Clinical Policy: Botulinum Toxins

Reference Number: PHW.PDL.236
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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. One of the following:

      i. Has focal spasticity,
      ii. Is under 18 years of age,
      iii. 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 four classes:

1. Beta-blockers (e.g., metoprolol, propranolol, timolol),
2. Antidepressants (e.g., amitriptyline, venlaxafine),
3. Anticonvulsants (e.g., Topiramate, valproic acid, divalproex),
4. Calcitonin gene-related peptide (CGRP)-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants),

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 four classes:

1. Beta-blockers (e.g., metoprolol, propranolol, timolol),
2. Antidepressants (e.g., amitriptyline, venlaxafine),
3. Anticonvulsants (e.g., Topiramate, valproic acid, divalproex),
4. CGRP-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants),

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. Peer-reviewed 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 **both** of the following:

    a. Has documentation of a positive clinical response to the medication
    b. One of the following:
        i. For the treatment of chronic migraine headache, requires repeat injection to reduce the frequency, severity, or duration of symptoms,
        ii. For the treatment of all other diagnoses, has the symptoms that returned to such a degree that repeat injection is required;

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 diagnosis of chronic migraine headache, is prescribed the Botulinum Toxin by or in consultation with one of the following:
    a. A neurologist,

b. A headache specialist who is certified in headache medicine by the UCNS; AND

7. If a prescription for a Botulinum Toxin is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59.

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: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	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: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	Spasticity Associated with Cerebral Palsy (off-label)	Dose: not to exceed 400 units per treatment session Duration: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	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: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	Upper and Lower Limb Spasticity in ADULTS	Dose: not to exceed 1500 units per treatment session Duration: Initial: 24 weeks (two treatment sessions) Renew: 48 weeks (four treatment sessions)
	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: Initial: 24 weeks (two treatment sessions) Renew: 48 weeks (four treatment sessions)
Myobloc (rimabotulinumtoxinB)	**Cervical Dystonia**	Dose: not to exceed 10000 units per treatment session Duration: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	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: Initial: 24 weeks (two treatment sessions) Renew: 48-52 weeks (four treatment sessions)
	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: Initial: 24 weeks (two treatment sessions) Renew: 48 weeks (four treatment sessions)

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Reviews, Revisions, and Approvals	Date
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