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

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

MBP 368.0 Zusdri (mitomycin intravesical solution) – New Policy

- Medical record documentation that Zusduri is prescribed by a hematologist/oncologist or urologist **AND**
- Medical record documentation of a diagnosis of recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) **AND**
- Medical record documentation of age greater than or equal to 18 years

AUTHORIZATION DURATION: Authorization will be for one 6 (six) month approval. Authorization of Zusduri for the treatment of LG-IR-NMIBC should not exceed the FDA-approved treatment duration of 6 weekly doses. 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

MBP 366.0 Ivra (melphalan) – New Policy

- Medical record documentation that Ivra will be used for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to generic melphalan products

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 6 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 365.0 Kyxata (carboplatin) – New Policy

- Medical record documentation Kyxata is being used as part of a combination regimen for the initial treatment of advanced ovarian carcinoma OR as a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to generic carboplatin products

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 6 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 362.0 Ryoncil (remestemcel-L-rknd) – New Policy

- Medical record documentation that remestemcel-L-rknd (Ryoncil) is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 2 months to less than 18 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD)

AUTHORIZATION DURATION: Initial approval will be for 2 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 1 month or less if the reviewing provider feels it is medically appropriate and will require documentation of the following:

- Medical record documentation of a complete response following initial treatment with Ryoncil AND documentation of recurrent steroid refractory graft-versus-host disease (GVHD)

MBP 363.0 Zevaskyn (prademagene zamikeracel) – New Policy

- Medical record documentation that Zevaskyn is prescribed by or in consultation with a dermatologist or wound care specialist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) **AND**
- Medical record documentation of at least one clinical feature of RDEB (recessive dystrophic epidermolysis bullosa) including but not limited to blistering, scarring and skin wounds **AND**
- Medical record documentation of genetic testing confirming mutation(s) in both alleles in the collagen type VII alpha 1 chain (COL7A1) gene **AND**
- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound AND all of the following:
    - documentation of the presence of partial-thickness RDEB wounds open chronically for greater than or equal to 6 months **AND**
    - documentation that member does not have current evidence or a history of squamous cell carcinoma (SCC) in the wound area **AND**
    - documentation that the wound area has not been previously treated with Zevaskyn **AND**
- Medical record documentation that member does not have an immune response to C7 by indirect immunofluorescence (IIF) **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 **AND**
- Medical record documentation that Zevaskyn will not be used concomitantly with another treatment indicated for dystrophic epidermolysis bullosa (DEB) (i.e. Vyjuvek, Filsuvez)

AUTHORIZATION DURATION/ QUANTITY LIMIT: Approve for three (3) months auth duration for one (1) application of up to twelve (12) gene-modified cellular sheets.

MBP 364.0 Kresladi (marnetegragene autotemcel) – New Policy

- Medical record documentation of an age greater than or equal to 9 months and less than 18 years of age **AND**
- Medical record documentation that Kresladi is being prescribed by or in consultation with an immunologist, hematologist, oncologist, infectious disease specialist, or other providers with expertise in the diagnosis and treatment of leukocyte adhesion deficiency-I (LAD-I) **AND**
- Medical record documentation of a confirmed diagnosis of severe LAD-I demonstrated by ONE of the following:
    - Flow cytometry indicating CD18 expression on < 2% neutrophils (polymorphonuclear neutrophils [PMNs]) **OR**
    - For patients in which CD18+ PMNs are ≥2%, all of the following:
        - <2% CD11a or CD11b expressing PMNs **AND**
        - Documented ITGB2 mutation **AND**
        - Clinical history consistent with LAD-I OR documented known family history of LAD-I **AND**
- Medical record documentation that the patient is considered to be an appropriate candidate for autologous transplantation of hematopoietic stem cells **AND**
- Medical record documentation that the patient is NOT pregnant or breastfeeding **AND**

- Medical record documentation that the patient does NOT have a medically-eligible human leukocyte antigen (HLA)-matched sibling stem cell donor OR a feasible HLA-matched sibling donor for stem cell collection is not identified (e.g., donor is in utero, is a newborn from whom cord blood was not collected, or is unable to undergo donation procedure because of medical impairments) **AND**
- Medical record documentation that the patient does NOT have hepatic dysfunction as defined by bilirubin > 1.5 times the upper limit of normal OR alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 2.5 times the upper limit of normal **AND**
- Medical record documentation that the patient does NOT have renal dysfunction or the requirement for either peritoneal dialysis or hemodialysis **AND**
- Medical record documentation that the patient does NOT have pulmonary dysfunction as defined by either the need for supplemental oxygen during the prior 2 weeks (in absence of acute infection) OR oxygen saturation (by pulse oximetry) < 90% **AND**
- Medical record documentation that the patient does NOT have a serious, untreated infection with persistent bloodstream pathogens **AND**
- Medical record documentation that the patient does NOT have active or metastatic locoregionally advanced malignancy (including hematologic malignancy) for which survival is anticipated to be less than 3 years **AND**
- Medical record documentation that the patient does NOT have significant medical conditions including documented human immunodeficiency virus (HIV) infection, poorly controlled diabetes, poorly controlled hypertension, poorly controlled cardiac arrhythmia or heart failure, or arterial thromboembolic events (including myocardial infarction or stroke) within the prior 6 months **AND**
- Medical record documentation that the patient has NOT received prior treatment with Kresladi

AUTHORIZATION DURATION: One (1) time approval (auth duration: 3 months) 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.

MBP 309.0 Bevacizumab (Avastin) and Biosimilars & 2026 Part B Step Therapy Drugs List & Criteria – Updated Policy

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

AUTHORIZATION DURATION:
For adjuvant treatment of Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer following initial surgical resection:
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

For all other indications:
Authorization will be open-ended

The following policies were reviewed with no changes:

- MBP 7.0 Aldurazyme
- MBP 43.0 Alpha 1-Antitrypsin Inhibitor Therapy
- MBP 44.0 Elaprase
- MBP 88.0 Halaven
- MBP 294.0 Trastuzumab (Herceptin) and Biosimilars
- MBP 347.0 Niktimvo

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

MBP 254.0 Leqvio (inclisiran) – Updated Policy

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia AND either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **OR**
  - Homozygous familial hypercholesterolemia (HoFH) AND either:
    - 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 a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500mg/dL AND either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  - Low-density lipoprotein (LDL) greater than 100 if the member is using Leqvio for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 55 if the member is using Leqvio for secondary prevention

AND

- Medical record documentation of age greater than or equal to 18 years for ASCVD **OR**
- Medical record documentation of age greater than or equal to 12 years for HeFH or HoFH **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha OR Praluent **AND**
- Medical record documentation that Leqvio is not being used in combination with another PCSK9 inhibitor