

## **“What’s New” Medical Pharmaceutical Policy September 2018 Updates**

### **MBP 181.0 Site of Care- New policy**

#### **DESCRIPTION:**

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital based outpatient setting. If medical necessity criteria for administration in the hospital based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

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

**Administration in the hospital based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days when one of the following criteria are met:**

- This is the initial medication infusion **OR**
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

**AUTHORIZATION DURATION:** Initial approval will be for a duration of 60 days. Administration in the hospital based outpatient setting for longer than 60 days will be required to meet the authorization criteria in the section below.

**Administration in the hospital based outpatient setting will be considered medically necessary for a duration of greater than 60 days when one of the following criteria are met:**

- The medication has a site of care restriction for administration per the FDA approved label **OR**
  - Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion **OR**
  - Both of the following:
    - All alternate non-hospital outpatient settings are not within a reasonable distance from the member’s home (within 50 miles) **AND**
    - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access
- OR**
- For IVIG any of the above criteria **OR**
    - Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) **OR**
    - Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

**AUTHORIZATION DURATION:** Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

**NOTE:** To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.

**LIMITATIONS:** If none of the above criteria are met and the proposed hospital based outpatient facility is considered a least costly site of care, the hospital outpatient infusion would be approved.

#### **LINE OF BUSINESS:**

This policy does not apply to the Medicaid or Medicare line of business. Eligibility and

**contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

### **MBP 179.0 Hemlibra (emicizumab-kxwh)- New policy**

#### **DESCRIPTION:**

Hemlibra (emicizumab-kxwh) is a humanized monoclonal modified immunoglobulin G4 (IgG4) antibody with a bispecific factor IXa- and factor X-directed antibody, bridges activated factor IX and factor X to restore the function of missing activated factor VIII that is needed for effective hemostasis. Emicizumab-kxwh has no structural relationship or sequence homology to FVIII and, therefore, does not induce or enhance the development of direct inhibitors to FVIII.

Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.

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

Hemlibra (emicizumab-kxwh) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that Hemlibra is being used for routine prophylaxis **AND**
- Medical record documentation that the member has clotting factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (i.e. Bethesda assay)

#### **LIMITATIONS:**

Hemlibra is not indicated for on-demand/perioperative control of bleeding episodes associated with a diagnosis of hemophilia A. Hemlibra is formulated to allow self-administration. Requests for routine prophylaxis in which Hemlibra will be self-administered should be submitted under the members Pharmacy Benefit for Prior Authorization. In the event a member is unable to self-administer, Hemlibra will be covered under the Medical Benefit if above Prior Authorization criteria are met, and it is documented that a health care professional will be administering weekly doses for routine prophylaxis. Hemlibra will not be covered for on-demand and perioperative control of bleeding episodes.

### **MBP 180.0 Kanuma (sebelipase alfa)- New policy**

#### **DESCRIPTION:**

Kanuma (sebelipase alfa) is a form of enzyme replacement therapy that binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebelipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol, and free fatty acids. In patients with lysosomal acid lipase (LAL) deficiency, replacement with sebelipase alfa, a recombinant form of LAL, results in improvement in disease-related hepatic and lipid parameters.

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

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

- Must be prescribed by a provider specializing in genetics or metabolism **AND**
- Medical record documentation of Lysosomal Acid Lipase deficiency as either Wolman disease **OR** Cholesteryl ester storage disease (CESD) **AND**
- Medical record documentation of confirmed diagnosis in one of three ways:  
Dried Blood Spot (DBS) test, leucocyte testing, or genetic testing **AND**

- Medical record documentation that the member will receive a weight and diagnosis appropriate dosing regimen

**QUANTITY LIMITS:**

**Rapidly progressing/ Wolman disease:** Patients 0-6 months of age. Kanuma will initially be approved for quantity sufficient for up to 3 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.

**Late onset/ CESD:** Patients 4 years of age and older will be approved for 1 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

**AUTHORIZATION DURATION:** Initial approval will be for a period of 3 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 medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

**MBP 48.0 Rituxan (rituximab)- Updated policy**

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

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**
- 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 of 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  $< 30,000/\text{mm}^3$  with active bleeding or  $< 20,000/\text{mm}^3$  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:**

- 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)**

○ **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/Relmitting 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/Relmitting 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).

#### **AUTHORIZATION DURATION:**

**For Multiple Sclerosis:** 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.

**For all other indications:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate (\*except for the diagnosis for ITP). Subsequent approvals will be for an additional 6 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)- New Indication**

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  $\geq 18$  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  $\geq 18$  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) $\geq 50\%$  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) $\geq 1\%$  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

### **3. Head and Neck Squamous Cell Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq 18$  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

### **4. Classical Hodgkin Lymphoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of Classical Hodgkin Lymphoma **AND**
- One of the following:
  - a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma**OR**
  - b. Medical record documentation of relapse following three (3) or more prior lines of therapy

### **5. Microsatellite Instability-High Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors OR colorectal cancer **AND**
- For solid tumors:
  - Medical record documentation of progression following prior treatment(s) **AND**
  - Medical record documentation of no satisfactory alternative treatment options
- For colorectal cancer:
  - Medical record documentation of progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan

## **6. Urothelial Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq 18$  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\*

\*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).

## **7. Gastric Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND**
- Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test **AND**
- Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)\* **AND**
- If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin))\*

\*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)

## **8. Cervical Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of recurrent or metastatic cervical cancer **AND**
- Medical record documentation that tumors express PD-L1 (CPS $\geq 1$ ) **AND**
- Medical record documentation of disease progression after receiving at least one prior line of therapy

**LIMITATIONS:** The treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

**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 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 132.0 Avycaz (ceftazidime/avibactam) – Updated Policy**

Avycaz (ceftazidime/avibactam) will be considered medically necessary when all of the following criteria are met:

- Prescribed by or in consultation with an infectious disease specialist AND
  - Medical record documentation of one of the following:
    - A diagnosis of complicated intra-abdominal infection caused by caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Citrobacter freundii* complex and *Pseudomonas aeruginosa* OR
    - A diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Citrobacter freundii* complex, *Proteus mirabilis*, and *Pseudomonas aeruginosa* OR
    - A diagnosis of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by the following susceptible microorganisms: *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa* and, *Serratia marcescens*
- AND**
- Medical record documentation of a creatinine clearance > 50 mL/min **AND**
  - Documentation of patient age ≥ 18 years **AND**
  - Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

**AUTHORIZATION DURATION:** Approval will be given for a duration of 14 days.

**LIMITATIONS:** a quantity limit of 3 vials per day should apply, with total duration of treatment not exceeding 14 days.

### **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 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 146.0 Probuphine (buprenorphine)– Updated Policy**

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

- Prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Prescriber must have enrolled, trained, and demonstrated competency in Probuphine procedures as described by the Probuphine REMS Program **AND**
- ~~• Probuphine must be prescribed by a participating provider or a provider who participates in the plan's designated behavioral health benefit program **AND**~~
- Medical record documentation of a diagnosis of opioid dependence **AND**
- Medical record documentation that patient is clinically stable by verifying **ALL** of the following:
  - No reports of significant withdrawal symptoms
  - Reports of low to no desire/need to use illicit opioids
  - No episodes of hospitalizations (for addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days
  - Consistent compliance with clinic visit requirements as evidenced by documentation of attendance to all scheduled appointments **at least** 6 months prior to the ordering of Probuphine **AND**
- Medical record documentation that patient is stable for at least the last 6 months on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablets or generic equivalent) **AND**
- Medical record documentation that the member is compliant with oral buprenorphine therapy, documented by all urine drug screens within 90 days of the request, one of which must be dated within 28 days of request date, for opiates and buprenorphine. The drug screen must be positive for buprenorphine and norbuprenorphine and negative for opiates. The presence of other non-opiate controlled substances must be consistent with prescribed controlled substances and documentation that their use is medically necessary and the benefit outweighs any risks associated with their use in the member must be provided. **AND**
- ~~• Medical record documentation of member abstinence from alcohol **AND**~~
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
- ~~• Member must be actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation~~

**AND**

- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Probuphine.

For re-authorization:

- ~~Member must be adherent to buprenorphine and must not be using opiates. Must be verified by all urine drug screens within the past 6 months, one of which must be dated within 28 days of request date for opiates and buprenorphine. All drug screens must be positive for buprenorphine and norbuprenorphine, and negative for opiates. The presence of other non-opiate controlled substances must be consistent with prescribed controlled substances and documentation that their use is medically necessary and the benefit outweighs any risks associated with their use in the member must be provided.~~  
**AND**
- ~~Medical record documentation that member continues to be actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation~~  
**AND**
- ~~Medical record documentation of continued member abstinence from alcohol~~  
**AND**
- Medical record documentation that Probuphine has **NOT** been used for greater than one year **AND**
- Medical record documentation that the new implants will be inserted into the contralateral arm **AND**
- Medical record documentation that member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Probuphine.

**QUANTITY LIMIT:** Four (4) implants (one kit) every 180 days

**AUTHORIZATION DURATION:** If approved, initial authorization duration will be six (6) months. After the initial 6 month implantation, if re-authorization criteria are met, one subsequent authorization duration will be given for six (6) months. Note: studies of Probuphine use past one year have not be assessed.

**The following policies were reviewed with no changes:**

- MBP 2.0 Synagis (palivizumab)
- MBP 15.0 Zevalin (Ibritumomab)
- MBP 36.0 Abraxane (paclitaxel protein bound particles)
- MBP 57.0 Tysabri (natalizumab)
- MBP 62.0 Remodulin IV (treprostinil)
- MBP 68.0 Nplate (romiplostim)
- MBP 82.0 Jevtana (cabazitaxel)
- MBP 125.0 Lemtrada (alemtuzumab)
- MBP 134.0 Cresemba IV (isavuconazonium sulfate)
- MBP 135.0 Unituxin (dinutuximab)
- MBP 154.0 Radicava (edaravone)