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Subject: Botulinum Toxins
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Clinical Documentation and Prior Authorization Required	√	Type of Review — Case Management	
Not Covered		Type of Review — Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Administrative Process (Internal Use Only)	RN

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

FDA-APPROVED INDICATIONS (NON-COSMETIC)

Botox[®] (onabotulinumtoxinA) 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.
- The prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).
- 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.
- The treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
- 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) and finger flexors (flexor digitorum profundus and flexor digitorum sublimis).
- 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.

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

In addition to the coverage criteria listed for each diagnosis, Tufts Health Plan may authorize coverage of **Botox, Dysport, Xeomin, or Myobloc** when the presence of a dystonia/movement disorder contributes to a significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed.

Note for all botulinum toxins:

- For Members 18 years of age and older, initial authorization will expire in 2 months from the original authorization date for any diagnosis.
 - Additional authorization may be given if documentation of an objective measurable effect is provided indicating clinical improvement of condition.
- For Members below the age of 18 years old and for subsequent authorizations for Members 18 years of age and older, authorization will be approved in 12-month intervals.
 - Additional authorizations may be given if documentation is provided indicating sustained clinical effectiveness.

For OnabotulinumtoxinA (Botox®):

1. **Blepharospasm** (eyelid spasms/blinking) **or Strabismus** (cross-eyes, esotropia, exotropia)

- Over the age of 12 years
- Documented diagnosis
- Dose of 100 units or less

2. **Spasmodic Torticollis** (Neurologically based)

- Documented diagnosis
- Dose of 300 units or less.

3. **Pediatric Limb Spasticity** (e.g., Cerebral Palsy)

- Over the age of 18 months
- Documented physical evidence of focal limb spasticity
- Dose of 400 units or less

Note: Botox will not be covered for Pediatric Limb Spasticity when one of the following conditions is present:

- A joint immobilized by a fixed contracture
- Severe weakness of the opposing muscle in the limb for which the injection is intended
- Diffuse hypertonia (excessive muscle tone)

4. **Anal fissures**

- Dose is 100 units or less
- Documented diagnosis and response failure to prescription topical therapy (nitroglycerin ointment)

5. **Jaw-closing oromandibular dystonia, and masseter spasticity**

- Documented diagnosis
- Failure of conventional therapy such as physical therapy or local anesthetic injections

6. **Laryngeal or spasmodic dysphonia**
 - Documented diagnosis using videostroboscopy
 - Dose of 100 units or less
7. **Focal limb dystonia: (Organic writer's cramp, foot dystonia)**
 - Documented diagnosis
 - Dose of 100 units or less
8. **Neurologically-based Limb Spasticity**
 - Documented diagnosis of one of the following:
 - Multiple Sclerosis
 - Stroke
 - Brain Injury
 - Spinal Cord Injury
 - Documented failure to control spasticity by conventional therapies:
 - Physical Therapy
 - Splinting
 - Bracing
 - Systemic antispasticity medication
 - Doses of 400 units or less for lower limb
 - Doses of 200 units or less for upper limb
9. **Hemifacial Spasms**
 - Documented diagnosis
10. **Primary Axillary Hyperhidrosis**
 - Treatment failure of the following prescription topical antiperspirant:
 - Drysol®
 - Aluminum Chloride (Hexahydrate) 20%
 - Dose of 100 units or less
11. **Palmar Hyperhidrosis**
 - Documented diagnosis
 - Treatment failure of the following prescription topical antiperspirant:
 - Drysol®
 - Aluminum Chloride (Hexahydrate) 20%
 - Dose of 100 units or less per palm
 - Injections should occur no sooner than 6 months apart
12. **Chronic Migraine Headaches**
 - Documented diagnosis of chronic migraine defined as
 - History of migraine headaches lasting 4 hours a day or longer
 - Migraine headaches occur on ≥ 15 days per month

- Concurrent treatment with at least 2 traditional migraine prophylaxis medications
- Dose of 155 units or less per treatment
- Injections should occur no sooner than 12 weeks apart

13. Urinary Incontinence

- Documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
- Inadequate response to or failure of one or more anticholinergic medication(s) indicated for the treatment of urinary incontinence (e.g., flavoxate, oxybutynin, trospium, Detrol[®] / Detrol[®] LA, Enablex[®], Toviaz[®], Vesicare[®])
- Dose of 200 units or less per treatment
- Injections should occur no sooner than 6 months apart.
- Must be ordered by a urologist.

For AbobotulinumtoxinA (Dysport[™])

1. Member has failed treatment with OnabotulinumtoxinA (Botox).
AND
2. Documented diagnosis of cervical dystonia
AND
3. The dose is 1000 units or less.

For IncobotulinumtoxinA (Xeomin[®])

1. **Blepharospasm** (eyelid spasms/blinking)
 - Member has failed treatment with OnabotulinumtoxinA (Botox)
 - Member is over the age of 18 years
 - Documented diagnosis
 - Dose of 100 units or less
2. **Cervical Dystonia**
 - Member has failed treatment with OnabotulinumtoxinA (Botox)
 - Member is over the age of 18 years
 - Documented diagnosis
 - Dose of 120 units or less

For RimabotulinumtoxinB (Myobloc[®])

1. Member has failed treatment with OnabotulinumtoxinA (Botox).
OR
2. Physician documents a diagnosis of spasmodic torticollis as described under OnabotulinumtoxinA.
AND
3. For spasmodic torticollis, the dose is 5000 units or less.
Note: Injections should occur no sooner than 3 months apart.

Limitations

1. Tufts Health Plan does not provide coverage for cosmetic procedures that involve the use of botulinum toxin injection.
2. Tufts Health Plan does **not** cover botulinum toxin therapy for the treatment of:
 - Any condition not listed above in the “Pharmacy Coverage Guidelines” or
 - Any patients with other types of muscle spasms not listed in the “Pharmacy Coverage Guidelines” including, but not limited to, smooth muscle spasms, myofascial pain, trigger points, and piriformis syndrome.
 - Plantar hyperhidrosis.
 - Migraine headaches that occur 14 days or less per month (i.e., episodic migraine), or for other forms of headache.
 - Other types of urinary incontinence not listed in the “Pharmacy Coverage Guidelines”.

Codes

The following HCPCS/CPT code(s) are:

Code	Description
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB,100 units
J0588	Injection, incobotulinumtoxinA, 1 unit
46505	Chemodenerivation of internal anal sphincter
64612	Chemodenerivation of muscle(s); muscle(s) innervated by facial nerve (eg, for blepharospasm, hemifacial spasm)
64613	Chemodenerivation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)
64614	Chemodenerivation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)
64650	Chemodenerivation of eccrine glands; both axillae
64653	Chemodenerivation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
67345	Chemodenerivation of extraocular muscle

Note: This list of codes may not be all-inclusive.

References

1. Botox (onabotulinumtoxinA) [package insert]. Irvine, CA: Allergan, Inc.; August 2011.
2. Botulinum Toxin Treatment for Hyperhidrosis, Winifred S. Hayes, Inc. February 2002.
3. Botulinum Toxin Treatment for Spasticity and Gastrointestinal Disorders, Winifred S. Hayes, Inc. January 28, 1999.
4. Brashear, Allison. “The Botulinum Toxins in the Treatment of Cervical Dystonia” [Sem Neurology 21(1): 85-90, 2001. Thieme Medical Publishers, Inc.]
5. Dysport (abobotulinumtoxinA) [package insert]. Brisbane, CA: Tercica, Inc.; May 2009.
6. Cruz F, Herschorn S, Aliotta P et al. Efficacy and Safety of OnabotulinumtoxinA in Patients with Urinary Incontinence Due to Neurogenic Detrusor Overactivity: A Randomised, Double-Blind, Placebo-Controlled Trial. *Eur Urol*, 2011; 60(4): 742-750.
7. Brin MD, M. Botulinum Toxin, chemistry, pharmacology, toxicity and immunology, *Muscle and Nerve*, Supplement 6, 1997, p. S146-160.

8. HCFA National Coverage Policy Botulinum Toxin A, NHIC September 2001.
9. Herschorn S, Gajewski J, Ethans K et al. Efficacy of Botulinum Toxin A Injection for Neurogenic Detrusor Overactivity and Urinary Incontinence: A Randomized, Double-Blind Trial. *J Urol*, 2011; 185(6): 2229-2235.
10. Khan S, Game X, Kalsi V et al. Long-Term Effect on Quality of Life of Repeat Detrusor Injections of Botulinum Neurotoxin-A for Detrusor Overactivity in Patients With Multiple Sclerosis. *J Urol*, 2011; 185(4): 1344-1349.
11. Myobloc (rimabotulinumtoxinB) [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; July 2009.
12. Naumann, M. et.al, "Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review). *Neurology*, 2008; 70;1707-1714.
13. Russman MD, B, Tilton MD, A., and Gormley MD, Mark, Cerebral Palsy: A rational approach to a treatment protocol and the role of Botulinum toxin in treatment, *Muscle and Nerve*, Supplement 6, 1997, p. S181-192.
14. Xeomin (incobotulinumtoxinA) [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; July 2011.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee in October 2001.

Subsequent Endorsement Date(s) and Changes Made:

1. December 14, 2004:
 - Add "when the presence of a dystonia/movement disorder contribute to a significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed" as an general qualifier to Clinical Coverage Criteria.
 - Add treatment of **Hemifacial Spasms** to the Clinical Coverage Criteria.
 - Add treatment of **Primary Axillary Hyperhidrosis** to the Clinical Coverage Criteria.
 - Add "ACE Inhibitors" to Exhibit B in the Coverage Limitations.
2. December 13, 2005:
 - For Botulinum Toxin A, delete the dose limit for Blepharospasm or Strabismus, Anal fissures, and Laryngeal or spasmodic dysphonia.
 - For Botulinum Toxin A, add the dose limit of "100 units or less" for Blepharospasm or Strabismus, Anal fissures, Laryngeal or spasmodic dysphonia, and Primary Axillary Hyperhidrosis.
3. November 14, 2006:
 - Add clinical coverage criteria for **Palmar Hyperhidrosis**
 - Remove age limitation "Over the age of 18 years" from criteria for Primary Axillary Hyperhidrosis
 - Add "Aluminum Chloride (Hexahydrate) 20%" to criteria for Primary Axillary Hyperhidrosis
4. November 13, 2007: No changes
5. September 9, 2008:
 - Removed criteria for treatment of Migraine Headaches
 - Removed corresponding Exhibits A and B in reference to remittive and prophylactic migraine therapies
6. January 13, 2009:
 - Added limitation that Plantar Hyperhidrosis is not a covered indication.
7. September 8, 2009:

- Changed established drug names from Botulinum Toxin A to OnabotulinumtoxinA (Botox) and Botulinum Toxin B to RimabotulinumtoxinB (Myobloc).
8. January 1, 2010:
 - Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
 9. January 12, 2010:
 - Added Dysport (abobotulinumtoxinA) to Medical Necessity Guidelines.
 10. May 11, 2010:
 - Updated HCPCS code descriptions for Botox and Myobloc.
 - Updated diagnosis of neurologically-based limb spasticity to differentiate dosing limitations for upper and lower limb spasticity.
 - Removed age limitation from diagnosis of spasmodic torticollis (neurologically based) and anal fissures.
 - Removed age limitation from AbobotulinumtoxinA and RimabotulinumtoxinB.
 - Updated initial authorization (2 months for Members 18 years of age and older, 12 months for Members below the age of 18 years old) and subsequent authorization intervals (12 months).
 - Removed limitation language requiring a response following two sequential treatments/sets of injections in a 4-6 month period, using maximum dose for the size of the muscle for authorization of coverage of additional botulinum toxin injections.
 11. July 13, 2010:
 - Removed requirement of starch iodine test and iontophoresis from coverage criteria for palmar hyperhidrosis.
 12. November 9, 2010:
 - Changed policy title from “OnabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport) and rimabotulinumtoxinB (Myobloc)” to “Botulinum Toxins”.
 - Added requirement of documented diagnosis of cervical dystonia to Dysport (abobotulinumtoxinA) criteria.
 - Added Xeomin (incobotulinumtoxinA) to pharmacy medical necessity guidelines.
 - Added coverage criteria for the diagnosis of chronic migraine headaches for OnabotulinumtoxinA (Botox).
 - Added limitation that Tufts Health Plan does not cover botulinum toxin therapy for the treatment of migraine headaches that occur 14 days or less per month (i.e., episodic migraine), or for other forms of headache.
 13. January 1, 2011:
 - Administrative Update: Added reimbursement code C9278.
 14. May 10, 2011:
 - Clarified note regarding length of authorization. For subsequent authorizations beyond 2 months, provider needs to submit documentation of an objective measurable effect indicating clinical improvement of condition. For authorizations beyond one year, provider needs to submit documentation of sustained clinical effectiveness.
 15. September 13, 2011:
 - Added coverage criteria for treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication for OnabotulinumtoxinA (Botox).

- Added limitation that Tufts Health Plan does not cover botulinum toxin for other types of urinary incontinence not listed in the “Pharmacy Coverage Guidelines”.

16. January 1, 2012:

- Administrative Update: Replaced reimbursement code C9278 with J0588.

17. April 10, 2012:

- Changed maximum dose of Botox for chronic migraine headaches from 150 units to 155 units or less per treatment.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health Plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity 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 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 revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our Web site at <http://www.tuftshealthplan.com/providers> to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Medicare Preferred, please refer to Tufts Medicare Preferred Prior Authorization Criteria.

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.