Banner Medicaid Internal Criteria Table of Contents

Date(s) of Review and Revision: 9/11/2024

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.

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

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

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

Celecoxib (Celebrex) Guideline

APPLICABLE AGENT(S):
Celecoxib (Celebrex) capsules
CRITERIA FOR INITIAL AUTHORIZATION:
1.Member has been on following drug therapy in previous 90 days
-Member is concurrently on anticoagulants/antiplatelet agents (e.g., warfarin, Xarelto, Pradaxa, Plavix, Eliquis)
-Member is currently receiving antiulcer agents (i.e. proton-pump inhibitors (PPIs) (e.g., pantoprazole, omeprazole, lansoprazole), histamine H2 receptor antagonists (H2RAs) (e.g., ranitidine, famotidine))
-Member has chronic use of oral corticosteroids (i. e. prednisone)
-Member is receiving methotrexate
-Member has a history of peptic ulcer disease (PUD) or history of gastrointestinal (GI) bleed
OR
2. Member is equal to or greater than 65 years old
OR
3.Member tried and failed or is intolerant to ONE formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs) (e.g., ibuprofen, diclofenac sodium, naproxen, etodolac, nabumetone)
OR
4.Member using for acute pain, including acute post-op pain

CRITERIA FOR RENEWAL:
1. Member is experiencing positive response to therapy

LENGTH OF AUTHORIZATION:
Initial Approval Duration: Lifelong approval

Etranacogene dezaparvovec-drlb (Hemgenix) Guideline

Effective Date: 4/1/2023

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.

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

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:
1. Member has diagnosis of osteoarthritis 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)
OR
5. Member at least 18 years of age with a diagnosis of osteoarthritis confirmed by radiology
AND
6. There is medical record documentation that the member has previously trialed non-pharmacologic therapy (exercise, physical therapy, weight loss, braces, local heat and cold application) for a minimum of 6 weeks
AND
7. 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

10. Member received at least one prior intra-articular corticosteroid injection or has a contraindication to corticosteroids

CRITERIA FOR RENEWAL:

It has been at least 6 months since the last treatment with this agent
AND
Medical record documentation supports that the patient experienced a significant improvement in knee pain and functional capacity from the last series of injections
AND
The medical record documentation support that the patient experienced improved pain and functional capacity for at least 6 months? (no intraarticular corticosteroids administered for at least 6 months)

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

Omnipod Guidelines
Effective Date: 9/1/2023

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

Valoctocogene roxaparvovec (Roctavian) Guideline

Effective Date: December 1, 2023

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.

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

Guideline: BH-042024

Effective Date: Apr 16, 2024

APPLICABLE AGENT(S):

Wegovy (Semaglutide)

CRITERIA FOR INITIAL AUTHORIZATION:

Patient is 45 years of age or older; AND
The patient does not have diabetes as evidenced by an A1c of <6.5%.
Physician attests patient has been educated on and is agreeable to behavioral modification and a reduced-calorie diet; AND
At baseline, patient has a BMI ≥ 27 kg/m2 and confirmation of established Cardiovascular disease (Cardiovascular disease is defined as symptomatic Peripheral Arterial Disease, previous myocardial infarction, or previous stroke) AND

Does not meet any of the following:

- Treatment with any glucose lowering medication or use with another GLP1 or DPP-4 inhibitor concomitantly
- New York Heart Association class IV heart failure
- Using the medication for weight loss only without any other concurrent cardiovascular condition

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 3 Months
Renewal Approval Duration: 3 Months

Lifetime approvals

Abatacept (Orencia)

Aripiprazole (Abilify)

Belimumab (Benlysta)

Celecoxib (Celebrex)

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

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Luxturna

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