MEDICAL BENEFIT ONLY MEDICATION PRIOR AUTHORIZATION CRITERIA

These medication prior authorization criteria apply to State and Local Government members, BadgerCare Plus members, and other persons whose Quartz benefits ONLY include coverage of drugs given by a health care provider (medical benefit)

August 15, 2021

Medical Benefit Drug

Prior Authorization Criteria

Afamelanotide (Scenesse)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- Diagnosis of Erythropoietic Protoporphyria (EPP)
- Adult patients
- 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.

Generic Name	Brand Name	GCN	HICL	Exception/Other
Agalsidase Beta	Fabrazyme			J0180

Agalsidase Beta (Fabrazyme®)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Agalsidase Beta (Fabrazyme)	Medical Benefit-Restricted (Infusion)	1mg/kg IV infusion every two weeks	None

CRITERIA FOR COVERAGE:

- Diagnosis of Fabry's Disease
- Prescribed by or in consultation of an expert in the treatment of Fabry's Disease
- Will not be used in combination with migalastat

Alglucosidase alfa (Myozyme, Lumizyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Alglucosidase alfa (Myozyme, Lumizyme)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Covered for persons with a diagnosis of Pompe disease

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

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

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

Bezlotoxumab (Zinplava)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE: All criteria must be met

- Has a confirmed diagnosis of current C diff infection and a positive stool test for toxigenic C difficile from a recent stool sample
- Prescribed by, or in consultation with, an Infectious Disease specialist
- Person is 18 years or older
- Has recurrent/refractory C diff infection
- Must be currently on standard of care antibiotics for C diff (vancomycin, fidaxomicin)
- Person has had a therapeutic failure, intolerance, or contraindication to fecal microbiota transplantation (FMT) unless FMT is not currently available

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

Biologic Therapy for Dermatology
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits (maintenance/28 days)	Approval Limits
Infliximab-biosimilar (Inflectra, Renflexis, Ixifi, Avsola)	Medical Benefit Restricted	N/A	12 months
Tildrakizumab (Ilumya)	Medical Benefit Restricted	NA	12 months
Ustekinumab (Stelara)	Medical Benefit Restricted	N/A	12 months
Infliximab-brand (Remicade)	Medical Benefit Not Covered	N/A	12 months

PSORIASIS/DERMATOLOGY GENERAL CRITERIA FOR COVERAGE:

- Prescribed by a Dermatologist
- Therapy must not be used in combination with other biologic DMARD (i.e. TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc)
- Diagnosis as listed with prerequisite therapy

1. Diagnosis of severe plaque psoriasis (PP)
- Significant functional disability, BSA involvement (>30%) **AND**
- Clinical failure/intolerance to at least ONE prior therapy.

2. Diagnosis of moderate to severe plaque psoriasis
- with significant functional disability, BSA involvement (>10%) **OR** debilitating palmar/plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals or intertriginous areas **AND**
- Clinical failure of prior therapy or contraindication to:
  - Topical: (e.g. topical corticosteroids, calcipotriene, retinoids) AND
  - Oral Therapy: (e.g. methotrexate, {DOES NOT include apremilast} AND
  - Phototherapy: (e.g. broad band UVB, narrow band UVB, PUVA, excimer)
    - If clinic-based phototherapy- record of phototherapy episodes provided. Adherence defined as 3 times per week for one month or if necessary, modified regimen based on required adjustments for tolerability
    - If home-based phototherapy- provision of data log recording use and dose adjustments as need for tolerability

- *Details including phototherapy, medication, dose, potency, frequency, duration must be provided for each therapy.* Failure is defined as the inability to **achieve a clinically significant reduction in** plaque thickness and/or erythema and/or scaling and/or itching and lack of **clinically significant** reduction in the BSA despite adherence to prescribed regimen for a minimum of 12 weeks (topical, systemic) and 4 weeks at maintenance phototherapy. Inability to attend phototherapy sessions will not constitute failure.

3. Hidradenitis supparativa (HS)
- Prescribed by a Dermatologist

- Severe and/or refractory disease (Hurley II/Hurley III stage) with lesions despite previous treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

4. For psoriatic arthritis (PsA), refer to the Rheumatology Biologic Therapy criteria

DRUG SPECIFIC CRITERIA FOR COVERAGE:

For infliximab biosimilar (PP, HS)

- General criteria met

For tildrakizumab:

- General criteria met
  AND
- Failure/ intolerance to two biologic DMARDs

For ustekinumab

- General criteria met
  AND
- Failure/ intolerance to four biologic DMARDs
- Documentation of inability to self-administer injections

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

CRITERIA FOR CONTINUATION OF THERAPY: (12 month renewal or persons new to the plan)

- 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.).
- 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**.**

Biologic Therapy for Gastroenterology
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit (maintenance/28 days) based on indication	Approval Limits
Infliximab Biosimilar infusion (Inflectra, Renflexis, Ixifi, Avsola)	Medical Benefit Restricted	NA	12 months
Vedolizumab (Entyvio)	Medical Benefit Restricted	N/A	12 months
Natalizumab (Tysabri)	Medical Benefit Restricted	NA	12 months
Infliximab BRAND infusion (Remicade)	Medical Benefit Not Covered	N/A	12 months
Ustekinumab (Stelara)	Medical Benefit Restricted	N/A	12 months

GASTROENTEROLOGY INDICATION GENERAL CRITERIA FOR COVERAGE:

- Prescribed by a Gastroenterologist
- Biologic therapies are not used in combination with other biologic DMARD therapies. Previously authorized biologic therapies will no longer be authorized when a new biologic therapy authorization is approved.
- Diagnosis of inflammatory bowel disease as described below.

1. **Diagnosis of moderate to severely active Crohn's disease in a high-risk individual (see definition) OR in a low-risk individual AND** intolerance/contraindication to 2 conventional therapies **OR** inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 2 conventional therapies **OR** demonstrated steroid dependence OR conventional therapy clinically inappropriate based on location of disease.

Therapy options

- Infliximab biosimilar
- Vedolizumab in adults if failure/intolerance of 2 anti-TNF trial,
  - OR contraindication to anti-TNF therapy
  - OR primary non-response to anti-TNF therapy
- Ustekinumab in adults if failure/intolerance of 2 anti-TNF trial
  - OR contraindication to anti-TNF therapy
  - OR primary non-response to anti-TNF therapy and failure/intolerance to vedolizumab or tofacitinib
- Natalizumab
  - General criteria met for diagnosis of moderate to severely active Crohn's disease in adults
  - Failure of two preferred anti-TNF therapies or a contraindication to anti-TNF therapy exists AND failure/intolerance to vedolizumab or ustekinumab
  - Must be used as monotherapy (without immunomodulatory therapy)
  - Patients and prescriber must be enrolled in the manufacturer TOUCH Risk-Management Program. Refer to touchprogram.com for details

2. **Diagnosis of moderate to severely active ulcerative colitis in a high-risk individual**

Therapy options (after short course of corticosteroids at least 2-4 weeks unless contraindicated)

- Infliximab biosimilar OR Vedolizumab
- Ustekinumab in adults

- If prior failure/intolerance of 2 anti-TNF therapy
- OR contraindication to anti-TNF therapy AND failure/intolerance to vedolizumab
- OR primary non-response to anti-TNF therapy AND failure/intolerance to vedolizumab

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS (listed drugs only):
For reduced interval or increased dose for ustekinumab (dose other than 90mg, interval less than every 8 weeks)

- Failure of a two-month trial of every 8 week therapy after completion of induction dosing regimen
- Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies.
- Provision of published literature supporting dose increase and/or frequency
- Failure of evidence-based first line alternatives

CRITERIA FOR CONTINUATION OF THERAPY:(12- month renewal or persons new to the plan)

- Prescriber (gastroenterologist or other specialist if co-managed by Rheumatology) provides clinical documentation from the previous 12 months that documents individual response to therapy, including individual improvement in functional status related to therapeutic response. Provision of recent labs, current symptoms and change in status should be provided to review for improvement and demonstrate effectiveness. Examples of documentation include laboratory assessment (i.e. CRP, hemoglobin, ESR, WBC, albumin, etc), symptom assessment (i.e. bleeding, stooling pattern, abdominal pain, extraintestinal complaints, fatigue, fever, etc) or recent endoscopy results.

- 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.

DEFINITIONS OF TERMS:

Inadequate Disease Control:
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

High Risk in Ulcerative Colitis:
-Patient with extensive colitis, deep ulcers, age<40 years, High CRP and ESR, steroid-requiring disease, history of hospitalization, *C difficile* infection, CMV infection

OR
-Low risk patient (with limited anatomic disease or mild endoscopic disease) AND inability to achieve remission on induction and maintenance therapy with conventional agents **OR** achieved remission on induction and maintenance therapy but has relapsed after steroid taper (primary non-response or secondary loss of response)

High Risk in Crohn's Disease:
-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)

Induction and Maintenance Therapy with Conventional Agents:
-Conventional therapy with immunomodulator therapy such as azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine as clinically appropriate based on location of disease
Contraindications to conventional agents will be considered as noted in criteria: some specific examples include: methotrexate- concerns related to teratogenicity in females and effects on sperm in males thiopurines (azathioprine, mercaptopurine)- EBV negative status and lymphoma risk,

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 or elevated ESR or CRP

Primary non-response to anti-TNF therapy: PNR- change drug class
Lack of response to therapy as assessed after induction regimen, (i.e. approximately 12 weeks into therapy).and the inability to achieve steroid-free complete remission, despite dose optimization. This can be managed by evaluation of inflammation (is there evidence of inflammatory activity causing lack of perceived response or something else?), dose escalation, addition of immunomodulator or by changing to a different drug or class of drug.

Secondary loss of response to anti-TNF therapy: SLR-change individual drug
Re-emerging symptoms appear where they were previously controlled and are due to inflammation and not other causes. (i.e. irritable bowel disease, infection, non-inflammatory component of IBD, etc). The inability to maintain steroid-free complete remission after achieving symptomatic response. This can be managed by assessment of drug concentrations and antibody levels to determine if dose increase or

therapy change to different drug. It would be reasonable to use same class of drug (i.e different anti-TNF). .

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. Dassopoulos T, Cohen RD, Scherl EJ, Schwartz RM, Kosinski L, Regueiro MD. Ulcerative Colitis Care Pathway. *Gastroenterology.* 2015;149(1):238-245.
2. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. *Gastroenterology.* 2014;147(3):702-705.
3. Rubin, D. Anathankrishnan A, Siegel C, Sauer B. ACG Clinical Guidelines Ulcerative colitis is Adults. Am J Gastroenterol. 2019; 114 (3) Mar: 384-413.

Biologic Therapy for Rheumatology
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Abatacept infusion (Orencia)	Medical Benefit Restricted	N/A	12 months
Infliximab biosimilar infusion (Inflectra, Renflexis, Ixifi, Avsola)	Medical Benefit Restricted	N/A	12 months
Tocilizumab infusion (Actemra)	Medical Benefit Restricted	N/A	12 months
Ustekinumab (Stelara)	Medical Benefit Restricted	N/A	12 months
Golimumab infusion (Simponi Aria)	Not Covered Medical Benefit	N/A	12 months
Infliximab Brand infusion (Remicade)	Not Covered Medical Benefit	N/A	12 months

Rituximab biosimilar is covered under medical benefit. It is not restricted and does not require prior authorization.

RHEUMATOLOGY INDICATION GENERAL CRITERIA FOR COVERAGE:

- Prescribed by a Rheumatologist
- Biologic therapies are not used in combination with other biologic DMARD therapies. Previously authorized therapies will be no longer authorized when new biologic therapy is authorization is approved.
- Diagnosis as listed with prerequisite therapy

1. **Rheumatoid arthritis (RA)** - moderate to severely active established (disease duration of greater than 6 months), reactive arthritis, or juvenile idiopathic arthritis (JIA)
   - Documented failure with a 3-month trial of methotrexate at therapeutic doses unless contraindicated

   OR
   - Persons intolerant to, or with a contraindication to MTX therapy should fail an adequate trial (3 months) with another disease modifying anti-rheumatic drugs such as hydroxychloroquine, sulfasalazine, leflunomide or minocycline

2. **Early RA** (less than 6 months disease duration) with feature of poor prognosis (at least one item) 1. Functional limitations (based on HAQ or similar tool) 2. Extraarticular disease (e.g. presence of rheumatoid nodules, RA vasculitis or Felty's syndrome (rheumatoid arthritis with splenomegaly and neutropenia) 3. positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies (anti-CCP antibodies) 4. bony erosions on X-ray.

3. **Ankylosing spondylitis (AS)** not controlled by a 2-month trial of scheduled prescription doses of two different NSAIDs (such as naproxen, nabumetone, diclofenac, etc.)

4. **Active Non-Radiographic Axial Spondyloarthropathy (NR-SpA)-** not controlled by a 2-month trial of scheduled prescription doses of two different NSAIDS (such as naproxen, nabumetone, diclofenac, etc)

5. **Moderate to severely active psoriatic arthritis (PsA)** and documented failure/intolerance to adequate trial (minimum 3 months) of methotrexate therapy (unless contraindication)

6. **Non-infectious uveitis** verified by an ophthalmologist or other eye specialist and ongoing symptoms despite an adequate trial with BOTH topical glucocorticoids and at least one systemic immunomodulator (e.g. oral corticosteroids, methotrexate, azathioprine, mycophenolate, or cyclosporine)

7. **Behcet's disease** with oral ulcers/mucocutaneous involvement – consider after topical steroids, colchicine (EULAR 2018)

8. **Systemic juvenile idiopathic arthritis (SJIA)** or adult-onset Still's disease AND Failure of an adequate trial (3 months) of corticosteroids and methotrexate

9. **Giant cell arteritis (GCA)** which has relapsed despite use of corticosteroids or methotrexate OR Contraindication to methotrexate and steroids OR Inability to taper corticosteroids

10. **Systemic sclerosis-associated interstitial lung disease (SSc-ILD)** diagnosed by rheumatologist or pulmonologist, medical documentation showing decline in pulmonary function despite use of at least one standard treatment (i.e. mycophenolate, cyclophosphamide or azathioprine) OR Contraindication to use of standard agents.

DRUG-SPECIFIC CRITERIA FOR COVERAGE:

For abatacept
- General criteria met AND Diagnosis of RA, JIA, PsA
- Failure/intolerance of two biologic DMARDs OR Contraindication to anti-TNF therapy
- Failure of adequate trial of self-injection (subcutaneous) or inability to self-administer abatacept injection.

For infliximab biosimilar
- General criteria met AND Diagnosis RA, AS, reactive arthritis, PsA, SJIA

For tocilizumab
- General criteria met AND Failure of adequate trial of self-injection (subcutaneous) or inability to self-administer tocilizumab injection.
- Diagnosis of moderate to severely active established RA, JIA or reactive arthritis AND Failure/intolerance to two biologic DMARDs OR Contraindication to anti-TNF therapy
  OR
- For Diagnosis of giant cell arteritis, SJIA, SSc-ILD
- For Intravenous only- Approval of therapy for chimeric antigen receptor (CAR) T cell to treat T-cell –induced severe or life-threatening cytokine release syndrome (CRS) in patients two years of age or older

For ustekinumab
- General criteria met AND Diagnosis of PsA
- Failure/intolerance to four biologic DMARDs
- Failure of adequate trial of self-injection (subcutaneous) or inability to self-administer ustekinumab injection.
- **FOR CLINIC ADMINISTRATION**- documentation of inability to complete self-injection at home. Note: infusion is only indicated for inflammatory bowel disease for one dose.

CRITERIA FOR CONTINUATION OF THERAPY (12-month renewal or persons new to the plan):
- Prescriber provides clinical documentation from the previous 12 months that describes response as stable disease or improvement seen on therapy. Examples of improvement include: laboratory assessment (i.e. C-reactive protein, ESR, anemia improvement), symptomatic improvements (i.e. fatigue, function, HAQ score if available, joint pain).
- Restrictions to specific network pharmacies and participation in medication management programs may apply.
- 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 therapies that have BOTH infusion and self-injection, use of self-injection first must have been completed before continuation or consideration of infusion therapy

Botulinum toxin (Botox, Dysport, Myobloc, Xeomin)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Botulinum toxin (Botox, Dysport, Myobloc, Xeomin)	Medical Benefit-Restricted	4 treatments per 12-month period for migraine headaches	For use in migraine headaches: yearly renewals to document efficacy Other indications: indefinite unless noted

CRITERIA FOR COVERAGE:
The clinician must rule out other causes of the condition and address (if appropriate) prior to submitting a request for coverage of botulinum toxin.

- Cervical Dystonia (Spasmodic Torticollis)-defined by clonic and/or tonic involuntary contractions of multiple neck muscles with sustained head torsion and/or tilt and limited range of motion in the neck that has endured for six months or longer.
- Hemifacial Spasm
- Esophageal Achalasia**:** In persons who are considered high-risk (due to age or other co-morbidities) for standard treatments including pneumatic balloon dilation and myotomy, or those who have failed previous treatment (e.g. CCB, nitrates) or as a temporizing measure prior to surgical intervention or as an alternative to surgical intervention
- Laryngeal spasm (spasmodic dysphonia/tremor)
- Cricopharyngeal spasm
- Strabismus
- Blepharospasm
- Chronic anal fissure unresponsive (e.g. nocturnal bleeding, pain) to an adequate trial of conservative therapeutic measures
- Gustatory hyperhidrosis (Frey's syndrome) following parotid surgery

The following conditions being treated must result in functional impairment (interference with joint function/mobility, interference with activities of daily living)

- Spasticity
  - Cerebral Palsy: in addition to physical/occupational therapy, conventional therapies (i.e. baclofen), or splinting
  - Upper and lower extremity spasticity (resulting from a stroke, traumatic or non-traumatic spinal cord injury, multiple sclerosis or other demyelinating disease of the central nervous system, traumatic brain injury or other central process) as a component of a rehabilitation and strengthening program
- Torsion dystonia**:** Oral therapies failed or were not tolerated
- Congenital muscular torticollis**:** Conservative treatment including physical therapy or stretching failed
- Focal hand dystonia
- Orofacial dyskinesia from TMJ disorder after trial of oral splits or failure of medication therapy

- Sialorrhea**:** When alternative treatments (e.g., anticholinergics or radiation to involved glands) failed or were not tolerated
- Urinary incontinence
  - Detrusor sphincter dyssynergia – 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 – Persons using clean intermittent self-catheterization who have incontinence and are unable to tolerate anticholinergics.
  - Overactive bladder- in persons who are refractory to behavioral modification, intolerant to anticholinergic therapies, and must be able to undergo post-void residual evaluation and self-catheterization.
- Facial dyskinesis due to aberrant nerve regeneration.
- Hyperhidrosis- **when causing persistent or chronic cutaneous conditions** (e.g., skin maceration, dermatitis, fungal infections)
  - 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
- Migraine Headache
  - Suffers from chronic daily headaches (at least 15 days/month) that are not rebound due to medication overuse
  - Has failed trials of at least three preventative medications (i.e. beta blockers, anticonvulsants, TCAs, calcium channel blockers, CGRP agents, etc.)
  - Has been disabled by the headaches (e.g. unable to work/attend school, unable to participate in ADLs, supported by headache diary, etc.) This can be described as moderate to severe disability by Migraine Disability Assessment (MIDAS test)
  - Person is seen, and BoNT 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)

- **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 REAPPROVAL/CONTINUATION OF THERAPY:*
for MIGRAINE HEADACHES:

- Provider provides clinical documents from the previous 12 months detailing individual response to therapy (specific details provided regarding symptom improvement, decreased frequency and severity of headaches, improved ability to participate in therapies/ADLs, improved MIDAS score, less medication use, fewer ER/UC visits, ability to return to work, etc.).

for all Other Diagnoses:

- 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 BADGERCARE 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

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

Positive Allosteric Modulators of $GABA_A$ Receptors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Brexanolone (Zulresso)	Medical Benefit-Restricted	None	One infusion per year

CRITERIA FOR COVERAGE (all of the following must be met):

- Has a diagnosis of moderate or severe postpartum depression
- Person is 18 years or older and ≤ 9 months postpartum
- Symptoms began within the third trimester and/or no later than 12 weeks after delivery
- Person meets ONE of the following:
  - Documentation shows potential risk of harm to self or others.

  OR
  - Documentation shows 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.

Burosumab (Crysvita)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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 BADGERCARE 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.

Complete Protein C5 Inhibitors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Eculizumab (Soliris)	Medical Benefit Restricted	None	▪ PNH/aHUS: Initial approval 12 months ▪ PNH/aHUS: Continuation indefinite ▪ M. Gravis: 12 months ▪ NMOSD: 12 months
Ravulizumab (Ultomiris)	Medical Benefit Restricted	None	

INITIAL CRITERIA FOR COVERAGE of ravulizumab or eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH):

- Confirmed diagnosis of PNH by flow cytometry:
    - Prescribed by, or in consultation with, a Hematologist or Oncologist.
    - Document baseline hemoglobin (≤ 9 mg/dL with symptoms of anemia), lactate dehydrogenase level (LDH ≥ 1.5 X ULN) and/or number of transfusions in last year.
    - Documentation of the clinical manifestations of disease (e.g. major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations).
    - Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diptheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.

INITIAL CRITERIA FOR COVERAGE of ravulizumab or eculizumab for the treatment of atypical hemolytic uremic syndrome (aHUS):

- Diagnosis of atypical hemolytic uremic syndrome (aHUS):
    - Prescribed by, or in consultation with, a Hematologist, Nephrologist or Oncologist.
    - Document baseline level of one or more values (e.g. lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange (PLEX)/infusion requirements).
    - Documentation states that Thrombotic Thrombocytopenic Purpura (TTP) and Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out. The secondary cause of aHUS is stated if known. (eculizumab is not indicated for STEC-HUS).
    - Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diptheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.

INITIAL CRITERIA FOR COVERAGE of eculizumab for the treatment of 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 Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 6 AND document a baseline level of one or more values (e.g. number of Myasthenia Gravis exacerbations/hospitalizations in the past year, number of PLEX or intravenous immune globulin (IVIG) infusions in the past year and/or Quantitative Myasthenia Gravis (QMG) score).
- Failure[2] of two immunosuppressive therapies for at least 6 months with a baseline refill pattern of at least 80% adherence. If intolerance occurs, one other immunosuppressive agent must be tried:
  - Immunosuppressive therapies include: prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus or rituximab.
  - If all immunosuppressive agents are contraindicated or not clinically appropriate, justification must be documented, and the requirement *may be waived.*
- Failure[*] of at least one of the following treatments:
  - Failure, intolerance, or contraindication to at least 3 months of therapeutic doses of IVIG
    OR
  - Failure, intolerance or contraindication to PLEX given at least four times per year without symptom control.
- Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diptheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.

[*] Failure to M. Gravis therapy is defined as a substantial increase in pretreatment clinical manifestations of the disease such as physical function (e.g. breathing, speaking, swallowing, chewing, muscle weakness of the neck), mobility/ambulation (muscle weakness of hands and limbs) and/or fatigue despite 80% adherence to prescribed regimen.

INITIAL CRITERIA OF COVERAGE of eculizumab for the treatment of neuromyelitis optica spectrum disorder (NMOSD)

- Diagnosis of Neuromyelitis Optica Spectrum Disorder confirmed by positive serologic test for anti-aquaporin-4 (AQP4) receptor antibody.
- Prescribed by neurologist, or in consultation with a specialist in the treatment of NMOSD**.**
- At least one core clinical characteristic of NMOSD (e.g. longitudinally extensive transverse myelitis [LETM], optic neuritis, intractable nausea/vomiting/hiccups, etc.).
- 18 years or older.
- Not used in combination with rituximab and no rituximab within the past 90 days.
- No IVIG within the past three weeks.
- No mitoxantrone within the previous 90 days.
- Failure or intolerance to mycophenolate, rituximab, IVIG, or plasma exchange.
- Documentation of completion of the full series of meningococcal vaccinations or as required by REMS program.

CRITERIA FOR CONTINUATION OF COVERAGE

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH):
  - Initiation criteria met.
  - Documentation of improvement or clinical stability, (e.g. improvement in hemoglobin, lactate dehydrogenase level, haptoglobin level and/or number of transfusions in the last year).

  OR
- Diagnosis of atypical hemolytic uremic syndrome (aHUS):
  - Initiation criteria met.

- Documentation of improvement or clinical stability for renewal (e.g. improvement in lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange (PLEX) infusion requirements).

OR

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease:
  - Initiation criteria met.
  - MG ADL score must improve with at least a 3-point reduction from baseline.
  - Documentation of improvement or clinical stability for renewal (e.g. number of myasthenia gravis exacerbations/hospitalizations in the past year, number of PLEX/IVIG infusions in the past year and/or QMG score).

OR

- Diagnosis of Neuromyelitis optica spectrum disorder:
  - Initial criteria met.
  - Documentation of improvement or clinical stability for renewal (e.g. number of relapses; improved in the past year, number of PLEX/IVIG infusions in the past year and/or vision, strength in arms/legs, reduced pain, vomiting/hiccups, bowel motility, etc).

- For members new to the plan, the prescriber must provide clinical documentation from the previous 12 months of the person's response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above).

*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**.**

OTHER INFORMATION:

Eculizumab is only available through a restricted program: Risk Evaluation Mitigation Strategy (REMS) and prescribers must be enrolled in the program 1-888-765-4747.

Myasthenia Gravis Foundation of America (MGFA) Abbreviated Classifications:

Class	Clinical Signs
I	Any ocular muscle weakness. All other muscle strength normal.
II	Mild muscle weakness with or without ocular muscle weakness
III	Moderate muscle weakness with or without ocular muscle weakness
IV	Severe muscle weakness with or without ocular muscle weakness. Use of feeding tube.
V	Intubation, with or without mechanical ventilation; except for routine postoperative care.

MGFA scoring tools are available here: www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx

American Academy of Neurology 2015 Core Clinical Characteristics for NMOSD

Optic neuritis	Acute brainstem syndrome
Acute myelitis	Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting	Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Canakinumab (Ilaris)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Canakinumab (Ilaris)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of Cryopyrin-associated Periodic Syndromes (CAPS) in adults and children over 4 years of age, Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Familial Mediterranean Fever, tumor necrosis factor receptor-associated periodic syndrome or other periodic syndromes.
  - Failure or intolerance to anakinra (Kineret).

OR

- Diagnosis of systemic juvenile idiopathic arthritis (SJIA) or adult-onset Still's disease.
  - Failure or intolerance to prior therapies such as glucocorticoids or NSAIDs.
  - Failure or intolerance to anakinra (Kineret).

CRITERIA FOR CONTINUATION OF THERAPY (SJIA only):

- Person is new to the plan and the prescriber provides clinical documentation from the previous 12 months showing a response to therapy (improvement or stable 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:
Per product labeling, healthcare providers should administer Canakinumab to the patient.

Caplacizumab-yhdp (Cablivi)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

All of the following must be met:

- Has a diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one ADAMST13 level below 20 percent
- Person is 18 years or older
- 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

Cerliponase Alfa (Brineura)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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)
- Age 3 years or older
- 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.

Prophylactic Calcitonin Gene-Related Peptide (CGRP) Inhibitors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Year	Approval Limits
Eptinezumab-jjmr (Vyepti)	Medical Benefit-Restricted	Four IV infusions	Initial: 12 months Renewal: Indefinite

INITIAL CRITERIA FOR COVERAGE for migraines (all of the following must be met):

- Prescribed by, or consultation with, a provider experienced in the medical management of migraine.
- Age 18 or older
- Person has at least 4 migraine days per month as supported by documentation.
- Person has had a treatment failure with at least 2 generic preventive migraine medications (e.g. anti-hypertensives, antiepileptics, antidepressants, botulinum toxin [chronic migraine only]). Failure is defined as a therapeutic failure of least a 6-week trial of each generic preventive medication or person is intolerant to the medication.
- **Failure* or intolerance to two self-administered prophylactic subcutaneous CGRP inhibitors**
- Person is disabled by the headaches (e.g. unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score).
- Combination therapy of two CGRP monoclonal antibody inhibitors will not be covered.

CONTINUATION CRITERIA FOR REAPPROVAL/CONTINUATION OF THERAPY after 12 months:

- **For Migraine:** Clinical documents from the previous 12 months provided (e.g. clinic note) showing person maintains a response to therapy (specific details regarding symptom improvement, decreased frequency of at least 2 days per month or 50% from baseline, decreased severity of headaches, improved ability to participate in therapies/ADLs, improved MIDAS score, less medication use, fewer ER/UC visits for migraine, ability to return to work/school, etc).
- Combination therapy of two CGRP monoclonal antibody inhibitors will not be covered.

*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:

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

IMPORTANT INFORMATION:

***For Migraine:** *Failure to a CGRP inhibitor is defined as an adequate 3-month trial of a monthly dosed CGRP inhibitor or a 6-month trial of a quarterly dosed CGRP inhibitor and the person did not experience:

-reduced frequency of at least 2 fewer migraines per month or 50% reduction from baseline, OR

-reduced severity of headaches, less acute medication use, improvement in MIDAS score, OR

-improvement in the ability to participate in therapies/ADLs/work/school or fewer ER/UC visits, despite 80% adherence to the prescribed preventive regimen.

Corticotropin Gel (Acthar HP)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Corticotropin Gel (Acthar HP)	Restricted	N/A	Initial: 3 months Renewal: 12 months

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
- Failure, contraindication or intolerance to an adequate trial of preferred formulary medications appropriate for the condition

CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:*
- 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:
Vigabatrin (Sabril) is an alternative treatment option for infantile spasm.

Please see www.**acthar**.com for more information regarding availability.

Crizanlizumab-tmca (Adakveo)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/month	Approval Limits
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).

Denosumab (Prolia, Xgeva)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Denosumab (Prolia, Xgeva)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE (Prolia):

- For the treatment of postmenopausal women who have **one of the following diagnosis 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 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):

- Prevention of skeletal-related events in patients with bone metastases from solid tumors

OR

- Multiple myeloma

OR

- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
- Documented intolerance to use of zoledronic acid

OR

- Renal deterioration (an increase in serum creatinine > 0.5 mg/dL over baseline in patients within 3 months following use of zoledronic acid) or a calculated CrCl < 30 ml/min

OR

- Contraindication to zoledronic acid

OR

- Person at high risk of toxicity related to use of zoledronic acid including baseline renal function impairment (CrCl between 45-60 ml/min)

OR

- 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

- For a different FDA labeled indication that is not addressed above

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 CARE CRITERIA:*

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

*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.

Drugs for Eosinophilic Conditions
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Reslizumab (Cinqair)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE of eosinophilic asthma:

- Failure or intolerance to benralizumab

AND

- Prescribed by an asthma specialist (Allergist, Immunologist, Pulmonologist)
- Age ≥ 18 years
- Has a diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm3 and other causes of eosinophilia such as hyper eosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out

AND

a. Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent** ≥ 3-month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier

**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)

OR

b. Patient has intolerance to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. 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

- 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

NOTE: 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

CRITERIA FOR CONTINUATION/RENEWAL for eosinophilic asthma*:

- The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing response to therapy such as:
  - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids to treat/prevent exacerbations
  - Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
  - Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings
  - Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

NOTE: 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

*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.

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

Table 2. High Dose Corticosteroid

Drug	High Daily Dose (Adult)
Beclomethasone HFA 40 or 80 mcg/puff	>400 mcg
Budesonide DPI 90, 180 or 200 mcg/inhalation	>640 mcg
Ciclesonide HFA 80 or 160 mcg	> 320 mcg
Flunisolide HFA 80 mcg/puff	>640 mcg
Fluticasone HFA/MDI: 44, 110,mcg/puff DPI: 50, 100, 250 mcg/inhalation	 >500 mcg >500 mcg
Mometasone DPI 200 mcg/inhalation	>440 mcg

Edaravone (Radicava)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

ALL OF THE FOLLOWING MUST BE MET:

- 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
- Person is currently using riluzole or has a documented contraindication/intolerance/or lack of therapeutic effect of therapy

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

Generic Name	Brand Name	GCN	HICL	Exception/Other
Elapegademase	Revcovi		45340	

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

CRITERIA FOR CONTINUATION/RENEWAL OF COVERAGE:

- The prescriber provides recent clinical documentation (within 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

Emapalumab (Gamifant)
Prior Authorization Criteria

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

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 related specialty
- Person is currently taking and will continue treatment with dexamethasone
- Overall treatment plan includes a hematopoietic stem cell transplantation (HSCT)
- Medical documentation is provided to show continued HLH signs and symptoms despite one of the following:
  - Prior treatment with at least two standard non-steroid HLH therapies (i.e. etoposide, alemtuzumab, antithymocyte globulin) in combination with a steroid medication
    OR
  - Retreatment with a previously effective therapy
    OR
  - Objective medical rationale for why first and second-line treatments cannot used

- Evidence 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)

CONTINUATION OF COVERAGE CRITERIA:

- For persons new to plan who are established on therapy, medical documentation must be provided to show that the initial criteria were met.
- Medical documentation from the past 6 months is provided to show both of the following: a 50% improvement in at least 3 signs/symptoms of active disease and 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 BADGERCARE 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.

Esketamine Nasal Inhalation (Spravato)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Esketamine (Spravato)	Medical Benefit-Restricted	None	12 Months

CRITERIA FOR COVERAGE (all of the following must be met):

- Has a diagnosis of treatment-resistant depression
  - 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 3 antidepressants
    OR
  - Symptoms of depression continue and there is documentation to show treatment limiting side effects with 3 antidepressants.
- Medication is prescribed by, or in consultation with, a Psychiatrist
- Person is 18 years or older
- Nasal esketamine will be used in combination with an antidepressant medication

CRITERIA FOR CONTINUATION OF COVERAGE/REAPPROVAL after 12 months:

- 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

Exon Skipping Drugs for Duchenne Muscular Dystrophy
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Casimersen (Amondys 45)	Medical Benefit-Restricted	None	12 months
Eteplirsen (Exondys 51)	Medical Benefit-Restricted	None	12 months
Golodirsen (Vyondys 53)	Medical Benefit-Restricted	None	12 months
Viltolarsen (Viltepso)	Medical Benefit-Restricted	None	12 months

***Only covered for participants covered by the Quartz Federal Employee Health Benefit (FEHB) plan. Excluded for other benefits.**

CRITERIA FOR COVERAGE:

- Diagnosis of Duchenne muscular dystrophy (DMD) with clinical documentation of a confirmed mutation of the DMD gene amendable to exon skipping by the requested drug
- Prescribed and monitored by a Neurologist or other expert in the treatment of pediatric neuromuscular disorders
- Person has a Forced Vital Capacity (FVC) ≥ 30% predicted
    - Can ambulate ≥ 180m in a 6-minute walk test (6MWT)

    OR
    - Brooke upper extremity function rating scale score ≤ 5
- On guideline recommended steroid therapy

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

- Initial criteria met

FOR BADGERCARE 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.

Hemophilia Factor Products
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Factor XIII Products			
Corifact	Medical Benefit-Restricted	None	None
Factor IX Products			
Eloctate, Esperoct, Nuwiq, Afstyla, Adynovate, Recombinate, Kovaltry, Kogenate FS, Helixate FS, Advate, Koate, Hemofil, Monoclate-P, Xyntha, Novoeight, JIVI, Tretten, Obizur	Medical Benefit-Restricted	None	None
Von Willebrand Factor Products			
Wilate, Alphanate, Humate-P, Vonvendi	Medical Benefit-Restricted	None	None
Factor VII Products			
NovoSeven RT, Sevenfact	Medical Benefit-Restricted	None	None
Factor X Products			
Coagadex	Medical Benefit-Restricted	None	None
Anti-Inhibitor Products			
Feiba NF	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

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

OTHER INFORMATION:

For Hemlibra (emicizumab-kxwh), refer to the individual Prior Authorization criteria.

Fosdenopterin (Nulibry)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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

Givosiran (Givlaari)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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).

Gonadotropin Releasing Hormone (GNRH) Agonist
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Histrelin implant Yearly (Supprelin LA, Vantas)	Medical (clinic administered)	None	Covered unless excluded by certificate
Leuprolide acetate suspension IM injection (Lupron Depot, Lupron Depot-Ped)	Medical (clinic administered)	None	Covered unless excluded by certificate
Leuprolide acetate suspension Sub Q injections (Eligard, Atrigel, Fensolvi)	Medical (clinic administered)	None	Covered unless excluded by certificate

CRITERIA FOR COVERAGE:

- Medications used for treatment of infertility are excluded from coverage unless specifically noted as covered in the certificate of coverage or included in specific state mandates.
- Medications used for the treatment of gender dysphoria are covered unless specifically excluded in the certificate of coverage.
- Medications used for all other diagnoses (ex. prostate cancer, endometriosis, dysmenorrhea, etc.) are covered and do not require prior authorization on the medical benefit.

The person's current certificate of coverage, SBC, or any related documents will be verified to assess exclusions or mandates with each request.

IMPORTANT INFORMATION

The drug must be obtained by the clinic and billed under the individual's medical benefit.

Hereditary Angioedema Medications
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Month	Approval Limits
C1 esterase inhibitor (Berinert, Cinryze, Haegarda, Ruconest)	Medical benefit-Restricted	Weight-based number of vials (Haegarda)	6 months (Haegarda)
Ecallantide (Kalbitor)	Medical benefit-Restricted	None	None
Icatibant (Firazyr)	Medical benefit-Restricted	None	None
Lanadelumab (Takhzyro)	Medical benefit-Restricted	2	6 months

CRITERIA FOR INITIAL COVERAGE:

- Diagnosis of Hereditary Angioedema (HAE)
  - Low C4 AND low C1 inhibitor level or function OR
  - Normal C1 inhibitor level AND family history of HAE AND high dose antihistamines did not work
- Prescribed by 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
- Requested product will not be used in combination with other HAE medication with the same FDA approved indication

- **For Haegarda and lanadelumab:**
  - Using for treatment of long term prophylaxis
  - History of ≥ 2 attacks per month or person's symptoms are moderate to severe

- **For Cinryze:**
  - Using for treatment of long term prophylaxis
  - History of ≥ 2 attacks per month or person's symptoms are moderate to severe AND failure (no reduction in frequency of attacks or severity of attacks) or intolerable side effects with both Haegarda and lanadelumab OR Age 6- 12 years

CRITERIA FOR QUANTITY EXCEPTIONS:

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

CRITERIA FOR CONTINUATION (new to plan)*:

- Documentation from the previous 12 months of a clinical response with current therapy

CRITERIA FOR CONTINUATION (6-month renewal)*:

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

FOR BADGERCARE COVERAGE (Takhzyro, Orladeyo):
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.

Homozygous Familial Hypercholesterolemia Drug
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Evinacumab (Evkeeza)	Medical Benefit-Restricted	None	Initial: 12 months Renewal: Indefinite

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/RENEWAL 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
- 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.

Immune Globulin
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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	Medical Benefit - Restricted		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, methotrexate) 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

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

- Prescriber provides clinical documentation from the previous 12 months pertinent to the indication of 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.

Generic Name	Brand Name	GCN	HICL	Exception/Other
Inebilizumab-cdon	Uplizna			J3590 J9399

Inebilizumab-cdon (Uplizna)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- Diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) with positive anti-aquaporin-4 (AQP4) antibody
- Prescribed by, or in consultation with a Neurologist or specialist in the treatment of NMOSD
- History of ≥ 1 relapse in the past 12 months or ≥ 2 relapses in the past 24 months
- Failure or intolerance to an adequate trial of at least one of the following rituximab, mycophenolate, or azathioprine
- Therapy must not be used in combination with other biologic treatments for NMOSD (examples: rituximab, satralizumab, eculizumab)

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.

Infused Disease Modifying Therapies for Multiple Sclerosis
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Alemtuzumab (Lemtrada)	Medical Benefit-Restricted		None
Natalizumab (Tysabri)	Medical Benefit-Restricted		None
Ocrelizumab (Ocrevus)	Medical Benefit-Restricted		None

CRITERIA FOR COVERAGE FOR RELAPSING FORMS OF MULTIPLE SCLEROSIS (Alemtuzumab, Natalizumab, Ocrelizumab):

- 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 (Gilenya), or cladribine (Mavenclad)
- **OR**
- Intolerance or labeled contraindication to at least two oral DMTs
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

CRITERIA FOR COVERAGE FOR PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS (Ocrelizumab):

- Clinical documentation of a diagnosis of a progressive form of multiple sclerosis
- Drug prescribed by, or in consultation with, a Neurologist or other expert in the treatment of multiple sclerosis
- Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

CRITERIA FOR CONTINUATION OF THERAPY (new to plan)*:

- Clinical assessment from the treating Neurologist from the previous 12 months documenting a relapsing form of multiple sclerosis (all drugs) or progressive form of multiple sclerosis (ocrelizumab only) 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).

IMPORTANT INFORMATION:
For criteria for coverage of natalizumab for patients with a diagnosis of inflammatory bowel disease please see the Quartz Biologic Therapies for Gastroenterology criteria.

Infused Oncology Agents
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Dose	Approval Limits
Atezolizumab (Tecentriq)	Medical Benefit-Restricted	None	Up to 12 months
Avelumab (Bavencio)	Medical Benefit-Restricted	None	Up to 12 months
Belantamab (Blenrep)	Medical Benefit-Restricted	None	Up to 12 months
Calaspargase (Asparlas)	Medical Benefit-Restricted	None	Up to 12 months
Carfilzomib (Kyprolis)	Medical Benefit-Restricted	None	Up to 12 months
Cemiplimab (Libtayo)	Medical Benefit-Restricted	None	Up to 12 months
Daratumumab (Darzelex, Darzelex Faspro)	Medical Benefit-Restricted	None	Up to 12 months
Durvalumab (Imfinzi)	Medical Benefit-Restricted	None	Up to 12 months
Elotuzumab (Empliciti)	Medical Benefit-Restricted	None	Up to 12 months
Enfortumab (Padcev)	Medical Benefit-Restricted	None	Up to 12 months
Iobenguane I-131 Therapeutic (Azedra)**	Medical Benefit-Restricted	3 (1 diagnostic, 2 therapeutic)	Up to 12 months
Ipilimumab (Yervoy)	Medical Benefit-Restricted	None	Up to 12 months
Lurbinectedin (Zepzelca)	Medical Benefit-Restricted	None	Up to 12 months
Isatuximab (Sarclisa)	Medical Benefit-Restricted	None	Up to 12 months
Lutetium (Lu) 177 (Lutathera)	Medical Benefit-Restricted	4	6 months
Mogamulizumab (Poteligeo)	Medical Benefit-Restricted	None	Up to 12 months
Moxetumomab (Lumoxiti)	Medical Benefit-Restricted	None	6 months
Naxitamab (Danyelza)	Medical Benefit-Restricted	None	Up to 12 months
Necitumumab (Portrazza)	Medical Benefit-Restricted	None	Up to 12 months
Nivolumab (Opdivo)	Medical Benefit-Restricted	None	Up to 12 months
Pembrolizumab (Keytruda)	Medical Benefit-Restricted	None	Up to 12 months
Polatuzumab Vedotin (Polivy)	Medical Benefit-Restricted	None	Up to 12 months
Radium (Ra) 223 (Xofigo)	Medical Benefit-Restricted	None	6 months
Ramucirumab (Cyramza)	Medical Benefit-Restricted	None	Up to 12 months
Sacituzumab Govitecan (Trodelvy)	Medical Benefit-Restricted	None	Up to 12 months
Siltuximab (Sutent)	Medical Benefit-Restricted	None	Up to 12 months
Tafasitamab (Monjuvi)	Medical Benefit-Restricted	None	Up to 12 months
Trabectedin (Yondelis)	Medical Benefit-Restricted	None	Up to 12 months
Tagraxofusp-erzs (Elzonris)	Medical Benefit-Restricted	None	Up to 12 months

***Also known as metaiodobenzylguanidine [MIBG], 131I-MIBG and iodine-131-labeled Iobenguane*

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/RENEWAL OF COVERAGE CRITERIA:*

- 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.

Interferons (Provider Administered)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Interferon alfa-2b (Intron A)	Medical Benefit - Restricted	None	12 months
Interferon alfa-n3 (Alferon N)	Medical Benefit - Restricted	None	12 months
Interferon gamma 1b (Actimmune)	Medical Benefit - Restricted	None	12 months

GENERIAL CRITERIA FOR COVERAGE:

- Medications is billed under the medical benefit
- Must be supplied and administered by a medical provider
- Medications administered in the clinic are not covered when billed under prescription drug coverage
- Treatment diagnosis is not suitable for home/self administration

DRUG-SPECIFIC CRITERIA FOR COVERAGE:

For Intron A:

- Palliative treatment of AIDS related Kaposi's sarcoma **OR**
- External genital or perianal warts **OR**
- Hepatitis B **OR**
- 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.

For Alfernon N:

- External genital or perianal warts

For Actimmune:

- Chronic granulomatous disease OR
- Congenital malignant osteopetrosis

OR

- Other FDA-labeled indications not listed

CRITERIA FOR CONTINUATION OF THERAPY(for renewal or new members):

- Initial criteria met and clinical documentation from the previous 12 months that describes 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, provider samples, and/or vouchers.

IMPORTANT INFORMATION:

- For PA criteria for Pegasys, Sylatron, or Peg-Intron, refer to the Pegylated Interferon PA criteria.
- For criteria for interferon beta (1-a and 1-b) please refer to the multiple sclerosis disease modifying therapy PA criteria.

Letermovir (Prevymis)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Letermovir (Prevymis)	Medical Benefit-Restricted	None	1 Course (up to 100 days post-transplant

CRITERIA FOR COVERAGE:
- Prescribed by, or in consultation with, a Hematologist, Oncologist, Infectious Disease, or Transplant specialist
- Person unable to tolerate/swallow the oral tablet of letermovir
- Covered for CMV prophylaxis in adults post-allogeneic hematopoietic stem cell transplant
- Are cytomegalovirus (CMV)-seropositive recipients (R+) or have CMV positive donor (D+)
- Drug is initiated within the first 28 days post-transplant
- The person does not have active CMV infection (CMV PCR level over 250 IU/ml) and not receiving preemptive treatment (ex. foscarnet)

CONTINUATION OF COVERAGE CRITERIA:*
- Prescriber provides an evidence-based clinical rationale for using a duration beyond 100 days post-transplant
- 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 100 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:
Letermovir should not be given in autologous stem cell transplants.
Use in solid organ transplants is considered experimental and not covered at this time.

Luspatercept (Reblozyl)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

For treatment if 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)

OR

For other FDA approved indications:
- Prescribed by, or in consultation with a specialist in treatment of the requested diagnosis

CRITERIA FOR COVERAGE CONTINUATION after 3 months:*
- 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 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

CONTINUATION 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).

Nusinersen (Spinraza)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Day	Approval Limits
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 BADGERCARE 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%

Omalizumab (Xolair)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Omalizumab (Xolair)	Medical Benefit-Restricted	None	Asthma – 12 months Urticaria: Initial – 6 months Subsequent – 12 months

CRITERIA FOR INITIAL COVERAGE:

ASTHMA
- Diagnosis of allergic asthma
- Age ≥6
- Moderate-to-severe persistent 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.)
- 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 high-dose inhaled corticosteroids (ICS) in combination with long acting beta$_2$ agonist (LABA) or leukotriene modifiers
- Exceptions based on adverse effects from 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
- Omalizumab in combination with an IL-5 inhibitor will only be considered on a case by case basis if each individual agent with combination high dose ICS/LABA did not control symptoms.

URTICARIA
- Person with chronic (at least 3 months), refractory urticaria despite use of ALL of the following:
  - scheduled, high dose non-sedating antihistamines
  - at least one short course of corticosteroids

IMMUNOTHERAPY PROTOCOL
- Immunotherapy (short-term use only) under the supervision of an Allergist

NASAL POLYPS

- Diagnosis of chronic rhinosinusitis with nasal polyposis Prescribed by 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
- Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (ex: nasal polyp score five out of eight)
- Persistent or worsening of nasal polyps despite being on a daily nasal steroid and previous failure or intolerance to one other nasal steroid spray (i.e. failed two nasal sprays or IM injections for polyps with one previous nasal spray)
- Trial and failure, contraindication or intolerance to oral corticosteroids for nasal polyps OR prior surgery for nasal polyps greater than six months ago
- Will be used in combination with a nasal corticosteroid medication
- No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation
- Not used in combination with other biologic therapies/systemic immunosuppressant therapies to treat inflammatory disease or autoimmune disease (eg, rheumatoid arthritis, inflammatory bowel disease, asthma, urticaria)

CRITERIA FOR CONTINUATION*:

ASTHMA

- Documentation in an office visit in the preceding 12 months there was clinical improvement from prior to initiating omalizumab, including at least one of the following:
    - Decreased frequency of corticosteroid use to treat or prevent an exacerbation
    - Decreased frequency of unscheduled clinic, urgent care or emergency department visits due to asthma
    - Increase in percent predicted FEV_1 from pre-treatment baseline
    - Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal wakening wheezing, sustained improvement in ACT scores
    - Reduction use of ICS, leukotriene or beta agonist therapy
- 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

URTICARIA

- Documentation in an office visit in the preceding 12 months there was clinical improvement from prior to initiating omalizumab, including at least one of the following:
    - Decrease in oral corticosteroid use
    - Reduction in exacerbation frequency
    - Reduction in exacerbation intensity

NASAL POLYPS

- Clinical documentation from an office visit from the previous 6-12 months showing response to therapy (e.g. reduction in nasal congestion/obstruction, reduction in nasal polyposis score, 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:
If the medication is going to be administered in the clinic, the medication is not covered under the pharmacy benefit, but may be covered under the medical benefit.
Note: Requests for omalizumab for indications other than asthma and chronic urticaria will be considered experimental as defined in the Certificate of Coverage and are not covered.

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

Table 2. High Dose Corticosteroid

Drug	High Daily Dose	
	Child 5-11	**Adult**
Beclomethasone HFA 40 or 80 mcg/puff	>200 mcg	>400 mcg
Budesonide DPI 90, 180 or 200 mcg/inhalation	>400 mcg	>800 mcg
Budesonide inhaled Inhalation for suspension	>1000 mcg	NA
Ciclesonide HFA 80 or 160 mcg	>160 mcg	> 320 mcg
Flunisolide HFA 80 mcg/puff	≥640 mcg	>640 mcg
Fluticasone HFA/MDI: 44, 110,mcg/puff DPI: 50, 100, 250 mcg/inhalation	>500 mcg >400 mcg	>500 mcg >500 mcg
Mometasone DPI 200 mcg/inhalation	≥440 mcg	>440 mcg

Onasemnogene abeparvovec (Zolgensma)
Prior Authorization Criteria

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

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 BADGERCARE 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

Drug Name	Drug Status	Quantity Limits/Cycle	Approval Limits
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.

Palivizumab (Synagis)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- 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

For infants receiving palivizumab and have been hospitalized with RSV infection, palivizumab will no longer be covered.

CRITERIA FOR A DURATION EXCEPTIONS:

The prescriber provides an evidence-based clinical rationale for requesting a treatment duration outside of the traditional RSV season based on the current year's prevalence data

IMPORTANT INFORMATION:

- The RSV season in Wisconsin is typically from November to April but has extended into May and started earlier in October.
- 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.

Patisiran (Onpattro)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Patisiran (Onpattro)	Medical Benefit-Restricted	None	Initial: 12 months Continuation: Indefinite

CRITERIA FOR COVERAGE:

- Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits
- Prescribed by, or in consultation with, a Neurologist, Cardiologist or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)
- Age ≥ 18
- Trial and failure, contraindication or intolerance to inotersen (Tegsedi) or clinical rationale why inotersen (Tegsedi) cannot be used

CRITERIA FOR CONTINUATION OF COVERAGE:*

- Initiation criteria met
- Clinical documentation from the previous 12 months of response to therapy or documentation of clinical stability (e.g. Karnofsky status, or other functional measure)
- For members new to the plan, the prescriber must provide clinical documentation of the person's initial response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above).

*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 BADGERCARE 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.

Pegfilgrastim
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Fill	Approval Limits
Pegfilgrastim-jmdb (Fulphila)	Medical Benefit-Restricted	1	12 months
Pegfilgrastim-cbqv (Udenyca)	Medical Benefit-Restricted	1	12 months
Pegfilgrastim-bmez (Ziextenzo)	Medical Benefit-Restricted	1	12 months
Pegfilgrastim-apgf (Nyvepria)	Medical Benefit-Restricted	1	12 months
Not Covered			
Pegfilgrastim (Neulasta, Neulasta OnPro)			

CRITERIA FOR COVERAGE of biosimilar pegfilgrastim products (e.g. Fulphila, Udenyca, Ziextenzo, Nyvepria):

- Filgrastim-product was not tolerated or there was a therapeutic failure (e.g. febrile neutropenia or chemotherapy delayed despite maximized filgrastim use)
- Indication/Reason for use of a **filgrastim product** was any one of the following:
    - Nonmyeloid malignancies receiving myelosuppressive chemotherapy with a febrile neutropenia rate of 10% or greater
    - Nonmyeloid malignancies receiving myelosuppressive chemotherapy who are at high risk for developing febrile neutropenia regardless of the expected rate of febrile neutropenia due to ANY of the following:
        - Prior radiotherapy or chemotherapy
        - Extraordinary high doses of myelosuppressive chemotherapy agents
        - Persistent neutropenia
        - History of recurring FN receiving chemotherapy of similar or less intensity
        - Poor performance status
        - Advanced cancer
        - Bone marrow involvement
        - Decreased immune function
        - Current infection
        - Age > 65 years
        - Liver dysfunction (bilirubin >2.0), Renal dysfunction (Creatinine clearance <50)
    - Receiving dose dense chemotherapy regimen
    - Person had febrile neutropenia during prior chemotherapy cycle, when no GCSF therapy was used
    - Chemotherapy dose reduction was not a viable option for preventing febrile neutropenia
    - Prolonged neutropenia caused a delay in chemotherapy treatment

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

Pegloticase (Krystexxa)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- Prescribed by, or in consultation and monitored by a Rheumatologist
- The person has a serum uric acid level > 6.0 mg/dL despite an adequate trial of maximized therapeutic doses of both allopurinol and febuxostat OR allopurinol and febuxostat are not tolerated
- The person has severe symptomatic tophaceous gout (chronic tophaceous gouty arthropathy in ≥ 4 joints or ≥ 1 unstable, complicated, or severe articular tophi) despite appropriate urate lowering therapy (as above) and appropriate NSAID, colchicine, and glucocorticoid use for acute attacks.
- Documentation that the person does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency

CRITERIA FOR CONTINUATION OF THERAPY:*

- Clinical documentation demonstrating the person has achieved and maintained (most recent value must be within the previous 2 months) a serum uric acid level < 6.0 mg/Dl
- 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.**

Restricted Progesterone
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Hydroxyprogesterone compounded	Medical Benefit Restricted	None	See Criteria Below
Hydroxyprogesterone (Makena)	Medical Benefit Restricted	None	See Criteria Below

CRITERIA FOR COVERAGE:

Women in the 2nd trimester (6 fills for 6 months)

- Administration in clinic; covered under Medical Benefit. Clinic must purchase medication for administration in clinic.
- Woman has a singleton pregnancy
- Has a history or preterm birth

(Illinois plans only) For the treatment of infertility (12 fills for 12 months)

- Resident of the state of Illinois
- Documentation of inability to conceive after 12 months of unprotected intercourse or inability to sustain a successful pregnancy OR
- Documentation of a medical condition that renders conception impossible through unprotected intercourse (e.g. congenital absence of the uterus or ovaries) OR
- Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy

CONTINUATION OF COVERAGE CRITERIA:

- 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 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 will not be covered to improve libido or for sexual dysfunction

Pulmonary Hypertension Drugs
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Epoprostenol (Veletri)	Medical Benefit-Restricted	None	None
Treprostinil (Remodulin equiv.)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of pulmonary arterial hypertension
- Prescribed by, or in consultation with, a Cardiologist or Pulmonologist

Restricted Medications with Miscellaneous Codes
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Varies	Medical Benefit-Restricted	Varies	▪ Up to 12 months ▪ IL plan only: • tick-borne disease: indefinite • Mental health condition or substance use disorder condition: indefinite • All other diagnosis: up to 12 months

CRITERIA FOR COVERAGE OF RESTRICTED MEDICATIONS BILLED WITH MISCELLANEOUS HCPCS CODES (non-oncology):

- Failure of an adequate trial, intolerance, or contraindication to clinically appropriate covered alternatives for the person's diagnosis
- FDA approved indications*

*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.

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

- **(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

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.

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:**

- 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.

Restricted Vaccine Criteria
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits/Series	Approval Limits
human papillomavirus vaccine (Gardasil 9)	Medical Benefit-Age Restricted	2-3	One series
Zoster vaccine recombinant (Shingrix)	Medical Benefit-Age Restricted	2	One series
Zoster vaccine live (Zostavax)	Medical Benefit-Age Restricted	1	One series

CRITERIA FOR COVERAGE:
Publication of Advisory Committee on Immunization Practices (ACIP) recommendations within the CDC Morbidity and Mortality Weekly Report (MMWR)

- Human papillomavirus vaccine.
  - Person is between the ages of 9 and 45 years at series initiation or as updated by ACIP
  - **FOR BADERCARE COVERAGE:** Please see Forward Health for criteria or diagnosis restrictions

- Zoster vaccine live (Zostavax):
  - Person is age 60 years or older or as updated by ACIP
    OR
  - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 60 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)
    OR
  - Person has managed Badgercare coverage
    OR
  - Person with coverage with Swedish American Health System: age 55 years or older

- Zoster vaccine recombinant, adjuvanted (Shingrix):
  - Person is age 50 years or older or as updated by ACIP
    OR
  - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 50 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)

IMPORTANT INFORMATION:
For zoster vaccines (Zostavax and Shingrix):
Those with a Medicare Select plan have coverage for the administration of the vaccine, but the vaccine itself is **NOT** covered. The vaccine is covered by the person's Medicare part D (drug) benefit.
Those with Medicare primary and State/Local (ETF) secondary: it is assumed all Medicare primary members have Medicare Part D. If a member has Medicare as primary but did not elect Part D then neither Quartz nor Navitus will pay for the immunization, and the member will have to pay out of pocket for them. If Quartz is primary, coverage of Zostavax will be provided by Quartz for persons 60 and older and coverage of Shingrix will be provided by Quartz for persons 50 and older.

Rilonacept (Arcalyst)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Rilonacept (Arcalyst)	Medical Benefit Restricted	None	None

CRITERIA FOR COVERAGE:

- 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 a Rheumatologist or Immunologist
- Failure or intolerance to an adequate trial of Kineret (Anakinra)

OR

- Diagnosis of symptomatic recurrent pericarditis (i.e. idiopathic or post-cardiac injury pericarditis)
- Prescribed or recommended by a cardiologist

Romosazumab-aqqg (Evenity)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- Medication must be administered by a health care provider
- 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 or after denosumab therapy
- For the treatment of postmenopausal women who have **one of the following diagnosis and the associated criteria**:
    - 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 CARE CRITERIA:*

- 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.

Sebelipase alfa (Kanuma)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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.

Teprotumumab-trbw (Tepezza)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Teprotumumab (Tepezza)	Medical Benefit-Restricted	None	1 course (8 doses)

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**.**

Testosterone
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Testosterone extended-release injection (Aveed)	Medical Benefit-Restricted	None	None
Testosterone implant (Testopel)	Medical Benefit-Restricted	None	None
Testosterone injection (generics, Xyosted)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

Testosterone Injections (generic cypionate and enanthate):

- Diagnosis of gender dysphoria or transsexualism, unless excluded by certificate

OR

- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism with clinically appropriate laboratory data demonstrating androgen deficiency*
- Symptomatic with symptoms other than sexual dysfunction
- Not for decreased libido or other sexual dysfunction

Testosterone Injections (Xyosted):

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

For extended release injections and implants:

- Above criteria met
- Documented trial and failure, contraindication or intolerance to topical testosterone AND non-extended release injections.

CRITERIA FOR CONTINUATION OF THERAPY:*

- Persons new to coverage who are established on therapy with a generic testosterone cypionate or enanthate injection 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.
- For all other testosterone formulations: the above criteria for new starts must be 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**.**

* 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.

Thrombopoietin Receptor Agonists
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Romiplostim (Nplate)	Medical Benefit-Restricted	For acute radiation injury only x1 dose	12 months

PRIOR AUTHORIZATION CRITERIA:

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

OR

- Medical documentation of acute hematopoietic radiation injury and request is for 1 dose

CONTINUATION OF COVERAGE CRITERIA (new to plan)*:

- Persons new to coverage who are established on therapy will have coverage under their drug benefit for up to 12 months. Restrictions to specific network pharmacies and participation in medication management programs may apply.

CONTINUATION OF COVERAGE/RENEWAL CRITERIA (12 month)*:

- 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.

Trilaciclib (Cosela)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Trilaciclib (Cosela)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Prescribed and monitored by a Hematologist or Oncologist
- Treatment diagnosis and regimen follow 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/RENEWAL OF COVERAGE CRITERIA:

- 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.