

Pharmacy Policy

Botox®

Policy Number: 9.209

Version Number: 2.0

Version Effective Date: 6/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth ACO

MassHealth MCO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Botox® (onabotulinumtoxinA)

Non-Formulary Products:

- Dysport® (botulinum toxin type A)
- Myobloc® (rimabotulinumtoxinB)
- Xeomin® (incobotulinumtoxinA)

The Plan may authorize coverage of the above product(s) for members meeting the following criteria:

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| Covered Use | All FDA approved and medically accepted indications as listed on the policy. |
| Exclusion Criteria | Botox, Dysport, Myobloc, and Xeomin are excluded from coverage for cosmetic procedures. |

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| <p>Required Medical Information</p> | <p>One of the following diagnoses:</p> <ol style="list-style-type: none"> 1. Cervical dystonia or Spasmodic torticollis (Botox, Dysport, Myobloc, or Xeomin) 2. Blepharospasm (Botox, Dysport, or Xeomin only) 3. Strabismus (Botox only) 4. Chronic excessive salivation (Myobloc or Xeomin only) 5. Primary Axillary Hyperhidrosis, despite trial of prescription topical agents (Botox only) 6. 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) (Botox only) 7. Upper limb spasticity (increased muscle tone in elbow flexors, wrist flexors, finger flexors, and thumb flexors) (Botox or Xeomin only) 8. Urinary incontinence (detrusor over activity) associated with a neurologic condition (e.g spinal cord injury, multiple sclerosis) (Botox only) or overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency (Botox or Myobloc only); AND <ol style="list-style-type: none"> a. An inadequate response, intolerance or a contraindication to a trial of at least two formulary anticholinergic agents; 9. A diagnosis of chronic migraines with more than 15 migraine days per month and headaches lasting 4 hours a day or longer (Botox only); AND <ol style="list-style-type: none"> a. An inadequate response (persistent 15 migraine headache days per month) or intolerance to at least 30-day trials of three migraine prophylaxis medications listed below from at three different therapeutic classes : <ul style="list-style-type: none"> ▪ Beta blockers: metoprolol, propranolol, timolol, atenolol, nadolol, nebivolol, pindolol ▪ Antidepressants: amitriptyline, venlafaxine ▪ Anticonvulsants: carbamazepine, divalproex, valproic acid, topiramate; AND b. Patient not taking CGRP concurrently; AND c. Injections will occur no sooner than 12 weeks apart. 10. Documentation of one of the following non-FDA approved medically accepted indications: <ol style="list-style-type: none"> a. Achalasia (Botox only) b. Chronic anal fissure (Botox only) c. Hemifacial Spasm (Botox or Dysport only) d. Oromandibular Dystonia (Botox only) e. Spasmodic dysphonia (laryngeal dystonia) (Botox only) f. Focal Upper Limb Dystonias (i.e. organic writer’s cramp) (Botox only) g. Palmar Hyperhidrosis (Botox only) h. Essential hand tremor(Botox only); AND <ol style="list-style-type: none"> i. An inadequate clinical response and/or intolerance to currently accepted therapeutic options recommended by a nationally recognized entity specific to the disease for which the member is being treated (or as determined by a review of the available clinical evidence |
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| | if recommendations from a nationally recognized entity have not been published) |
| Age Restrictions | <p><u>Botox:</u></p> <ul style="list-style-type: none"> • Cervical dystonia or spasmodic torticollis - 16 years or older • Blepharospasm - 12 years or older • Strabismus - 12 years or older • Primary Axillary Hyperhidrosis- 18 years or older • Upper limb spasticity- 2 years or older • Lower limb spasticity- 2 years or older • Chronic migraine- 18 years or older • Overactive bladder or urinary incontinence- 18 years or older <p><u>Dysport:</u></p> <ul style="list-style-type: none"> • Cervical dystonia or spasmodic torticollis - 18 years or older • Upper limb spasticity- 2 years or older • Lower limb spasticity- 2 years or older <p><u>Myobloc:</u></p> <ul style="list-style-type: none"> • Cervical dystonia or spasmodic torticollis - 18 years or older • Chronic excessive salivation: 18 years or older <p><u>Xeomin:</u></p> <ul style="list-style-type: none"> • Cervical dystonia or spasmodic torticollis - 18 years or older • Blepharospasm - 18 years or older • Upper limb spasticity - 2 years or older • Chronic excessive salivation: 2 years or older |
| Prescriber Restriction | The prescriber is a specialist appropriate to the disease state being treated. |
| Coverage Duration | Initial and Reauthorization: 12 months |
| Other criteria | <p>Reauthorization:</p> <ol style="list-style-type: none"> 1. Clinically significant reduction in symptom severity/ frequency, or improvement of functional ability. |

Applicable Coding:

| Code | Medication |
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| J0585 | Botox® (onabotulinumtoxin A) |
| J0586 | Dysport (botulinum toxin type A) |
| J0587 | Myobloc (rimabotulinumtoxinB) |
| J0588 | Xeomin (incobotulinumtoxinA) |

Clinical Background Information and References

1. Simpson DM, Gracies J-M, Graham JM, et al. Assessment: Botulinum neurotoxin for the treatment of spasticity (an evidence-based review): Report of the Therapeutics and Technology Assessment subcommittee of the American Academy on Neurology; Neurology 2008; 70;1691-1698.
2. Simpson DM, Blitzer A, Brashear A., et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology; Neurology 2008;70;1699-1706.
3. Naumann M, So CE, Argoff M., et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology; Neurology 2008; 70;1707-1714.
4. Botulinum toxin type a: Drug Information. Lexi-comp, Inc. UptoDate®, Accessed June 1, 2015; available from <http://uptodate.com>.
5. Botox® (onabotulinumtoxin A) prescribing information. Allergan, Inc. Irvine, CA 92612. August 2011. revised January 2016
6. Xeomin® (incobotulinumtoxin A) prescribing information. Merz pharmaceuticals, LLC. Greensboro, NC 27410. August 2010, revised December 2015
7. Myobloc® (rimabotulinumtoxin B) prescribing information. Solstice Neurosciences, Inc. South San Francisco, CA 94080. May 2010.
8. Dysport® (abobotulinumtoxin A) prescribing information. Tercica, Inc., a subsidiary of the Ipsen Group. Brisbane, CA 94005. April 2010, revised July 2015
9. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012 Apr 24;78(17):1337-45. Accessed via <http://www.guideline.gov/content.aspx?id=36898>. June 2016
10. Hayes Medical Technology Directory. Botulinum Toxin Treatment for Migraine Headache. Winifred Hayes, Inc. September 22, 2011. Updated October 15, 2013
11. Govindarajan, Raghav, et al. "Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache Payment policy perspectives." Neurology: Clinical Practice (2016): 10-1212.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|-------------------|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

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Policy Revisions History

| Review Date | Summary of Revisions | Revision Effective Date | Approved by |
|-------------|--|-------------------------|---------------|
| 12/1/2020 | 9.106 Botox Policy retired, new policy created | 1/1/2021 | P&T Committee |
| 2/11/2021 | P&T annual review. Added Dysport, Myobloc, and Xeomin to the policy for applicable diagnoses. Updated lower limb spasticity age limit to 2 years and up. Removed limb spasticity in children from unapproved indications (because now labeled for spasticity in ages 2 and up). Added duration between injection criterion to migraines. | 6/1/2021 | P&T Committee |

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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