IMPORTANCE 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/promis/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:

The Department of Human Services’ (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to new drugs in therapeutic classes already included in the Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred, new quantity limits, and classes of drugs to be added.

*01-17-09  09-17-08  27-17-07
02-17-07  11-17-07  30-17-08
03-17-07  14-17-07  31-17-09
08-17-08  24-17-07  32-17-07  33-17-08

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
The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

**DISCUSSION:**

DHS is modifying the Dose and Duration of Therapy section of the guidelines to determine the medical necessity of Botulinum Toxins. Previously this section detailed the dose and duration from package labeling that would be approved for each agent within the class and for each diagnosis. The Dose and Duration of Therapy section has been revised to issue approvals of requests for prior authorization of Botulinum Toxins consistent with package labeling. There are no other changes to the medical necessity guidelines.

**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. DHS 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
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.
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.

   AND

January 31, 2017
(Replacing October 11, 2016)
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:
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 overactivity 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
MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

13. 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.

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 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

Approvals of requests for prior authorization of Botulinum Toxins will be
consistent with package labeling.

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:

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