERIA (new to the plan/renewals):†

- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy (e.g. improvement in PASI, PGA, TBSA affected, etc.).
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, clear skin, those with high supra-therapeutic trough levels, etc.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

References:

1. Menter A, Gelfand JM, Connor C, Armstrong AW, Cordoro KM, Davis D, et al. Joint American academy of dermatology-national psoriasis foundation guideline of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol 2020; 82: 1445-1486. *This reference provides details on how to manage relative contraindications and risk factors for use/management of non-biologic therapies*.
2. Menter A, Strober BE, Kaplan DH, Kivelevitch D, Prater EF, Stoff B, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019; 80:1029-1072.
3. Elmets CA, Korman NJ, Prater EF, Wong EB, Rupani RN, Kivelevitch D, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021; 84: 432-470. *This reference provides details on topical therapies and duration of use and locations.*

Created: 10/13
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Last Revised: 10/15/24 – Updated duration limit

Tocilizumab (Actemra) Infusion
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3262	Tocilizumab (Actemra) infusion	Medical Benefit-Restricted	NA	12 months
Q5133	Tocilizumab (Tofidence) infusion	Medical Benefit-Restricted	NA	12 months
Q5135	Tocilizumab (Tyenne) infusion	Medical Benefit-Restricted	NA	12 months

CRITERIA FOR COVERAGE FOR ALL DIAGNOSES:

- Failure of adequate trial of self-injection (subcutaneous) or inability to self-administer tocilizumab injection.
- Diagnosis as listed

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS (RA):

- Prescribed by or in consultation with a Rheumatologist
- 3-month trial and failure, intolerance, or contraindication to ONE of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- Trial and failure, intolerance, or contraindication to TWO of the following
    - Adalimumab
    - Certolizumab
    - Etanercept
    - Upadacitinib
    - Golimumab
    - Tofacitinib/Tofacitinib ER
    - Infliximab

CRITERIA FOR COVERAGE FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA):

- Prescribed by or in consultation with a Rheumatologist
- Age ≥ 2 years
- 3-month trial and failure, intolerance, or contraindication to ONE of the following:
    - Methotrexate
    - Nonsteroidal anti-inflammatory drugs (NSAIDs such as naproxen, ibuprofen)
    - Systemic steroids (e.g. prednisone)

CRITERIA FOR COVERAGE FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA):

- Prescribed by or in consultation with a Rheumatologist
- 3-month trial and failure, intolerance, or contraindication to ONE of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- Trial and failure, intolerance, or contraindication to TWO of the following

- Adalimumab
- Etanercept
- Infliximab
- Tofacitinib/Tofacitinib XR

CRITERIA FOR COVERAGE FOR GIANT CELL ARTERITIS (GCA):
- Prescribed by or in consultation with a Rheumatologist
- Trial and failure (symptoms relapsed) of corticosteroids or methotrexate
  OR
- Contraindication to methotrexate
  OR
- Inability to taper corticosteroids.

CRITERIA FOR COVERAGE FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD):
- Prescribed by or in consultation with a Rheumatologist or Pulmonologist
- Trial and failure (decline in pulmonary function) or contraindication to use of ONE standard agent:
  - Mycophenolate
  - Cyclophosphamide
  - Azathioprine

CRITERIA FOR COVERAGE FOR CYTOKINE RELEASE SYNDROME (CRS):
- Diagnosis of chimeric Antigen Receptor (CAR) T-cell to treat T-cell – induced severe or life-threatening CRS
- Age ≥ 2 years

CRITERIA FOR COVERAGE FOR CORONAVIRUS 2019 (COVID-19) DISEASE:
- Treatment of COVID-19 in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non0invasive, or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO)

(MN PLANS ONLY) CRITERIA FOR COVERAGE FOR CANCER-RELATED CONDITIONS:
Person with stage four metastatic cancer and tocilizumab is being used to treat cancer-related graft versus host disease or checkpoint inhibitor-induced musculoskeletal side effects

CONTINUATION OF COVERAGE CRITERIA (new to the plan/renewals):†
- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy including individual improvements in functional status related to therapeutic response.
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, clear skin, those with high supra-therapeutic trough levels, etc.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
For information regarding coverage of tocilizumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com

Absolute contraindications to methotrexate are pregnancy, nursing, alcoholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Steroid Dependence: Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

References:

1. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium. (nccn.org).
2. Onel KB, Horton DB, Lovell DJ, Shenoi S, Cuello CA, Angeles-Han ST, Becker ML, Cron RQ, Feldman BM, Ferguson PJ, Gewanter H, Guzman J, Kimura Y, Lee T, Murphy K, Nigrovic PA, Ombrello MJ, Rabinovich CE, Tesher M, Twilt M, Klein-Gitelman M, Barbar-Smiley F, Cooper AM, Edelheit B, Gillispie-Taylor M, Hays K, Mannion ML, Peterson R, Flanagan E, Saad N, Sullivan N, Szymanski AM, Trachtman R, Turgunbaev M, Veiga K, Turner AS, Reston JT. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022 Apr;74(4):553-569

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Revised: 10/15/2024
Effective: 01/01/2025

P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Tofersen (Qalsody)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1304	Tofersen (Qalsody)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of ALS in patients
- Mutation in the superoxide dismutase 1 (SOD1) gene
- Prescribed by, or in consultation with, a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS)
- Age ≥ 18 years
- Forced vital capacity (FVC) ≥ 50%

CRITERIA FOR CONTINUATION/RENEWAL:*

- Documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

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Created: 07/23
Effective: 05/01/24 Client Approval: P&T Approval: N/A

Trilaciclib (Cosela)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1448	Trilaciclib (Cosela)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Prescribed and monitored by, or in consultation with, a Hematologist, Oncologist, or other specialist in treating malignancy
- Treatment diagnosis and regimen follow Food and Drug Administration (FDA) labeled indication OR National Comprehensive Cancer Network (NCCN) category 1 or 2 recommendations

OR

- **(Minnesota plans only)**: The person has stage four metastatic cancer and the requested drug is being used as supportive care for their cancer treatment

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):*

- Initial criteria for coverage met

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Created: 05/21
Effective: 08/01/2023 Client Approval: P&T Approval: N/A

Ublituximab (Briumvi)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2329	Ublituximab (Briumvi)	Medical Benefit-Restricted		12 months

CRITERIA FOR COVERAGE:

- Clinical documentation of a diagnosis of relapsing multiple sclerosis
- Drug prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis
- Failure (acute relapse or new lesion formation) while on higher efficacy oral disease modifying therapies (DMT - such as dimethyl fumarate, fingolimod, or cladribine (Mavenclad)
  OR
- Intolerance to, inability to take, or labeled contraindication to at least two oral DMTs
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):†

- Clinical assessment from the treating Neurologist from the previous 12 months documenting a relapsing form of multiple sclerosis and that the person is established on therapy
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

†Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

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P&T Revision Date: 10/15/2024
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Ustekinumab (Stelara) Infusion and biosimilars
Prior Authorization Criteria
DC-0081

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J3358,Q5138, Q9997, , Q9999, C9399, J3590	Ustekinumab (Stelara, Wezlana, Pyzchiva, Selarsdi, Otulfi, Yesintek, Steqeyma)	Medical Benefit-Restricted	IBD induction: 1 dose	3 months

*Initial and renewal approvals limited to 12 months for IL and MN plans

CRITERIA FOR COVERAGE OF MODERATE TO SEVERELY ACTIVE CROHN'S DISEASE (CD):

- Prescribed by or in consultation with a Gastroenterologist
- High-risk adult individual (characteristics include: age<30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, structuring and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc
  OR
- Low-risk adult individual and ≥ ONE of the following:
  - 3-month trial and failure, intolerance, or contraindication to one conventional therapy (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC):

- Prescribed by or in consultation with a Gastroenterologist
- High-risk adult individual (characteristics include: extensive colitis, deep ulcers, age <40 years at diagnosis, High CRP and ESR, steroid-requiring disease, history of hospitalization, *C difficile* infection, CMV infection, etc)
- Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

(MN PLANS ONLY) CRITERIA FOR COVERAGE FOR CHECKPOINT INHIBITOR-INDUCED COLITIS:

- Person with stage four metastatic cancer and ustekinumab is being used to treat checkpoint inhibitor-induced colitis

CRITERIA FOR QUANTITY EXCEPTIONS or CONTINUATION OF COVERAGE (new to plan/renewal): ‡

- For additional IV loading dose:
  - Based on subtherapeutic drug concentrations and absences (or low levels) of drug antibodies
  - Provision of published literature supporting re-loading
  - Failure of evidence-based first line alternatives

‡Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
For information regarding coverage of ustekinumab on the prescription benefit please see the Quartz prescription drug benefit prior authorization criteria library at www.QuartzBenefits.com

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Inadequate Disease Control of UC/CD:
Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc) and/or recent endoscopy results demonstrating ongoing inflammation

Steroid Dependence:
-Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis
-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs
-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin
-endoscopy, colonoscopy, sigmoidoscopy

Ulcerative Colitis Disease Severity:
Based on the degree of presentation of the signs and symptoms and change in baseline inflammatory status
Moderate disease - more than four stools per day with minimal signs of toxicity, anemia, abdominal pain, low grade fever
Severe disease - more than six bloody stools per day, fever, tachycardia, anemia, elevated ESR or CRP

Crohn's Disease Classification:
Structuring - narrowing of bowel that may cause bowel obstruction
Penetrating - fistulae may form between bowel and other structures
Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

1. Menter A, Gelfand JM, Connor C, Armstrong AW, Cordoro KM, Davis D, et al. Joint American academy of dermatology-national psoriasis foundation guideline of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol 2020; 82: 1445-1486. *This reference provides details on how to manage relative contraindications and risk factors for use/management of non-biologic therapies*.
2. Menter A, Strober BE, Kaplan DH, Kivelevitch D, Prater EF, Stoff B, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019; 80:1029-1072.

3. Elmets CA, Korman NJ, Prater EF, Wong EB, Rupani RN, Kivelevitch D, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021; 84: 432-470. *This reference provides details on topical therapies and duration of use and locations.*
4. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020; 158:1450-1461.
5. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
6. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.
7. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.

Guideline Note:

Effective Date:	04/01/2025
P&T Approval Date:	10/2023
P&T Review Date:	04/15/2025

Revision History:

Date	Notes
03/21/2025	Add Otulfi, Yesintek, Steqeyma

Vadadustat (Vafseo)
Prior Authorization Criteria
DC-0151

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits*
J0901	Vadadustat (Vafseo)	Medical benefit - restricted	3/day	6 months (initial) 12 months (renewal)

INITIAL CRITERIA FOR COVERAGE includes ALL of the following [A,B,D]:

- Diagnosis of chronic kidney disease (CKD)
- Patient has been on dialysis for at least 3 months
- Adequate iron stores confirmed by both of the following:
    - Patient's ferritin level is greater than 100mcg/L
    - Patient's transferrin saturation (TSAT) is greater than 20%
- Hemoglobin level less than 11 g/dL
- Trial and failure, contraindication or intolerance to one of the following:
    - Retract
    - Procrit
    - Aranesp
- Prescribed by or in consultation with one of the following: hematologist OR nephrologist
- Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

CONTINUATION OF COVERAGE CRITERIA includes one of the following [C]:

- The person is new to coverage and already established on therapy*
- All of the following:
    - Patient demonstrates positive clinical response to therapy (e.g., increase in hemoglobin)
    - Hemoglobin level does not exceed 11g/dL
    - Adequate iron stores confirmed by both of the following:
        - Patient's ferritin level is greater than 100mcg/L
        - Patient's transferrin saturation (TSAT) is greater than 20%
    - Trial and failure, contraindication or intolerance to one of the following:
        - Retacrit
        - Procrit
        - Aranesp
    - Patient is not on concurrent treatment with an erythropoeitin stimulating agent [ESA] (e.g., Aranesp, Epogen, Procrit)

* Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Endnotes

A. Efficacy in each study was based on the difference in mean change of Hb from baseline to the primary evaluation period (Weeks 24 to 36). [1]
B. In both the INNO2VATE-1 and INNO2VATE-2 trials, Vafseo was non-inferior to darbepoetin alfa in correcting and maintaining Hb levels. Recommended Starting Dose of Vafseo: Adults Not Being Treated with an ESA: The recommended starting dose is 300 mg orally once daily. Adults Being Switched from an ESA: When converting from an ESA to Vafseo, the recommended starting dose is 300 mg orally once daily. [1]
C. If the Hb level exceeds 11 g/dL, interrupt the dose of Vafseo until Hb is less than or equal to 11 g/dL then resume with a dose that is 150 mg less than the dose prior to interruption. [1]
D. Evaluate iron status in all patients before and during treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of therapy. [1]

References

1. Vafseo Prescribing Information. Akebia Therapeutics, Inc. Cambridge, MA. March 2024.
2. ClinicalTrials.gov. Efficacy and Safety Study to Evaluate Vadadustat for the Correction or Maintenance Treatment of Anemia in Participants With Incident Dialysis-dependent Chronic Kidney Disease (DD-CKD) [NCT02865850]. Available at: https://www.clinicaltrials.gov/study/NCT02865850?cond=NCT02865850&rank=1#participation-criteria. Accessed August 5, 2024.
3. ClinicalTrials.gov. Efficacy and Safety Study to Evaluate Vadadustat for the Maintenance Treatment of Anemia in Participants With Dialysis-dependent Chronic Kidney Disease (DD-CKD). Available at : https://www.clinicaltrials.gov/study/NCT02892149?cond=NCT02892149&rank=1#participation-criteria. Accessed August 5, 2024.
4. Executive Summary of the KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease: Known Knowns AND Known Unknowns. Available at : https://kdigo.org/wp-content/uploads/2017/02/KDIGO-2024-CKD-Guideline-Executive-Summary.pdf. Accessed August 5, 2024.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Available at: https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf. Accessed August 5, 2024.

Guideline Note:

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Revision History:

Date	Notes
12/12/2024	New criteria

Vedolizumab (Entyvio) Infusion
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3380	Vedolizumab (Entyvio)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE OF MODERATE TO SEVERLY ACTIVE CROHN'S DISEASE (CD):

- Prescribed by or in consultation with a Gastroenterologist
- High-risk individual (characteristics include: age <30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)
  OR
- Low-risk individual and ≥ ONE OF THE FOLLOWING:
  - 3-month trial and failure, intolerance, or contraindication to one conventional therapy (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease
- Failure/Intolerance/Contraindication to ONE of the following:
  - Adalimumab
  - Infliximab
  - Certolizumab (Cimzia)

CRITERIA FOR COVERAGE FOR MODERATE TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC):

- Prescribed by or in consultation with a Gastroenterologist
- High-risk individual (characteristics include: extensive colitis, deep ulcers, age <40 years at diagnosis, High CRP and ESR, steroid-requiring disease, history of hospitalization, *C difficile* infection, CMV infection, etc)
- Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

(MN PLANS ONLY) CRITERIA FOR COVERAGE FOR CHECKPOINT INHIBITOR-INDUCED COLITIS:

- Person with stage four metastatic cancer and vedolizumab is being used to treat checkpoint inhibitor-induced inflammatory bowel disease

CONTINUATION OF COVERAGE CRITERIA (new to the plan/renewals):†

- The prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy including individual improvements in functional status related to therapeutic response.
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, clear skin, those with high supra-therapeutic trough levels, etc.

†Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

IMPORTANT INFORMATION:
While the anti-TNF agents have been deemed safe in pregnancy, there are product specific differences. Certolizumab does not appear to cross the placenta and therefore, it may pose less risk to a fetus. For pregnant women established on anti-TNF therapy, therapy interruptions prior to delivery are recommended with infliximab (8-10 weeks prior) and adalimumab (4-5 weeks prior). For pregnant women established on anti-TNF therapy and requiring an adjustment to anti-TNF therapy, consideration will be given to use of certolizumab.

Contraindications to therapy are based on package label and must be clearly documented in the clinical notes included with request. Review of the package label for black box warnings and absolute contraindications as needed. Patient specific contraindications will be documented in the request.

Inadequate Disease Control of UC/CD:
Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc) and/or recent endoscopy results demonstrating ongoing inflammation

Steroid Dependence:
-Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis
-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs
-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin
-endoscopy, colonoscopy, sigmoidoscopy

Ulcerative Colitis Disease Severity:
Based on the degree of presentation of the signs and symptoms and change in baseline inflammatory status
Moderate disease - more than four stools per day with minimal signs of toxicity, anemia, abdominal pain, low grade fever
Severe disease - more than six bloody stools per day, fever, tachycardia, anemia, elevated ESR or CRP

Crohn's Disease Classification:
Stricturing - narrowing of bowel that may cause bowel obstruction
Penetrating - fistulae may form between bowel and other structures
Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

1. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020; 158:1450-1461.
2. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
3. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.
4. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.

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P&T Revision Date: 10/15/2024
Last Revised: 10/15/24 – Updated duration limit

Velmanase alfa-tycv (Lamzede)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0217	Velmanase alfa-tycv (Lamzede)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of alpha-mannosidosis
- Disease is confirmed by one of the following:
  - Deficiency in alpha-mannosidase enzyme activity as measured in fibroblasts or leukocytes.
  - Molecular genetic testing confirms mutations in the MAN2B1 gene.
- Treatment is only for non-central nervous system disease manifestations (e.g., large head, prominent forehead, protruding jaw, skeletal abnormalities)

CRITERIA FOR CONTINUATION/RENEWAL*:

- Patient does not show evidence of progressive disease while on therapy as evidenced by one of the following:
  - Reduction in serum oligosaccharide concentration from baseline
  - Improvement in clinical signs and symptoms from baseline (e.g., 3-minute stair climbing test, 6-minute walking test, pulmonary function, quality of life)

*Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Guideline Note

Effective Date:	01/01/2025
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P&T Review Date:	04/01/2024

Voretigene Neparovec (Luxturna)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3398	Voretigene neparovec (Luxturna)	Medical Benefit-Restricted	One treatment per eye	12 months

CRITERIA FOR COVERAGE:
- Diagnosis of inherited retinal dystrophy with biallelic RPE65 gene mutations
- Visual acuity of ≤ 20/60 OR visual field ≤ 20 degrees in both eyes
- Clinical documentation of sufficient viable retinal cells (such as retinal thickness > 100 microns within the posterior pole on spectral domain optical coherence tomography)

CRITERIA FOR QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based rationale for using a dosing regimen outside of the quantity limit

CRITERIA FOR DURATION EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale based on sufficient published literature to support retreatment

FOR QUARTZ BADGERCARE PLUS AND/OR MEDICAID SSI COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

Created: 04/20
Effective: 08/01/2023 Client Approval: P&T Approval: N/A