“What’s New” Medical Pharmaceutical Policy October 2019 Updates

MBP 117.0 Beleodaq (belinostat)- Updated policy

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

- Must be prescribed by a hematologist/oncologist AND
- Documentation of age > 18 years AND
- Medical record documentation of a diagnosis of relapsed or refractory peripheral T-cell lymphoma

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 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 119.0 Keytruda (pembrolizumab)- Updated policy

14. Esophageal Cancer
- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of locally advanced or metastatic squamous cell carcinoma of the esophagus AND
- Medical record documentation that tumors express PD-L1 (CPS ≥10) as determined by an FDA-approved test AND
- Medical record documentation of disease progression after one or more prior lines of systemic therapy for advanced disease

MBP 139.0 Darzalex (daratumumab)- Updated policy

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

- Prescription written by a hematologist/oncologist AND
- Medical record documentation a diagnosis of multiple myeloma AND
  - If newly diagnosed multiple myeloma:
    - Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) AND
    - Medical record documentation that Darzalex will be given in combination with one of the following options:
      - Bortezomib (Velcade), melphalan, AND prednisone [VMP] OR
      - Lenalidomide (Revlimid) AND dexamethasone OR
    - Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), melphalan, AND prednisone [VMP] OR
  - If relapsed/refractory multiple myeloma:
    - One of the following:
      - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited
to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR

- Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) AND one of the following:
  - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone OR
  - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone

**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 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 201.0 Zulresso (brexanolone)- New policy**

**DESCRIPTION:**

Zulresso (brexanolone) is a gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults. The exact mechanism of action is not fully understood, but is thought to be related to positive allosteric modulation of GABA-A receptors.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Zulresso (brexanolone) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by (or in consultation with) a psychiatrist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis postpartum depression (PPD) as defined by ALL of the following:
  - Patient has a diagnosis of a major depressive episode AND
  - Patient experienced onset of symptoms within the third trimester or within 4 weeks of delivery AND
- Medical record documentation that patient is less than or equal to 6 months postpartum AND
- Medical record documentation that current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale (e.g. a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than or equal to 17 on the Hamilton Depression Rating Scale (HAM-D), etc.)

**AUTHORIZATION DURATION:** One-time authorization of one 60-hour infusion of Zulresso

Note: The safety and efficacy of repeated Zulresso infusions have not been studied. Additional infusion(s) of Zulresso for future cases of PPD associated with additional pregnancies will be reviewed for medical necessity based on the above criteria. More than one administration of Zulresso per pregnancy/birth is considered investigational and not covered.
MBP 202.0 Evenity (romosozumab-aqqg) - New policy

DESCRIPTION:

Evenity (romosozumab-aqqg) is a sclerostin inhibitor monoclonal antibody that inhibits sclerostin, a regulatory factor in bone metabolism that inhibits Wnt/Beta-catenin signaling pathway regulating bone growth; romosozumab increases bone formation and to a lesser extent, decreases bone resorption.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Evenity (romosozumab-aqqg) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Evenity is prescribed by a rheumatologist or endocrinologist AND
- Medical record documentation that the patient has not had a myocardial infarction or stroke within the past 12 months AND
- Medical record documentation of a diagnosis of postmenopausal osteoporosis AND
- Medical record documentation that the member has not previously received greater than or equal to 12 monthly doses of Evenity AND
- Medical record documentation that the patient is at high-risk of a fracture, determined by the presence of ONE or more of the following:
  - Previous osteoporotic fracture OR
  - Spine or hip DXA T-Score of -2.5 or below OR
  - FRAX calculation of the 10-year hip fracture risk of 3% or greater OR
  - FRAX calculation of the 10-year risk of major osteoporotic fractures of 20% or greater OR
  - Medical record documentation that the patient has failed or is intolerant to at least one prior osteoporosis therapy

QUANTITY LIMITS: 12 visits over 12 months

AUTHORIZATION DURATION: Approval will be for 12 months, or less if there is medical record documentation of a previous incomplete course of therapy with Evenity.

Note: The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

The following policies were reviewed with no changes:

- MBP 64.0 Arranon (nelarbine)
- MBP 65.0 Torisel (temsirolimus)
- MBP 90.0 Benlysta (belimumab)
- MBP 93.0 Nulojix (belatacept)
- MBP 96.0 Voraxaze (glucarpidase)
- MBP 111.0 Marqibo (vincristine sulfate liposome injection)
- MBP 133.0 Signifor LAR (pasireotide LAR)
- MBP 159.0 Kymriah (tisagenlecleucel)
- MBP 162.0 Yescarta (axicabtagene ciloleucel)
- MBP 166.0 Adcetris (brentuximab vedotin)
- MBP 167.0 Vabomere (meropenem-vaborbactam)
- MBP 168.0 Parsabiv (etelcalcetide)
- MBP 169.0 Baxdela IV (delafloxacin)
- MBP 170.0 LutaThera (lutetium Lu 177 dotatate)
- MBP 172.0 Trisenox (arsenic trioxide)
• MBP 184.0 Azedra (iobenguane I 131)
• MBP 186.0 Libtayo (cemiplimab-rwlc)
• MBP 187.0 Zemdri (plazomicin)
• MBP 189.0 Lumoxiti (moxetumomab pasudotox-tduk)