DRUG DETERMINATION POLICY

Title: DDP-31 Botulinum Toxin

Effective Date: 6/26/24

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:

The 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. General considerations for use

A. Appropriate medication use [must meet all listed below]:

1. Diagnosis: meets standard diagnostic criteria that designate signs, symptoms, and test Results to support specific diagnosis.

2. Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved use: Compendium support (Lexicomp®) for use of a drug for a non-FDA approved indication or dosage regimen.

3. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

B. Dose Rounding: medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturers strength of the requested medication for patients weighing above 10 Kg (see DDP-21 Dose Rounding and Wastage).

C. Dosage Regimens per Indication: See Appendix I

II. Food and Drug Administration (FDA) approved indications.

A. Spasticity.

1. Upper extremity spasticity [must meet all listed below]:

a. Age: at least two years.

b. Diagnosis and severity [must meet all listed below]:

i. Increased muscle tone in biceps, 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 [must meet all listed below]:

a. Age: at least two years.

b. Diagnosis and severity [must meet both listed below]:

i. Increased muscle tone in ankle or toe flexors.

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

B. Chronic migraine headaches [must meet all listed below]:

1. Age: at least 18 years old.

2. Diagnosis and severity [must meet all listed below]:

a. Neurologist evaluated: established a diagnosis of chronic migraine headache (migraine-like or tension-like).

b. Frequency and duration: headache occurring at least 15 days per month for more than three months, which, on at least eight days per month has the features of migraine headache.

c. Severity: interfering with routine daily functioning.

C. Cervical Dystonia (Spasmodic Torticollis) [must meet all listed below]:

1. Age: at least 16 years.

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

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

D. Blepharospasms, strabismus or hemi-facial spasms [must meet all listed below]:

1. Age: at least 12 years.

2. Diagnosis and severity [must meet both listed below]:
    a. Associated with dystonia.
    b. Benign essential blepharospasm or VII nerve disorders.
3. Exclusions: infection at injection site or neuromuscular disease (e.g. Myasthenia Gravis).

E. Bladder Dysfunction [must meet all listed below]:

1. Neurogenic urinary incontinence.
    a. Age: at least 18 years.
    b. Diagnosis and severity [must meet both listed below]:
        i. Due to neurological condition (e.g., Multiple Sclerosis, spinal cord injury).
        ii. Detrusor over-activity.
    c. Other therapies: Trial of one anticholinergic, one β-3 agents and surgery listed below unless all are contraindicated. Medication trial must result in an inadequate response after four consecutive months of use per medication or severe adverse reaction.
        i. Anticholinergics and β-3 agonist
        ii. Surgical treatment or balloon sphincter dilatation: failed or not indicated.
2. Overactive bladder [must meet all listed below]:
    a. Age: at least 18 years.
    b. Diagnosis and severity [must meet both listed below]:
        i. Symptoms of urge urinary incontinence, urgency, and frequency.
        ii. Identified from clinical evaluation.
    c. Other therapies: Trial of one anticholinergic and one β-3 agents listed below unless all are contraindicated. Medication trial must result in an inadequate response after four consecutive months of use per medication or severe adverse reaction
        i. Anticholinergics: e.g. oxybutynin, tolterodine, solifenacin, tropium.
        ii. β-3 agonist: Myrbetriq.
3. Exclusions: acute urinary tract infection, acute urinary retention.

F. Primary axillary hyperhidrosis

1. Age: at least 18 years.
2. Diagnosis and severity [must meet all listed below]:
    a. Severe primary axillary hyperhidrosis not adequately managed by topical agents.

b. Hyperhidrosis Disease Severity Scale: 3 or 4 (see Appendix II).

c. The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infection, secondary microbial infections).

3. Other therapies: contraindicated, inadequate response or significant adverse effects to two topical therapies for two months each; one being 20% aluminum chloride hexahydrate.

III. Non-FDA approved indications.

A. Spasticity of cerebral palsy [must meet all listed below]:

1. Age: at least 18 months to 18 years.

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

3. Exclusions: 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 [must meet all listed below]:

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: contraindication to or no indication for procedures listed below:

a. Pneumatic dilation or surgical myotomy

C. Anal fissure [must meet all listed below]:

1. Diagnosis and severity: at least two months [must meet all listed below]:

a. Nocturnal pain and bleeding.

b. Post-defecation pain.

2. Other therapies [must meet all listed below]:

a. Topical nitrates: contraindicated, inadequate response after three months or significant adverse effects.

b. Surgery: unless contraindicated or not indicated.

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

D. Laryngeal dystonia.

1. Diagnosis and severity [must meet both listed below]:

a. Adductor-type spasmodic dysphonia confirmed by fiber optic laryngoscopy.

b. Moderate to severe difficulty in phonation.

E. Appropriate medication use for other Non-FDA approved indications [must meet one listed below]:

1. FDA approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Off-label use: at least two supporting studies from major peer-reviewed medical journals that support the off-label use as safe and effective.

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

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

III. Approval

A. Provider based: Prior authorization for the botulinum Toxin claim to pay will not be required for the listed in-network specialty practitioners. (see Appendix III)

B. Initial: seven months.

C. 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: by Diagnoses

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

B. Chronic Pain: myofascial, temporomandibular joint dysfunction, 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.

4.0 Coding:

COVERED CODES – MEDICAL BENEFIT				
Code	**Brand Name**	**Generic Name**	**Billing Units (1 Unit)**	**Prior Approval**
J0585	Botox	onabotulinumtoxinA	1 unit	Y
J0588	Xeomin	incobotulinumtoxinA	1 unit	Y

EXCLUDED CODES AND PRODUCTS			
HCPCS Code	**Brand Name**	**Generic Name**	**Benefit Plan Reference/Reason**
J0586	Dysport	abobotulinumtoxinA	Not a Preferred agent
J0597	Myopbloc	abobotulinumtoxinA	Not a Preferred agent
NA	Jeuveau	prabotulinumtoxinA	Only indicated for cosmetic use, cosmetic treatments are excluded

5.0 References, Citations & Resources:

1. Onabotulinumtoxin A Milliman Care Guidelines® Ambulatory Care 19th 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 August 2022.
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.
7. Board of Directors of the American Headache Society. The American Headache Society consensus statement: update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039. doi:10.1111/head.14153[PubMed 34160823]
8. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. Am J Gastroenterol. 2020;115(9):1393-1411. doi:10.14309/ajg.0000000000000731[PubMed 32773454]
   ACG clinical guidelines: management of benign anorectal disorders. Am J Gastroenterol.
9. 2021;116(10):1987-2008. doi:10.14309/ajg.0000000000001507[PubMed 34618700]

6.0 Appendices:

See pages 8 - 9.

7.0 Revision History:

Original Effective Date: 08/23/2012

Next Review Date:

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
4/20	Annual review; revised age for spasticity/CP, cervical dystonia, clarified criteria instructions, changed other therapies language, changed other therapies needed for migraine, revised dosing table.
9/20	Off cycle review, removed pharmacologic therapy for achalasia, clarified instructions, formatting, approved by P&T 12/9/20
1/21	Off cycle review; clarified dx/severity of migraine, added back laryngeal dystonia; added appropriate drug use to non-FDA approved indications, clarified duration of other therapies for bladder diagnoses; removed exclusion of laryngeal dystonia and hyperhidrosis
5/21	Annual review; no changes
4/22	Annual review for May P & T Workgroup and June P and T Committee, added exempt providers
10/22	Off- cycle review; added primary axillary hyperhidrosis
4/23	Annual review; replace contraindication with exclusions, add TMJ to exclusions, add references, removed administration codes in coding section
4/24	Annual review, removed monitoring and Patient Safety table, reformatted bullets, revised coding section to align with PDL and policy

Appendix I: Dosage Regimens

FDA-Approve Indications			
Condition	**Recommended product (Level A-B*)[6]**	**Average Dose**	**Frequency**
Upper limb spasticity	A-Dysport (aboBoTN) A-Xeomin (incoBoTN) A-Botox (onoBoTN)	≤ 400 units total given 12.5 - 50 units/site	3 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	3 months
Neurogenic bladder	NA	200 units total given in multiple sites	3 to 6 months
Overactive bladder	NA	100 units total given in multiple sites	3 months
Cervical Dystonia	A-Dysport (aboBoTN) B-Xeomin (incoBoTN) B-Botox (onoBoTN)	200-300 units total given in multiple sites	2 months
Strabismus	NA	10 units total; 1.25-5 units/site	2 to 6 months
blepharospasm	B-Xeomin (incoBoTN) B-Botox (onoBoTN)	5 units/site	3 months
Hyperhidrosis	Botox	50 units per axilla	6 months
Non-FDA Approved Indications			
Condition		**Average dose**	**Frequency**
Spasticity of CP	NA	3-6 units/Kg (maximum 50 units per site); 82-220 total units given in multiple sites	3 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.*

Appendix II: Hyperhidrosis Disease Severity Scale (HDSS)

Scale Underarm Sweating Severity

1. Never noticeable/never interfers with my daily activities
2. Tolerable/sometimes interfers with my daily activities
3. Barely tolerable/frequently interfers with my daily activities
4. Intolerable/always interfering with my daily activities

Appendix III: Authorization not required for the listed in-network specialty practitioners

Category	Code	Description
SPEC	CRS	Colon and Rectal Surgeons
	NEUR	Neurologist
	NPSP	Nurse Practitioner Specialists
	OPTH	Ophthalmologist
	PAIN	Pain Management
	PDPR	Ped Physical Med & Rehab
	PHYS	Rehab Medicine (Physiatrist)
	UROL	Urology