“What’s New” Medical Pharmaceutical Policy Updates February 2017

MBP 146.0 Probuphine (buprenorphine)- New 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 attendence 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**

  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

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.

MBP 11.0 Botulinum Toxin and Derivatives - REVISED New criteria

Botulinum Toxin Type A (Botox and Xeomin) are considered to be medically necessary for the following indications when the following criteria are met:

Medical record documentation of a diagnosis of:

1. **Strabismus in members ≥ 12 years of age**
2. **Blepharospasm associated with dystonia in members ≥ 12 years of age**
3. **Facial nerve (VII) disorders**
4. **Cervical dystonia**
5. **Chronic Migraine Headache**

   Botulinum toxin A for the treatment of chronic migraine headache may be considered medically necessary when all of the following criteria are met:
   - Physician provided medical record documentation of a history of 15 or more migraine headache days per month that last 4 or more hours per day**AND**
   - Physician provided medical record documentation of a completed Neurology consult and recommendation**AND**
   - Physician provided medical record documentation of failure, intolerance or contraindication to an adequate trial of at least two different migraine prophylaxis medications (eg, beta-blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications)
6. **Primary Axillary Hyperhidrosis**

   Botulinum toxin A for the treatment of severe primary axillary,palmer or pedal hyperhidrosis may be considered medically necessary when the following criteria are met:
   - Physician provided documentation of failure of a 6 month trial of non-surgical treatments with topical dermatologics (e.g., aluminum chloride, tannic acid, luteraldehyde, antichloinergics)**AND**
   - record documentation of one of the following:
     - Underlying chronic medical condition such as dermatitis, fungal condition, skin maceration, or secondary microbial condition as a result of hyperhidrosis**OR**
     - Sweating is intolerable and causes functional impairment that interferes with member's ability to perform age-appropriate professional or social normal daily activities
7. **Urinary incontinence due to neurogenic bladder**

   Botulinum toxin A for the treatment of urinary incontinence due to neurogenic bladder is considered medically necessary when the following criteria are met:
   - Medical record documented failure of anticholinergic medication therapy
8. **Overactive Bladder**

   Botulinum toxin A for the treatment of overactive bladder is considered medically necessary when the following criteria are met:

- Medical record documentation of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults **AND**
- Medical record documentation of failure of two anticholinergic medication therapies **AND**
- Medical record documentation of a minimum of three urinary urgency incontinence episodes and at least 24 micturations in three days

9. Torsion dystonia
10. Orofacial dyskinesia
11. Spasmodic torticollis
12. Organic writer's cramp
13. Hereditary spastic paraplegia
14. Multiple sclerosis
15. Neuromyelitis optica
16. Schilder's disease
17. Spastic hemiplegia
18. Infantile cerebral palsy
19. Esotropia
20. Exotropia
21. Intermittent heterotropia
22. Other and unspecified heterotropia
23. Heterophoria
24. Paralytic strabismus
25. Mechanical strabismus
26. Unspecified disorder of eye movements
27. Laryngeal spasm
28. Achalasia and cardiospasm
29. Anal spasm
30. Anal fissure
31. Upper Limb Spasticity

Botulinum toxin A for the treatment of upper limb spasticity is considered medically necessary when the following criteria are met:

- Medical record documentation that Botox or Xeomin is being used for the treatment of upper limb spasticity **AND**
- Documentation that the patient is at least 18 years of age

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Botox** only) are:

1. Lower Limb Spasticity

- Medical record documentation that Botox is being used for the treatment of lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus) **AND**
- Documentation that patient is at least 18 years of age **AND**
- Medical record documentation of failure to control spasticity with conventional therapies, e.g., physical therapy, splinting/bracing, or systemic antispasticity medication

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Dysport**) are:

1. **Cervical dystonia**

OR

2. Upper Limb Spasticity

- Medical record documentation that Dysport is being used for the treatment of upper limb **AND**
- Documentation that the patient is at least 18 years of age.

OR

3. Pediatric Lower Limb Spasticity

- Medical record documentation that Dysport is being used for the treatment of the lower limb(s) **AND**
- Documentation that the member is between 2 and 17 years of age

***Note: Adult lower limb spasticity is indicated under Botox Only, NOT Dysport.*

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type B (**Myobloc**):

1. **Cervical dystonia**

Botulinum toxin is considered **investigational** for

- headache or migraine other than chronic migraine
- myofascial pain syndrome
- tremors such as benign essential tremor, chronic motor tic disorder, and tics associated with Tourette syndrome
- treatment of upper limb spasticity in pediatric patients
- treatment of lower limb spasticity pediatric patients (with exception of Dysport)
- treatment of hyperhidrosis in body areas other an axillary

As treatment of wrinkles or other cosmetic indications. Cosmetic procedures are an exclusion per the "Exclusions" section of the applicable benefit documents

MBP 73.0 Arzerra (ofatumumab) - REVISED New criteria

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

1. **Chronic Lymphocytic Leukemia/Small Lympocytic Lymphoma**
   - Prescribed by a hematologist or oncologist **AND** who meet **ONE** of the following situations:
     - Medical record documentation of previously untreated chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) **AND**
     - Medical record documentation that Arzerra is being given in combination with chlorambucil **AND**
     - Medical record documentation that fludarabine-based therapy is considered inappropriate

     OR
     - Medical record documentation of relapsed chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) **AND**
     - Medical record documentation that Arzerra is being used in combination with fludarabine and cyclophosphamide

     OR
     - Medical record documentation of extended treatment of chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) **AND**
     - Medical record documentation that patient is in complete or partial response after at least two lines of therapy for recurrent or progressive CLL

     OR
     - Medical record documentation of chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) **AND**
     - Medical record documentation that CLL is refractory to both fludarabine and alemtuzumab

   - ~~Prescribed by an oncologist **AND**~~
   - ~~Medical record documentation of diagnosis chronic lymphocytic leukemia (CLL) **AND**~~
   - ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fludarabine **and/or** Rituxan~~

AUTHORIZATION DURATION: Initial approval will be for 12 ~~6~~ months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 ~~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 128.0 Blincyto (blinatumomab)- REVISED New criteria

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

- Prescription written by an oncologist/hematologist **AND**
- ~~Age greater than or equal to 18 years **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 cycle (8 month) course. Subsequent approval for treatment past the initial 5 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request. ~~for 2 cycles (3 months) or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 3 cycles (5 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 the member experiences toxicity or worsening of disease.~~