Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Botulinum Toxins – Pharmacy Services

BY

Sally Kozak
Deputy Secretary
Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

PURPOSE:

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

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Botulinum Toxins will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Botulinum Toxins to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-11	09-25-11	27-25-11	33-25-11
02-25-11	11-25-11	30-25-11	
03-25-11	14-25-11	31-25-11	
08-25-12	24-25-11	32-25-11	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Botulinum Toxins:

- Revision of the guideline for chronic spasticity that therapeutic failure of or a contraindication or an intolerance to one oral drug for spasticity does not apply to beneficiaries with focal spasticity or to beneficiaries under 18 years of age.
- Revision to the guidelines for chronic migraine headache to include calcitonin gene-related peptide-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants) as an additional previous therapy option.
- Addition of guidelines to the requests for renewal of the prior authorization section specific to chronic migraine headache.
- Addition of a guideline to the requests for renewal of the prior authorization section that the prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Addition of a guideline to the requests for renewal of the prior authorization section that the beneficiary does not have a contraindication to the prescribed drug.
- Addition of a guideline to the requests for renewal of the prior authorization section that the beneficiary has documentation of the proposed injection site(s) and the dose that will be injected into each site.
- Specification that requests for renewal of prior authorization for prescriptions that exceed the quantity limit require prior authorization.

The revisions to the guidelines to determine medical necessity of prescriptions for Botulinum Toxins submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

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 and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Botulinum Toxins

A. Prescriptions That Require Prior Authorization

All prescriptions for Botulinum Toxins must be prior authorized.

B. 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 the beneficiary:

1. Is prescribed the Botulinum Toxin for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding a cosmetic condition; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed drug; **AND**

5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site; **AND**

6. For a non-preferred Botulinum Toxin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Botulinum Toxins approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Botulinum Toxins at: https://papdl.com/preferred-drug-list; **AND**

7. For a diagnosis of chronic spasticity, **all** of the following:

    a. Has spasticity that interferes with activities of daily living or is expected to result in joint contracture with future growth,

    b. **One** of the following:

        i. Has focal spasticity,
        ii. Is under 18 years of age,
        iii. Is 18 years of age or older and has a history of therapeutic failure of or a contraindication or an intolerance to one oral drug for spasticity,

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

d. Is requesting the Botulinum Toxin to enhance function or allow for additional therapeutic modalities to be employed,

e. Will use the requested Botulinum Toxin in conjunction with other appropriate therapeutic modalities such as physical therapy, occupational therapy, gradual splinting, etc.;

AND

8. For a diagnosis of axillary hyperhidrosis, has a history of therapeutic failure of or a contraindication or an intolerance to a topical drug such as aluminum chloride 20%; **AND**

9. For a diagnosis of chronic migraine headache, **all** of the following:

   a. **One** of the following:

      i. Has a history of therapeutic failure of at least **one** migraine preventive drug from at least **two** of the following four classes:

         a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
         b) Antidepressants (e.g., amitriptyline, venlafaxine),
         c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
         d) Calcitonin gene-related peptide (CGRP)-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants)

      ii. Has a history of a contraindication or an intolerance that prohibits a trial of at least **one** migraine preventive drug from at least **two** of the following four classes:

         a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
         b) Antidepressants (e.g., amitriptyline, venlafaxine),
         c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
         d) CGRP-targeting migraine preventive therapies (e.g., monoclonal antibodies or gepants),

   b. Has a diagnosis of chronic migraine headache according to the current International Headache Society Classification of Headache Disorders that is not attributed to other causes including medication overuse,

   c. Is prescribed the Botulinum Toxin by or in consultation with **one** of the following:

      i. A neurologist
      ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS);

AND

10. For a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition, has a history of therapeutic failure of or a contraindication or an intolerance to at least one anticholinergic drug used in the treatment of urinary incontinence; **AND**

11. For a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, has a history of therapeutic failure of or a contraindication or an intolerance to at least two drugs (e.g., antimuscarinics or beta-3 adrenergic agonists) used in the treatment of overactive bladder; **AND**

12. If a prescription for a Botulinum Toxin is for a quantity that exceeds the quantity imits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

    NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR BOTULINUM TOXINS: The determination of medical necessity of a request for renewal of a prior authorization for a Botulinum Toxin that was previously approved will take into account whether the beneficiary:

1. If the frequency of injection exceeds the dose and duration of therapy limits, has documentation of **both** of the following:

    a. The previous treatment was well tolerated but inadequate
    b. Peer-reviewed medical literature supports more frequent dosing as safe and effective for the diagnosis and requested dose;

    AND

2. If the frequency of injection is consistent with the dose and duration of therapy limits, **both** of the following:

    a. Has documentation of a positive clinical response to the drug

    b. **One** of the following:

        i. For the treatment of chronic migraine headache, requires repeat injection to reduce the frequency, severity, or duration of symptoms

ii. For the treatment of all other diagnoses, has symptoms that returned to such a degree that repeat injection is required;

AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed drug; **AND**

5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site; **AND**

6. For a diagnosis of chronic migraine headache, is prescribed the Botulinum Toxin by or in consultation with **one** of the following:

   a. A neurologist
   b. A headache specialist who is certified in headache medicine by the UCNS;

   AND

7. If a prescription for a Botulinum Toxin is for a quantity that exceeds the quantity limits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html

   NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

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

D. Dose and Duration of Therapy

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

Requests for authorization of a Botulinum Toxin will not be approved for one year from the most recent injection when there is no benefit after two sequential therapies using maximum doses.

E. Five-Day Supply

The Department of Human Services does not consider a delay in the receipt of Botulinum Toxins to present an immediate need and will NOT cover five-day supplies of Botulinum Toxins pending approval of a request for prior authorization.

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