

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

A. Prescriptions That Require Prior Authorization

All prescriptions for Botulinum Toxins, regardless of the quantity prescribed, must be prior authorized.¹

B. Emergency Supplies

The Department does not consider a delay in the receipt of Botulinum Toxins to present an emergency and, therefore, will NOT cover emergency supplies of Botulinum Toxins pending approval of a request for prior authorization.

C. 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:

1. The recipient is being treated for a condition where use of a Botulinum Toxin is a Federal Food and Drug Administration (FDA) approved indication or another medically accepted indication, excluding a cosmetic condition. The requesting prescriber must provide documentation from the medical record of the diagnosis and, when appropriate, the prior treatment of the approved indications.

AND

2. The prescriber submitted documentation of the proposed injection site(s) and the dose that will be injected into each site.

AND

3. The recipient is not pregnant or breastfeeding

AND

4. The recipient has a documented history of therapeutic failure, contraindication or intolerance of the preferred Botulinum Toxins approved for the indication

¹ Botulinum Toxin products are not interchangeable or bioequivalent. Dosing units are specific to the preparation of the Botulinum Toxin.

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AND

5. For a diagnosis of strabismus, whether:

- a. The recipient is 12 years of age or older AND
- b. The recipient has a deviation of less than 50 prism diopters AND
- c. Treatment has the potential to restore binocular vision AND
- d. Strabismus is not due to Duane's Syndrome with lateral rectus muscle weakness, restrictive strabismus or secondary strabismus caused by prior surgery.

AND

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

AND

7. For a diagnosis of chronic migraine headache, the recipient has a history of therapeutic failure, contraindication, or intolerance to at least three migraine prophylaxis medications (e.g. beta-blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications).

AND

8. The recipient has a history of chronic migraine headache not attributed to other causes including medication overuse, as defined by:

- a. Headache (tension-type and/or migraine) on ≥ 15 days per month for at least three months

AND

- b. At least five of these attacks meet at least two of the following:
 - i. Unilateral location
 - ii. Pulsating quality
 - iii. Moderate or severe intensity
 - iv. Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)

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AND

- c. During headache, at least one of the following is present:
 - 1. Nausea and/or vomiting **OR**
 - 2. Photophobia and phonophobia

OR

- d. Headaches are treated and relieved by triptan(s) or ergotamine(s) before the expected development of associated symptoms of migraine

AND

- 9. 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 the Quantity Limits Chapter.

OR

- 10. The recipient 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 recipient.

- 11. For repeat treatment:

- a. When the frequency of injection exceeds the dosing and duration of therapy limits, the prescriber must submit documentation of the following:

- i. The previous treatment was well tolerated but inadequate

AND

- ii. Medical literature supports more frequent dosing intervals as safe and effective for the diagnosis and requested dose

AND

- b. When the frequency of injection is consistent with the dosing and duration of therapy limits, the prescriber must submit documentation of the following:

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- i. The previous treatment was well tolerated and the recipient showed evidence of measurable improvement in severity of symptoms

AND

- ii. The symptoms returned to such a degree that repeat injection is required

OR

- c. The recipient 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 recipient.

D . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above, to assess the medical necessity of the request for a prescription for a Botulinum Toxin. If the guidelines in Section C. 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.

E. Dose and Duration of Therapy

Dosing limits are as follows:

- a. For Botox:
 - i. Spasticity in adults - 600 units/90 days
 - ii. Spasticity associated with cerebral palsy in children over age 18 months (for children and recipients under 25 kg, weight based dosing applies) - 400 units/90 days
 - iii. Severe axillary hyperhidrosis - 50 units/axilla/90 days
 - iv. Blepharospasm - 200 units/90 days
 - v. Cervical Dystonia - 300 units/90 days
 - vi. Chronic Migraine - 200 units/84 days
 - vii. Strabismus - ≤ 25 units/muscle/injection/90 days
 - viii. Spasmodic dysphonia – 10 units/ 90 days
- b. For Dysport in cervical dystonia:

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- i. Initial 500 units/90 days
 - ii. Renewal up to 1,000 units/90 days
- c. For Myobloc in cervical dystonia:
- i. Initial therapy 2500 units total/90 days
 - ii. Renewal up to 10,000 units/90 days
- d. For Xeomin:
- i. Cervical Dystonia - 120 units/90 days
 - ii. Blepharospasm - 35 units/eye/90 days

The Department will not approve a request for authorization for one year from the most recent injection when there is no benefit after two sequential therapies using maximum doses.

References:

1. Myobloc (package insert). South San Francisco, CA: Solstice Neurosciences, Inc.; 2009
2. Botox (package insert). Irvine, CA: Allergan; August 2009
3. Dysport (package insert). Wrexham, LL13 9UF, UK: Ipsen Biopharm, Ltd.; 2009
4. Simpson DM, Giracies JM, et al. Botulinum Neurotoxin vs. Tizanidine in Upper Limb Spasticity: A Placebo-controlled Study. *J. Neurol Neurosurg Psychiatry* 2008; doi:10.1136/jnnp.2008.255965-7
5. 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
6. 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
7. 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
8. Garza et al. Chronic migraine. *UpToDate*; June 2011.
9. Xeomin (package indert). Greensboro, NC: Merz Pharmaceuticals, LLC; 2011