Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

    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;

   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.

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BOTULINUM TOXINS PRIOR AUTHORIZATION FORM *(form effective 1/6/2025)*

☐New request ☐Renewal request	Total # of pages _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Units/package size:	Total quantity requested per treatment:
Injection site(s) & dose per site:		
Diagnosis (*submit documentation*):		Dx code (*required*):
Dates of previous administration and injection sites *(submit documentation)*:		

Complete all sections that apply to the beneficiary and this request.
Check all that apply and SUBMIT DOCUMENTATION for each item.

INITIAL requests

☐**For a NON-PREFERRED Botulinum Toxin:**
- ☐Has a history of trial and failure of or a contraindication or an intolerance to the preferred Botulinum Toxins that are approved or medically accepted for treatment of the beneficiary's diagnosis (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

☐**For a diagnosis of CHRONIC SPASTICITY:**
- ☐Has spasticity that interferes with activities of daily living
- ☐Has spasticity that is expected to result in joint contracture with future growth
- ☐If the beneficiary has contractures, has been considered for surgical intervention
- ☐One of the following:
  - ☐Has focal spasticity
  - ☐Is under 18 years of age
  - ☐Is 18 years of age or older and tried and failed or has a contraindication or an intolerance to an oral medication for spasticity
- ☐Botulinum Toxin is prescribed to enhance function or allow for additional therapeutic modalities to be used
- ☐Will use the requested botulinum toxin in conjunction with other appropriate therapeutic modalities (e.g., PT, OT, gradual splinting, etc.)

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☐ **For a diagnosis of AXILLARY HYPERHIDROSIS:**
- ☐ Tried and failed or has a contraindication or an intolerance to a topical agent such as aluminum chloride 20% solution

☐ **For a diagnosis of CHRONIC MIGRAINE HEADACHE:**
- ☐ Has a diagnosis of migraine headache consistent with the current International Headache Society Classification of Headache Disorders
- ☐ Migraine headache is not attributable to other causes, such as medication overuse
- ☐ Is prescribed the Botulinum Toxin by or in consultation with a headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties or a neurologist
- ☐ Tried and failed or has a contraindication or an intolerance to at least one drug used for migraine prevention from at least 2 of the following classes:
  - ☐ Anticonvulsants (e.g., divalproex, topiramate, valproic acid)
  - ☐ Antidepressants (e.g., amitriptyline, venlafaxine)
  - ☐ Beta blockers (e.g., metoprolol, propranolol, timolol)
  - ☐ CGRP-targeting migraine preventive therapies (e.g., gepants, monoclonal antibodies)

☐ **For a diagnosis of URINARY INCONTINENCE due to detrusor overactivity:**
- ☐ Has an associated neurologic condition
- ☐ Tried and failed or has a contraindication or an intolerance to an anticholinergic drug used for the treatment of urinary incontinence (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, trospium)

☐ **For a diagnosis of OVERACTIVE BLADDER:**
- ☐ Has symptoms of urge urinary incontinence, urgency, and frequency
- ☐ Tried and failed or has a contraindication or an intolerance to at least 2 drugs used for the treatment of overactive bladder (e.g., anticholinergics, beta-3 adrenergic agonists)

RENEWAL requests

☐ Experienced a positive clinical response to the Botulinum Toxin

☐ One of the following:
- ☐ For the treatment of chronic migraine headache, requires repeat injection to reduce the frequency, severity, or duration of symptoms
- ☐ For the treatment of all other diagnoses, has symptoms that returned to such a degree that repeat injection with Botulinum Toxin is required

☐ The frequency of injection of Botulinum Toxin exceeds the FDA-approved package labeling
- ☐ The previous treatment was well-tolerated but inadequate
- ☐ The requested dose and increased frequency of injection of Botulinum Toxin are supported by medical literature as safe and effective for the diagnosis

☐ **For a diagnosis of CHRONIC MIGRAINE HEADACHE:**
- ☐ Is prescribed the Botulinum Toxin by or in consultation with a headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties or a neurologist

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: