Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 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,

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

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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 least 2 agents (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:

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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. 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 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 1/3/2022)*

☐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:		Suite #:	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)*:		

INITIAL requests

Request for a non-preferred agent: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of the preferred Botulinum Toxins that are FDA-approved for the beneficiary's diagnosis and age? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No ☐N/A *Submit documentation of all medications tried and outcomes.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐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
- ☐If the beneficiary is 18 years of age or older, tried and failed or has a contraindication or an intolerance to an oral medication for spasticity
- ☐Botulinum Toxin is being 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.)

☐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 medications in other drug classes that are used for migraine prevention:
  - ☐Anticonvulsants (e.g., divalproex, topiramate, valproic acid)
  - ☐Antidepressants (e.g., amitriptyline, venlafaxine)
  - ☐Beta blockers (e.g., metoprolol, propranolol, timolol)

☐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 medication used for the treatment of urinary incontinence

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

RENEWAL requests

Check the items below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Experienced a positive clinical response to the Botulinum Toxin
☐Symptoms have 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 are supported by medical literature as safe and effective for the diagnosis

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: