"What's New" Medical Pharmaceutical Policy Updates March 2017

MBP 147.0 Lartruvo (olaratumab)- New Policy

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

- Must be prescribed by an oncologist/hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amendable to curative treatment with radiotherapy or surgery **AND**
- Medical record documentation that Lartruvo will be administered in combination with doxorubicin for the first eight (8) treatment cycles

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 149.0 Ameluz (aminolevulinic acid)- New Policy

Ameluz (aminolevulinic acid) will be considered medically necessary when ALL of the following criteria are met:

- Must be prescribed by an dermatologist **AND**
- Medical record documentation of a diagnosis of actinic keratosis of mild-to-moderate severity on the face and/or scalp **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND**
- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp

QUANTITY LIMIT: 2 grams per application (1 tube=2grams)

AUTHORIZATION DURATION: Initial approval will be for a period of 3 months. One additional 3 month approval may be granted if there is medical record documentation that lesions have not completely resolved within 3 months after the initial treatment

MBP 150.0 Sustol (granisetron ER)- New Policy

Sustol (granisetron ER) will be considered medically necessary when the following criteria are met:

- Medical record documentation that Sustol is being used for the prevention of acute or delayed nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone **AND**
- Medical record documentation that member has a treatment failure or contraindication to Aloxi (palonosetron)

OR

- Medical record documentation that Sustol is being used for prevention of acute or delayed chemotherapy induced nausea and vomiting from low, or minimally emetogenic chemotherapy for members who have a treatment failure or contraindication to Aloxi (palonosetron) **AND** ondansetron OR granisetron **AND**

- Medical record documentation that Sustol is being given in combination with dexamethasone.

The following antineoplastic agents are considered MODERATELY emetogenic (not a complete list):

- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Carboplatin
- Carmustine ≤ 250 mg/m^2
- Clofarabine
- Cyclophosphamide ≤ 1500mg/m^2
- Cytarabine >200mg/m^2
- Dactinomycin
- Daunorubicin
- Dinutuximab
- Doxorubicin <60 mg/m^2
- Epirubicin ≤ 90 mg/m^2
- Idarubicin
- Ifosfamide <2 g/m^2 per dose
- Interferon alfa ≥ 10 million IU/m^2
- Irinotecan
- Melphalan
- Methotrexate ≥250 mg/m^2
- Oxaliplatin
- Temozolomide
- Trabectedin

QUANTITY LIMIT: One 10mg syringe per 7 days (56 syringes/12month authorization) *based on FDA Max dosing*

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)- REVISED New criteria

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

1. **Unresectable or Metastatic Melanoma**
   - 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 unresectable or metastatic melanoma **AND**
   - Medical record documentation that Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

2. **Metastatic Non-Small Cell Lung 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 metastatic NSCLC meeting one of the following situations:
     - Medical record documentation that tumors have high PD-L1 expression (Tumor Proportion Score (TPS)≥50% as determined by an FDA-approved test **AND**
     - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

     OR
     - Medical record documentation that tumors express PD-L1 (TPS)≥1% as determined by an FDA-approved test **AND**
     - Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**
     - For patients with EGFR or ALK genomic tumor aberrations: medical record

documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

- ~~Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with tumor expression of PD-L1 as determined by an FDA-approved test and disease progression while on or after platinum-based chemotherapy~~

3. Head and Neck Squamous Cell Carcinoma

- 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 Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic and had disease progression on or after platinum-containing chemotherapy

MBP 126.0 Opdivo (nivolumab)- REVISED New Indication

5. *Squamous Cell Carcinoma of the Head and Neck (SCCHN)*

- 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 recurrent or metastatic squamous cell carcinoma of the head and neck **AND**
  Medical record documentation of disease progression while on or after receiving a platinum-based therapy

MBP 139.0 Darzalex (daratumumab)- REVISED New Indication

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 of a diagnosis of multiple myeloma **AND**
- 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 ~~6~~ 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional ~~6~~ 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 144.0 Tecentriq (atezolizumab)- REVISED New criteria

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

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 that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

2. **Non-Small Cell Lung Cancer:**
- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of non-small cell lung cancer **AND**
- Medical record documentation that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - 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.).

AUTHORIZATION DURATION: Initial approval will be for ~~6~~ 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional ~~6~~ 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.

The following policies were reviewed with no changes:

- MBP 4.0 Intravenous Immune Globulin (IVIG)
- MBP 7.0 Aldurazyme (laronidase)
- MBP 18.0 Fabrazyme (agalsidase beta)
- MBP 23.0 Velcade (bortezomib)
- MBP 29.0 Elitek (rasburicase)
- MBP 38.0 Clolar (clofarabine)
- MBP 39.0 Naglazyme (galsulfase)
- MBP 42.0 Boniva IV (ibandronate)
- MBP 43.0 Alpha 1-Antitrypsin Inhibitor Therapy
- MBP 44.0 Elaprase (idursulfase)
- MBP 46.0 Dacogen (decitabine)
- MBP 49.0 Erythropoeitin and Darbepoetin Therapy
- MBP 50.0 Vectibix (panitumumab)
- MBP 55.0 Myozyme (alglucosidase alfa)
- MBP 58.0 Prialt (ziconotide intrathecal infusion)