"What's New" Medical Pharmaceutical Policy September 2023 Updates
The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 264.0 Enjaymo (sutimlimab-jome) – Updated Policy

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Enjaymo is prescribed by or in consultation with hematologist **AND**
- Medical record documentation of a diagnosis of primary cold agglutinin disease (CAD) confirmed by all of the following:
    - Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin) **AND**
    - Positive polyspecific direct antiglobulin test (DAT) **AND**
    - Positive monospecific DAT specific for C3d **AND**
    - Cold agglutinin titer ≥ 64 at 4 degrees Celsius

  AND
- Medical record documentation of hemoglobin level ≤ 10.0 g/dL OR transfusion dependent for new starts **AND**
- ~~Medical record documentation of a history of at least one blood transfusion within 6 months of starting Enjaymo **AND**~~
- Medical record documentation that secondary causes of cold agglutinin disease (CAD) have been ruled out **AND**
- Medical record documentation of a prescribed dose that is consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Enjaymo will not be used in combination with rituximab ± bendamustine or fludarabine **AND**
- Medical record documentation that patient is vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae subgroup B) at least 2 weeks prior to treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab ± bendamustine or fludarabine

MBP 286.0 Hemgenix (etranacogene dezaparvovec-drlb) – Updated Policy

Hemgenix (etranacogene dezaparvovec-drlb) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation that the member is a male based on assigned sex at birth and age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate or severe hemophilia B with Factor IX level < 2 IU/dL or ≤ 2% of normal **AND**
- Medical record documentation of one of the following:
    - Member has current use of Factor IX prophylaxis therapy for at least 2 months with > 150 exposure days^ of treatment with Factor IX protein **OR**
    - Member has current of historical life-threatening hemorrhage **OR**
    - Member has repeated, serious spontaneous bleeding episodes

  AND
- Medical record documentation that the member has a recent negative inhibitor status to Factor IX prior to administration of Hemgenix **AND**
- Medical record documentation that the member does not have an active hepatitis B or hepatitis C infection* assessed within the last 6 months **AND**
- Medical record documentation that the member does not have uncontrolled HIV** assessed within the last 6 months **AND**

- Medical record documentation that the member does not have evidence of advanced cirrhosis*** assessed within the last 6 months **AND**
- Medical record documentation that the member has not received any previous gene therapy for hemophilia B **AND**
- Medical record documentation that Hemgenix is being dosed according to the Food and Drug Administration approved labeling**** **AND**
- Medical record documentation of the frequency of bleeds within the previous 12 months

AUTHORIZATION DURATION: One (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

^Exposure days is the number of days a patient was exposed to exogenous factor.
*In the Hope-B trial members were excluded at screening if they were currently receiving antiviral therapy for this/these infection(s) and/or positive for any of the following: Hepatitis B surface antigen, except if in the opinion of the investigator this is due to a previous Hepatitis B vaccination rather than an active Hepatitis B infection, Hepatitis B virus deoxyribonucleic acid (HBV DNA), Hepatitis C virus ribonucleic acid (HCV RNA)
**In the Hope-B trial members were excluded at screening and the last lead-in visit if they had a positive human immunodeficiency virus (HIV) serological test, not controlled with anti-viral therapy as shown by CD4+ counts ≤200/microL
***In the Hope-B trial members were excluded at screening and the last lead-in visit if they had ALT > 2 times upper limit of normal (ULN), AST > 2 times ULN, total bilirubin > 2 times ULN, alkaline phosphatase (ALP) > 2 times ULN, creatinine > 2 times ULN. Also patients were excluded at screening if they had any known significant medical condition that may significantly impact the transduction of the vector and/or expression and activity of the protein, including but not limited to: disseminated intravascular coagulation, accelerated fibrinolysis, advanced liver fibrosis (suggestive of or equal to METAVIR Stage 3 disease; e.g., a FibroScan™ score of ≥9 kPa is considered equivalent)
****Hemgenix is administered as a single IV infusion. To calculate the Hemgenix dose use the following equation:

Hemgenix dose (in mL)= patient body weight (in kilogram) X 2
Number of vials needed= Hemgenix dose (in mL) / 10 (round up to the next whole number of vials)

MBP 289.0 Elfabrio (pegunigalsidase alfa-iwxj) – New Policy

Elfabrio (pegunigalsidase alfa-iwxj) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Fabry disease **AND**
- Prescribed by a metabolic specialist with experience in treating Fabry disease

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 290.0 Epkinly (epcoritamab-bysp) – New Policy

Epkinly (epcoritamab-bysp) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Epkinly is written by a hematologist or oncologist **AND**

- Medical record documentation of a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma **AND**
- Medical record documentation of prior therapy with at least two lines of systemic therapy

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

MBP 291.0 Lamzede (velmanase alfa-tycv) – New Policy

Lamzede (velmanase alfa-tycv) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of alpha-mannosidosis supported by:
  - Enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity (<0.54 nmol/min/mg)

  OR
  - Molecular genetic testing that reveals pathogenic variants in the MAN2B1 gene

  AND
- Medical record documentation that the patient is prescribed Lamzede (velmanase alfa-tycv) for the treatment of non-central nervous system manifestations of alpha-mannosidosis **AND**
- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression (i.e., improvement or stabilization in motor function, improvement in forced vital capacity % (FVC), reduction in frequency of infections, etc.)

MBP 292.0 Omisirge (omidubicel-onlv) – New Policy

Omisirge (omidubicel-onlv) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Omisirge is prescribed by a hematologist and/or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of a hematological malignancy planned for umbilical cord blood transplantation following myeloablative conditioning **AND**
- Medical record documentation that a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor is not readily available **AND**
- Medical record documentation that patient has not had a prior allogeneic hematopoietic stem cell transplantation (HSCT)

AUTHORIZATION DURATION: One time authorization for one administration of Omisirge

MBP 293.0 Qalsody (tofersen)– New Policy

Qalsody (tofersen) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS) **AND**
- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) with a confirmed mutation in the superoxide dismutase 1 (SOD1) gene **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for **12 months** or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation that member is tolerating and compliant with prescribed Qalsody regimen **AND**
- Medical record documentation of regular physician follow-up

The following policies were reviewed with no changes:

- MBP 7.0 Aldurazyme (laronidase)
- MBP 18.0 Fabrazyme (agalsidase beta)
- MBP 23.0 Velcade (bortezomib)

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicare GHP members only:

Note: For Medicaid GHP Family members please refer to the Pennsylvania Medical Assistance Statewide Preferred Drug List (PDL) https://papdl.com/preferred-drug-list for specific coverage information and policy criteria for any drug listed below.

MBP 13.0 Viscosupplementation – Updated Policy

Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, and **Visco-3** require Prior Authorization and will be considered medically necessary when all of the following criteria are met:

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose

intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**

- Physician documentation of failure on, intolerance to or contraindication to three (3) of the following: Durolane, Euflexxa, Gelsyn-3, Synvisc, and/or Synvisc One

AUTHORIZATION DURATION/QUANTITY LIMIT: Initial approval will be for **six (6) months** and will be **limited to one (1) treatment course** to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  1. Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
  2. Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
  3. Six months or longer have elapsed since the last injection in the previous series.

LIMITATIONS:

- Durolane treatment course is limited to 1 injection in a 6-month period
- Euflexxa treatment course is limited to 3 injections, one week apart, in a 6-month period
- Gel-One treatment course is limited to 1 injection in a 6-month period.
- Gelsyn-3 treatment course is limited to 3 injections in a 6-month period.
- GenVisc 850 treatment course is limited to 5 injections in a 6-month period.
- Hyalgan (sodium hyaluronate) treatment course is limited to 5 injections in a 6-month period.
- Hymovis treatment course is limited to 2 injections in a 6-month period.
- Monovisc treatment course is limited to 1 injection in a 6-month period.
- Orthovisc treatment course is limited to 4 injections in a 6-month period.
- Supartz treatment course is limited to 5 injections in a 6-month period.
- Synojoynt treatment course is limited to 3 injections in a 6-month period.
- Synvisc (Hylan G-F 20) treatment course is limited to 3 injections in a 6-month period.
- Synvisc One treatment is limited to 1 injection in a 6-month period.
- Triluron treatment course is limited to 3 injections in a 6-month period.
- TriVisc treatment course is limited to 3 injections in a 6-month period.
- Visco-3 treatment course is limited to 3 injections in a 6-month period.
- Treatment requires referral to and should be rendered by a participating Orthopedic surgeon or Rheumatologist.
- Bilateral injections may be allowed if both knees meet the required coverage criteria

MBP 42.0 Boniva (ibandronate sodium) Intravenous – Updated Policy

1. Treatment and prevention of osteoporosis in postmenopausal women:
   - Intolerance to oral bisphosphonates; **OR**
   - Inability to remain in an upright position for a minimum of 30-60 minutes after ingestion; **OR**
   - Disruption of the alimentary tract due to any of the following reasons, and to a degree which precludes the use of oral bisphosphonates:
     - Obstructing stricture or neoplasm of the esophagus, stomach or intestine;
     - Short bowel syndrome secondary to extensive small bowel resection;
     - Motility disorder;

    - Malabsorption secondary to enterovesical, enterocutaneous or enterocolic fistulas;
    - Prolonged paralytic ileus following surgery or injury

AND

- Failure on, intolerance to or contraindication to zoledronic acid – (applies to insured individuals naïve to previous IV Boniva therapy)

AND

- If a brand drug is being requested when a therapeutically equivalent generic drug exists:
    - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

MBP 94.0 Eylea (aflibercept) – Updated Policy

- Medical record documentation of a diagnosis of retinopathy of prematurity (ROP)

NOTES:

- In clinical trials, prematurity was defined as a maximum gestational age at birth of 32 weeks or a maximum birth weight of 1500 grams [3.3 lbs].

AUTHORIZATION DURATION

- **Retinopathy of Prematurity (ROP):** 12 months
- **All other indications:** Approvals will be given for a lifetime duration.

Part B Step Therapy was added to the following drugs:

- Gel-One
- Hymovis
- Monovisc
- Synojoynt
- Triluron
- TriVisc