


<b>ISSUE DATE</b>  November 8, 2021	<b>EFFECTIVE DATE</b>  January 3, 2022	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Botulinum Toxins (Type A and Type B) – Pharmacy Services		<b>BY</b>   Sally A. 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.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

**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 (Type A and Type B) 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 (Type A and Type B) will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Botulinum Toxins (Type A and Type B) to the appropriate MCO.

**BACKGROUND:**

*01-21-25	09-21-24	27-21-16	33-21-24
02-21-12	11-21-14	30-21-19	
03-21-12	14-21-15	31-21-27	
08-21-27	24-21-22	32-21-12	

**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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

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 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;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

### **DISCUSSION:**

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Botulinum Toxins (Type A and Type B):

- Updated formatting and language for consistency with other Statewide PDL prior authorization guidelines;
- Addition of a guideline that the beneficiary 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;
- Addition of a guideline that the beneficiary is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
- Addition of a guideline that the beneficiary is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
- Addition of a guideline that the beneficiary does not have a contraindication to the prescribed medication;
- Deletion of the guideline that the beneficiary is not pregnant or breastfeeding;
- Revision of the guideline for a non-preferred Botulinum Toxin that the beneficiary has a history of therapeutic failure, contraindication, or intolerance of the preferred Botulinum Toxins approved or medically accepted for the beneficiary's diagnosis or indication;
- Deletion of examples for chronic spasticity;
- Deletion of the guidelines specific to a diagnosis of strabismus;
- Revision of the guidelines specific to a diagnosis of chronic migraine;
- Revision of the guideline for a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition that the beneficiary has a history of therapeutic failure, contraindication, or intolerance to at least one anticholinergic medication used in the treatment of urinary incontinence; and
- Addition of examples of other agents used for a diagnosis of overactive bladder.

The revisions to the guidelines to determine medical necessity of prescriptions for Botulinum Toxins (Type A and Type B) 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 (Type A and Type B) 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 (Type A and Type B)] 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

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I  
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

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 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 medication; **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, contraindication, or intolerance of 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 documented spasticity that interferes with activities of daily living or is expected to result in joint contracture with future growth,
  - b. If the beneficiary is age 18 or older, has documented therapeutic failure, contraindication, or intolerance to one oral medication for spasticity,
  - c. If the beneficiary developed contractures, the beneficiary has been considered for surgical intervention,
  - d. The Botulinum Toxin is being requested to enhance function or allow for additional therapeutic modalities to be employed,

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- 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, contraindication, or intolerance to a topical agent such as 20 percent aluminum chloride;

**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 medication from at least **two** of the following three classes:
      - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
      - b) Antidepressants (e.g., amitriptyline, venlafaxine),
      - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
    - ii. Has a history of contraindication or intolerance that prohibits a trial of at least **one** migraine preventive medication from at least **two** of the following three classes:
      - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
      - b) Antidepressants (e.g., amitriptyline, venlafaxine),
      - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
  - 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, contraindication, or intolerance to at least 1 anticholinergic medication 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, contraindication, or intolerance to at

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least 2 agents (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 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. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:  
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 intervals 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, has documentation of **both** of the following:
  - a. Tolerability and a positive clinical response to the medication
  - b. The symptoms returned to such a degree that repeat injection is required.

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

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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. 5-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 5-day supplies of Botulinum Toxins pending approval of a request for prior authorization.

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