DRUG DETERMINATION POLICY

Title: DDP-31 Botulinum Toxin

Effective Date: 11/05/2019

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Health Plan covers Botulinum Toxin when criteria are met. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. FDA approved indications

A. Spasticity.

1. Upper extremity spasticity.

a. Age: at least 18 years.

b. Diagnosis and severity:

i. Increased muscle tone in elbow, wrist, finger and thumb flexors.

ii Stroke or other non-stroke related upper extremity spasticity.

iii. Pain or abnormal hand or forearm position interfering with daily functioning.

c. Exclusions: prior surgical treatment or infection at injection site.

2. Lower extremity spasticity.

    a. Age: at least 18 years.

    b. Diagnosis and severity:

        i. Increased muscle tone in ankle or toe flexors.

        ii. Pain or increased muscle tone interfering with daily functioning.

B. Chronic migraine headaches.

    1. Age: at least 18 years old.

    2. Diagnosis and severity:

        a. Neurologist evaluated: established a diagnosis of chronic migraine headache.

        b. Frequency and duration (three months): at least 15 days per month for greater than four hours per day.

        c. Severity: interfering with routine daily functioning.

    3. Other therapies: contraindicated, failed or had significant adverse events.

        a. Abortive treatment (ten days per month): must try at least two agents from separate classes.

            i. Ergotamine derivatives: e.g., ergotamine, dihydroergotamine (DHE).

            ii. Triptans: e.g., sumatriptan.

            iii. Combination analgesic: opioids, acetaminophen, NSAIDS.

        b. Preventive treatment: must try two agents from separate classes (three months).

            i. Valproic acid: divalproex (Depakote), valproate (Depacon).

            ii. Second generation anticonvulsant: topiramate (Topamax).

            iii. Beta blockers: metoprolol (Lopressor/Toprol XL), propranolol (Inderal), timolol.

C. Cervical Dystonia (Spasmodic Torticollis).

    1. Age: at least 18 years.

    2. Diagnosis and severity: abnormal head position and neck pain interfering with daily functioning.

    3. Contraindications: fixed contracture with decreased range of motion, prior surgical treatment, infection at injection site or neurological diagnosis.

D. Blepharospasms, strabismus or hemifacial spasms.

1. Age: at least 12 years.

2. Diagnosis and severity:

   a. Associated with dystonia.

   b. Benign essential blepharospasm or VII nerve disorders.

3. Contraindications: infection at injection site or neuromuscular disease (e.g. Myasthenia Gravis).

E. Bladder Dysfunction.

1. Neurogenic urinary incontinence.

   a. Age: at least 18 years.

   b. Diagnosis and severity.

      i. Due to neurological condition (e.g., Multiple Sclerosis, spinal cord injury).

      ii. Detrusor over-activity.

   c. Other therapies:

      i. Anticholinergics and β-3 agonist (one of each): contraindicated, failed or had significant adverse effects.

      ii. Surgical treatment or balloon sphincter dilatation: failed or not indicated.

2. Over active bladder.

   a. Age: at least 18 years.

   b. Diagnosis and severity:

      i. Symptoms of urge urinary incontinence, urgency, and frequency.

      ii. Identified from clinical evaluation.

   c. Other therapies: contraindicated, failed or had significant adverse effects (one of both below):

      i. Anticholinergics: e.g. oxybutynin, tolterodine, solifenacin, tropium.

      ii. β-3 agonist.: Myrbetriq.

3. Contraindications: acute UTI, acute urinary retention.

II. Non-FDA approved indications

A. Spasticity of cerebral palsy.

1. Age: children (over 18 months) and adolescents.

2. Diagnosis and severity: physical evidence of focal limb spasticity.

3. Contraindication: joint immobilization by a fixed contracture, severe weakness of opposing muscle in the limb for which the injection is intended, diffuse hypertonia.

B. Achalasia.

1. Diagnosis and severity.

a. Esophageal manometry confirmation.

b. Upper gastrointestinal endoscopy: rule out other causes (peptic stricture, Cancer, lower esophageal compression).

c. Progressive dysphagia for liquids and solids.

2. Other therapies.

a. Long-acting nitrates or calcium channel blockers: contraindication, failed or had significant adverse effects.

b. Pneumatic dilation or surgical myotomy: unless contraindicated or not indicated.

C. Anal Fissure.

1. Diagnosis and severity: at least two months of symptoms with at least one of the following:

a. Nocturnal pain and bleeding.

b. Post-defecation pain.

2. Other therapies.

a. Topical nitrates: contraindicated, failed or significant adverse effects.

b. Surgery: unless contraindicated or not indicated.

3. Contraindication: Inflammatory bowel disease, HIV disease, hemorrhoids, anal fistula, perianal abscess, perianal cancer, previous perianal surgery.

E. Dosage regimen: limited to maximum dosage as indicated in the FDA approved package insert or as listed in Appendix I.

III. Approval

A. Initial: seven months.

B. Re-approval: one year.

1. Continue to meet criteria for diagnosis as applicable with significant improvement in symptoms.

a. Migraine: 50% decreased headache frequency and/or severity (documented in chart notes).

IV. Exclusions:

A. Movement disorders or spasticity: spasticity from conditions other than stroke or Cerebral Palsy; tremor (essential, head or voice); tardive dyskinesia; motor tics; laryngeal dystonia; fixed contracture of joint.

B. Chronic Pain: myofascial, inflammatory, musculoskeletal, neuropathic, postoperative, post-herpetic, neck or shoulder pain; headache (acute, episodic, tension, cranial neuralgia, acute, med-overuse, neuromuscular diagnosis headaches); plantar fasciitis; brachial plexus injury; trigeminal neuralgia; gynecologic pain syndromes.

C. Gastrointestinal Disorders: anal sphincter; chronic idiopathic constipation (children); gastroparesis; upper esophageal sphincter disorder; sialorrhea.

D. Other: Benign Prostatic Hyperplasia (BPH) with lower urinary tract symptoms; clubfeet; gustatory sweating (Frey's); obesity; depression; hyper-lacrimation; masseter hypertrophy; refractory interstitial cystitis; hyperhidrosis.

4.0 Coding:

AFFECTED CODES				
Code	**Brand Name**	**Generic Name**	**Billing Units (1 Unit)**	**Prior Approval**
J0585	Botox	onabotulinumtoxinA	1 unit	Y
J0586	Dysport	abobotulinumtoxinA	5 units	Y
J0588	Xeomin	incobotulinumtoxinA	1 unit	Y
J0587	Myobloc	rimabotulinumtoxinB	100 units	Y
NA	Jeuveau	prabotulinumtoxinA	NA	Y, excluded, cosmetic use
ADMINISTRATION CODES				
64650	Destruction by Neurolytic agent			
64653	Destruction by Neurolytic agent			

5.0 References, Citations & Resources:

1. Onabotulinumtoxin A Milliman Care Guidelines® Ambulatory Care are19th Edition, assessed May 16, 2016.

2. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012; 78:1337-45.

3. Botox, Migraine, and the American Academy of Neurology: An Antidote to Anecdote. JMCP June 2008;14(5); 465-467.

4. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Onbotulinumtoxin A , abobotuulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, prabotulinumtoxin A accessed October 2019.

5. *Clin-eguide Drug Facts and Comparisons eAnswers.* Onbotulinumtoxina [database online]: Wolters Kluwer Health Inc; 2016.

6. Practice guideline update summary: Botulinum neurotoxin for the treatment blepharospasm, cervical dystonic, adult spasticity and headache. Neurology 2016; 86:818-1826.

6.0 Appendices:

Appendix I: Dosage Regimens

FDA-Approve Indications			
Condition	**Recommended product (Level A-B*)[6]**	**Average Dose**	**Duration of effect**
Upper limb spasticity	A-Dysport (aboBoTN) A-Xeomin (incoBoTN) A-Botox (onoBoTN)	≤ 400 units total given 12.5 - 50 units/site	12 weeks
Lower limb spasticity	A-Botox (onoBoTN) A-Dysport (aboBoTN)	≤ 500 units total given in multiple sites	3 months
Migraine	A-Botox (onoBoTN)	≤ 200 units total given in multiple sites	12 weeks
Neurogenic bladder	NA	200 units total given in multiple sites	8-12 weeks
Overactive bladder	NA	100 units total given in multiple sites	12 weeks
Cervical Dystonia	A-Dysport (aboBoTN) B-Xeomin (incoBoTN) B-Botox (onoBoTN)	200-300 units total given in multiple sites	4 weeks - 3 months
Strabismus	NA	25 units total; 2.5-5 units/site	6-8 weeks to 6-12 months
blepharospasm	B-Xeomin (incoBoTN) B-Botox (onoBoTN)	5 units/site	12.5 weeks
Non-FDA Approved Indications			
Condition		**Average dose**	**Duration of effect**
Spasticity of CP	NA	3-6 units/Kg (max 12 units/Kg); 82-220 total units given in multiple sites	1-6 months
Achalasia	NA	15-25 units/quadrant or ≤ 50units on either side of IAS	Single treatment; may repeat
Anal fissure	NA	20 units both sides	Single injection

**A-Intervention should be offered; B- Intervention should be considered; NA - rating not available.*

7.0 Revision History:

Original Effective Date: 08/23/2012

Next Review Date: 11/05/2020

Revision Date	Reason for Revision
8/19	Moved to new format; replaced abbreviations, clarified other therapies for urinary incontinence, added dosage regimen limits, many formatting changes