"What's New" Medical Pharmaceutical Policy December 2021 Updates
The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 144.0 Tecentriq (atezolizumab) – Updated Policy

1. **Locally Advanced or Metastatic Urothelial Carcinoma:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis 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**~~
     - Patient is not eligible for cisplatin-containing therapy **AND**
     - Tumors express PD-L1 (greater than or equal to 5%) as determined by an FDA-approved test

     OR
     - Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)

2. **Non-Small Cell Lung Cancer:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
     - Medical record documentation of disease progression during or following platinum-containing chemotherapy

     OR
     - Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.)

     OR
     - Medical record documentation of a non-squamous histologic subtype **AND**
     - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
     - Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, AND carboplatin **OR** paclitaxel protein-bound AND carboplatin **AND**
     - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

     OR
     - Medical record documentation that Tecentriq will be given as first-line treatment for metastatic disease **AND**
     - Medical record documentation that tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]) as determined by an FDA-approved test **AND**
     - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

     OR
     - Medical record documentation of stage II to IIIA disease **AND**
     - Medical record documentation of use as adjuvant treatment following resection and platinum-based therapy **AND**

- Medical record documentation that tumors have PD-L1 expression on ≥1% of tumor cells as determined by an FDA-approved test **AND**
- Medical record documentation that Tecentriq is being given as a single agent.

~~**3. Breast Cancer:**~~

- ~~Prescription written by an oncologist **AND**~~
- ~~Medical record documentation of a diagnosis of advanced or metastatic triple negative (ER-negative, PR-negative, HER2-negative) breast cancer **AND**~~
- ~~Medical record documentation that tumors express PD-L1 (greater than or equal to 1%) as determined by an FDA-approved test **AND**~~
- ~~Medical record documentation that Tecentriq will be used in combination with protein-bound paclitaxel (Abraxane).~~

MBP 196.0 Ultomiris (ravulizumab-cwvz) – Updated Policy

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescription is written by a hematologist **AND**
- Medical record documentation of ~~18 years of age or older~~ 1 month of age or older **AND**
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
- Medical record documentation of patient being vaccinated with the meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations **AND**
- Physician 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 ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment **OR**
  - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

MBP 224.0 Tecartus (brexucabtagene autoleucel) – Updated Policy

Mantle Cell Lymphoma (MCL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Acute Lymphoblastic Leukemia (ALL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

MBP 245.0 Empaveli (pegcetacoplan) – New Policy

Empaveli (pegcetacoplan) will be considered medically necessary when all of the following criteria are met:

- 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 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

AUTHORIZATION DURATION: 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

The following policies were reviewed with no changes:

- MBP 97.0 Kyprolis (carfilzomib)
- MBP 206.0 Khapzory (levoleucovorin calcium)
- MBP 223.0 Blenrep (belantamab mafodotin-blmf)