Medicare Advantage Medical Utilization Review Policy

Policy:	**Botulinum Toxins – Botox Utilization Management Medical Policy** • Botox® (onabotulinumtoxinA injection – Allergan)
Date	09/25/2023
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

OVERVIEW

Botox, a botulinum toxin, is indicated for the following uses:[1]

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

In addition, botulinum toxin type A has been used to treat a multitude of disorders characterized by abnormal muscle contraction.[2] The benefit of this drug has also been demonstrated in the treatment of gastrointestinal, genitourinary, ocular, and autonomic nervous system disorders.[2,3]

Of note, with regard to the indication of migraine headache prophylaxis, an updated assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; update 2021) notes that several medications are cited as having established or probable efficacy in migraine prevention.[39,40] Based on the level of evidence for efficacy and the American Academy of Neurology scheme for classification of evidence, the following oral treatments have established efficacy and should be offered for migraine prevention: antiepileptic drugs (divalproex sodium, valproate sodium, topiramate [not for women of childbearing potential without a reliable method of birth control]); beta-blockers (metoprolol, propranolol, timolol); and frovatriptan (for short-term preventive treatment of menstrual migraine). The following treatments are probably effective and should be considered for migraine prevention: antidepressants (amitriptyline, venlafaxine); beta-blockers (atenolol, nadolol); and angiotensin receptor blockers (candesartan). Additionally, the following treatments are possibly effective and can be considered for migraine prevention: calcium channel blockers (e.g., verapamil) and angiotensin converting enzyme inhibitors (e.g., lisinopril).[41,42]

Other Uses with Supportive Evidence

Botox has been studied in a variety of indications outside of FDA-approved uses. 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 achalasia (2020) recommends the use of botulinum toxin therapy as first-line therapy for patients with achalasia who are unfit for definitive therapies.[5]
- **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]
- **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]
- **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]
- **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]
- **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).
- **Hemifacial Spasm:** Per the AAN, botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C).[13] Data with Botox and Dysport® (abobotulinumtoxin A injection) are cited in the recommendations regarding hemifacial spasm.
- **Hyperhidrosis, Gustatory:** AAN guidelines state that botulinum toxin may be considered for this use (Level C). Botox is recommended as a first-line option for gustatory sweating by the International Hyperhidrosis Society.[16,17]
- **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] AAN guidelines state that botulinum toxins are probably safe and effective and

should be considered for palmar hyperhidrosis (plantar and facial hyperhidrosis are not addressed in the AAN guideline).[17]

- **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] Another double-blind, randomized, placebo-controlled study involving 30 patients showed no difference in spontaneous and evoked pain reduction between Botox and isotonic saline.[24]
- **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]
- **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]
- **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] AAN guidelines note that botulinum toxin is probably safe and effective and should be considered (Level B).[17]

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:

- **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]
- **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]

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. Previous therapy is required to be verified by a clinician in the Coverage Review Department when noted in the criteria as **[verification of therapies required]**.

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.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Blepharospasm Associated with Dystonia or Strabismus.

Criteria. Approve for 1 year.

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

A) For blepharospasm: Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months.

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

2. Cervical Dystonia.
(Note: Cervical dystonia is also known as spasmodic or cervical torticollis).

Criteria. Approve for 1 year.

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 has tried at least one topical agent.
Note: Examples of topical agents include topical aluminum chloride, Qbrexza (glycopyrronium cloth 2.4% for topical use).

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.
(Note: For headache that does not fit this criterion, see Other Uses with Supportive Evidence - Headache Prophylaxis in Patients with Chronic Daily Headache [i.e., Chronic Tension-Type Headache]).

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

A) Patient has ≥ 15 migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy); AND

B) Patient has tried at least TWO standard prophylactic (preventative) pharmacologic therapies, each from a different pharmacologic class **[verification of therapies required]**; AND
Note: Standard prophylactic (preventative) pharmacologic therapies include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant. 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]**.

C) Patient meets ONE of the following (i, ii, or iii):
- **i.** Patient has had inadequate efficacy to both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
- **ii.** Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
- **iii.** Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy and has experienced adverse event(s) severe enough to warrant discontinuation to another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber; 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. Overactive Bladder with Symptoms of Urge Urinary Incontinence, Urgency, and Frequency.
(Note: For treatment of urinary incontinence associated with a neurological condition [e.g., spinal cord injury, multiple sclerosis, spina bifida], see FDA-Approved Indications below.)

Criteria. Approve for 1 year if the patient has tried at least one other pharmacologic therapy.
Note: Examples of other pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication.

Dosing. Approve up to a maximum dose of 100 units, administered not more frequently than once every 12 weeks.

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6. Spasticity, Limb.
(Note: For other forms of spasticity that do not fit this condition of approval, see Other Uses with Supportive Evidence, Spasticity).

Criteria. Approve for 1 year.

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.
- **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.
- **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.

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7. Urinary Incontinence Associated with a Neurological Condition.
Note: Examples of neurological conditions include spinal cord injury, multiple sclerosis, or spina bifida. For treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, see FDA-Approved Indications above.

Criteria. Approve for 1 year if the patient has tried at least one other pharmacologic therapy.
Note: Examples of other pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication.

Dosing. Approve one of the following regimens (A or B):
A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.
B) 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.

Other Uses with Supportive Evidence

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8. Achalasia.

Criteria. Approve for 1 year.

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

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9. Anal Fissures.

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.

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10. Chronic Facial Pain/Pain Associated with Temporomandibular Dysfunction.

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.

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11. Chronic Low Back Pain.

Criteria. Approve for 1 year in patients who meet the following conditions (A and B):
A) Patient has tried at least two other pharmacologic therapies; AND
Note: Examples of pharmacologic therapies include nonsteroidal anti-inflammatory drugs (NSAIDs), antispasmodics, muscle relaxants, opioids, or antidepressants.
B) Botox is being used as part of a multimodal therapeutic pain management program.

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.

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12. Dystonia, other than cervical.
Note: Examples of dystonias include focal dystonias, tardive dystonia, anismus, or laryngeal dystonia/spasmodic dysphonia. For cervical dystonia, refer to FDA-Approved Indications above.

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.

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13. Essential Tremor (ET).

Criteria. Approve for 1 year if the patient has tried at least one other pharmacologic therapy.
Note: Examples of pharmacologic therapies for essential tremor include primidone, propranolol, benzodiazepines, gabapentin, or topiramate.

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.

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

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.

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15. Hyperhidrosis, Palmar/Plantar and Facial.

Criteria. Approve for 1 year if the patient has tried at least one topical agent (e.g., aluminum chloride).

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.

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16. Myofascial Pain.

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.

17. Ophthalmic Disorders, Other Than Blepharospasm or Strabismus.

Note: Examples of ophthalmic disorders include esotropia, exotropia, nystagmus, or facial nerve paresis. For blepharospasm associated with dystonia or strabismus, refer to FDA-Approved Indications above.

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. Plantar Fasciitis.

Criteria. Approve for 1 year if the patient has tried two other treatment modalities.

Note: Examples of other treatment modalities include padding and strapping of the foot, therapeutic orthotic insoles, oral anti-inflammatory drugs, corticosteroid injections, or stretching.

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.

19. 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.

20. Spasticity, Other Than Limb (e.g., spasticity secondary to spastic hemiplegia,[43] hemiparesis,[43] hemifacial spasm).

Note: For limb spasticity, refer to FDA-Approved Indications above.

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.

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21. Headache Prophylaxis in Patients with Chronic Daily Headache (i.e., Chronic Tension-Type Headache).[43]
(Note: For migraine headache, see FDA-Approved Indications Migraine Headache Prophylaxis in Patients with Chronic Migraine.)

Criteria.[43] Approve in patients who meet all of the following conditions (A or B):

A) Initial Therapy. Approve for 1 year if the patient meets all of the following criteria (i, ii, and iii):
- i. Patient has > 15 headache days per month with headache lasting 4 hours per day or longer for a period of at least 3 months; AND
- ii. Patient has significant disability due to the headaches; AND
- iii. Patient has tried and been refractory to at least one standard and usual conventional therapy; OR

B) Continuation of Therapy. Approve for 1 year if the patient has demonstrated a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin.

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

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 Care Continuum Policy	07/11/2018
Policy revision	Statement added to dosing to allow for approval of doses that are below the recommended maximum daily dose for each indication.	n/a
Policy revision	Removed the following criterion: "For all approvable indications, failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype/product used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype." L33646 provides this verbiage and it has since been interpreted as optional criterion because of the 'could' language. Not required to issue approval or denial but can be used when considering an appeal.	n/a
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Determination L33646 and Botulinum Toxin - Botox Care Continuum Utilization Review Policy.	09/11/2019
Policy revision	Non-clinical update to policy to add the statement "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."	1/30/2020
Policy revision	**FDA-Approved Uses:** • "Cervical Dystonia" updated to "Cervical Dystonia (spasmodic torticollis)". • Migraine Prophylaxis – removed initial vs continuation criteria; changed requirement to greater than or equal to 15 days (previously greater than 15 days); removed requirement that patient have symptoms for at least 3 months; defined standard and usual conventional therapy as two other prophylactic therapies and one triptan (or contraindication to triptan); removed requirement that patient be experiencing significant disability; added requirement for verification of prophylactic therapies tried.	06/08/2020

	• 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. • Removed previous conventional therapy trial requirements for the following indications: anal fissures, other dystonias, other ophthalmic disorders, chronic sialorrhea, other spasticity • "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. • Removed all criteria requirments for achalasia.	
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. **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".	08/12/2021

	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	**Spasticity other than limb:** removed examples of cerebral palsy, brain injury, spinal cord injury, multiple sclerosis. Added examples of spastic hemiplegia, hemiparesis.	02/21/2023
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 prophylactic pharmacologic therapies [verification of therapy required].	09/25/2023