“What’s New” Medical Pharmaceutical Policy March 2024 Updates
The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 61.0 Flolan or Veletri (epoprostenol) – Updated Policy

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 90.0 Benlysta (belimumab) – Updated Policy

For active, autoantibody positive, Systemic Lupus Erythematosus (SLE)

- Medical record documentation of age greater than or equal to 5 years **AND**
- Physician provided documentation of a diagnosis of systemic lupus erythematosus **AND**
- Medical record documentation that patient has active disease OR recurrent flares OR inability to wean steroids in systemic lupus erythematosus **AND**
- Positive ANA/anti-dsDNA antibody **AND**
- Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant) **AND**
- No severe active CNS involvement **AND**
- Must be prescribed by a Rheumatologist **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

MBP 119.0 Keytruda (pembrolizumab) – Updated Policy

2. ~~Stage IB (T2a ≥ 4 cm), II, or IIIa~~ Neoadjuvant or Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) **AND**
  - Keytruda is being used in the adjuvant setting following resection and platinum-based chemotherapy **AND**
  - Keytruda is being used as a single agent

OR

- Medical record documentation of resectable (Tumors ≥ 4 cm or Node Positive) non-small cell lung cancer (NSCLC) **AND**
- Keytruda is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following resection

7. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
  - Disease progression during or following platinum-containing chemotherapy

OR

- Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
  OR
- Patient is not eligible for any platinum-containing chemotherapy
  OR
- Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** **AND**
- Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** **AND**
- Patient is ineligible for or has elected not to undergo cystectomy
  OR
- ~~Patient is not eligible for cisplatin-containing chemotherapy **AND**~~
- Keytruda is being used in combination with Padcev

8. Gastric Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that Keytruda will be used as first-line treatment **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
  - Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**
  - Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

  OR
  - Medical record documentation of locally advanced unresectable or metastatic HER-2 negative gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**
  - Medical record documentation that Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

9. Cervical Cancer

- Prescription written by a hematologist/oncologist **AND**
- One of the following:
  - Medical record documentation of recurrent or metastatic cervical cancer **AND**
  - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
  - Medical record documentation of disease progression after receiving at least one prior line of therapy

  OR
  - Medical record documentation of persistent, recurrent or metastatic cervical cancer **AND**
  - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
  - Medical record documentation that Keytruda will be used in combination with chemotherapy (paclitaxel, cisplatin or carboplatin), with or without bevacizumab

  OR
  - Medical record documentation of FIGO 2014 Stage III-IVA cervical cancer **AND**
  - Medical record documentation that Keytruda will be used in combination with chemoradiotherapy (cisplatin and external beam radiation therapy [EBRT] followed by brachytherapy [BT])

*Note: FIGO 2014 Stage III-IVA includes patients with tumor involvement of the lower vagina with or without extension onto pelvic sidewall or hydronephrosis/non-functioning kidney or has spread to adjacent pelvic organs.

18. Biliary Tract Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced unresectable or metastatic biliary tract cancer **AND**

- Medical record documentation that Keytruda will be used in combination with gemcitabine and cisplatin

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, neoadjuvant/adjuvant treatment of non-small cell lung cancer, and adjuvant treatment of renal cell carcinoma:
Initial approval will be for 6 months. One subsequent approval 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 patient experiences toxicity or worsening of disease.

- Authorization of Keytruda for the adjuvant treatment of metastatic melanoma, of non-small cell lung cancer, and of renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months).
- Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy.
- Authorization for the treatment of neoadjuvant/adjuvant treatment of non-small cell lung cancer should not exceed the approved treatment duration of 12 weeks of neoadjuvant treatment and 39 weeks of adjuvant therapy.

For requests exceeding the above limits, 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

MBP 148.0 Exondys 51 (eteplirsen) – Updated Policy

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Elevidys)*

MBP 214.0 Vyondys 53 (golodirsen) – Updated Policy

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Elevidys)*

MBP 226.0 Viltepso (viltolarsen) – Updated Policy

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Elevidys)*

MBP 241.0 Amondys 45 (casimersen) – Updated Policy

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Elevidys)*

MBP 307.0 Elevidys (delandistrogene moxeparvovec-rokl) – New Policy

Elevidys (delandistrogene moxeparvovec-rokl) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene **AND**
- One of the following:
    - Medical record documentation that the member is a male based on assigned sex at birth

OR

- Medical record documentation that the member is a female based on assigned sex at birth AND
- Medical record documentation that the member has a confirmed X-inactivation of the unmutated X-chromosome OR confirmed biallelic variants in the *DMD* gene (cytogenetic or molecular) alteration involving the Xp21 locus

AND

- Medical record documentation of patient age of at least 4, but no older than 5, years of age **AND**
- Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene **AND**
- Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) **AND**
- Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that patient has been initiated on corticosteroids for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days* **AND**
- Medical record documentation that the patient is on the appropriate weight-based dose **AND**
- Medical record documentation that the patient has never received Elevidys treatment in their lifetime **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy **AND**
- Medical record documentation that the patient will not receive exon-skipping therapies for Duchenne Muscular Dystrophy [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

***** Deflazacort is <u>not</u> recommended for use as a peri-Elevidys infusion corticosteroid

MBP 309.0 Bevacizumab (Avastin) and Biosimilars – New Policy

Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), and Zirabev (bevacizumab-bvzr) do not require prior authorization.

Avastin (bevacizumab) used for intravitreal injection does NOT require prior authorization. Otherwise, Avastin (bevacizumab) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to **<u>all</u>** of the following: Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr).

AUTHORIZATION DURATION:
<u>For adjuvant treatment of Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer following initial surgical resection:</u>
Authorization will be for one (1) 21 month approval. Authorization of Avastin for adjuvant treatment should not exceed the FDA-approved treatment duration of 21 months (28 cycles). 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

<u>For all other indications</u>:
Authorization will be open-ended

MBP 311.0 Xacduro (sulbactam and durlobactam) – New Policy

Xacduro (sulbactam and durlobactam) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Hospital-acquired Bacterial Pneumonia (HABP) or Ventilator-associated Bacterial Pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus complex* **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Xacduro is prescribed by or in consultation with Infectious Disease **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments or combination therapy depending on severity **OR**
    - Medical record documentation of history of previous intolerance to or contraindication to two (2) preferred alternative antibiotics or combination therapy depending on severity, shown to be susceptible on the culture and sensitivity.

AUTHORIZATION DURATION: 14 Days

QUANTITY LIMITS: 168 vials per 14 days

IMPORTANT NOTE: The manufacturer of Xacduro has not entered into a rebate agreement with CMS to date so Xacduro is not currently a Medicaid-covered drug.

MBP 312.0 Veopoz (pozelimab-bbfg) – New Policy

Veopoz (pozelimab-bbfg) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of CD55-deficient protein losing enteropathy (CHAPLE disease) with a confirmed genotype of biallelic CD55 loss-of-function mutation **AND**
- Medical record documentation of age ≥ 1 year **AND**
- Prescribed by or in consultation with a hematologist, gastroenterologist, or a provider specialized in rare genetic hematologic diseases **AND**
- Medical record documentation that the patient is vaccinated with the meningococcal vaccine **AND**
- Medical record documentation that Veopoz will not be used in combination with Soliris (eculizumab) **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 no worsening of clinical symptoms, increase in or stabilization of albumin and IgG concentration)

MBP 313.0 Rezzayo (rezafungin) – New Policy

Rezzayo (rezafungin) will be considered medically necessary 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 non-neutropenic patient with a diagnosis of candidemia or invasive candidiasis (other than endocarditis, osteomyelitis, or meningitis) **AND**

- Medical record documentation that Rezzayo is prescribed by an infectious disease specialist **AND**
- Medical record documentation that member has limited or no alternative treatment options

AUTHORIZATION DURATION: 4 weeks