"What's New" Medical Pharmaceutical Policy April 2026 Updates

The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 222.0 Zepzelca (lurbinectedin) – Updated Policy

For metastatic small cell lung cancer (SCLC):

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Zepzelca is written by a hematologist or oncologist **AND**
- Medical record documentation of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

For extensive-stage small cell lung cancer (ES-SCLC):

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Zepzelca is written by a hematologist or oncologist **AND**
- Medical record documentation of extensive-stage small cell lung cancer (ES-SCLC) **AND**
- Medical record documentation that Zepzelca will be used as maintenance treatment in combination with atezolizumab or atezolizumab and hyaluronidase-tqjs **AND**
- Medical record documentation of disease that has NOT progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide.

MBP 245.0 Empaveli (pegcetacoplan) – Updated Policy

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Medical record documentation of flow cytometry confirming diagnosis **AND**
- Medical record documentation that Empaveli is prescribed by a hematologist **AND**
- Medical record documentation of a prescribed dose of Empaveli that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae type B* **AND**
- Medical record documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of pegcetacoplan due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of pegcetacoplan treatment; **OR**
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause

C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

- Medical record documentation of a diagnosis of C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) **AND**
- Medical record documentation that Empaveli is being used to reduce proteinuria **AND**
- Medical documentation of age 12 years or older **AND**
- Medical record documentation that Empaveli is prescribed by a hematologist or nephrologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B. **AND**
- Medical record documentation of eGFR ≥30 mL/min/1.73 m^2, proteinuria ≥1 g/day, AND urine protein-to-creatinine ratio (UPCR) ≥1 g/g **AND**

- Medical record documentation of optimized doses of angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, sodium-glucose cotransporter-2 (SGLT2) inhibitor, or immunosuppressant medication **AND**
- Medical record documentation of a prescribed dose of Empaveli that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

AUTHORIZATION DURATION:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require of:

- Medical record documentation:
  - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) **AND**
  - Reduced need or elimination of transfusion requirements **OR**
  - Stabilization of hemoglobin levels

C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require the following:

- Provider assessment of response to therapy or documentation of a decrease or maintenance in proteinuria compared to baseline.

MBP 186.0 Libtayo (cemiplimab-rwlc) – Updated Policy

Cutaneous Squamous Cell Carcinoma (cSCC)

- Prescription written by a hematologist or oncologist **AND**
- Documentation that the patient is 18 years of age or older **AND**
- One of the following:
  - Medical record documentation of a diagnosis of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC **AND**
  - Medical record documentation that the patient is not a candidate for curative surgery or curative radiation

  OR
  - Medical record documentation of adjuvant treatment for cutaneous squamous cell carcinoma (cSCC) **AND**
  - Medical record documentation that the patient is at high risk of recurrence after surgery and radiation.

AUTHORIZATION DURATION:

For adjuvant treatment of Cutaneous Squamous Cell Carcinoma (cSCC):

One initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Libtayo for the adjuvant treatment of Cutaneous Squamous Cell Carcinoma should not exceed the FDA-approved treatment duration of 48 weeks. For requests exceeding the above limit, medical record documentation of the following is required:

- 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

For all other indications:

Initial approval will be for 12 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 166.0 Adcetris (brentuximab vedotin) – Updated Policy

Relapsed or Refractory Large B-Cell Lymphoma (LBCL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of relapsed or refractory Large B-Cell Lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) Not Otherwise Specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) **AND**
- Medical record documentation that Adcetris will be used in combination with lenalidomide and a rituximab product **AND**
- Medical record documentation of two (2) or more prior lines of systemic therapy **AND**
- Medical record documentation that patient is not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or chimeric antigen receptor (CAR) T-cell therapy.

MBP 306.0 Vyjuvek (beremagene geperpavec-svdt) – Updated Policy

- Medical record documentation that Vyjuvek is prescribed by or in consultation with a dermatologist who specializes in epidermolysis bullosa (EB) management **AND**
- ~~Medical record documentation of age greater than or equal to 6 months **AND**~~
- Medical record documentation of diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**
- Medical record documentation of genetic testing confirming mutation(s) in the COL7A1 gene **AND**
- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound **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.

MBP 342.0 Opdivo Qvantig (nivolumab-hyaluronidase-nvhy) – Updated Policy

1. ***Melanoma***
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ~~≥ 18 years~~ 12 years of age **AND**
   - Medical record documentation of one of the following:
     - A diagnosis of unresectable or metastatic melanoma **AND**
     - Opdivo Qvantig is being used as a single agent ~~following combination treatment with intravenous nivolumab and ipilimumab~~

     OR
     - A diagnosis of completely resected (no evidence of disease) Stage IIB, Stage IIC, Stage III, or Stage IV melanoma **AND**
     - Opdivo Qvantig is being used in the adjuvant setting **AND**
     - Opdivo Qvantig is being used as a single agent

2. ***Renal Cell Carcinoma***
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 18 years of age **AND**
   - Medical record documentation of use as a single agent ~~for relapse or for surgically unresectable~~ advanced ~~or metastatic~~ renal cell carcinoma **AND**
   - Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

3. ***Colorectal Cancer***
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ ~~18 years~~ 12 years of age **AND**
   - Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
   - Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease **AND**

- One of the following:
    - Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan ~~**AND**~~ as a single agent **OR**
    - Medical record documentation that Opdivo Qvantig is being used ~~as a single agent or~~ as a single agent following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).

4. ***Hepatocellular Carcinoma (HCC)***
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation of a diagnosis of unresectable or metastatic hepatocellular carcinoma **AND**
    - One of the following:
        - Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar) **AND**
        - Medical record documentation that Opdivo Qvantig will be used as a single-agent following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).

        OR
        - Medical record documentation that Opdivo Qvantig is being used as a single-agent in the first-line setting following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).

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

MBP 242.0 Evkeeza (evinacumab-dgnb) – Updated Policy

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Medical record documentation of one of the following:
    - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
    - Diagnosis made based on history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH in both parents)

  AND
- Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist **AND**
- Medical record documentation of age greater than or equal to 1 year ~~5 years~~ **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose AND ezetimibe defined as:
    - Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 1 year ~~5 years~~ of age and less than 18 years of age OR
    - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease OR
    - Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease

AND

- Medical record documentation of Evkeeza to be used in adjunct with maximum tolerated statin dose **AND**
- For members greater than or equal to 10 years of age, medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **AND**
- If the request is for use in combination with Juxtapid:

- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 6-month trial of maximum tolerated Juxtapid dose without the concomitant use of Evkeeza

The following policies were reviewed with no changes:

- MBP 42.0 Boniva IV

The following policies were reviewed with no changes and apply to GHP members only:

MBP 329.0 Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection) – Updated Policy

- Medical record documentation that the member is 50 to 59 years of age **AND**
- Medical record documentation of a diagnosis of chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney disease, or chronic liver disease ~~**AND**~~
- ~~Medical record documentation that the member is at an increased risk of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)~~

The following policy updates and reviews apply to Medicare GHP members only:

MBP 141.0 Nucala (mepolizumab) – Updated Policy

- Documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe eosinophilic chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation that Nucala is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ~~>~~ ≥ 300 cells/mcL (0.30 K/µl) during the 12-month period before screening and/or ~~>~~ ≥ 150 cells/mcL (0.15 K/µl) within 3 months of the start of therapy **AND**
- Medical record documentation of one severe or two moderate exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, antibiotics, emergency department or urgent care visits, or hospitalization) despite current therapy or intolerance to triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) **AND**
- ~~Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**~~
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for COPD treatment (e.g. Dupixent (dupilumab))