Pharmacy Medical Necessity Guidelines

Botulinum Toxins: Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinum toxin B), and Xeomin® (incobotulinumtoxinA)

Effective: 07/01/2015

<table>
<thead>
<tr>
<th>Clinical documentation and prior authorization required</th>
<th>Type of review – case management</th>
<th>Type of review – clinical review Fax: 617-673-0988</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not covered</td>
<td>✅</td>
<td></td>
</tr>
<tr>
<td>Pharmacy (RX) or medical (MED) benefit</td>
<td>RX</td>
<td>Department to review RxUM</td>
</tr>
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</table>

OVERVIEW

FDA-APPROVED INDICATIONS (NON-COSMETIC)

Botox® (onabotulinumtoxinA) is indicated for

Bladder Dysfunction
- The treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Injection of the bladder with Botox is performed using cystoscopy.
- The treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Blepharospasm and Strabismus
- The treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

Cervical Dystonia
- The treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Chronic Migraine
- The prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).

Primary Axillary Hyperhidrosis
- The treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

Upper Limb Spasticity
- The treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus).

Dysport™ (abobotulinumtoxinA)
- Is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients.

Myobloc® (rimabotulinumtoxinB)
- Is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Xeomin® (incobotulinumtoxinA) is indicated for the treatment of adults with
- Cervical dystonia to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients.
- Blepharospasm who were previously treated with onabotulinumtoxinA (Botox).
**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of Botox®, Dysport®, Xeomin®, Myobloc® for members when all the following criteria are met and limitations do not apply:

**Botox**
To be used for the treatment of:
- Spasmodic torticollis or cervical dystonia for a Member 16 years
- Strabismus or Blepharospasms associated with dystonia in Members 12 years of age or older
- Seventh Cranial Nerve Disorders such as hemifacial spasms, jaw closing, or mandibular dystonia, masseter spasticity, and orofacial dyskinesia in a Member 12 years of age or older
- Upper/Lower limb spasticity due to cerebral palsy in a pediatric Member, upper/lower limb spasticity due to multiple sclerosis, stroke, brain injury, or spinal cord injury
- Achalasia in a Member who has failed or is at high risk of complications from pneumatic dilation or surgical myotomy
- Spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm), or laryngeal dystonia
- Primary Axillary Hyperhidrosis in Members 18 years of age or older that has failed treatment with one topical agent such as Dry-Sol or Aluminum Chloride Hexahydrate 20%
- Urinary Incontinence in a Member due to detrusor overactivity (detrusor hyperreflexia) caused by spinal cord injury that has failed therapy with at least 1 antimuscarinic agent such as oxybutynin, tolterodine, fesoterodine, darifenacin, solifenacin or trosipium
- Overactive bladder not caused by a spinal cord injury in a Member who has failed therapy, or provider has indicated clinical inappropriateness with mirabegron and at least 2 antimuscarinic agents, such as oxybutynin, tolterodine, fesoterodine, darifenacin, solifenacin or trosipium
- Chronic Anal Fissures in a Member that has tried and failed treatment with either topical nitroglycerin or nifedipine ointment
- Chronic migraine headache, defined as occurring greater than 15 days per month and lasting longer than 4 hours, in Members 18 years of age or older when all of the following criteria are met:
  - Member has been evaluated by a neurologist or headache specialist **AND**
  - Member is identified as compliant with prior treatment **AND**
  - Member is concurrently treated with at least 2 traditional migraine prophylaxis medications **AND**
  - Member has tried and failed for at least three months each or contraindication to all of the following therapeutic categories/medications:
    - Beta blockers (e.g., propranolol)
    - Divalproex sodium
    - Topiramate
    - Tricyclic Antidepressants

**Dysport**
To be used for the treatment of:
- cervical dystonia spasmodic torticollis in Members 18 years or age or older
- spasmodic torticollis in Members 18 years or age or older **AND**
- Member has tried and failed treatment with or provider documented clinical inappropriateness of treatment with Botox or Myobloc **OR**
- Member is new to Network health and has been stable on Dysport prior to enrollment

**Myobloc**
To be used for the treatment of:
- spasmodic torticollis or cervical dystonia for a Member 18 years and older

**Xeomin**
- Blepharospasms in Members 18 years of age or older **AND**
- Member has tried and failed treatment with or provider documented clinical inappropriateness of treatment with Botox **OR**
- Member is new to Network health and has been stable on Xeomin prior to enrollment
**LIMITATIONS**

1. Tufts Health Plan – Network Health will not provide coverage of coverage of Botox, Dysport, Xeomin, Myobloc for the treatment of a cosmetic indication such as glabellar lines (wrinkles, frown lines), aging neck, or blepharoplasty (eyelid lift).

2. Initial requests will be approved for 1 year except when used for the treatment of upper/lower limb spasticity due to cerebral palsy in a pediatric Member, in which case initial requests will be approved for life of plan.

3. Subsequent authorizations may be given in 12 month intervals when the provider indicates improvement with therapy.

**CODES**

The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>J0585</td>
<td>Injection, onabotulinumtoxinA, 1 unit</td>
</tr>
<tr>
<td>J0586</td>
<td>Injection, abobotulinumtoxinA, 5 units</td>
</tr>
<tr>
<td>J0587</td>
<td>Injection, rimabotulinumtoxinB, 100 units</td>
</tr>
<tr>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, 1 unit</td>
</tr>
<tr>
<td>46505</td>
<td>Chemodenervation of internal anal sphincter</td>
</tr>
<tr>
<td>52287</td>
<td>Cystourethroscopy, with injection(s) for chemodenervation of the bladder</td>
</tr>
<tr>
<td>64612</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)</td>
</tr>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)</td>
</tr>
<tr>
<td>64616</td>
<td>Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticolis)</td>
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<tr>
<td>64617</td>
<td>Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed</td>
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<tr>
<td>64642</td>
<td>Chemodenervation of one extremity; 1-4 muscle(s)</td>
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<tr>
<td>64643</td>
<td>Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>64644</td>
<td>Chemodenervation of one extremity; 5 or more muscle(s)</td>
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<tr>
<td>64645</td>
<td>Chemodenervation of one extremity; each additional extremity, 5 or more muscle(s) (list separately in addition to code for primary procedure)</td>
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<tr>
<td>64646</td>
<td>Chemodenervation of trunk muscle(s); 1-5 muscle(s)</td>
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<tr>
<td>64647</td>
<td>Chemodenervation of trunk muscle(s); 6 or more muscle(s)</td>
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<tr>
<td>64650</td>
<td>Chemodenervation of eccrine glands; both axillae</td>
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<tr>
<td>64653</td>
<td>Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day</td>
</tr>
<tr>
<td>67345</td>
<td>Chemodenervation of extracuticular muscle</td>
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**Note:** This list of codes may not be all-inclusive.

**REFERENCES**


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**APPROVAL HISTORY**

- 06/11/2009: Reviewed by the Pharmacy and Therapeutics Committee
- 09/04/2014: Reviewed by the Pharmacy and Therapeutics Committee
- 05/12/2015: Updated title of criteria to include Botulinum Toxins. Removed NSAIDS and Serotonin 5-HT1 receptor from previous treatment requirement for the diagnosis of chronic migraine headaches.

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**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable *Member Handbook* and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable *Member Handbook*. Check the applicable *Preferred Drug List* (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For *Tufts Health Unify* (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the *Tufts Health Unify Prior Authorization Medical Necessity Guidelines*.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.