Coverage Policy/Guideline

Name:	Botox	Page:	1 of 7
Effective Date:	1/6/2025	Last Review Date:	11/2024
Applies to:	☒ Arizona		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Botox under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
   2. Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults or pediatric patients 5 years of age or older who have an inadequate response to or are intolerant of an anticholinergic medication
   3. Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
   4. Treatment of spasticity in patients 2 years of age and older
   5. Treatment of cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain
   6. Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Safety and effectiveness have not been established in patients under age 18.
   7. Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

B. Compendial Uses
   1. Achalasia
   2. Chronic anal fissures
   3. Essential tremor
   4. Excessive salivation (ptyalism)
   5. Hemifacial spasm
   6. Spasmodic dysphonia (laryngeal dystonia)
   7. Oromandibular dystonia
   8. Myofascial pain syndrome
   9. Focal hand dystonia
   10. Facial myokymia
   11. Hirschsprung disease with internal sphincter achalasia

12. Orofacial tardive dyskinesia
13. Painful bruxism
14. Palatal myoclonus
15. First bite syndrome
16. Palmar or gustatory (Frey's syndrome) hyperhidrosis

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Botox

Policy/Guideline:

Prescriber Specialty:
The medication must be prescribed by, or in consultation with a provider specialized in treating the member's condition.

Exclusions:
Coverage will not be provided for cosmetic use.

Criteria for Initial Approval:

A. Blepharospasm
Authorization of 12 months may be granted for treatment of blepharospasm when all of the following are met:
1. Member is 12 years of age or older
2. Member is diagnosed with blepharospasm including blepharospasm associated with dystonia, benign essential blepharospasm or VII nerve disorder.

B. Cervical dystonia
Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:
1. There is abnormal placement of the head with limited range of motion in the neck
2. Member is 18 year of age and older.

C. Chronic migraine prophylaxis
Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:
1. Member experiences headaches 15 days or more per month.
2. Member experiences headaches lasting 4 hours or longer on at least 8 days per month.
3. Member completed an adequate trial of (or has a contraindication to) two oral migraine preventative therapies coming from at least 2 of the following classes with a trial of each medication at least 60 days in duration:

a. Antidepressants (e.g., amitriptyline, venlafaxine)
b. Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)
c. Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)
d. Calcitonin gene-related peptide (CGRP)-targeting therapies (e.g., fremanezumab, galcanezumab, epitinezumab, rimegepant, atogepant).

4. Member has signs and symptoms consistent with chronic migraine diagnostic criteria as defined by the International Headache Society (IHS).
5. Member is 18 years of age or older

D. Overactive bladder with urinary incontinence

Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence, urgency, and frequency when all of the following criteria are met:

1. The member has tried and failed behavioral therapy.
2. The member has had an inadequate response or experienced intolerance to two agents from either of the following classes:
   a. Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
   b. Beta-3 adrenergic agonist (e.g., Myrbetriq [miraberon], Gemtesa [vibegron]).
3. Member is 18 years of age or older.

E. Primary axillary, palmar, and gustatory (Frey's syndrome) hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis when all of the following criteria are met:

1. Significant disruption of professional and/or social life has occurred because of excessive sweating; and
2. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.
3. Member is 18 years of age or older.

F. Strabismus

Authorization of 12 months may be granted for treatment of strabismus when all of the following are met:

1. Strabismus interference with normal visual system development is likely to occur and spontaneous recovery is unlikely.
2. Member is 12 years of age or older.

Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

G. Upper or lower limb spasticity

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity when all of the following are met:

1. Member is 2 years of age or older

2. Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition causing limb spasticity (including focal spasticity or equinus gait due to cerebral palsy).

H. Urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)

Authorization of 12 months may be granted for treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met:

1. The member has tried and failed behavioral therapy
2. The member has had an inadequate response or experienced intolerance to one agent from either of the following classes:
   a. Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
   b. Beta-3 adrenergic agonist (e.g., Myrbetriq [miraberon]
3. Member is 5 years of age or older.

I. Achalasia

Authorization of 12 months may be granted for treatment of achalasia when the member has tried and failed or is a poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy.

J. Chronic anal fissures

Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates.

K. Essential tremor

Authorization of 12 months may be granted for treatment of essential tremor.

L. Excessive salivation

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea or ptyalism) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

M. Hemifacial Spasm

Authorization of 12 months may be granted for treatment of hemifacial spasm.

N. Spasmodic dysphonia (laryngeal dystonia)

Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

O. Oromandibular dystonia

Authorization of 12 months may be granted for treatment of oromandibular dystonia.

P. Myofascial Pain Syndrome

Authorization of 12 months may be granted for treatment of myofascial pain syndrome when the member has tried and failed all of the following:

1. Physical therapy
2. Injection of local anesthetics into trigger points
3. Injection of corticosteroids into trigger points

Q. Focal hand dystonia
Authorization of 12 months may be granted for the treatment of focal hand dystonias.

R. Facial myokymia
Authorization of 12 months may be granted for the treatment of facial myokymia.

S. Hirschsprung disease with internal sphincter achalasia
Authorization of 12 months may be granted for the treatment of Hirschsprung's disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy.

T. Orofacial tardive dyskinesia
Authorization of 12 months may be granted for the treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine).

U. Painful bruxism
Authorization of 12 months may be granted for the treatment of painful bruxism when the member has had an inadequate response to a night guard and has had an inadequate response to pharmacologic therapy such as diazepam.

V. Palatal myoclonus
Authorization of 12 months may be granted for the treatment of palatal myoclonus when the member has disabling symptoms (e.g., intrusive clicking tinnitus) who had an inadequate response to clonazepam, lamotrigine, carbamazepine or valproate.

W. First bite syndrome
Authorization of 12 months may be granted for the treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants.

Continuation of Therapy:

A. All members (including new members) requesting authorization for continuation of therapy for approvable conditions other than migraine prophylaxis must meet ALL initial authorization criteria and be experiencing benefit from therapy.

B. Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the member has achieved or maintained a reduction in monthly headache frequency since starting therapy with Botox.

Dosage and Administration:
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines**.**

Adults: Dosing should not exceed a cumulative dose of 400 units every 84 days
Pediatric (patients less than 18 years of age): Dosing should not exceed the lessor of 10 units/kg or 340 units every 84 days.

Approval Duration and Quantity Restrictions:

Approval:

- Chronic migraine prophylaxis: initials = 6 months; renewals = 12 months
- All others: 12 months

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