Prior Authorization Drug Protocol Management

onabotulinum toxin type A (Botox®); rimabotulinum type B (Myobloc®); abobotulinum toxin A (Dysport®); & incobotulinumtoxin A (Xeomin®) Criteria

Botox® (onabotulinum toxin type A) will be granted initial authorizations for a 3-month duration for the following conditions:

1. Achalasia
   a. Esophageal achalasia
   b. Internal anal sphincter (IAS) achalasia
2. Anal Fissure
3. Blepharospasm (≥ 12 years of age)*; (adult patients)§
   a. Seventh nerve palsy
   b. Benign essential blepharospasm
4. Cerebral Palsy
   a. Equinus foot deformity
5. Chronic facial pain associated with temporomandibular dysfunction
6. Dystonia
   a. Cervical dystonia*, ^, ¶, §
   b. Writer’s cramp
7. Esotropia
8. Exotropia
9. Facial Myokymia
10. Focal hypertonia (lower limb)
11. Hemifacial spasm
12. Hertwig-Magendie sign
13. Contracture in Duchenne muscular dystrophy
14. Axillary Hyperhidrosis, severe* - (see below criteria)†
15. Salivary hypersecretion
   a. Drooling in Parkinson’s disease
   b. Salivary fistula
16. Strabismus* (≥ 12 years of age)
17. Tremor
   a. Essential hand tremor
   b. Essential voice tremor
   c. Multiple sclerosis-related tremor, upper limbs (see criteria below)
18. Spasmodic torticollis*
19. Upper limb spasticity in adult patients to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors*
20. Chronic pain and pelvic floor spasms in women
21. Migraine prophylaxis, chronic* (see criteria below)
22. Urinary incontinence due to detrusor over-activity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)]* (see criteria below)
23. Overactive bladder* (see criteria below)

* FDA labeled indication (Botox®)
^ FDA labeled indication (Myobloc®)
¶ FDA labeled indication (Dysport®)
§ FDA labeled indication (Xeomin®)
†Reviewed by NHP

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters. Re-authorizations will be granted in 6-month intervals.

Note: All other requests will be reviewed on a case by case basis. Risk-benefit assessment should precede any decision for use in unlabeled indications as well as establishing that the patient is unresponsive to conventional treatment options.
Axillary Hyperhidrosis
This is a rare, genetically-based condition that can be quite disturbing; apparent peak incidence during adolescence. Treatment with SQ injections of botulinum toxin has proven efficacious and can result in long-term remission.

NHP may approve requests for this therapy for a 3-month duration under the following conditions:
- Treatment is provided by a network contracted dermatologist
- A letter of medical necessity from this provider is needed.
- The patient should have failed an adequate trial of topical therapy.
- Once therapy is initially approved, recurrent treatment with Botox® will only be authorized for the member at a
  minimal interval of every 3 to 4 months. Subsequent requests also require a letter of medical necessity and clinical review.

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters. Re-authorizations will be granted in 6-month intervals.

Chronic Migraine Prophylaxis
Botox® for the prophylaxis of chronic migraines* will be authorized when the following criteria have been met: Note: * all non-migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage.

1. The prescriber is a neurologist or headache specialist or the prescription is being written for the member in consultation with a neurologist or headache specialist
2. The member is ≥ 18 years of age
3. The member has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer
4. The member has had an adequate trial of at least THREE (3) different prophylactic migraine medications each with different mechanisms of action (a total of 3 required trials) that have each been tried for at least 60 days in duration within the past 3 years. All three trials must be from Level A or Level B categories within the American Academy of Neurology guidelines (See table 1 below). Note: triptans will not be considered as ‘prophylactic options.’

Acceptable trials include:
1. Antiepileptic agents: divalproex sodium, valproate
2. Antiepileptic agents: topiramate
3. Beta-blockers: metoprolol, propranolol, timolol, atenolol, or nadolol
4. Antidepressants: amitriptyline
5. Antidepressants: venlafaxine

Initial requests will be approved for up to 200 units every 3 months for 2 treatments only.

Recertification: requests may be approved for every 3-month dosing for the requested duration up to a 12-month period when documentation of improvement via physician assessment is submitted indicating evidence of effectiveness, including the following:
   a. A decrease in the frequency of migraine headaches (i.e., the number of headaches per month)
   b. A decrease in the severity of migraine headaches

Urinary Incontinence associated with a neurological condition:
Botox® is indicated for the treatment of urinary incontinence due to detrusor over-activity associated with a neurologic condition (e.g., Spinal cord injury, MS, etc.) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Requests for coverage of Botox® for this indication will be authorized initially for a 12 month duration when the following criteria have been met:

1. The member is ≥ 18 years of age
2. The member has a neurological condition resulting in urinary incontinence due to detrusor muscle activity
3. The member has had an adequate trial of at least three (3) long-acting urinary antispasmodic (must be different chemical entities)

The recommended dose is 200 units per treatment and should not be exceeded. Patients may be considered for re-treatment when the clinical effects diminish [median time to qualifying for re-treatment in the double-blind, placebo-controlled clinical studies with Botox® 200 units was 295-337 days (42-48 weeks)]. Re-treatment should be at an interval no sooner than 12 weeks from the prior bladder injection.
Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters. Re-authorizations will be granted for a 12-month interval.

**Botox®, Myobloc®, Dysport®, & Xeomin® will NOT be covered for the following:**
- Cervicogenic headaches
- Tension type headaches

**Overactive bladder**
Botox® is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have inadequately responded to or are intolerant of anticholinergic agents. Requests for Botox® for this indication will be authorized for a 6-month duration when the following criteria are met:
  1. The member is ≥ 18 years of age
  2. The member has a diagnosis of overactive bladder/urinary incontinence
  3. The member has had an adequate trial of at least three (3) long-acting urinary antispasmodic

  Note: The recommended dose is 100 Units; which is also the max recommended dose. The recommended dilution is 100 Units/10 mL with 0.9% non-preserved saline solution.

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters. Re-authorizations will be granted in 6-month intervals.

**Multiple Sclerosis-related tremor/spasticity (upper limbs)**
Botox® for upper limb tremor/spasticity related to MS will be authorized for a 6-month duration when the following criteria are met:
  1. The tremor/spasticity is a result of the multiple sclerosis condition
  2. The member has had an adequate trial of at least one (1) oral agent to treat the condition with a documented side effect, allergy, inadequate response, or treatment failure. These agents may include: Baclofen, tizanidine, dantrolene, diazepam, clonazepam, gabapentin, etc.
    (Note: phenol injections will also be considered as an appropriate trial for more severe spasticity).

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters. Re-authorizations will be granted in 12-month intervals.

Note: The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of Botox and muscles to be injected.

**Myobloc®‡**
Coverage of rimabotulinum toxin type B (Myobloc®) will be granted for the following conditions:
  1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®) AND
  2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months AND
  3. Patient is greater than 18 years old

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters.

**Dysport®‡**
Coverage of abobotulinum toxin A (Dysport®) will be granted for the following conditions:
  1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®) AND
  2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months AND
  3. Patient is greater than 18 years old

Recertification: Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters.

**Xeomin®‡**
Coverage of incobotulinum toxin A (Xeomin®) will be granted for the following conditions:
  1. Patient has failed treatment or has developed resistance to botulinum toxin type A (Botox®) AND
  2. Patient has not had a botulinum toxin type A (Botox®) injection within the last 4 months AND
  3. Patient is greater than 18 years old
**Recertification:** Improvement and/or stabilization of overall disease activity per physician assessment supported by objective and/or subjective parameters.

**EXCLUSIONS:**
Botox®, Myobloc®, Dysport®, & Xeomin® will NOT be covered for cosmetic reasons including but not limited to the following:

- Facial rhytides
- Frown lines
- Glabellar lines/wrinkling
- Horizontal neck rhytides
- Hyperfunctional facial lines
- Mid and lower face and neck rejuvenation
- Platysmal bands
- Rejuvenation of the periorbital region
- Lateral canthal lines (Crow’s feet)

***Botox® Cosmetic is not a covered benefit***

***Dysport 300 units [abobotulinum toxin A (glabellar lines)] is not a covered benefit***

Table 1:

<table>
<thead>
<tr>
<th>Level A: Medications with established efficacy (≥2 Class II trials)</th>
<th>Level B: Medications are probably effective (1 Class I or 2 Class II studies)</th>
<th>Level C: Medications are possibly effective (1 Class II study)</th>
<th>Level D: Inadequate or conflicting data to support or refute medication use</th>
<th>Other: Medications that are established as possibly or probably ineffective</th>
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<tr>
<td>Antiepileptic drugs</td>
<td>Antidepressants/SSRI/SSNR/TCA</td>
<td>ACE inhibitors</td>
<td>Carbamazepine</td>
<td>Established as not effective</td>
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<tr>
<td>Divalproax sodium</td>
<td>Antidepressants</td>
<td>Angiotensin receptor blockers</td>
<td>Acetazolamide</td>
<td>Antiepileptic drugs</td>
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<td>Sodium valproate</td>
<td>Verapamil</td>
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<td>Lamotrigine</td>
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<td>Topiramate</td>
<td>β-Blockers</td>
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<td>Acenocoumarol</td>
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<td>p-Blockers</td>
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<td>Propranolol</td>
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<td>Antiepileptic drugs</td>
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Abbreviations: ACE = angiotensin-converting enzyme; MRM = menstrual related migraine; SSNRI = selective serotonin-norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor; TCA = tricyclic antidepressant.

* Classification based on original guideline and new evidence not found for this report.

* For short-term prophylaxis of MRM.

References:

Implementation Date: 12/1/05
Updated: 01/03/2011 (Exclusions section update w/ new Dysport product); 05/17/11 (Xeomin BART); 09/19/13 (Dysport 300 units glabellar lines product; 04/08/13 file & Botox crow’s feet); 06/09/14 (Migraine trials to 3 based on specialist input)