

ISSUE DATE October 20, 2016	EFFECTIVE DATE October 31, 2016	NUMBER *See below
SUBJECT Prior Authorization of Botulinum Toxins - Pharmacy Services		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISE to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Botulinum Toxins for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is modifying the guidelines to determine the medical necessity of Botulinum Toxins in response to the Food and Drug Administration approved indication of Dysport (abobotulinumtoxin A) for the treatment of Pediatric Lower Limb Spasticity. The guideline specifying documented therapeutic failure, contraindication or intolerance to one oral medication is revised to apply only to recipients age 18 and older. This guideline will not apply to a determination of medical necessity for recipients under 18 years of age. There are no other changes to the medical necessity guidelines.

*01-16-31	09-16-29	27-16-28	
02-16-27	11-16-27	30-16-27	
03-16-27	14-16-28	31-16-33	
08-16-29	24-16-30	32-16-26	33-16-28

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

PROCEDURE:

The procedures for prescribers to request prior authorization of Botulinum Toxins are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Botulinum Toxins when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Botulinum Toxins

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

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

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

AND

5. For a diagnosis of chronic spasticity resulting from cerebral palsy, multiple sclerosis, traumatic brain injury, spinal cord injury, or stroke, whether:

- a. The recipient has documented spasticity that:

- i. Interferes with activities of daily living, **OR**
- ii. Is expected to result in joint contracture with future growth

AND

- b. If the recipient is age 18 or older, has documented therapeutic failure, contraindication or intolerance to one oral medication for spasticity

AND

- c. If the recipient developed contractures, the recipient has been considered for surgical intervention

AND

- d. The botulinum toxin is being requested to;

- i. Enhance function, **OR**
- ii. Allow for additional therapeutic modalities to be employed

AND

- e. The requested botulinum toxin will be used in conjunction with other appropriate therapeutic modalities such as physical therapy, occupational therapy, gradual splinting, etc.

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AND

6. 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

7. 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

8. 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

9. 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:

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- 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)

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

- 10. For a diagnosis of urinary incontinence due to detrusor over activity associated with a neurologic condition, whether the recipient has a history of therapeutic failure, contraindication, or intolerance to at least two agents used in the treatment of urinary incontinence

AND

- 11. For a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, whether the recipient has a history of therapeutic failure, contraindication, or intolerance to at least 2 agents 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 the Quantity Limits Chapter.

OR

- 13. The recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer,

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the services are medically necessary to meet the medical needs of the recipient.

14. 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:

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

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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
 - ix. Urinary incontinence – 200 units/84 days
 - x. Overactive bladder – 100 units/84 days
 - xi. Maximum cumulative dose across all indications – 360 units/3-month interval

- b. For Dysport in cervical dystonia:
 - 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

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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; January 2013
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 Type A Produce Sustained Decreases in the Limitations Associated With Focal Upper-Limb Post 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 insert). Greensboro, NC: Merz Pharmaceuticals, LLC; 2011
10. Miller et al. Management and prognosis of cerebral palsy. UpToDate; Accessed February 10, 2014.
11. Abrams et al. Chronic complications of spinal cord injury. UpToDate; Accessed February 10, 2014.
12. Ozcakir, S, Sivrioglu, K. Botulinum Toxin in Poststroke Spasticity. *Clinical Medicine & Research* 2007; 5 (2): 132-138