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

MBP 40.0 Orencia IV (abatacept)- New Indication

Orencia IV (abatacept) will be considered medically necessary when all of the following criteria are met:

1. Rheumatoid arthritis that is refractory to DMARD therapy, including TNF(Tumor necrosis factor) antagonists:
    - Documentation of a diagnosis of moderate to severe RA in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
    - Member must be at least 18 years old; **AND**
    - Must be prescribed by a rheumatologist; **AND**
    - Documentation of inadequate response to minimum 3 month trial of one preferred TNF alpha inhibitor Enbrel OR Humira)

2. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
    - Insured individual is 6 years of age or older ; **AND**
    - Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid **AND**
    - Must be prescribed by a rheumatologist; **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 4 month trial of one preferred TNF alpha inhibitor (Enbrel **OR** Humira)

3. Psoriatic Arthritis (PsA):
    - Prescription written by a rheumatologist **AND**
    - Medical record documentation of a diagnosis of active psoriatic arthritis **AND**
    - Medical record documentation of age ≥ 18 years of age **AND**
    - Medical record documentation of an inadequate response to a minimum 3 month trial of one preferred TNF-alpha inhibitor (Humira* **OR** Enbrel*)

MBP 50.0 Vectibix (panitumumab)- Revised Criteria

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

1. Metastatic Colorectal Cancer

- Prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic colorectal carcinoma; **AND**
    - ~~Medical record documentation of use~~ Used in combination with FOLFOX for first line treatment; **OR**
    - ~~Medical record documentation of use~~ Used as monotherapy ~~following~~ with disease progression on (or intolerance or contraindication to) ~~following~~ fluoropyrimidine, ~~(5-fluorouracil or Xeloda® [capecitabine]),~~ oxaliplatin ~~(Eloxatin®)~~, AND irinotecan ~~(Camptosar®)~~ containing chemotherapy regimens; **AND**
- Medical record documentation of wild-type *RAS* (defined as wild-type (negative) in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use)
- ~~Physician provided documentation of KRAS testing performed prior to therapy verifies KRAS wildtype (negative); **AND**~~
- ~~Medical record documentation, if used with an oxaliplatin-based regimen, of RAS wildtype (negative).~~

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.

LIMITATIONS: Vectibix is not indicated for the treatment of patients with RAS-mutant metastatic colorectal cancer or for whom RAS mutation status is unknown

Note: Vectibix is not effective for the treatment of patients with RAS-mutant mCRC (defined as a RAS mutation in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), or exon 4 (codons 117 and 146) of KRAS and NRAS.

~~Current evidence in the published peer-reviewed medical literature does not show a treatment benefit for the use of Vectibix in individuals whose tumors exhibited KRAS mutations in codon 12 or 13. Use of Vectibix in the treatment of colorectal cancer with these mutations is not medically necessary and therefore **NOT COVERED**.~~

MBP 76.0 Actemra IV (tocilizumab)- Revised Criteria

Indications which Do Not Require Prior Authorization for use:

Claims submitted with the following diagnosis for use Do Not require prior authorization for use:

- Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)

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

Actemra IV (tocilizumab) will be considered medically necessary when all of the following criteria are met:

1. Adults with moderate to severe rheumatoid arthritis:
   - Medical record documentation that member is 18 years of age or greater **AND**
   - Prescription written by a rheumatologist **AND**
   - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis); **AND**
   - Medical record documentation of a therapeutic failure on, contraindication to or intolerance to 12 weeks of Humira* **AND** Enbrel*

     *Requires prior authorization

2. Active systemic juvenile idiopathic arthritis (SJIA).
   - Prescription written by a rheumatologist **AND**
   - Patient is 2 years of age or older **AND**
   - Medical record documentation of a diagnosis of systemic juvenile idiopathic arthritis

3. Active polyarticular juvenile idiopathic arthritis (PJIA)
   - Medical record documentation that member is 2 years of age or greater **AND**
   - Prescription is written by a rheumatologist; **AND**
   - Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
   - Physician provided documentation of a therapeutic failure on, contraindication to or

intolerance to a minimum 4 month trial of Humira* **AND** Enbrel*

*Requires prior authorization

MBP 106.0 Injectable Antipsychotic Medications- New Indication

The following Injectable Antipsychotic Medications (Invega Trinza, Invega Sustenna, Aristada, Abilify Maintena, Zyprexa Relprevv, or Risperdal Consta) will be considered medically necessary when the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of use for an FDA approved indication.
    - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Aristada – Schizophrenia
    - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
    - Invega Trinza – Schizophrenia
    - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.

MBP 126.0 Opdivo (nivolumab)- New Indication

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

1. *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 Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

2. *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 a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
    - Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

3. *Renal Cell Carcinoma*
    - Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**

- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

4. *Classical Hodgkin Lymphoma (CHL)*
- 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 classical Hodgkin lymphoma (CHL) that has relapsed or progressed after:
    - Autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris). OR
    - Three (3) or more lines of systemic therapy that includes autologous HSCT

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

6. Urothelial Carcinoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient > 18 years of age **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND 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

  AND
- Medical record documentation that Opdivo is NOT being used in combination with any other agent

7. Colorectal Cancer
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 12 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease **AND**
- Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, or irinotecan

MBP 128.0 Blincyto (blinatumomab)- Revised criteria

Blincyto (blinatumomab) will be considered medically necessary when all of the following criteria are met:
- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of ~~Philadelphia chromosome-~~**negative** relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Initial approval will be limited to one lifetime ~~5~~ 9 cycle (~~8 month~~ 20 month) course. Subsequent approval for treatment past the initial ~~5~~ 9 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MBP 152.0 Bavencio (avelumab)- New Indication

Bavencio (avelumab) will be considered medically necessary when ALL of the following criteria are met for each indication:

Merkel Cell Carcinoma

- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) AND
- Medical record documentation of age ≥12 years

Urothelial Carcinoma

- Prescribed by a hematologist/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
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

MBP 155.0 Ocrevus (ocrelizumab)- Revised Criteria

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

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation Ocrevus is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
- Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis **AND**
- For members with a diagnosis of a relapsing form of multiple sclerosis, medical record documentation of therapeutic failure on, intolerance to, or contraindication to two ~~three~~ formulary alternatives.

MBP 157.0 Brineura (cerliponase alfa)- New Policy

Brineura (cerliponase alfa) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the prescription is written by a pediatric neurologist **AND**
- Medical record documentation that the patient is 3 years of age or older **AND**
- Medical record documentation of a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (LINCL) confirmed by the following test results:
  - Deficient TPP1 activity in leukocytes on the enzyme activity test **AND**
  - Pathogenic variant/mutation in the TPP1/CLN2 gene (note- may be absent in up to 20% of patients, but if present is confirmatory of diagnosis) **AND**
- Medical record documentation of the baseline score on the motor domain of the CLN2 clinical rating scale **AND**
- **For Commercial Lines of Business only**: Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility)

QUANTITY LIMIT: 2 doses per month (24 doses per year)

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 the following Reauthorization criteria are met:

- **For Medicaid Lines of Business only:** Medical record documentation that there is continued benefit from treatment based on the prescriber's professional judgment
- **For Commercial Lines of Business only**: Medical record documentation that patient remains to be ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility).

MBP 158.0 Tepadina (thiotepa)- New Policy

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

- Prescription written by a pediatric hematologist/oncologist or pediatric transplant specialist **AND**
- Medical record documentation that the patient's disease is class 3 in severity as evidenced by the presence of ALL of the following:
    - Liver size > 2 cm
    - Presence of liver fibrosis; and
    - Inadequate iron chelation **AND**
- Medical record documentation that the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT) **AND**
- Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide **AND**
- Medical record documentation that the patient is under 18 years of age

OR

Requests for any of the following indications will be reviewed based on medical necessity:

- For treatment of adenocarcinoma of the breast or ovary
- For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities.
- For treatment of superficial papillary carcinoma of the urinary bladder.

AUTHORIZATION DURATION: Approved requests should be authorized one time for a total of **two doses**, with a quantity limit for an appropriate number of vials* of each strength based on the patient's weight (dose is 5mg/kg).

*Supplied as 15mg single-dose vial or 100mg single-dose vial

The following policies were reviewed with no changes:

- MBP 59.0 White Blood Cell Stimulating Factors
- MBP 78.0 Istodax (romidepsin)
- MBP 110.0 Xofigo (radium Ra 223 dichloride)
- MBP 114.0 Vimizim (elosulfase alfa)
- MBP 120.0 Sylvant (siltuximab)
- MBP 121.0 Dalvance (dalbavancin)
- MBP 122.0 Sivextro (tedizolid phosphate) IV
- MBP 136.0 Imlygic (talimogene laherparepvec)
- MBP 137.0 Yondelis (trabectedin)
- MBP 138.0 Onivyde (irinotecan liposome injection)
- MBP 140.0 Empliciti (elotuzumab)
- MBP 80.0 Xiaflex (collagenase clostridium histolyticum)