Banner
University Family Care

Banner Medicaid Internal Criteria Table of Contents

Date(s) of Review and Revision: 4/9/2025

Effective 6.1.25

GLIC001 Behavioral health medications Guideline

APPLICABLE AGENT(S) - PREFERRED medications:

>6 years not prescribed by BH provider

Product Name: haloperidol concentrate, haloperidol tablets, loxapine, perphenazine, thioridazine, thiothixene, generic pimozide, fluphenazine (tablets, concentrate and elixir), trifluoperazine, chlorpromazine (tabs and inj and oral solution), generic ziprasidone, generic aripiprazole, Latuda, generic risperidone (tabs and oral solution), risperidone ODT tabs, generic quetiapine, generic olanzapine (tabs and ODT tabs)

>18 years not prescribed by BH provider

Product Name: Clozapine (tablets and ODT), Aristada, Abilify Maintena, Invega Sustenna, Invega Trinza, Risperdal Consta, Perseris

Initial Approval Criteria:

Medication being requested for an FDA approved dose and indication and there is compendial support

*Please note: Banner Health recommends member is seen by a behavioral health specialist or PCP prescribes in consult with behavioral health provider initially.

Renewal Approval Criteria:

Member continues to meet the above requirements

LENGTH OF AUTHORIZATION

Initial Approval Duration: 6 months
Renewal Approval Duration: 12 months
NOTE: Abilify(Aripiprazole) and Lexapro(Escitalopram) have lifetime approvals.

GLIC002 Botulinum Toxins Guideline

Botulinum Toxins

Applicable agents:

Onabotulinumtoxin A (Botox)

CRITERIA FOR INITIAL AUTHORIZATION:
OnabotulinumtoxinA may be indicated for **1 or more** of the following:

- Achalasia, as indicated by **1 or more** of the following:
  Initial course, as indicated by **ALL** of the following:
  -Achalasia confirmed by esophageal manometry
  -Failure of or patient not candidate for pneumatic dilation or surgical myotomy (eg, elderly patient)
  -No response to pharmacologic treatment (eg, long-acting nitrates, calcium channel antagonists)
  -Other causes of dysphagia (eg, peptic stricture, carcinoma, lower esophageal ring or extrinsic compression) ruled out by upper gastrointestinal endoscopy
  -Progressive dysphagia for liquids and solids

  Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

- Anal fissure, as indicated by **1 or more** of the following:
  Initial course, as indicated by **ALL** of the following:
  -At least 2 months of symptoms, including **1 or more** of the following:
  Nocturnal pain and bleeding
  Postdefecation pain
  -Failure of or intolerance to topical nitrates or topical calcium channel blockers
  -No anal fistula
  -No HIV disease
  -No inflammatory bowel disease

-No perianal cancer
-No previous perianal surgery
-Patient not surgical candidate or has refused surgery

Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

●Blepharospasm, as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 12 years or older
-Blepharospasm, as indicated by **1 or more** of the following:
-Benign essential blepharospasm
-Blepharospasm associated with dystonia
-Blepharospasm associated with facial nerve (cranial nerve VII) disorder such as Bell palsy
-No infection at proposed injection site
-No neuromuscular disease (eg, myasthenia gravis)

Subsequent course, as indicated by **ALL** of the following:

-Age 12 years or older
-Favorable response to prior administration of onabotulinumtoxinA

●Cervical dystonia (spasmodic torticollis), as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 16 years or older
-Neck pain or abnormal head position causing adverse effect on daily functioning
-No fixed contractures causing decreased neck range of motion
-No infection at proposed injection site
-No neuromuscular disease (eg, myasthenia gravis)

Subsequent course, as indicated by **ALL** of the following:

-Age 16 years or older

Favorable response to prior administration of onabotulinumtoxinA

●Hemifacial spasm, as indicated by **1 or more** of the following:

Initial course
Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

●Hyperhidrosis (axillary), as indicated by **1 or more** of the following
Initial course, as indicated by **ALL** of the following:
-Age 18 years or older
- Axillary hyperhidrosis, with Hyperhidrosis Disease Severity Scale (HDSS) score of 2 or more
-Inadequate response to 1 or more months of topical treatment (eg, aluminum chloride), as evidenced by no improvement in HDSS score, or patient intolerant to topical treatment due to unacceptable skin irritation
-No infection at proposed injection site
-Secondary causes of hyperhidrosis (eg, hyperthyroidism) have been evaluated and, if necessary, treated.
-Significant effect of hyperhidrosis upon daily activities

Subsequent course, with favorable response to prior administration of botulinum toxin A

●Laryngeal dystonia (ie, adductor spasmodic dysphonia), as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:
-Adductor-type spasmodic dysphonia confirmed by fiberoptic laryngoscopy
-Moderate to severe difficulty in phonation

Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

●Migraine headache prophylaxis needed, as indicated by **1 or**

more of the following:

Initial course, as indicated by **ALL** of the following:

-Age 18 years or older

-Migraine headache lasting 4 hours to 72 hours, as indicated by 5 or more attacks with **ALL** of the following:

-Headache symptoms, as indicated by **2 or more** of the following:

-Aggravation by or causing avoidance of routine physical activity

-Moderate or severe pain intensity

-Pulsating quality

-Unilateral location

-Migraine-associated symptoms, as indicated by **1 or more** of the following:

-Nausea or vomiting

-Photophobia and phonophobia

-Other potential causes of headaches have been excluded.

-Migraine headache frequency occurring 15 or more days per month for 3 or more months

-Use of preventive medication (eg, beta-blocker, tricyclic antidepressant, anticonvulsant) has been ineffective or not tolerated for trial of at least 3 months.

-No neuromuscular disease (eg, myasthenia gravis)

Subsequent course, as indicated by **ALL** of the following:

-Age 18 years or older

-Favorable response to prior administration of onabotulinumtoxinA

●Motor tics, as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 16 years or older

-Patient unable to adequately suppress tics

-Tics causing interference with daily functioning

Subsequent course, as indicated by **ALL** of the following:

-Age 16 years or older

-Favorable response to prior administration of onabotulinumtoxinA

●Overactive bladder with or without urgency urinary incontinence, as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 18 years or older
-Failure of or intolerance to anticholinergic Medication
-No acute urinary retention
-No acute urinary tract infection

Subsequent course, as indicated by **ALL** of the following:

-Age 18 years or older
-Favorable response to prior administration of onabotulinumtoxinA

●Sialorrhea (excessive salivation), as indicated by **1 or more** of the following:

Initial course
Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

●Spasticity, as indicated by **1 or more** of the following:

Initial course, as indicated by **1 or more** of the following:

-Child with cerebral palsy receiving rehabilitation
-Upper or lower extremity spasticity in individual age 2 years or older

Subsequent course, with favorable response to prior administration of onabotulinumtoxinA

●Strabismus, as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 12 years or older
-Deviation of 50 prism diopters or less
-No infection at proposed injection site

-Strabismus not due primarily to Duane syndrome with lateral rectus weakness

-Strabismus not due primarily to restrictive strabismus
-Strabismus not due primarily to secondary strabismus caused by prior surgical over-recession of antagonist muscle

Subsequent course, as indicated by **ALL** of the following:

-Age 12 years or older
-Favorable response to prior administration of onabotulinumtoxinA

●Upper extremity focal dystonia (eg, writer's cramp), as indicated by **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 16 years or older
-Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning
-No infection at proposed injection site
-No prior surgical treatment

Subsequent- course, as indicated by **ALL** of the following:

Age 16 years or older
-Favorable response to prior administration of onabotulinumtoxinA

●Urinary incontinence due to neurogenic detrusor overactivity, as indicated by **1 or more** of the following:

Adult and **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:
-Age 18 years or older
-Condition secondary to spinal cord injury, spinal dysraphism, or neurologic disease (eg, multiple sclerosis)

-Failure of or intolerance to pharmacologic therapy including anticholinergic medication
-No acute urinary retention unless patient receiving regular clean intermittent catheterization
-No acute urinary tract infection

Subsequent course, as indicated by **ALL** of the following:

-Age 18 years or older
-Favorable response to prior administration of onabotulinumtoxinA

Child or adolescent and **1 or more** of the following:

Initial course, as indicated by **ALL** of the following:

-Age 5 years to younger than 18 years
-Condition secondary to spinal cord injury, spinal dysraphism, or transverse myelitis
-Failure of or intolerance to pharmacologic therapy including anticholinergic medication
-No acute urinary tract infection

Subsequent course, as indicated by **ALL** of the following:

-Age 5 years to younger than 18 years
-Favorable response to prior administration of onabotulinumtoxinA

Botox (OnabotulinumtoxinA) use above 400units/3months may be considered medically necessary for the treatment of spasticity related to neurological disease when ALL of the following criteria are met:

Date(s) of Review and Revision: 4/9/2025

Effective 6.1.25

Diagnosis:

- The patient has a documented diagnosis of spasticity associated with one of the following neurological conditions, including but not limited to:
  - Stroke
  - Multiple Sclerosis (MS)
  - Cerebral Palsy (CP)
  - Traumatic Brain Injury (TBI)
  - Spinal Cord Injury (SCI)
  - Other related neurological disorders

2. Functional Impairment:
   - The spasticity results in significant functional impairment or pain that affects activities of daily living (ADLs) or mobility.
3. Conservative Treatment:
   - The patient has had conservative management with PT and/or OT, splinting, bracing, medications, etc. with insufficient benefit to resolve functional impairment.
4. Previous Botox Use:
   - If applicable, the patient has demonstrated a positive response to prior Botox injections with documented improvement in muscle tone, function, or pain management.
5. Dose Justification:
   - Up to 600 units per treatment session may be authorized if all of the following are met:
     - The patient has severe spasticity involving multiple muscle groups.
     - The standard 400-unit dose was insufficient to achieve adequate symptom relief.
     - A specialist (e.g., neurologist, physiatrist) has provided clinical justification for higher doses based on individual patient needs.
6. Frequency of Treatment:
   - Repeat treatment may be authorized at intervals of at least 12 weeks if there is documented evidence of continued benefit and absence of significant adverse effects.

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CRITERIA FOR RENEWAL:

Positive clinical response to initial therapy

INSERT QUANTITY LIMITS:

Dose: ≤ 400 units within a 3-month period
Primary Focal Hyperhidrosis, Axilla: 100 units within a 3-month period
Overactive Bladder: 200 units within a 3-month period
Chronic Migraine: 200 units within a 3-month period

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 12 months
Renewal Approval Duration: 12 months

Date(s) of Review and Revision: 4/9/2025

Effective 6.1.25

GLIC003 Casimersen (Amondys 45) Guideline

APPLICABLE AGENT(S):

o Casimersen (Amondys 45)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Diagnosis of Duchenne muscular dystrophy with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping AND

2. Patient is ambulatory AND

3. Medication is prescribed by or in consult with a neurologist who has experience treating children AND

4. Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided] AND

5. Dosing is in accordance with the Food and Drug Administration approved labeling AND

6. If member meets ALL of the above criteria, reviewing pharmacist will send their approval recommendation to a Medical Director for final review.

CRITERIA FOR RENEWAL:

1 - One of the following:

1.1 Patient has been on therapy for less than 12 months and all of the following:

1.1.1 Patient is maintaining ambulatory status AND

1.1.2 Patient is tolerating therapy AND

1.1.3 Dose will not exceed 30 milligrams per kilogram of body weight once weekly AND

1.1.4 Prescribed by or in consultation with a neurologist who has experience treating children AND

1.1.5 Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

OR

1.2 Patient has been on therapy for 12 months or more and all of the following:

1.2.1 Patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients) AND

1.2.2 Patient is maintaining ambulatory status AND

1.2.3 Patient is tolerating therapy AND

1.2.4 Dose will not exceed FDA approved dosing AND

1.2.5 Prescribed by or in consultation with a neurologist who has experience treating children AND

1.2.6 Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

LENGTH OF AUTHORIZATION:

o Initial Approval Duration: 12 months

o Renewal Approval Duration: 12 months

GLIC004 Etranacogene dezaparvovec-drlb (Hemgenix) Guideline

APPLICABLE AGENT(S):

Etranacogene dezaparvovec-drlb (Hemgenix)

CRITERIA FOR INITIAL AUTHORIZATION:

1.Member is 18 years or older with Hemophilia B (congenital Factor IX deficiency) who has FDA approved indication of:

Currently using Factor IX prophylaxis therapy and is stable on it for at least 2 months and has received at least 150 exposure days, or

Has current or historical life-threatening hemorrhage, or

Has repeated, serious spontaneous bleeding episodes

AND

2.Has not received prior treatment with any gene therapy for hemophilia B

AND

3. AAV5 Neutralizing Antibody test processing conducted with CSL Behring and documentation provided to demonstrate the patient does not have anti-AAV antibody (eg AAV-5) titers exceeding 1:678)

AND

4.Must not have history of inhibitors to Factor IX or a positive inhibitor screen as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Hemgenix

AND

5.Prescribed by hematologist

AND

6.Member must not have active hepatitis C infection, an active HIV infection or decompensated cirrhosis. Documentation of liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)]

AND

7. Member will have close monitoring of transaminase levels once per week for 3 months after Hemgenix administration to mitigate the risk of potential hepatotoxicity

AND

8. Send to medical director for review and MRIoA for review

CRITERIA FOR RENEWAL:

N/A. No renewal allowed. One infusion per lifetime.

INSERT QUANTITY LIMITS

1. One infusion per lifetime

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months
Renewal Approval Duration: N/A. No renewal allowed. One infusion per lifetime.

GLIC005 Ezetimibe (Zetia) Guideline

Ezetimibe (Zetia) tablets

CRITERIA FOR INITIAL AUTHORIZATION:
1.Medication prescribed for FDA approved or compendial supported diagnosis
2.If the request is prescribed for the diagnosis of primary hypercholesterolemia or mixed dyslipidemia, and member has tried and failed or experienced intolerance to statin therapy

LENGTH OF AUTHORIZATION:
Initial Approval Duration: Lifelong approval

GLIC007 Hyaluronic acid agents Step Therapy Guideline

APPLICABLE AGENT(S):

Preferred	Non-Preferred
Euflexxa	Durolane, Gel-One, Genvisc 850, Hyalgan, Hymovs, Monovis, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, Visco-3, Synvisc

CRITERIA FOR STEP THERAPY AUTHORIZATION:

New Start

1. Member at least 18 years of age with a diagnosis of moderate to severe (grade III or higher) osteoarthritis confirmed by radiology
   AND
2. There is medical record documentation that the member has previously trialed and failed to adequately respond to non-pharmacologic therapy (exercise, physical therapy, weight loss, braces, local heat and cold application) for a minimum of 6 weeks
   AND
3. There is medical record documentation that the member has trialed and failed to adequately respond to simple analgesics (acetaminophen, topical capsaicin, oral or topical NSAIDs) for a minimum of 6 weeks
   AND
4. Member received at least one prior intra-articular corticosteroid injection or has a contraindication to corticosteroids

Renewal/Continuation of therapy

1. Member at least 18 years of age with a diagnosis of moderate to severe (grade III or higher) osteoarthritis confirmed by radiology and previously been treated for the same knee with any hyaluronic acid/viscosupplementation product
   AND
2. It has been at least 6 months since the last treatment with this agent
   AND

3. Medical record documentation supports that the patient experienced a significant improvement in knee pain and functional capacity from the last series of injections
   AND
4. Medical record documentation supports that the patient experienced improved pain and functional capacity for at least 6 months (including no intraarticular corticosteroids administered for at least 6 months)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 3 months
Renewal Approval Duration: 1 year

GLIC008 Omnipod Guidelines
APPLICABLE AGENT(S):

Omnipod (All pharmacy products)

CRITERIA FOR INITIAL AUTHORIZATION:

Diagnosis of type 1 or type 2 diabetes mellitus and is currently established on therapy with an insulin pump
AND
Patient or caregiver is able to monitor blood glucose on average 4 or more times per day as per provider documentation or patient uses a continuous glucose monitor
OR
For new starts, the member has a diagnosis of type 1 or 2 diabetes mellitus and is being managed with multiple daily insulin injections of at least 3 injections per day with frequent dose adjustments of insulin for the past 6 months
AND

Provider has determined patient or caregiver is able to use an insulin pump and provided education
AND
The patient's age is within the manufacturer recommendations for the requested indication
AND
The member has experienced any of the following while on multiple daily injections of insulin (3 or more injections per day):

Elevated hemoglobin A1c level of greater than 7.0%
History of recurrent hypoglycemia or hypoglycemia unawareness
Wide fluctuations in blood glucose before mealtime
Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
History of severe glycemic excursions

CRITERIA FOR RENEWAL:

Continues to meet documentation of medical necessity above

INSERT QUANTITY LIMITS

Omnipod starter kit: 1 kit per 12 months

Omnipod pod refills: 10 pods/30 days

Omnipod pod refills: 15 pods/30 days for members utilizing greater than 100 units of insulin per day

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months
Renewal Approval Duration: 12 months

GLIC009 Omidubicel-onlv (Omisirge) Guideline

APPLICABLE AGENT(S):

- Omidubicel-onlv (Omisirge)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Must be indicated for Allogenic Hemopoetic Stem Cell Transplantation

AND

2. Patient must be ≥12 years of age and eligible for allo-HSCT

AND

3. Patient must have a hematologic malignancy (acute myelogenous leukemia, acute lymphoblastic leukemia, and chronic myeloid criteria) planned for UCBT following myeloablative conditioning

AND

4. Therapy is used to reduce the time to neutrophil recovery and incidence of infection

AND

5. Patients must not have a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor readily available

AND

6. Patient must not have received a prior allo-HSCT

AND

7. Omisirge will be used as a one-time treatment

AND

8. Omisirge is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center.

CRITERIA FOR RENEWAL:

1. N/A

INSERT QUANTITY LIMITS

1. Intravenous Suspension: Single dose consists of a Cultured Fraction (CF), a minimum of 8 x 108 total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2 x 107 CD34+ cells, and a Non-cultured Fraction (NF), a minimum of 4 x 108 total viable cells with a minimum of 2.4 x 107 CD3+ cells

LENGTH OF AUTHORIZATION:

Initial Approval Duration: Coverage will be provided for 1 dose per lifetime

Renewal Approval Duration: N/A

GLIC010 Protein C Concentrate (Ceprotin) Guideline

APPLICABLE AGENT(S):

- Protein C Concentrate (Ceprotin)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Indicated for Protein C Deficiency, Severe. Individual must meet ALL of the following criteria:
    a. Documented diagnosis of protein C deficiency is confirmed by documentation of ONE of the following:
        i. Plasma protein C activity below the lower limit of normal based on age specific reference range for the reporting laboratory
        ii. Plasma protein C antigen below the lower limit of normal based on age specific reference range for the reporting laboratory
        iii. Genetic testing demonstrating biallelic pathogenic variants in the PROC gene

b. Acquired causes of protein C deficiency have been excluded (eg: recent use of vitamin K antagonists within 30 days, vitamin K deficiency, chronic liver disease, recent thrombosis, recent surgery or disseminated intravascular coagulation)
c. Current or prior history of symptoms associated with severe protein C deficiency (eg: purpura fulminans, thromboembolism)
d. Medication is prescribed by or in consultation with a hematologist

CRITERIA FOR RENEWAL:

1. Continuation of Ceprotin is considered medically necessary for Protein C Deficiency, Severe when the above criteria are still being met, AND there is documentation of beneficial response.

INSERT QUANTITY LIMITS

1. Quantity Limit: Doses approved up to 4,440 IU/kg intravenously per 28 days

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 12 months

Renewal Approval Duration: 12 months

GLIC011 Sebelipase Alfa (Kanuma) Guideline

APPLICABLE AGENT(S):

- Sebelipase Alfa (Kanuma)

CRITERIA FOR INITIAL AUTHORIZATION:

Sebelipase alfa may be indicated when ALL of the following are present:

1. Diagnosis of lysosomal acid lipase deficiency, as indicated by 1 or more of the following:
   a) Absence or deficiency of lysosomal acid lipase enzyme activity
   b) Molecular genetic testing with mutations in both alleles of LIPA gene

2. Laboratory or clinical findings of lysosomal acid lipase deficiency, as indicated by 1 or more of the following:
   a) Alanine aminotransferase level at least 1.5 times upper limit of normal
   b) Signs and symptoms of infantile-onset disease (eg, abdominal distention, anemia, diarrhea, growth failure, hepatosplenomegaly, hyperbilirubinemia)

3. Patient is under care of physician with expertise in lysosomal acid lipase deficiency.

CRITERIA FOR RENEWAL:

2. Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial authorization section

AND

3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions including anaphylaxis, etc.

AND

4. Treatment has resulted in clinical benefit as evidenced in one or more of the following:
   - Improvement in weight-for-age z-scores for patients exhibiting growth failure
   - Improvement in LDL
   - Improvement in HDL
   - Improvement in triglycerides
   - Improvement of AST or ALT

OR

5. Dose escalation in pediatric and adult patients with a suboptimal clinical response to the 1 mg/kg dose defined by at least one of the following:
   - Poor growth
   - Deteriorating biochemical markers [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST)], and/or parameters of lipid metabolism [e.g., low-density lipoprotein cholesterol (LDL-c), triglycerides (TG)]

OR

6. Dose escalation for patients with rapidly progressive disease presenting within the first 6 months of life who have a suboptimal clinical response to the 1 mg/kg dose of 3 mg/kg dose defined by at least one of the following:
   - Poor growth
   - Deteriorating biochemical markers [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST)]
   - Persistent or worsening organomegaly

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INSERT QUANTITY LIMITS

1. Quantity Limit: Kanuma 20 mg/10 mL single-dose vials: 112 vials per 28 day supply

2. Max Dose: 560 billable units once weekly

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months

Renewal Approval Duration: Renewed annual

GLIC012 Valoctocogene roxaparvovec (Roctavian) Guideline

APPLICABLE AGENT(S):

Valoctocogene roxaparvovec (Roctavian)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Member is 18 years or older with severe Hemophilia A (Congenital factor VIII deficiency; severe is defined as pre-treatment factor VIII level less than 1 IU/dL)

AND

2. The member meets both of the following (a and b).

a. Member has been adherent to Factor VIII prophylaxis therapy for at least 12 months and has received at least 150 exposure days

b. Occurrence of one or more serious spontaneous bleeding event while on routine prophylaxis

AND all of the following:

3. Member has not received prior treatment with any other therapy containing an adeno-associated viral vector

4. Patient has been tested and found negative for active factor VIII inhibitors. Member's inhibitor level assay <1 Bethesda Unit (BU) on two consecutive occasions at least one week apart within the last 12 months. Patient is not receiving a bypassing agent (e.g. Feiba)

5. Member has no pre-existing antibodies to AAV5 capsid as measured by AAV5 total assay FDA-approved test.

6. Member has completed attestation of alcohol abstinence and has received abstinence education from the physician.

7. Prescribed by or in consultation with a hematologist.

8. Provider agrees to monitor the patient according to the FDA approved label. This includes factor VIII level tests, ALT monitoring, and steroid treatment as appropriate.

9. Provider must provide documentation member does not have active infections, either acute or uncontrolled chronic, known significant hepatic fibrosis (stage 3 or 4), or cirrhosis, or known hypersensitivity to mannitol.

10. Send to medical director and MRIoA for review.

CRITERIA FOR RENEWAL:

N/A. No renewal allowed. One infusion per lifetime.

INSERT QUANTITY LIMITS

Dose: 6 x 1013 vector genomes/kg as a single one-time dose per lifetime

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months

Renewal Approval Duration: N/A. No renewal allowed. One infusion per lifetime.

GLIC013 Viltolarsen (Viltepso) Guideline

APPLICABLE AGENT(S):

- Viltolarsen (Viltepso)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Patient must have the diagnosis of Duchenne Muscular Dystrophy (DMD). Submission of medical records (e.g., chart notes, laboratory values) as genetic test is required to confirm that a patient's mutation of the DMD gene is amenable to exon 53 skipping.

AND

2. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD

AND

3. Patient has been on stable dose of oral corticosteroids for at least 24 weeks prior to starting therapy unless contraindicated or intolerant.

AND

4. Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, casimersen, or eteplirsen).

AND

5. Patient has had kidney function testing prior to starting therapy completed.

AND

6. Patient is not in medically intractable congestive heart failure and is not ventilator dependent.

AND

7. If the patient is ambulatory, functional level determination of baseline assessment of ambulatory function (six-minute walk test (6MWT), time to run/walk 10-meter test (TTRW), time to climb 4-stair test

(TTCLIMB), time to stand (TTSTAND) or North Star Ambulatory Assessment (NSAA)) is required

AND

8. If not ambulatory, patient must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more.

CRITERIA FOR RENEWAL:

1. Documentation of improvement, maintenance or slowing of disease progression:

   a. For ambulatory patients – submission of 6MWT, TTRW, TTCLIMB, TTSTAND or NSAA
   b. For non-ambulatory patients – submission of Brooke Upper Extremity Function Scale (five or less) documented OR a Forced Vital Capacity document (30% or more)

AND

2. Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, casimersen, or eteplirsen)

AND

3. Provider attests patient has been compliant with treatment

INSERT QUANTITY LIMITS

1. Only available as 250 mg/5 mL (50 mg/mL) single-dose vial

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months

Renewal Approval Duration: 6 months

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GLIC014 Voretigene Neparvovec (Luxturna)

APPLICABLE AGENT(S):
Luxturna – Medical Review
CRITERIA FOR INITIAL AUTHORIZATION:
1. One dose per eye may be approved if ALL the following criteria are met:
    a. Age 1 year or older
    b. Diagnosis of retinal dystrophy confirmed via genetic testing:
        a. RPE65 mutation in both alleles
    c. Prescribed by ophthalmologist or retinal surgeon with experience providing subretinal injections.
    d. Viable retinal cells determined by ONE of the following:
        a. spectral domain optical coherence tomography confirming retinal thickness greater than 100 microns within posterior pole.
        b. ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
        c. Any remaining visual field within 30° of fixation as measured by III4e isopter or equivalent
    e. Member has not had intraocular surgery within the previous six months
    f. Member has not previously received Luxturna through BUHP or another Payer
2. IF member meets ALL the above criteria, reviewing pharmacist will send their approval recommendation to a Medical Director for final review.

CRITERIA FOR RENEWAL:

N/A. Members will only be approved for 1 injection per eye per lifetime

LENGTH OF AUTHORIZATION:

Initial approval duration: 3 months for 1 dose per eye
Renewal approval duration: N/A

Date(s) of Review and Revision: 4/9/2025

Effective 6.1.25

GLIC015 Zepbound (Tirzepatide) Guidelines
APPLICABLE AGENT(S):

- Zepbound®

CRITERIA FOR INITIAL AUTHORIZATION:

All of the following are met:

- Age ≥18 years and diagnosis of moderate to severe obstructive sleep apnea (OSA), evidenced by an Apnea hypopnea Index (AHI) ≥15 measured on Polysomnography (PSG) or Home Sleep Apnea Test (HSAT):
  - **Moderate: AHI of 15–30 respiratory events per hour of sleep**
  - **Severe: AHI of >30 respiratory events per hour of sleep**

  AND

  Documented failure of traditional OSA treatment with PAP for at least 90 days within the past six months

- The patient does not have diabetes as evidenced by an A1c of <6.5% AND
- The patient does not have any of the following:
  - Diagnosis of central or mixed sleep apnea
  - Diagnosis of obesity hypoventilation syndrome or daytime hypercapnia
  - Major craniofacial abnormalities
  - Planned procedure for sleep apnea or obesity AND

Submission of medical records (e.g., chart notes) documenting all the following:

- BMI (Body mass index) greater than or equal to 30 kg/m2 AND
- Used in combination with a reduced calorie diet and increased physical activity
  - Submission of documentation of a 500 kcal/day diet deficit, 150 minutes of weekly exercise, or a relevant program, with adjustments for mobility if needed. The intervention must be documented for at least 3 months.

CRITERIA FOR RE-AUTHORIZATION:

- Patient has tolerated, reports symptom improvement and been titrated up to minimum dose of 10 mg as approved for maintenance dosing for OSA as demonstrated per claims history
- Patient has not developed Type II Diabetes
- Patient will continue use in combination with reduced-calorie diet and increased physical activity
- A documented 10% weight loss is required

LENGTH OF AUTHORIZATION:

- Initial Approval Duration: 6 Months
- Renewal Approval Duration: 12 Months

QUANTITY LIMIT: Four pens per 28 days

Lifetime approvals

Abatacept (Orencia)

Aripiprazole (Abilify)

Belimumab (Benlysta)

Denosumab (Prolia)

DDAVP/Desmopressin

Escitalopram (Lexapro)

Ezetimibe (Zetia)

Lithium Carbonate

Lubiprostone (Amitiza)

Metformin ER osmotic and modified release

Sacubitril/Valsartan

Januvia (Sitagliptin)

Onglyza (Saxagliptin)

Rifaximin (Xifaxin)

Tradjenta (Linagliptin)

Valacyclovir at renewal: For Herpes prophylaxis only

REFERENCES:

Ezetimibe (Zetia)

Grundy SM, et al. 2018 ACC/AHA Guideline for the Treatment of Blood cholesterol: A report of the ACC/AHA taskforce on practice guideline.

Zetia Prescribing Information. Merck/Schering-Plough Pharmaceuticals, Whitehouse Station. NJ 0889. February 2019.

Continuous Glucose Monitors

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2

Diabetes Technology: Standards of Medical Care in Diabetes- 2020. Diabetes Care 2020;43(Supplement 1): S77-S88. https://doi.org/10.2337/dc20-S007

Feig DS, Donovan LE, Corcoy R, Murphy KE, Amiel SA et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomized controlled trial. Lancet. 2017;390(10110):2347-2359.

Garber AJ et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary, Endocrine Practice, 2020;26(1):107-139. https://doi.org/10.4158/CS-2019-0472.

Date(s) of Review and Revision: 4/9/2025

Effective 6.1.25

Diabetic Glucose Monitors:

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2

Diabetes Technology: Standards of Medical Care in Diabetes- 2020. Diabetes Care 2020;43(Supplement 1): S77-S88. https://doi.org/10.2337/dc20-S007

Garber AJ et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary, Endocrine Practice, 2020;26(1):107-139. https://doi.org/10.4158/CS-2019-0472.

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed 29 July 2022.

Euflexxa

American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (non-Arthroplasty) Evidence-Based Clinical Practice Guideline. (Aug 2021). https://www.aaos.org/oak3cpg

Migliore A and Procopio S. Effectiveness and utility of hyaluronic acid in osteoarthritis. Clin Cases Miner Bone Metab. 2015 Jan-Apri; 12(1):31-33. doi: 10.11138/ccmbm/2015.12.1.031

Turajane T, Amphansap T, Labpiboonpong V and Maungsiri S. Total knee replacement following repeated cycles of intra-articular sodium hyaluronate (500-730 Kda) in failed conservative treatment of knee osteoarthritis: a 54-month follow up. J Med Assoc Thai. 2009 Dec; 92 suppl 6: S63-8.

Navarro-Sarabia F, Coronel P, Collantes E, et al. AMELIA study group. A 40-month multicentre, randomised placebo-controlled study to assess the efficacy and carry-over effect of repeated intra-articular injections of

hyaluronic acid in knee osteoarthritis: the AMELIA project. Ann Rheum Dis. 2011 Nov;70(11):1957–62

Ceprotin® intravenous infusion [prescribing information]. Lexington, MA: Baxalta/Shire; October 2024.

Protein C Deficiency. National Organization of Rare Disorders. Updated 2016. Available at: https://rarediseases.org/rare-diseases/protein-c-deficiency/. Accessed on October 15, 2024.

Cooper PC, Pavlova A, Moore GW, et al. Recommendations for clinical laboratory testing for protein C deficiency, for the subcommittee on plasma coagulation inhibitors of the ISTH. J Thromb Haemost. 2020 Feb;18(2):271-277.

Cuker, A., Kavakli, K., Frenzel, L., et. al, BENEGENE-2 Trial Investigators (2024). Gene Therapy with Fidanacogene Elaparvovec in Adults with Hemophilia B. The New England journal of medicine, 391(12), 1108–1118. https://doi.org/10.1056/NEJMoa2302982

Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf. Accessed Sep 2024.

Kanuma [package insert]. Boston, MA; Alexion Pharmaceuticals, Inc; November 2021. Accessed October 2024.

Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. 2015 Sep 10;373(11):1010-20. doi: 10.1056/NEJMoa1501365.

Jones SA, Rojas-Caro S, Quinn AG, et al. Survival in infants treated with sebelipase Alfa for lysosomal acid lipase deficiency: an open-label, multicenter, dose-escalation study. Orphanet J Rare Dis. 2017 Feb 8;12(1):25. doi: 10.1186/s13023-017-0587-3.

Luxturna

Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc. December 2019.

Russel, S, Bennett, J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2- hRPE65v2) in patients with RPE65-mediated inherited

retinal dystrophy: a randomized, controlled, open-label, phase 3 trial. The Lancet. 2017;390: 849-860.

FDA Advisory Committee Briefing Document: Spark Therapeutics, INC, Luxturna (voretigene neparvovec).2017; https://www.fda.gov/media/108385/download Accessed March 21, 2022

Roctavian [package insert]. Novato, Ca. BioMarin Pharmaceutical Inc.; June 2023.

Single-Arm study to Evaluate The Efficacy and Safety of Valoctocogene Roxaparvovec in Hemophilia A Patients (BMN 270-301). December 2022. Available at https://classic.clinicaltrials.gov/ct2/show/NCT03370913

Viltepso [package insert]. Paramus, NJ: NS Pharma, Inc.; March 2021.

Watanabe N, Nagata T, Satou Y, et al. NS-065/NCNP-01: An Antisense Oligonucleotide for Potential Treatment of Exon 53 Skipping in Duchenne Muscular Dystrophy. Mol Ther Nucleic Acids. 2018;13:442– 449. doi:10.1016/j.omtn.2018.09.017

Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apneawith Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J ClinSleep Med*. 2019;15(2):335-343. Published 2019 Feb 15. doi:10.5664/jcsm.7640

Zepbound

Winslow DH, Bowden CH, DiDonato KP, McCullough PA. A randomized, double-blind, placebo-controlled study of an oral, extended-release formulation of phentermine/topiramate for the treatment of obstructive sleep apnea in obese adults. *Sleep*. 2012;35(11):1529-1539. Published 2012 Nov 1. doi:10.5665/sleep.2204

Blackman A, Foster GD, Zammit G, et al. Effect of liraglutide 3.0 mg in individuals with obesity and moderate or severe obstructive sleep apnea: the SCALE Sleep Apnea randomized clinical trial. *Int J Obes (Lond)*. 2016;40(8):1310-1319. doi:10.1038/ijo.2016.52

Date(s) of Review and Revision: 4/9/2025

Malhotra A, Grunstein RR, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity [published correction appears in N Engl J Med. 2024 Oct 17;391(15):1464. doi: 10.1056/NEJMx240005]. *N Engl J Med*. 2024;391(13):1193-1205. doi:10.1056/NEJMoa2404881

Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apneawith Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J ClinSleep Med*. 2019;15(2):335-343. Published 2019 Feb 15. doi:10.5664/jcsm.7640

Winslow DH, Bowden CH, DiDonato KP, McCullough PA. A randomized, double-blind, placebo-controlled study of an oral, extended-release formulation of phentermine/topiramate for the treatment of obstructive sleep apnea in obese adults. *Sleep*. 2012;35(11):1529-1539. Published 2012 Nov 1. doi:10.5665/sleep.2204

Blackman A, Foster GD, Zammit G, et al. Effect of liraglutide 3.0 mg in individuals with obesity and moderate or severe obstructive sleep apnea: the SCALE Sleep Apnea randomized clinical trial. *Int J Obes (Lond)*. 2016;40(8):1310-1319. doi:10.1038/ijo.2016.52

Malhotra A, Grunstein RR, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity [published correction appears in N Engl J Med. 2024 Oct 17;391(15):1464. doi: 10.1056/NEJMx240005]. *N Engl J Med*. 2024;391(13):1193-1205. doi:10.1056/NEJMoa2404881

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