Department:	Pharmacy Management	**Original Approval:**	04/11/2019
Policy No:	PM570	**Last Approval:**	12/12/2025
Policy Title:	OnabotulinumtoxinA (Botox) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for onabotulinumtoxinA (Botox):

1. History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
2. Diagnosis
3. Labs/Diagnostics
4. Dosing and duration requested
5. Initial/Extended approval
6. Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
7. Prescribed by or in consultation with a specialist, when indicated.

Background

Botox (onabotulinumtoxinA) is indicated for the following uses:[1]

1. **Blepharospasm** associated with dystonia, including benign essential blepharospasm or seventh (VII) nerve disorders in patients ≥ 12 years of age.
2. **Cervical dystonia,** in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
3. **Hyperhidrosis, severe primary axillary** which is inadequately managed with topical agents in adults.
4. **Migraine headache prophylaxis (prevention),** in adults with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

5. **Neurogenic detrusor overactivity** in pediatric patients ≥ 5 years of age who have had an inadequate response to or are intolerant of an anticholinergic medication.
6. **Overactive bladder** with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.
7. **Spasticity** in patients ≥ 2 years of age.
8. **Strabismus** in patients ≥ 12 years of age.
9. **Urinary incontinence due to detrusor overactivity** associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

In regard to the indication of migraine headache prophylaxis, an updated position statement for the prevention of migraines from the American Headache Society (2024) notes that specifically for prevention of chronic migraine with or without aura, Botox should be considered a first-line treatment recommendation without a requirement for prior failure of other classes of migraine preventative treatment.[4]

Other Uses with Supportive Evidence
Botulinum toxin type A has been used to treat a multitude of disorders characterized by abnormal muscle contraction.[2] The benefit of these products has also been demonstrated in the treatment of gastrointestinal, genitourinary, ocular, and autonomic nervous system disorders.[2,3]

Botulinum toxins have been studied in a variety of indications outside of FDA-approved uses. Literature is available to support use of Botox in the following conditions:

1. **Achalasia:** The American College of Gastroenterology (ACG) clinical guideline for the diagnosis and management of achalasia (2020) recommends the use of botulinum toxin as first-line therapy for patients with achalasia who are unfit for definitive therapies for the treatment of achalasia such as pneumatic dilation or surgical myotomy.[5]
2. **Anal Fissures:** The ACG clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections may be attempted for patients in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).[6]
3. **Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction:** Data from several open-label studies, as well as one randomized, placebo-controlled trial, support the efficacy of Botox in the treatment of chronic facial pain/chronic facial pain associated with hyperactivity of the masticatory muscles.[7-10]
4. **Chronic Low Back Pain:** In one 8-week, randomized, double-blind, placebo-controlled trial in 31 patients with chronic low back pain (no causative factor identified in the majority of patients; history of disc disease in 6 patients, discectomy in 3 patients, and

trauma in 4 patients), Botox in addition to their current pharmacologic treatment regimen resulted in significantly greater improvement in pain relief and degree of disability compared with placebo.[11] A 14-month, open-label, prospective study evaluated the short- and long-term effects of paraspinal muscle injections of Botox in 75 patients with refractory chronic low back pain. A total of 53% and 52% of patients reported significant pain relief at 3 weeks and 2 months, respectively.[12]

5. **Dystonia, other than Cervical:** Guidelines from the American Academy of Neurology (AAN) support use of botulinum toxins in focal dystonias of the upper extremity (should be considered; Level B recommendation).[13] Botulinum toxin A is the most widely accepted treatment for spasmodic dysphonia, a focal laryngeal dystonia, viewed as the treatment of choice by the American Academy of Otolaryngology-Head and Neck Surgery.[14] Per the guideline, clinicians should offer, or refer to a clinician who can offer, botulinum toxin injections for treatment of dysphonia caused by spasmodic dysphonia and other types of laryngeal dystonia. AAN guidelines note that botulinum toxin is probably effective and should be considered for adductor type laryngeal dystonia (Level B).[13]
6. **Essential Tremor:** According to the clinical practice parameter on essential tremor by the AAN, propranolol and primidone are first-line therapy in the treatment of essential tremor.[15] Second-line medication options include alprazolam, atenolol, sotalol, gabapentin, and topiramate. Botulinum toxin A may also reduce tremor. The guidelines recommend that botulinum toxin A may be considered in medically refractory cases of limb, head, and voice tremor associated with essential tremor (Level C for limb, head, and voice tremor).
7. **Hemifacial Spasm:** Per the AAN, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C).[13] Data with Botox and Dysport® (abobotulinumtoxinA injection) are cited in the recommendations regarding hemifacial spasm.
8. **Hyperhidrosis, Gustatory:** Botox is recommended as a first-line option for gustatory sweating by the International Hyperhidrosis Society.[16]
9. **Hyperhidrosis, Palmar/Plantar and Facial:** The efficacy of Botox is well-established in the treatment of primary focal/palmar hyperhidrosis based on data from both randomized, double-blind, placebo-controlled studies and open-label studies.[3,18,19] Guidelines from the International Hyperhidrosis Society support use of Botox in patients who have failed to respond to topical therapy.[16,20,21]
10. **Myofascial Pain:** Data from several retrospective reviews and open-label trials support the efficacy of Botox in the treatment of myofascial pain syndromes associated with various muscle groups.[7,22] In one randomized, controlled trial in 40 patients with chronic myofascial pain of various forms, Botox resulted in a significantly greater reduction in pain score from baseline compared with intramuscularly administered methylprednisolone at 30 days and 60 days post injection.[23,24]

11. **Ophthalmic Disorders, other than Blepharospasm or Strabismus:** Botulinum toxin A has been successful in improving or treating many ophthalmic disorders. One retrospective review (n = 54) concluded that Botox may have a role in the treatment of esotropia in patients > 18 months of age.[25] Botox improved visual acuity in case reports and one small, open-label study in patients with acquired symptomatic nystagmus from multiple sclerosis or brain-stem hemorrhage.[26,27] Data from uncontrolled studies have shown Botox to be beneficial in the treatment of sixth nerve palsy.[28,29]
12. **Plantar Fasciitis:** In one randomized, double-blind study (n = 36), botulinum toxin A exhibited more rapid and sustained improvement over the duration of the study as compared with patients who received steroid injections.[30] The clinical consensus statement on the diagnosis and treatment of heel pain (developed by the American College of Foot and Ankle Surgeons) published in 2010 list botulinum toxin injection as a Tier 2 option (Grade I); Tier 1 treatment options include: padding and strapping of the foot (Grade B), therapeutic orthotic insoles (Grade B), oral anti-inflammatory agents (Grade I), corticosteroid injections (Grade B), and Achilles and plantar fascia stretching (Grade B) [Grade B recommendations are supported by fair evidence, Grade I recommendations indicate there is insufficient evidence to make a recommendation].[31]
13. **Sialorrhea, Chronic:** Botulinum toxin A has been studied in the treatment of sialorrhea associated with Parkinson's Disease, parkinsonian syndromes, cerebral palsy, head and neck carcinoma, neurodegenerative disease, stroke, and amyotrophic lateral sclerosis.[3] A review of the literature on medical treatment of sialorrhea found that Botox is probably effective for the treatment of this condition (level B evidence).[32]

Dosing Considerations

Definitive dosing has not been established for off-label uses of botulinum toxins, including Botox. In general, Botox is not recommended to be injected more frequently than once every 3 months, and botulinum toxins appear to have an approximately 3-month duration of effect or longer, depending on the site of injection. The Botox prescribing information advises that in a 3-month interval, adults should not exceed a total dose of 400 units. Pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval. Specific considerations by indication are noted below:

1. **Achalasia:** Botox has been studied for achalasia in several trials. Doses higher than 100 units per treatment have not been shown to be more effective.[34]
2. **Sialorrhea, Chronic:** Xeomin® (incobotulinumtoxinA injection) is indicated for this use.[35] Per Xeomin labeling, the maximum recommended dose for adults is 100 units (50 units per side) and for pediatric patients is 75 units (37.5 units per side), administered not more frequently than once every 16 weeks. Recommendations for maximum dosing and frequency for Botox are based on suggested relative conversion of 1:1 for Botox to Xeomin.[36,37]

For Medicare: This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications/Criteria

Medicaid and Individual & Family (Cascade Select) Members	***Continue to criteria for approval below.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***
Medicare Members	***Step-utilization of Part D drugs not required.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***

Medicaid/Cascade Criteria

1. **Blepharospasm.** Approve for 1 year if the patient is ≥ 12 years of age.
   Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

   Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months.

2. **Cervical Dystonia.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Cervical dystonia is also referred to as spasmodic torticollis.

   Dosing. Approve up to a maximum dose of 300 units, administered not more frequently than once every 3 months.

3. **Hyperhidrosis, Primary Axillary.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND
   - **C)** The prescriber has excluded secondary causes of hyperhidrosis; AND
   - **D)** Patient has tried at least one topical prescription agent for axillary hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.
     Note: Examples of prescription topical agents for the treatment of axillary hyperhidrosis include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), Qbrexza (glycopyrronium cloth 2.4% for topical use), Sofdra (glycopyrronium 12.45% topical gel).

   Dosing. Approve up to a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.

4. **Chronic Migraine Headache Prevention.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has ≥ 15 migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiating a migraine-preventive medication); AND
   - **C)** Botox is being prescribed by or in consultation with a neurologist or headache specialist; AND
   - **D)** If the patient is currently taking Botox for chronic migraine headache prevention, the patient has had a significant clinical benefit from the medication as determined by the prescriber.
     Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Botox was initiated.

   Dosing. Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.

5. **Neurogenic Detrusor Overactivity (NDO), Pediatric.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 5 years of age; AND
   B) Patient has tried at least one other pharmacologic therapy for the treatment of neurogenic detrusor overactivity (NDO).
   Note: Examples of other NDO pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to the FDA-Approved Indication below.

   Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

6. **Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult).** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one other pharmacologic therapy for the treatment of overactive bladder (OAB).
   Note: Examples of other OAB pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to the FDA-Approved Indication below.

   Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

7. **Spasticity, Limb(s).** Approve for 1 year if the patient is ≥ 2 years of age.

   Dosing. Approve ONE of the following regimens (A, B or C):
   A) Lower limb spasticity: Approve ONE of the following regimens (i or ii):
      i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
      ii. Patient is < 18 years of age: Approve up to a maximum dose of 8 units/kg (not to exceed 300 units), administered not more frequently than once every 12 weeks.
   B) Upper limb spasticity: Approve ONE of the following regimens (i or ii):

i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR

ii. Patient is < 18 years of age: Approve up to a maximum dose of 6 units/kg (not to exceed 200 units), administered not more frequently than once every 12 weeks.

C) If treating BOTH upper AND lower limb spasticity: Approve ONE of the following regimens (i or ii):

i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR

ii. Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 12 weeks.

8. Strabismus. Approve for 1 year if the patient is ≥ 12 years of age.
Note: Common types of strabismus include esotropia, exotropia, hypertropia, hypotropia.

Dosing. Approve up to a maximum dose of 25 units in any one muscle, administered not more frequently than once every 3 months.

9. Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurological Condition (Adult). Approve for 1 year if the patient meets BOTH of the following (A and B):
Note: Examples of neurological conditions associated with urinary incontinence include spinal cord injury, multiple sclerosis, spina bifida.

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other pharmacologic therapy for the treatment of urinary incontinence.
Note: Examples of other pharmacologic therapies for urinary incontinence include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, refer to the FDA-Approved Indication above. For treatment of pediatric neurogenic detrusor overactivity (NDO), refer to the FDA-Approved Indication above.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

10. Achalasia. Approve for 1 year if the patient is ≥ 18 years of age.
Note: Achalasia is also referred to as esophageal achalasia or achalasia cardia.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

11. **Anal Fissure, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

    Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

12. **Dystonia, Focal Upper Limb.** Approve for 1 year if the patient is ≥ 18 years of age.
    Note: An example of focal upper limb dystonia is focal hand dystonia.

    Dosing. Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

13. **Essential Tremor.** Approve for 1 year if the patient meets BOTH of the following (A and B):
    A) Patient is ≥ 18 years of age; AND
    B) Patient has tried at least one other pharmacologic therapy for the treatment of tremors.
    Note: Examples of pharmacologic therapies for essential tremor include primidone, propranolol, atenolol, sotalol, alprazolam, gabapentin, topiramate.

    Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

14. **Hemifacial Spasm.** Approve for 1 year if the patient is ≥ 18 years of age.

    Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

15. **Hyperhidrosis, Gustatory.** Approve for 1 year if the patient is ≥ 18 years of age.
    Note: Gustatory hyperhidrosis is also referred to as Frey's Syndrome.

    Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

16. **Hyperhidrosis, Primary Palmar/Plantar/Craniofacial.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
    A) Patient is ≥ 18 years of age; AND
    B) Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND
    C) The prescriber has excluded secondary causes of hyperhidrosis; AND

D) Patient has tried at least one topical agent for the treatment of hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.
Note: Examples of topical agents for the treatment of hyperhidrosis include topical aluminum chloride antiperspirants.

Dosing. Approve ONE of the following regimens (A or B):
A) Hyperhidrosis, Primary Craniofacial: Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months; OR
B) Hyperhidrosis, Primary Palmar/Plantar: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

17. **Laryngeal Dystonia (Spasmodic Dysphonia).** Approve for 1 year if the patient is ≥ 18 years of age.

    Dosing. Approve up to a maximum dose of 25 units, administered not more frequently than once every 3 months.

18. **Oromandibular Dystonia.** Approve for 1 year if the patient is ≥ 18 years of age.
    Note: Oromandibular dystonia is also referred to as orofacial dystonia.

    Dosing. Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

19. **Sialorrhea, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

    Dosing. Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

Medicare Criteria
FDA-Approved Indications
1. **Blepharospasm**.

   Criteria. Approve for 1 year if the patient is ≥ 12 years of age. [IC-L]

   Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months.

2. **Cervical Dystonia.**
   Note: Cervical dystonia is also referred to as spasmodic torticollis.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age. [IC-L]

Dosing. Approve up to a maximum dose of 300 units, administered not more frequently than once every 3 months.

3. Hyperhidrosis, Primary Axillary.

Criteria. Approve for 1 year if the patient meets the following (A, B, C and D):

A) Patient is ≥ 18 years of age; [IC-L] AND

B) Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; [IC-ISGP] AND

C) The prescriber has excluded secondary causes of hyperhidrosis; [IC-L] AND

D) Patient has tried at least one topical prescription agent for axillary hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance. [IC-ISGP]
Note: Examples of prescription topical agents for the treatment of axillary hyperhidrosis include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), Qbrexza (glycopyrronium cloth 2.4% for topical use), Sofdra (glycopyrronium 12.45% topical gel).

Dosing. Approve up to a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.

4. Chronic Migraine Headache Prevention.

Criteria. Approve for 1 year in patients who meet all of the following conditions (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has ≥ 15 migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiating a migraine-preventive medication); AND

C) If the patient is currently taking Botox for chronic migraine headache prevention, the patient has had a significant clinical benefit from the medication as determined by the prescriber. [IC-ISGP]
Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Botox was initiated.

Dosing. Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.

5. Neurogenic Detrusor Overactivity (NDO), Pediatric.

Criteria. Approve for 1 year if the patient meets the following (A and B):
A) Patient is ≥ 5 years of age; [IC-L] AND
B) Patient has tried at least one other pharmacologic therapy for the treatment of neurogenic detrusor overactivity (NDO). [IC-L]
Note: Examples of other NDO pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to the FDA-Approved Indication below.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

6. Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult).

Criteria. Approve for 1 year if the patient meets the following (A and B):
A) Patient is ≥ 18 years of age; [IC-L] AND
B) Patient has tried at least one other pharmacologic therapy for the treatment of overactive bladder (OAB). [IC-L]
Note: Examples of other OAB pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to FDA-Approved Indications below.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

7. Spasticity, Limb(s).

Criteria. Approve for 1 year if the patient is ≥ 2 years of age. [IC-L]

Dosing. Approve one of the following regimens (A or B):
A) Lower limb spasticity: Approve one of the following regimens (i or ii):
i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
ii. Patient is < 18 years of age: Approve up to a maximum dose of 8 units/kg (not to exceed 300 units), administered not more frequently than once every 12 weeks.
B) Upper limb spasticity: Approve one of the following regimens (i or ii):

i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
ii. Patient is < 18 years of age: Approve up to a maximum dose of 6 units/kg (not to exceed 200 units), administered not more frequently than once every 12 weeks.

C) If treating BOTH upper AND lower limb spasticity: Approve ONE of the following regimens (i or ii):
i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
ii. Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 12 weeks.

8. Strabismus.
Note: Common types of strabismus include esotropia, exotropia, hypertropia, hypotropia.

Criteria. Approve for 1 year if the patient is ≥ 12 years of age. [IC-L]

Dosing. Approve up to a maximum dose of 25 units in any one muscle, administered not more frequently than once every 3 months.

9. Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurological Condition (Adult).
Note: Examples of neurological conditions associated with urinary incontinence include spinal cord injury, multiple sclerosis, spina bifida.

Criteria. Approve for 1 year if the patient meets the following (A and B):
A) Patient is ≥ 18 years of age; [IC-L] AND
B) Patient has tried at least one other pharmacologic therapy for the treatment of urinary incontinence. [IC-L]
Note: Examples of other pharmacologic therapies for urinary incontinence include a beta-3 adrenergic agonist or an anticholinergic medication. For treatment of adult overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, see FDA-Approved Indication above. For treatment of pediatric neurogenic detrusor overactivity (NDO), refer to the FDA-Approved Indication above.

Dosing. Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

10. Achalasia.

Note: Achalasia is also referred to as esophageal achalasia, achalasia cardia or cardiospasm.

Criteria. Approve for 1 year.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

11. Anal Fissure, Chronic.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

12. Dystonia, Focal Upper Limb .

Note: An example of focal upper limb dystonia is focal hand dystonia.

Criteria. Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

B) Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 3 months.

13. Essential Tremor (ET).

Criteria. Approve for 1 year if the patient meets the following (A and B):

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other pharmacologic therapy for the treatment of tremors.
Note: Examples of pharmacologic therapies for essential tremor include primidone, propranolol, atenolol, sotalol, alprazolam, gabapentin, topiramate.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

14. Hyperhidrosis, Gustatory.

Note: Gustatory hyperhidrosis is also referred to as Frey's Syndrome.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

15. Hyperhidrosis, Primary Palmar/Plantar/Craniofacial.

Criteria. Approve for 1 year if the patient meets the following (A, B, C and D):

A) Patient is ≥ 18 years of age; AND

B) Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living; AND

C) The prescriber has excluded secondary causes of hyperhidrosis; AND

D) Patient has tried at least one topical agent for the treatment of hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.
Note: Examples of topical agents for the treatment of hyperhidrosis include topical aluminum chloride antiperspirants.

Dosing. Approve ONE of the following regimens (A or B):

A) Hyperhidrosis, Primary Craniofacial: Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months; OR

B) Hyperhidrosis, Primary Palmar/Plantar: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

16. Laryngeal Dystonia (Spasmodic Dysphonia).

Criteria. Approve for 1 year.

Dosing. Approve up to a maximum dose of 25 units, administered not more frequently than once every 3 months.

17. Oromandibular Dystonia.

Note: Oromandibular dystonia is also referred to as orofacial dystonia.

Criteria. Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.
B) Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 3 months.

18. Sialorrhea, Chronic.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age.

Dosing. Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

19. Spasticity, Other Than Limb (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm).
Note: For limb spasticity, refer to FDA-Approved Indications above.

Criteria. Approve for 1 year.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 3 months.

Conditions not recommended for approval:

1. **Cosmetic Uses**. Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, or rejuvenation of the periorbital region. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.
2. **Gastroparesis.** The ACG issued clinical guidelines on the management of gastroparesis (2013).[38] ACG does not recommend the use of botulinum toxin injected into the pylorus as a treatment for gastroparesis. This is based on two double-blind, placebo-controlled studies which did show some improvement in gastric emptying, but no improvement in symptoms compared with placebo.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Individual & Family (Cascade Select)	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

List of Appendices

None.

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Botox® injection [prescribing information]. Madison, NJ: Allergan; Botox® injection [prescribing information]. Madison, NJ: Allergan; August 2022.	

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Revision History

Revision Date	Revision Description	Revision Made By
04/04/2019	New policy	Jennifer Farley, PharmD
04/11/2019	Approval	UM Pharmacy Subcommittee
02/24/2020	Annual review- no changes	Jennifer Farley, PharmD
02/27/2020	Approval	UM Pharmacy Subcommittee
01/06/2021	Annual review. Clarified dosing	Jennifer Farley, PharmD
01/07/2021	Approval	UM Pharmacy Subcommittee

04/12/2021	Clarified wording regarding the use of CGRP Antagonists. Updated reauthorization criteria to exclude concurrent use of preventative CGRP Antagonists	Jennifer Farley, PharmD
05/02/2021	Approval	UM Pharmacy Subcommittee
02/28/2022	Annual review. Clarified dosing for adults using Botox for one or more indications. Clarified rationale on why Botox is not recommended for chronic tension headaches.	Alan Gabot, PharmD
03/02/2022	Approval	UM Pharmacy Subcommittee
01/04/2023	Annual review. No changes	Alan Gabot, PharmD
01/05/2023	Approval	UM Pharmacy Subcommittee
06/06/2023	Early update. Added Dysport, Xeomin, and Mybloc to the policy. Included other covered indications for Botox aside from chronic migraine headaches. Criteria for chronic migraine headaches were updated. Updated title of policy to "Botulinum Toxins Clinical Coverage Criteria"	Alan Gabot, PharmD
07/06/2023	Approval	UM Pharmacy Subcommittee
12/11/2023	Early update. Added description noting that the policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). For Botox for "Migraine Headache Prevention: The following sentence was added to the current Note regarding the requirement for standard prophylactic (preventative) pharmacologic therapies: A patient who has already tried a calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of chronic migraine, is not required to try two standard prophylactic pharmacologic therapies [verification of therapy required].	Alan Gabot, PharmD
12/18/2023	Approval	UM Pharmacy Subcommittee

01/09/2024	Early update. Added Daxxify to the policy.	Alan Gabot, PharmD
01/10/2024	Approval	UM Criteria Subcommittee
12/10/2024	Annual review. Removed Dysport, Daxxify, Myobloc and Xeomin from the policy. Each drug will have their own policy. Criteria for Botox has been separated between Medicaid/Cascade Select Criteria and Medicare Criteria.	Alan Gabot, PharmD
12/11/2024	Approval	UM Criteria Subcommittee
02/11/2025	Early update (for Medicare). Achalasia: The following Note was added: Achalasia is also referred to as esophageal achalasia or achalasia cardia. Anal Fissure, Chronic: The diagnosis was updated from "Anal Fissure" to as listed. The dosing limitation was lowered from 400 units to 100 units. Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction: This Other Use with Supportive Evidence was removed from the Policy. Chronic Low Back Pain: This Other Use with Supportive Evidence was removed from the Policy. Dystonia, Focal Upper Limb: This Other Use with Supportive Evidence was added to the Policy. A new dosing limitation was added. Dystonia, other than Cervical: This Other Use with Supportive Evidence was removed from the Policy. Essential Tremor: The Note providing pharmaceutical examples of medications used to treat tremors was updated to add both atenolol and sotalol, and benzodiazepines were replaced with alprazolam. Hyperhidrosis, Primary Axillary: Requirements were added that hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living and that the prescriber has excluded secondary causes of hyperhidrosis. The requirement for a trial of at least one topical agent was updated to add that the trial was for a prescription agent for at least 4 weeks and the patient experienced inadequate efficacy or	

	significant intolerance. The Note providing examples of prescription topical agents for the treatment of axillary hyperhidrosis was updated to include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), and Sofdra (glycopyrronium 12.45% topical gel). Hyperhidrosis, Primary Palmar/Plantar/Facial: This Other Use with Supportive Evidence was updated from "Hyperhidrosis, Palmar/Plantar/Facial" to as listed. Requirements were added that hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living and that the prescriber has excluded secondary causes of hyperhidrosis. The requirement for a trial of at least one topical agent was updated to add that the trial was for at least 4 weeks and the patient experienced inadequate efficacy or significant intolerance. Laryngeal Dystonia (Spasmodic Dysphonia): This Other Use with Supportive Evidence was added to the Policy. A new dosing limitation was added. Myofascial Pain: This Other Use with Supportive Evidence was removed from the Policy. Neurogenic Detrusor Overactivity (NDO), Pediatric: The following Note was added: For treatment of adult urinary incontinence due to detrusor overactivity associated with a neurological condition, refer to criteria for the FDA-Approved Indication below. Ophthalmic Disorders, other than Blepharospasm or Strabismus: This Other Use with Supportive Evidence was removed from the Policy. Oromandibular Dystonia: This Other Use with Supportive Evidence was added to the Policy. A new dosing limitation was added. Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult): The dosing limitation was increased from 100 units to 200 units. The Note referring to the treatment of adult urinary incontinence was updated to add "due to detrusor overactivity". Plantar Fasciitis: This Other Use with Supportive Evidence was removed from the	

	Policy. Spasticity, Limb(s): A new dosing limitation for treating both upper and lower extremities for pediatric patients < 18 years of age was added. Strabismus: The following Note was added: Common types of strabismus include esotropia, exotropia, hypertropia, hypotropia. Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurological Condition (Adult): The diagnosis was updated from "Urinary Incontinence Associated with a Neurological Condition (Adult)" to as listed. The following Note was added: For treatment of pediatric neurogenic detrusor overactivity (NDO), refer to criteria for the FDA-Approved Indication below.	
02/12/2025	Approval	UM Criteria Subcommittee
12/11/2025	Annual review. **Chronic Migraine Headache Prevention:** The qualifier "chronic" was added to the condition of approval. Also, the requirement "prior to initiation of Botox therapy" was clarified to "prior to initiating a migraine-preventative medication." **Essential Tremor:** The dosing limitation was decreased from 400 units to 100 units. **Spasticity, Other Than Limb:** The dosing limitation was decreased from 400 units to 100 units. **Hyperhidrosis, Gustatory**: The dosing limitation was decreased from 400 to 100 units. **Hyperhidrosis, Primary Craniofacial**: The qualifier "facial" was replaced with "craniofacial.". The dosing limitation was decreased from 400 to 100 units.	Alan Gabot, PharmD
12/12/2025	Approval	UM Criteria Subcommittee