"What's New" Medical Pharmaceutical Policy November 2018 Updates

MBP 5.0 Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)- Updated policy

For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis

AND

- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* ~~AND Enbrel*~~ **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

MBP 40.0 Orencia IV (abatacept)- Updated policy

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**
   - Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Documentation of inadequate response to minimum 3 month trial of Humira* ~~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 that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 4 month trial of Humira* ~~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 moderate to severe active psoriatic arthritis which must include the following:
     - Documentation of either active psoriatic lesions OR a documented history of psoriasis. **AND**
   - Medical record documentation of age ≥ 18 years of age **AND**

- Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of one preferred biologic (Humira* **AND** Cosentyx*)

MBP 48.0 Rituxan (rituximab)- Updated policy

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

1. **For Rheumatoid Arthritis:**
   All of the following criteria must be met:
   - Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
   - At least 18 years of age or older; **AND**
   - Prescription written by a rheumatologist; **AND**
   - Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
   - Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
   - Physician documentation of an inadequate response to 12 weeks of therapy with ~~etanercept (Enbrel) **AND**~~ adalimumab (Humira); **AND**

   LIMITATIONS:
   If criteria are met, approval will be limited to one course of therapy defined as two infusions, one given on day 1 and another on day 15.
   Additional courses may be considered medically necessary if the following criteria are met:
   - At least 6 months has elapsed since the previous treatment course; **AND**
   - Physician documentation of improvement or lack or progression in the signs and symptoms of rheumatoid arthritis; **AND**
   - Physician documentation showing previous treatment course did not result in active infection.

2. **For Chronic Immunothrombocytopenia (ITP):**
   All of the following criteria must be met:
   - Diagnosis of primary chronic ITP **AND**
   - Platelet count of < 30,000/mm^3 with active bleeding or < 20,000/mm^3 with increased risk of bleeding **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND IVIg* AND splenectomy (*prior authorization required)

   Authorization Duration*: If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.

3. **For Chronic Lymphoid Leukemia:**
   Note: *Prior authorization is not required for diagnosis codes C91.10, C91.11 and C91.12. In the event a requestor would like a medical necessity review completed the following criteria would apply:*
   - Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL)
   - ~~Medical record documentation of a diagnosis of chronic lymphoid leukemia used in combination with fludarabine and cyclophosphamide~~

4. For Microscopic Polyarteritis Nodosa

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

5. For Wegner's Granulomatosis

- Medical record documentation of a diagnosis of Wegner's granulomatosis used in combination with glucocorticoids

6. **For Non-Hodgkin Lymphoma**

Note: *Prior authorization is not required for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

7. **For Multiple Sclerosis (MS)**

Note: *Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Multiple Sclerosis

~~**For Primary Progressive MS (PPMS):**~~

~~All of the following criteria must be met:~~

- ~~Medical record documentation of prescription written by a neurologist **AND**~~
- ~~Medical record documentation of a diagnosis of PPMS~~

~~**For Secondary Progressive MS (SPMS)/Relapsing Progressive MS (RPMS):**~~

~~All of the following criteria must be met:~~

- ~~Medical record documentation of prescription written by a neurologist **AND**~~
- ~~Medical record documentation of a diagnosis of SPMS or relapsing progressive MS **AND**~~
  - ~~Medical record documentation of rapidly progressing disease (ex. EDSS score increase of >1 in 1 year) **OR**~~
  - ~~Medical record documentation of slowly progressing disease (ex. EDSS score change of < 1 in 1 year) and therapeutic failure on, contraindication to, or intolerance to Aubagio ^~~

~~**For Relapsing/Remitting MS (RRMS):**~~

~~All of the following criteria must be met:~~

- ~~Medical record documentation of prescription written by a neurologist **AND**~~
- ~~Medical record documentation of a diagnosis of Relapsing/Remitting MS (RRMS) **AND**~~
  - ~~Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three alternatives one of which must be Tysabri* **OR**~~
  - ~~Medical record documentation of poor prognosis and therapeutic failure on, contraindication to, or intolerance to Tysabri*~~

~~*NOTE: According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.* **Patients who are anti-JCV antibody positive should avoid Tysabri use.**~~

~~(* requires prior authorization, ^QL apply)~~

~~(**NOTE to reviewer: Studied dose for MS is 1gm given on day 1 and 15, repeated every 6 months**)~~

8. **For Refractory Chronic Debilitating Myasthenia Gravis**
   - Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
   - Prescribed by or in consultation with a neuromuscular specialist **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

9. **For Pemphigus Vulgaris (PV)**
   - Prescription written by a dermatologist **AND**
   - Member is 18 years of age or older **AND**
   - Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
   - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids AND a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

MBP 59.0 White Blood Cell Stimulating Factors - Updated policy

Leukine: May also be considered medically necessary for the following:

10. **Delayed Neutrophil Recovery or Graft Failure**
   - Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm^3 or greater.

MBP 74.0 Cimzia (certolizumab pegol)- Updated policy

2. Rheumatoid Arthritis
- Physician documentation for 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**
- Prescription written by a rheumatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* ~~**AND** Enbrel*~~ (*requires prior authorization)

MBP 76.0 Actemra IV (tocilizumab)- Updated policy

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 that Actemra is not being used concurrently with a TNF blocker or other biologic agent **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 **AND**
   - Medical record documentation that Actemra is not being used concurrently with a TNF blocker or other biologic agent **AND**

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**
   - Medical record documentation that Actemra is not being used concurrently with a TNF blocker or other biologic agent **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 81.0 Prolia (denosumab)- Updated policy

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

1. **For post-menopausal women at high risk for fractures:**
   - Physician provided documentation of a diagnosis of post-menopausal osteoporosis; and
   - Physician provided documentation of previous osteoporotic fracture or high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture); ~~and~~ **OR**
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

2. **For increasing bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:**
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

3. **For increasing bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer:**

- Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

4. **For the treatment of men at high risk for fractures:**
   - Physician provided documentation of a diagnosis of osteoporosis; and
   - Physician provided documentation of previous osteoporotic fracture or high risk of fracture (defined as spine or hip DXA T-score of less than or equal to -2.0, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture); ~~and~~ **OR**
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

5. **For the treatment of glucocorticoid-induced osteoporosis:**
   - Medical record documentation of a diagnosis of glucocorticoid-induced osteoporosis **AND**
   - Medical record documentation that the patient is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone **AND**
   - Medical record documentation that the patient is going to remain on systemic glucocorticoid therapy for at least 6 months **AND**
   - Medical record documentation of previous osteoporotic fracture or high risk of fracture defined as DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a ≥3% probability of hip fracture OR ≥20% probability of major osteoporosis-related fracture **OR**
   - Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

MBP 91.0 Yervoy (Ipilimumab)- Updated policy

3. 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-based therapy **AND**
- Medical record documentation that Yervoy is being given in combination with nivolumab (Opdivo).

AUTHORIZATION DURATION:

For Unresectable or metastatic melanoma, colorectal cancer and Advanced Renal Cell Carcinoma:
Approval will be for one (1) **6-month** authorization for the FDA-approved maximum of up to four (4) doses of Yervoy. Requests for authorization exceeding these limits will require the following:
- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- 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 112.0 Simponi Aria (golimumab)- Updated policy

Rheumatoid Arthritis
- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of ~~etanercept (Enbrel*) AND~~ adalimumab (Humira*) therapy.

MBP 119.0 Keytruda (pembrolizumab)- Updated policy

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 Keytruda is being given as monotherapy **AND**
    - 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 Keytruda is being given as monotherapy **AND**
    - 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.

OR

    - Medical record documentation of metastatic nonsquamous NSCLC **AND**
    - Medical record documentation that Keytruda will be given in combination with pemetrexed AND ~~carboplatin~~ either carboplatin or cisplatin **AND**
    - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation 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
      OR
    - Patient is not eligible cisplatin-containing chemotherapy* **AND**
    - Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test
      OR

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

*Note: In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

9. Primary Mediastinal Large B-cell Lymphoma (PMBCL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of refractory primary mediastinal large B-cell lymphoma (PMBCL) **AND**
- Medical record documentation of relapse following two (2) prior lines of therapy

MBP 126.0 Opdivo (nivolumab)- Updated policy

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 **AND**
- Medical record documentation that Opdivo is being used as a single agent or in combination with ipilimumab (Yervoy).

9.Small Cell Lung Cancer (SCLC)

- 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 small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression after two different lines of therapy, one of which must be a platinum-based chemotherapy.

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)

~~AND~~

- ~~Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on platinum-containing chemotherapy~~

MBP 182.0 Crysvita (burosumab-twza)- New policy

Crysvita (burosumab-twza) is an anti-FGF23 monoclonal antibody that binds to and inhibits the activity of fibroblast growth factor 23 (FGF23), thereby restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

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

Crysvita (burosumab-twza) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the patient is at least 1 year of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
    - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
    - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

  AND
- Medical record documentation that the patient is not concurrently using vitamin D analogs or phosphate supplements.

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 12 months or less if the reviewing provider feels it is medically appropriate and the following criteria are met:

- Medical record documentation that patient is being followed regularly by and receiving medication from an endocrinologist or nephrologist **AND**
- Medical record documentation that Crysvita is improving patient's disease as evidenced by normalized or improved serum phosphorus levels **AND**
- Medical record documentation that the patient is not concurrently using Vitamin D analogs or phosphate supplements.

MBP 183.0 Andexxa (andexanet alfa)- New policy

Andexxa (andexanet alfa) is an antidote that binds and sequesters the FXa inhibitors Xarelto (rivaroxaban) and Eliquis (apixaban). In addition, andexanet alfa inhibits the activity of Tissue Factor Pathway Inhibitor (TFPI), increasing tissue factor-initiated thrombin generation.

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

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

- Medical record documentation that Andexxa is being used for the reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients treated with rivaroxaban and apixaban.

AUTHORIZATION DURATION: Authorization will be limited to one course of treatment

The following policies were reviewed with no changes:

- MBP 11.0 Botulinum Toxin
- 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 58.0 Prialt (ziconotide intrathecal infusion)
- MBP 73.0 Arzerra (ofatumumab)
- MBP 147.0 Lartruvo (olaratumab)
- MBP 148.0 Exondys 51 (eteplirsen)
- MBP 150.0 Sustol (granisetron ER)
- MBP 159.0 Kymriah (tisagenlecleucel)
- MBP 160.0 Besponsa (inotuzumab ozogamicin)
- MBP 161.0 Aliqopa (copanlisib)