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, regardless of the quantity prescribed, must be prior authorized.[1]

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:

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

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

[1] Botulinum Toxin products are not interchangeable or bioequivalent. Dosing units are specific to the preparation of the Botulinum Toxin.

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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

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

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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

a. The recipient has a history of chronic migraine headache not attributed to other causes including medication overuse, as defined by:

i. Headache (tension-type and/or migraine) on ≥15 days per month for at least three months

AND

ii. At least five of these attacks meet at least two of the following:

a) Unilateral location
b) Pulsating quality
c) Moderate or severe intensity
d) Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)

AND

iii. During headache, at least one of the following is present:

a) Nausea and/or vomiting

OR

b) Photophobia and phonophobia

OR

iv. Headaches are treated and relieved by triptan(s) or ergotamine(s) before the expected development of associated symptoms of migraine

AND

9. For a diagnosis of urinary incontinence due to detrusor over activity 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

10. 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

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OR

11. 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.

12. 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.

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 the request for 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 recipient.

D. Dose and Duration of Therapy

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

☐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:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

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

INITIAL requests – complete questions applicable to drug requested and beneficiary's diagnosis

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.*
Axillary hyperhidrosis: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of prescription-strength aluminum chloride antiperspirant?	☐Yes ☐No	*Submit documentation.*
Overactive bladder: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of at least two other medications used to treat OAB?	☐Yes ☐No	*Submit documentation of all medications tried and outcomes.*
Urinary incontinence due to detrusor overactivity associated with a neurologic condition: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of at least two other medications used to treat urinary incontinence?	☐Yes ☐No	*Submit documentation of all medications tried and outcomes.*

Migraine, chronic: Check all of the following that apply to the beneficiary and *submit documentation for each*.
- ☐diagnosed with chronic migraine as per the International Headache Society's Classification of Migraines
- ☐history of trial & failure, contraindication, or intolerance of triptans and/or ergotamine medications to relieve migraine symptoms
- ☐history of trial & failure, contraindication, or intolerance of an agent in at least 3 of the following drug classes used for migraine prevention:
  ☐anticonvulsants ☐beta blockers ☐calcium channel blockers ☐NSAIDs ☐tricyclic antidepressants

Spasticity, chronic: Check all of the following that apply to the beneficiary and *submit documentation for each*.
- ☐has spasticity caused by: ☐cerebral palsy ☐multiple sclerosis ☐spinal cord injury ☐stroke ☐traumatic brain injury
- ☐has spasticity that: ☐interferes with activities of daily living ☐is expected to result in joint contracture
- ☐if the beneficiary has developed contractures, has been considered for surgical intervention
- ☐if ≥ 18 years of age, has tried & failed, or has a contraindication or intolerance of, an oral medication for spasticity
- ☐drug is being requested to either: ☐enhance function --OR-- ☐allow for additional therapeutic modalities to be employed
- ☐drug will be used in conjunction with other appropriate therapeutic modalities (eg, OT, PT, gradual splinting)

Strabismus: Check all of the following that apply to the beneficiary and *submit documentation for each*.
- ☐does NOT have Duane's syndrome, restrictive strabismus, or strabismus caused by surgery
- ☐current deviation measures LESS than 50 prism diopters

All other diagnoses: Submit documentation supporting the use of the requested agent for the beneficiary's diagnosis & other treatments tried.

RENEWAL requests

Submit documentation supporting the need for repeat injection and dates/injections sites of previous administration.

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

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