Policy:	**Botulinum Toxins – Botox Utilization Management Medical Policy** • Botox® (onabotulinumtoxinA injection – Allergan/AbbVie)
Date:	06/23/2026
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States/Territories:	Noridian JE: California, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada Noridian JF: Alaska, Idaho, Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah, Wyoming
Applicable NCDs, LCDs, and/or LCAs	L35172, A57186, L35170, A57185

SUMMARY OF EVIDENCE

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:

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- **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.[14] Second-line medication options include alprazolam, atenolol, sotalol, gabapentin, and topiramate. The guidelines recommend botulinum toxin A may be considered in medically refractory cases of limb, head, and voice tremor associated with essential tremor (Level C), while an evidence-based review and assessment (2013) supports Botox as a Level B recommendation.[14,28] A 2023 multicenter, double-blind, randomized controlled trial published in NEJM demonstrated that botulinum toxin type A injections significantly improved essential head tremor, with 31% of treated patients achieving at least a 2-point improvement on the Clinical Global Impression scale compared to 9% in the placebo group ($P = 0.009$).[34]
- **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 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 Axillary, Palmar, Plantar, and Craniofacial:** Guidelines from the International Hyperhidrosis Society support use of Botox in patients with focal axillary, palmar, plantar, and craniofacial hyperhidrosis who have failed to respond to topical antiperspirant therapy.[15-17,33] Also, 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

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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

The general approach for first time botulinum toxin injections is to focus on using minimum effective starting doses and titrate based on patient response for further treatments.[27] Toxin distribution varies between the commercially available botulinum toxin products.[1] Labeling for the botulinum toxin products states there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity. Studies have attempted to establish a conversion ratio between botulinum toxin products with variable results; however, conversion ratios of 1:1 for Botox to Xeomin, 1:2-3 for Botox to Dysport have been suggested.[18]

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, an adult should not exceed a total dose of 400 units and a pediatric patient should not exceed a total dose of the lesser of 10 units/kg or 340 units.

Definitive dosing has not been established for off-label uses of botulinum toxins, including Botox. 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]
- **Essential Tremor**: Published clinical trial data and consensus among movement disorder specialists suggest doses between 75 to 100 units are effective.[34]
- **Hemifacial Spasm**: While no standardized dose has been established, a retrospective review of 470 botulinum toxin type A injection sessions administered to 68 patients over 16 years reported doses of up to 100 units, with an average dose of 34.5 units per session.[35]
- **Hyperhidrosis, Gustatory and Primary Craniofacial**: Botox is administered as intradermal injections spaced 0.5 – 1 cm apart in a grid pattern over the affected facial area. Typical dosages utilized are 1-5 units per cm^2.[2, 36-29]
- **Laryngeal (Spasmodic) Dystonia:** No recommended dose for this off label indication has been established; however, compendia recommend an upper limit of 25 units which is supported by several clinical trials utilizing multiple dosing regimens without exceeding 25 units.[29-32]
- **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]

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ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

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 indication(s). All approvals are provided for 1 year in duration. In cases where a dosing interval is provided in months, one month is equal to 30 days.

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 Sources of Information 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 Sources of Information 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 <u>not</u> necessarily mean that the applicable condition or diagnosis is excluded from coverage.

<u>Note</u>: 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 with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

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Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Blepharospasm. ^
Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

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.

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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.

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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; AND
C) The prescriber has excluded secondary causes of hyperhidrosis; IC-L AND
D) Patient meets ONE of the following (i or ii):
- **i.** Patient has tried at least one topical prescription agent for axillary hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance; OR IC-EC
  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).
- **ii.** Patient has failed to respond to a 6-month trial of other noninvasive conservative management for axillary hyperhidrosis.
  Note: Examples of other noninvasive conservative management include systemic anticholinergics, tranquilizers, topical dermatologics such as aluminum chloride, tannic acid, or glutaraldehyde, or non-steroid anti-inflammatory drugs.

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

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4. Chronic Migraine Headache Prevention. ^

Criteria. Approve for 1 year in patients who meet all of the following conditions (A, B, C, and D):
A) Patient is ≥ 18 years of age; [IC-L] 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. [IC-EC]
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.

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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, IC-EC]
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). ^

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, IC-EC]
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.

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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, IC-EC]

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.

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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 or achalasia cardia.

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.

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.

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

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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.

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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.

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17. Oromandibular Dystonia. ^
Note: Oromandibular dystonia is also referred to as orofacial dystonia.

Criteria. Approve for 1 year.

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

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18. Sialorrhea, Chronic. ^

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 100 units (50 units per side), administered not more frequently than once every 16 weeks.
B) Patient is < 18 years of age: Approve up to a maximum dose of 75 units (37.5 units per side), administered not more frequently than once every 16 weeks.

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19. Hemifacial Spasm. ^

Criteria. Approve for 1 year.

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

20. Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS). #

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

A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
- **i.** The diagnosis has been established based on symptoms, frequency and cystoscopic findings consistent with IC/BPS; AND
- **ii.** The condition is refractory to or the patient has failed ALL of the following management options for a minimum of 6 months (a, b, c, and d):
  - **a)** Conservative management/standard of care which may consist of education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy; AND
  - **b)** Pharmacological therapy (at least 1 agent); AND
  - **c)** Bladder instillations; AND
  - **d)** Hydrodistention; OR

B) Subsequent Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** The prescriber has documentation of an informed clinical decision regarding repeat botulinum toxin injections; AND
- **ii.** The prescriber has reassessed the degree of persistent IC/BPS and assessed the previous response to botulinum toxin; AND
- **iii.** The patient has had a positive response to the initial botulinum toxin injections.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Botox is not recommended in the following situations:

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 under the Medicare benefit.

2. 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	Date
Policy created	New Medicare Advantage Medical Policy	04/15/2020
Policy revision	**FDA-Approved Uses:** • "Cervical Dystonia" updated to "Cervical Dystonia (spasmodic torticollis)". • Pediatric dosing added for "Spasticity, Lower Limb" and "Spasticity, Upper Limb" in accordance with updated FDA labeling. **Other Uses with Supportive Evidence:** • "Benign Prostatic Hyperplasia" removed from policy. • "Salivary Hypersecretion" updated to "Sialorrhea, Chronic." • "Speech/Voice Disorder (e.g., dysphonias)" renamed to laryngeal dystonia/spasmodic torticollis. This approval condition was rolled up into "Dystonia, other than cervical" and laryngeal dystonia/spasmodic dysphonia was added to the list of examples.	06/08/2020
Policy revision	*Added new indication Plantar Fasciitis – requires trial of two other treatment modalities *Added plantar and facial hyperhidrosis as covered conditions *Added spina bifida to the list of examples for Urinary Incontinence Associated with a Neurological Condition and added pediatric dosing for this indication	03/05/2021
Policy revision	**Cervical Dystonia:** The phrase "spasmodic torticollis" was removed from the approval condition. **Hyperhidrosis, Primary Axillary:** Examples of topical therapies were moved to a Note.	08/02/2021

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	Migraine Headache Prevention: The approval condition was reworded to as listed; previously this was titled "Migraine Headache Prophylaxis in a Patient with Chronic Migraine." Regarding other pharmacotherapies, the phrase "other prophylactic" was revised to "standard prophylactic (preventative)". Examples of standard prophylactic (preventative) therapies were moved from criteria into a Note. Criteria were added requiring that the patient has experienced inadequate efficacy or adverse events to standard prophylactic (preventative) therapies. Regarding the requirement for a trial of a triptan, criteria were added such that this requirement only applies to a patient not currently receiving Botox. Examples of triptans were removed. For a patient currently receiving Botox, a triptan trial is not required; instead, the patient must have a significant clinical benefit as determined by the prescriber. **Spasticity, Limb:** The approval conditions of "Spasticity, Lower Limb" and "Spasticity, Upper Limb" were rolled together into this approval condition. **Urinary Incontinence Associated with a Neurological Condition:** Examples of neurological conditions were moved from the approval condition into a Note. **Anal Fissure:** The phrase "anal sphincter" was removed from the approval condition. **Chronic Low Back Pain:** Examples of pharmacologic therapies were moved from criteria into a Note. **Dystonia, other than Cervical:** Examples of dystonia were moved from the approval condition into a Note. **Essential Tremor:** Examples of pharmacologic therapies were moved from criteria into a Note. **Hyperhidrosis, Gustatory:** The approval condition was reworded to as listed; previous this was titled "Frey's Syndrome (gustatory sweating)". A Note was added that gustatory hyperhidrosis is also referred to as Frey's Syndrome. **Ophthalmic Disorders, other than Blepharospasm or Strabismus:** Examples of ophthalmic disorders were moved from the approval condition into a Note. **Plantar Fasciitis:** Examples of treatment modalities were moved from criteria into a Note. **Spasticity, other than Limb:** The phrase "Spasticity, other than Lower and Upper Limb" was revised to "Spasticity, other than Limb". **Cosmetic Uses:** Examples were moved from the approval condition into a Note. **Dosing:** In dosing for adult lower limb spasticity, the phrase "divided among 5 muscles" was removed. In dosing for adult upper limb spasticity, the phrase "divided among selected muscles" was removed. In dosing for achalasia, the phrase "into the lower esophageal sphincter" was removed. In dosing for sialorrhea, dosing was updated to reflect the maximum dose of 75 units (37.5 units per side) for a patient < 18 years of age (per Xeomin labeling). In the following Other Uses with Supportive Evidence, the dosing was updated such that the maximum dose for patients < 18 years of age is the lesser of 10 units/kg or 340 units in 3 months (adult maximum dosing remains unchanged at 400 units in 3 months): Anal Fissure; Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction; Chronic Low Back Pain; Dystonia, other than Cervical; Essential Tremor; Hyperhidrosis, Gustatory; Hyperhidrosis, Palmar/Plantar and Facial; Myofascial Pain; Ophthalmic Disorders, other than Blepharospasm or Strabismus; Plantar Fasciitis; and Spasticity, other than Limb.	
Policy revision	**Migraine Headache Prevention:** The requirement for a Botox-naïve patient to try at least one triptan (unless contraindicated) was removed.	08/01/2022
Policy revision	**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	09/25/2023

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	prophylactic pharmacologic therapies [verification of therapy required].	
Policy revision	**FDA Labeled Indications** **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 to criteria. Previously there was not an age requirement in place. **Cervical Dystonia**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Hyperhidrosis, Primary Axillary**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Migraine Headache Prevention**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Pediatric Neurogenic Detrusor Overactivity (NDO)**: New indication and criteria added. **Adult Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency**: An age requirement of ≥ 18 years was added to criteria. 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 to criteria. Previously there was not an age requirement in place. **Strabismus**: New indication and criteria added. Previously, diagnosis was captured under FDA Labeled Indications as "Blepharospasm associated with dystonia or Strabismus". **Adult Urinary Incontinence Associated with a Neurological Condition**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. "Adult" was added to diagnosis to distinguish from pediatric NDO indication. **Other Uses with Supportive Evidence** **Anal Fissure**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Chronic Low Back Pain**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Essential Tremor**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Hyperhidrosis, gustatory**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Hyperhidrosis, palmar/plantar and facial**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Myofascial Pain**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Ophthalmic Disorders, other than Blepharospasm or Strabismus**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Plantar Fasciitis**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Sialorrhea**: An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Dosing**: Dosing considerations for patients ≤ 18 years of age were removed where age ≥ 18 years of age requirement was added to criteria.	10/16/2023
Policy 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.	05/07/2024

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	Based on commercial policy revision	
Policy 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 <u>adult</u> 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 <u>adult</u> 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)"	12/11/2024

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	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.	
Policy revision	**Laryngeal Dystonia (Spasmodic Dysphonia):** The dosing limitation was decreased from 400 units to 25 units.	05/21/2025
Policy revision	No criteria changes. Formatting and notation updates.	06/18/2025
Policy revision	**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.	10/07/2025
Policy revision	**Blepharospasm:** Added following note for the indication: Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders. **Anal Fissure, Chronic:** Removed age requirement. **Sialorrhea, Chronic:** Removed age requirement. **Hyperhidrosis, Primary Axillary**: Added the following criteria - Patient has failed to respond to a 6-month trial of other noninvasive conservative management for axillary hyperhidrosis. Note: Examples of other noninvasive conservative management include systemic anticholinergics, tranquilizers, topical dermatologics such as aluminum chloride, tannic acid, or glutaraldehyde, or non-steroid anti-inflammatory drugs. **Chronic Migraine Headache Prevention**: Added the following criteria - Botox is being prescribed by or in consultation with a neurologist or headache specialist. **Hemifacial spasm**: Previously this indication fell under Spasticity other than Limb, which was removed from the policy, replaced by more specific Hemifacial spasm. **Interstitial Cystitis (IC)/Bladder Pain Syndrome (BPS)**: new indication added to policy.	02/04/2026, effective 02/22/2026
Policy review	No criteria changes, CMS surveillance review	04/02/2026
Policy review	No criteria changes, CMS surveillance review	06/23/2026

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