Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2021**
Policy Number: PHW.PDL.236	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
Policy Name: Botulinum Toxins	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2022: policy revised according to DHS revisions effective 01/03/2022

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Botulinum Toxins

Reference Number: PHW.PDL.236
Effective Date: 01/01/2020
Last Review Date: 10/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Botulinum Toxins are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Botulinum Toxins (Type A and Type B)

A. Prescriptions That Require Prior Authorization

All prescriptions for Botulinum Toxins must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Botulinum Toxin, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the Botulinum Toxin for an indication that is included in the U.S. Food and drug administration (FDA)-approved package labeling OR a medically accepted indication, excluding a cosmetic condition;

   AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

   AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

   AND

4. Does not have a contraindication to the prescribed medication;

   AND

5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site.

AND

6. For a non-preferred Botulinum Toxin, has history of therapeutic failure, contraindication or intolerance of the preferred Botulinum Toxins approved or medically accepted for the member's diagnosis or indication

   See the Preferred Drug List (PDL) for the list of preferred Botulinum Toxins at: https://papdl.com/preferred-drug-list.

   AND

7. For a diagnosis of chronic spasticity **all** of the following:

   a. Has documented spasticity that interferes with activities of daily living or is expected to result in joint contracture with future growth,

   b. If the member is age 18 or older, has documented therapeutic failure, contraindication or intolerance to one oral medication for spasticity,

   c. If the member developed contractures, the recipient has been considered for surgical intervention,

   d. The botulinum toxin is being requested to enhance function or allow for additional therapeutic modalities to be employed,

   e. Will use the requested botulinum toxin in conjunction with other appropriate therapeutic modalities such as physical therapy, occupational therapy, gradual splinting, etc.;

   AND

8. For a diagnosis of axillary hyperhidrosis, has a history of therapeutic failure, contraindication or intolerance to a topical agent such as 20 percent aluminum chloride

   AND

9. For a diagnosis of chronic migraine headache, **all** of the following:

   a. **One** of the following:

      i. Has a history of therapeutic failure to at least one migraine preventative medication from at least **two** of the following three classes:

         1. Beta-blockers (e.g., metoprolol, propranolol, timolol),

2. Antidepressants (e.g., amitriptyline, venlaxafine),
3. Anticonvulsants (e.g., Topiramate, valproic acid, divalproex),

ii. Has a history of contraindication or intolerance that prohibits a trial of at least **one** migraine preventative medication from at least **two** of the following three classes:

1. Beta-blockers (e.g., metoprolol, propranolol, timolol),
2. Antidepressants (e.g., amitriptyline, venlaxafine),
3. Anticonvulsants (e.g., Topiramate, valproic acid, divalproex),

b. Has a diagnosis of chronic migraine headache according to the current International Headache Society Classification of Headache Disorders that is not attributed to other causes including medication overuse,

c. Is prescribed the Botulinum Toxin by or in consultation with **one** of the following:

i. A neurologist,
ii. A headache specialist who is certified in headache medicine by the united Council for Neurologic Subspecialties (UCNS);

AND

10. For a diagnosis of urinary incontinence due to detrusor over activity associated with a neurologic condition, has a history of therapeutic failure, contraindication, or intolerance to at least 1 anticholinergic medication used in the treatment of urinary incontinence;

AND

11. For a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, has a history of therapeutic failure, contraindication, or intolerance to at least 2 agents (e.g., antimuscarinics or beta-3 adrenergic agonists) used in the treatment of overactive bladder;

AND

12. If a prescription for a Botulinum Toxin is in a quantity that exceeds the dosing limits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are

medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR BOTULINUM TOXINS: The determination of medical necessity of a request for renewal of a prior authorization for a Botulinum Toxin that was previously approved will take into account whether the member:

1. If the frequency of injection exceeds the dose and duration of therapy limits, has documentation of **both** of the following:

   a. The previous treatment was well tolerated but inadequate,
   b. Medical literature supports more frequent dosing intervals as safe and effective for the diagnosis and requested dose;

   AND

2. If the frequency of injection is consistent with the dose and duration of therapy limits, has documentation of **both** of the following:

   a. Tolerability and a positive clinical response to the medication
   b. The symptoms returned to such a degree that repeat injection is required.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for a Botulinum Toxin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. **Approval Duration:**

Dose and duration of approvals of requests for prior authorization of Botulinum Toxins will be consistent with package labeling.

Requests for authorization of a Botulinum Toxin will not be approved for one year from the most recent injection when there is no benefit after two sequential therapies using maximum doses.

Botox (onabotulinumtoxinA)	**Cervical Dystonia**	Dose: not to exceed 400 units per treatment session Duration: 12 weeks (single treatment session)
	Blepharospasm (a focal dystonia)	Dose: not to exceed 5 units per site per treatment session (maximum of 200 units total in a 30-day period) Duration: 12 weeks (single treatment session)
	Strabismus	Dose: not to exceed 25 units per muscle per treatment session Duration: 12 weeks (single treatment session)
	Other Dystonias (off-label)	Dose does not exceed 400 units per single treatment with the following exceptions: a. Oromandibular dystonia: 25 units per muscle per treatment session; b. Laryngeal dystonia (spasmodic dysphonia): 3 units per treatment session Duration: 12 weeks (single treatment session)
	Upper and Lower Limb Spasticity	Dose: not to exceed 400 units per treatment session Duration: 12 weeks (single treatment session)
	Spasticity Associated with Cerebral Palsy (off-label)	Dose: not to exceed 400 units per treatment session Duration: 12 weeks (single treatment session)
	Chronic Migraine	Dose: not to exceed 200 units per treatment session Duration: 24 weeks (two 12-week treatment sessions)
	Primary Axillary Hyperhidrosis	Dose: not to exceed 50 units per axilla per treatment session Duration: 12 weeks (single treatment session)

	Overactive Bladder	Dose: not to exceed 100 units per treatment session Duration: 12 weeks (single treatment session)
	Urinary Incontinence	Dose: not to exceed 200 units per treatment session Duration: 12 weeks (single treatment session)
	Esophageal Achalasia (off-label)	Dose: not to exceed 100 units Duration: 12 weeks (single treatment session)
	Hirschsprung's Disease and Internal Anal Sphincter Achalasia (off-label)	Dose: not to exceed 100 units Duration: 12 weeks (single treatment session)
	Chronic Anal Fissure (off-label)	Dose: not to exceed 100 units Duration: 12 weeks (single treatment session)
Dysport (abobotulinumA)	**Cervical Dystonia**	Dose: not to exceed 1000 units per treatment session Duration: 12 weeks (single treatment session)
	Upper and Lower Limb Spasticity in ADULTS	Dose: not to exceed 1500 units per treatment session Duration: 12 weeks (single treatment session)
	Lower Limb Spasticity in PEDIATRICS	Dose: not to exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1000 units, whichever is lower, per treatment session Duration: 12 weeks (single treatment session)
Myobloc (rimabotulinumtoxinB)	**Cervical Dystonia**	Dose: not to exceed 10000 units per treatment session Duration: 12 weeks (single treatment session)
	Chronic Sialorrhea	Dose: not to exceed 3500 units per treatment session Duration: 12 weeks (single treatment session)
Xeomin (incobotulinumtoxinA)	**Chronic Sialorrhea**	Dose: not to exceed 100 units per treatment session Duration: 16 weeks (single treatment session)

	Cervical Dystonia	Dose: not to exceed 120 units per treatment session Duration: 12 weeks (single treatment session)
	Blepharospasm (a focal dystonia)	Dose: not to exceed 50 units per eye per treatment session Duration: 12 weeks (single treatment session)
	Upper Limb Spasticity	Dose: not to exceed 400 units per treatment session Duration: 12 weeks (single treatment session)

E. References:

1. Abrams GM, Wakasa M. Chronic complications of spinal cord injury and disease. Aminoff MJ, Silveira MJ, eds. Waltham, MA: UpToDate Inc. Updated February 22, 2021. Accessed August 2, 2021.
2. Barkoudah E, Glader L. Treatment of spasticity, dystonia and associated orthopedic issues. Patterson MC, Phillips WA, Goddeau Jr. RP, Armsby C, eds. Waltham, MA UpToDate Inc. Updated February 25, 2021. Accessed August 2, 2021.
3. Botox (package insert). Madison, NJ: Allergan USA, Inc; February 2021.
4. Dysport (package insert). Wrexham, LL13 9UF, UK: Ispen Biopharm, Ltd.; July 2020.
5. Davis TL, Brodsky MA, et al. Consensus Statement on the use of Botulinum Neurotoxin to Treat Spasticity in Adults. Pharmacy and Therapeutics 2006; 31(11): 666-682.
6. Elovic EP, Brashear A, et al. Repeated Treatments with Botulinum Toxin Typr A Produce Sustained Decreases in the Limitations Associated With Focal Upper-Limb Past Stroke Spasticity for Caregivers and Patients. Arch Phys med. Rehabil 2008; 89(5): 799-806.
7. Garza I, Schwedt T. Chronic migraine. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated December 9, 2020. Accessed August 2, 2021.
8. Gormley EA, Lightner DJ, Faraday M, Vasavada SP; American Urological Association; Society of Urodynamics, Female Pelvic Medicine. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015 May;193(5):1572-80. doi: 10.1016/j.juro.2015.01.087. Epub 2015 Jan 23. PMID: 25623739.
9. International Headache Society. Headache Classification Committee of the International Headache Society (IHS): the international classification of headache disorders, 3rd edition. Cephalalgia. 2018; Vol. 38(1):1-211.
10. Lightner DJ, Gomelsky A, Souter L et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. J Urol 2019; 202: 558.

11. Lukacz ES. Urgency urinary incontinence/overactive bladder (OAB) in females: Treatment. Schmader KE, Brubaker L, Givens J, Eckler K, eds. Waltham MA: UpToDate Inc. Updated May 18, 2021. Accessed August 17, 2021.
12. Mancini et al. A Randomized, Double-blind, Dose-ranging Study to Evaluate Efficacy and Safety of Three Doses of Botulinum Toxin Type A (Botox) for the Treatment of Spastic Foot. Neurol Sci 2005; 26:26-31.
13. Myobloc Package Insert. Rockville, MD: Solstice Neurosciences, LLC; September 2020.
14. Nepple KG. Management of bladder dysfunction in children. Baskin LS, Mattoo TK, Kim MS, eds. Waltham MA: UptoDate Inc. Updated June 22, 2021. Accessed August 17, 2021.
15. Ozcakir, S, Sivrioglu, K. Botulinum Toxin in Poststroke Spasticity. Clinical Medicine & Research 2007; 5 (2): 132-138.
16. .Sialorrhea in Cerebral Palsy. AACPDM Sialorrhea Care Pathway Team: L Glader (team lead), C Delsing, A Hughes, J Parr, L Pennington, D Reddihough, K van Hulst, J van der Burg. Available at: https://www.aacpdm.org/publications/carepathways/sialorrhea.
17. Simpson DM, Giracies JM, et al. Botullinum Neurotoxin vs. Tizanidine in Upper Limb Spasticity: A Placebo-controlled Study. J. Neurol Neurosurg Phychiatry 2008; doi:10.1136/jnnp.2008.255965-7.
18. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(19):1818-1826. doi:10.1212/WNL.0000000000002560.
19. Xeomin (package indert). Raleigh, NC: Merz Pharmaceuticals, LLC; April 2021.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021