UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxins – Botox Utilization Management Medical Policy
- Botox® (onabotulinumtoxinA injection – Allergan/AbbVie)

REVIEW DATE: 10/02/2024

OVERVIEW

Botox (onabotulinumtoxinA), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

- **Blepharospasm** associated with dystonia, including benign essential blepharospasm or seventh (VII) nerve disorders in patients ≥ 12 years of age.
- **Cervical dystonia,** to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.
- **Hyperhidrosis, severe primary axillary** which is inadequately managed with topical agents in adults.
- **Migraine headache prophylaxis (prevention),** in adults with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
- **Neurogenic detrusor overactivity (NDO) in pediatric patients** ≥ 5 years of age who have had an inadequate response to or are intolerant of an anticholinergic medication.
- **Overactive bladder (OAB)** 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.
- **Spasticity** in patients ≥ 2 years of age.
- **Strabismus** in patients ≥ 12 years of age.
- **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.[2]

Other Uses with Supportive Evidence

Botulinum toxin type A has been used to treat a multitude of disorders characterized by abnormal muscle contraction and the benefit of these products has been demonstrated in the treatment of gastrointestinal, genitourinary, ocular, and autonomic nervous system disorders.[3,8]

Botulinum toxins have been studied in a variety of indications outside of FDA-approved uses.[18-20] Literature is available to support use of Botox in the following conditions:

- **Achalasia:** The American College of Gastroenterology (ACG) clinical guideline for the diagnosis and management of esophageal achalasia (2020) recommends the use of botulinum toxin (formulation not specified) 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.[4]
- **Anal Fissure:** The ACG clinical guideline for the management of benign anorectal disorders (2021) suggests that botulinum toxin A injections (formulation not specified) may be attempted for patients with chronic anal fissures in whom calcium channel blockers fail or as an alternative option to calcium channel blockers (conditional recommendation; quality of evidence low).[5]

- **Dystonia, Focal Upper Limb:** Historical guidelines for the treatment of movement disorders from the American Academy of Neurology (AAN) support use of botulinum toxins in focal limb dystonia of the upper extremity (focal hand dystonia, i.e. writer's cramp) [Level B recommendation].[7] Botulinum toxin is considered the treatment of choice for most focal dystonias.[6] An evidence-based review and assessment (2013) for the treatment of focal upper limb dystonia indicate Botox should be considered (Level B recommendation).[28]
- **Essential Tremor:** According to the clinical practice parameter on essential tremor by the AAN (2011; reaffirmed 2022), propranolol and primidone are first-line therapy in the treatment of essential tremor.[14] Second-line medication options include alprazolam, atenolol, sotalol, gabapentin (as monotherapy), and topiramate. 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 recommendation for limb, head, and voice tremor). An evidence-based review and assessment (2013) for the treatment of tremor indicate Botox should be considered (Level B recommendation).[28]
- **Hemifacial Spasm:** Per historical AAN guidelines for the treatment of movement disorders, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C recommendation).[7] Data with Botox and Dysport® (abobotulinumtoxinA injection) are cited in the recommendations regarding hemifacial spasm. An evidenced-based review and assessment (2013) for the treatment of hemifacial spasm indicate Botox® (onabotulinumtoxinA injection) should be considered (Level B recommendation) and Dysport may be considered (Level C recommendation).[28]
- **Hyperhidrosis, Gustatory:** Botox is recommended as a first-line option for gustatory sweating by the International Hyperhidrosis Society.[15]
- **Hyperhidrosis, Primary Palmar, Plantar, and Facial:** Guidelines from the International Hyperhidrosis Society support use of Botox in patients with focal palmar, plantar, and craniofacial hyperhidrosis who have failed to respond to topical antiperspirant therapy.[15-17] The efficacy of Botox is well-established in the treatment of primary and focal palmar hyperhidrosis based on data from both randomized, double-blind, placebo-controlled studies and open-label studies.[19,21]
- **Laryngeal Dystonia (Spasmodic Dysphonia):** Botulinum toxin A is the most widely accepted treatment for spasmodic dysphonia, a focal laryngeal dystonia, and is viewed as the treatment of choice by the American Academy of Otolaryngology-Head and Neck Surgery (2018).[9] 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. Historical AAN guidelines for the treatment of movement disorders note that botulinum toxin is probably effective and should be considered for adductor type laryngeal dystonia (spasmodic dysphonia) [Level B recommendation].[7] An evidence-based review and assessment (2013) for the treatment of adductor laryngeal dystonia indicate Botox may be considered (Level C recommendation).[28]
- **Oromandibular Dystonia:** Small clinical trials have shown botulinum toxin A to be effective in treating oromandibular dystonia.[11,12] The American Academy of Oral Medicine clinical practice statement on oromandibular dystonia recommend the use of botulinum type A injections (Botox is mentioned).[10] A five year trial with Dysport for the treatment of focal movement disorders including oromandibular dystonia showed effectiveness and no new safety concerns.[13] An evidence-based review and assessment (2013) for the treatment of oromandibular dystonia indicate Botox and Dysport may be considered (level C recommendation).[28] Of note, Meige syndrome is a variant that describes the co-existence of blepharospasm and oromandibular dystonia.[27]
- **Sialorrhea:** 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.[18] 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).[24]

Dosing Information

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.[1] 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:

- **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.[4]
- **Anal Fissures:** The ACG guidelines (2021) suggest botulinum toxin A injections (formulation not specified) may be used at doses of 5-100 units in patients with refractory, chronic anal fissures.[5]
- **OAB:** The American Urological Association (AUA) guideline on [non-neurogenic] OAB (2024) indicate patients with inadequate response and minimal side effects to Botox 100 units may be offered 200 units.[25]
- **Sialorrhea:** Xeomin® (incobotulinumtoxinA injection) is indicated for this use.[22] 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.[23]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Botox. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Botox as well as the monitoring required for adverse events and long-term efficacy, approval for a diagnosis of migraine headache prevention requires Botox to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Medical benefit coverage is not recommended for Botox Cosmetic or cosmetic conditions.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Botox is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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. **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 initiation of Botox therapy); 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 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.

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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 400 units, administered not more frequently than once every 3 months.

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

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

16. Hyperhidrosis, Primary Palmar/Plantar/Facial. 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 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 400 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Botox is not recommended in the following situations:

1. Cosmetic Uses. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.
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.

2. **Gastroparesis.** The ACG issued clinical guidelines on the management of gastroparesis (2013).[26] 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.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Blepharospasm**: Diagnosis was changed from "Blepharospasm associated with dystonia or Strabismus" to "Blepharospasm" with the following Note added: "This includes blepharospasm associated with dystonia, including benign essential blepharospasm and seventh (VII) nerve disorders." An age requirement of ≥ 12 years was added. Previously there was not an age requirement in place. **Cervical Dystonia**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. **Hyperhidrosis, Primary Axillary**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. **Migraine Headache Prevention**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. **Neurogenic Detrusor Overactivity (NDO), Pediatric:** New indication, age ≥ 5 years, criteria, and dosing added. Previously, diagnosis and dosing was captured under FDA Labeled Indications as "Urinary Incontinence Associated with a Neurological Condition". **Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency (Adult)**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. "Adult" was added to diagnosis to distinguish from pediatric NDO indication. **Spasticity, Limb**: An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place. **Strabismus**: New indication, requirement of age ≥ 12 years, criteria, and dosing added. Previously, diagnosis and dosing was captured under FDA Labeled Indications as "Blepharospasm associated with dystonia or Strabismus". **Urinary Incontinence Associated with a Neurological Condition (Adult)**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. "Adult" was added to diagnosis to distinguish from pediatric NDO indication. Dosing considerations for patients ≤ 18 years of age were removed. **Achalasia**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Anal Fissure**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Chronic Low Back Pain**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Dystonia other than cervical**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Essential Tremor**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Hemifacial Spasm**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed.	10/11/2023

	Hyperhidrosis, Gustatory: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Hyperhidrosis, Palmar/Plantar and Facial**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Myofascial Pain**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Ophthalmic Disorders, other than Blepharospasm or Strabismus**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Plantar Fasciitis**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed. **Sialorrhea, Chronic**: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. Dosing considerations for patients ≤ 18 years of age were removed.	
Selected Revision	**Migraine Headache Prevention:** The requirement that the patient has tried and had an inadequate efficacy or adverse event to at least two standard prophylactic pharmacologic therapies was removed from the criteria.	04/10/2024
Annual Revision	**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.	10/02/2024

	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.	