



TITLE:	BOTULINUM TOXIN POLICY
POLICY #:	MM-PNP-040
VERSION #:	01
DEPARTMENT:	Utilization Management
ORIGINAL EFFECTIVE DATE:	02/28/2024
CURRENT REVISION DATE:	N/A

1. PURPOSE

Provides guidelines regarding the review of requests for botulinum toxin agents.

2. SCOPE

Medical and Pharmacy UM Departments

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Brand Selection for Medically Necessary Indications for Commercial Medical Plans

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Myobloc (rimabotulinumtoxinB) brand is more costly to Curative than other botulinum toxin agents for certain indications. There is a lack of reliable evidence that Myobloc (rimabotulinumtoxinB) and Daxxify (daxibotulinumtoxinA-lamn) are superior to the lower cost botulinum toxin agents:

- **Botox (onabotulinumtoxinA),**
- **Dysport (abobotulinumtoxinA), and**
- **Xeomin (incobotulinumtoxinA)**

For the following medically necessary indications (agent specifics follow this list):

- Cervical dystonia
- Excessive salivation (chronic sialorrhea/ptyalism)
- Primary axillary, palmar, and gustatory (Frey's syndrome) hyperhidrosis (Botox and Dysport only)
- Upper limb spasticity,
- Overactive bladder, urinary incontinence,

- o Spasticity, cervical dystonia, hemifacial spasm, myofascial pain syndrome, focal hand dystonia, facial myokymia,
- o Hyperhidrosis,
- o Migraine prophylaxis, tremor, orofacial tardive dyskinesia,
- o Chronic anal fissures, achalasia, Hirschsprung disease,
- o Excessive salivation, spasmodic dystonia, oromandibular dystonia, bruxism, palatal myoclonus,
- o First bite syndrome.

Note: Requires Precertification and is only available for buy and bill by the administering provider.

Precertification of botulinum toxin (Botox [onabotulinumtoxinA]; Dysport [abobotulinumtoxinA]; and Xeomin [incobotulinumtoxinA]) is required of all Curative participating providers and members in applicable plan designs.

Exclusions

Coverage will not be provided for cosmetic use such as, but not limited to reduce skin wrinkling.

OnabotulinumtoxinA (Botox Brand of Botulinum Toxin Type A)

Prescriber Specialties

The medication must be prescribed by, or in consultation with, *one* of the following:

- Blepharospasm, strabismus: neurologist or ophthalmologist;
- Overactive bladder, urinary incontinence: neurologist, urologist, or gynecologist;
- Spasticity, cervical dystonia, hemifacial spasm, myofascial pain syndrome, focal hand dystonia, facial myokymia: neurologist, orthopedist, otolaryngologist, or physiatrist;
- Hyperhidrosis: neurologist, internist, or dermatologist;
- Migraine prophylaxis, tremor, orofacial tardive dyskinesia: neurologist, pain specialist, or physiatrist;
- Chronic anal fissures, achalasia, Hirschsprung disease: gastroenterologist, proctologist, or colorectal surgeon;
- Excessive salivation, spasmodic dystonia, oromandibular dystonia, bruxism, palatal myoclonus: neurologist or otolaryngologist;
- First bite syndrome: neurologist or oncologist.

Exclusions

Coverage will not be provided for cosmetic use such as, but not limited to reduce skin wrinkling.

Criteria for Initial Approval

Curative considers onabotulinumtoxinA (Botox) medically necessary for *any* of the following indications:

- **Achalasia**

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;

- **Anal fissures, chronic**

Treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates;

- **Blepharospasm**

Treatment of blepharospasm when *all* of the following are met:

- Member is 12 years of age or older; *and*
- Member is diagnosed with blepharospasm including blepharospasm associated with dystonia, benign essential blepharospasm or VII nerve disorder;

- **Cervical dystonia**

Treatment of adults with cervical dystonia (e.g., torticollis) when *all* of the following are met:

- There is abnormal placement of the head with limited range of motion in the neck; *and*
- Member is 18 year of age and older;

- **Chronic sialorrhea (excessive salivation)**

Treatment of chronic sialorrhea (excessive salivation or ptyalism) when the member has been refractory to pharmacotherapy (e.g., anticholinergics);

- **Essential tremor**

Treatment of essential tremor;

- **Facial myokymia**

Treatment of facial myokymia;

- **First bite syndrome**

Treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants;

- **Focal hand dystonia**

Treatment of focal hand dystonias;

- **Hemifacial Spasm**

Treatment of hemifacial spasm;

- **Hirschsprung disease with internal sphincter achalasia**

Treatment of Hirschsprung's disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy;

- **Migraine prophylaxis, chronic**

- **Prevention of chronic migraine when *all* of the following criteria are met:**

- Member experiences headaches 15 days or more per month; *and*

- Member experiences headaches lasting 4 hours or longer on at least 8 days per month; *and*
- 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:
 - Antidepressants (e.g., amitriptyline, venlafaxine);
 - Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium);
 - Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol); *and*
 - Member has signs and symptoms consistent with chronic migraine diagnostic criteria as defined by the International Headache Society (IHS); *and*
- Member is 18 years of age or older;

- **Myofascial Pain Syndrome**

Treatment of myofascial pain syndrome when the member has tried and failed *all* of the following:

- Physical therapy; *and*
- Injection of local anesthetics into trigger points; *and*
- Injection of corticosteroids into trigger points;

- **Orofacial tardive dyskinesia**

Treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine);

- **Oromandibular dystonia**

Treatment of oromandibular dystonia;

- **Overactive bladder with urinary incontinence**

Treatment of overactive bladder with urinary incontinence, urgency, and frequency when *all* of the following criteria are met:

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

- **Painful bruxism**

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;

- **Palatal myoclonus**

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;

- **Primary axillary, palmar, and gustatory (Frey's syndrome) hyperhidrosis**

Treatment of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis when *all* of the following criteria are met:

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

- **Spasmodic dysphonia (laryngeal dystonia)**

Treatment of spasmodic dysphonia (laryngeal dystonia);

- **Strabismus**

Treatment of strabismus when *all* of the following are met:

- Strabismus interference with normal visual system development is likely to occur and spontaneous recovery is unlikely; *and*
- Member is 12 years of age or older;

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

- **Upper or lower limb spasticity**

Treatment of upper or lower limb spasticity when all of the following are met:

- Member is 2 years of age or older; *and*
- 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);

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

Treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when *all* of the following criteria are met;

- The member has tried and failed behavioral therapy; *and*
- The member has had an inadequate response or experienced intolerance to one agent from *either* of the following classes:

- Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]); *or*
- Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron]); *and*
- Member is 5 years of age or older;

Curative considers all other indications as experimental and investigational

Continuation of Therapy

- Curative considers continuation of onabotulinumtoxinA (Botox) therapy medically necessary for all members (including new members) requesting reauthorization for an indication listed in Section I.B. (excluding chronic migraine prophylaxis) who meet all initial authorization criteria and are experiencing benefit from therapy.
- Curative considers continuation of onabotulinumtoxinA (Botox) therapy medically necessary for treatment of chronic migraine prophylaxis when the member has achieved or maintained a reduction in monthly headache frequency since starting therapy with onabotulinumtoxinA (Botox).

AbobotulinumtoxinA (Dysport Brand of Botulinum Toxin Type A)

Prescriber Specialties

The medication must be prescribed by, or in consultation with, *one* of the following:

- Cervical dystonia, spasticity, hemifacial spasm: neurologist, orthopedist, or physiatrist;
- Blepharospasm: neurologist or ophthalmologist;
- Chronic anal fissures: gastroenterologist, proctologist, or colorectal surgeon;
- Excessive salivation: neurologist or otolaryngologist;
- Primary axillary hyperhidrosis: neurologist, dermatologist, or internist.

Exclusions

Coverage will not be provided for cosmetic use such as, but not limited to reduce skin wrinkling.

Criteria for Initial Approval

Curative considers abobotulinumtoxinA (Dysport) medically necessary for the treatment of *any* of the following indications:

- **Blepharospasm**

Treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm;

- **Cervical dystonia**

Treatment of adults with cervical dystonia (e.g., torticollis) when *all* of the following are met:

- Member is 18 years of age or older; *and*
- Member has abnormal placement of the head with limited range of motion in the neck;

- **Chronic anal fissures**

Treatment of chronic anal fissures when the member has not responded to first-line therapy such as topical calcium channel blockers or topical nitrates;

- **Chronic sialorrhea (excessive salivation)**

Treatment of chronic sialorrhea (excessive salivation) when the member has been refractory to pharmacotherapy (e.g., anticholinergics);

- **Hemifacial spasm**

Treatment of hemifacial spasm;

- **Primary axillary hyperhidrosis**

Treatment of primary axillary hyperhidrosis when *all* of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating; *and*
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash;

- **Upper or lower limb spasticity**

Treatment of upper or lower limb spasticity when *all* of the following are met:

- Member is 2 years of age or older; *and*
- Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition causing limb spasticity (e.g., focal spasticity or equinus gait due to cerebral palsy).

Curative considers all other indications as experimental and investigational

Continuation of Therapy

Curative considers continuation of rimabotulinumtoxinB (Myobloc) therapy medically necessary for all members (including new members) who meet all initial authorization criteria and are experiencing benefit from therapy.

IncobotulinumtoxinA (Xeomin Brand of Botulinum Toxin Type A)

Prescriber Specialties

The medication must be prescribed by, or in consultation with, *one* of the following:

- Chronic sialorrhea: neurologist or otolaryngologist;
- Cervical Dystonia and Upper limb spasticity: neurologist, orthopedist, or physiatrist;
- Blepharospasm: neurologist or ophthalmologist.

Exclusions

Coverage will not be provided for cosmetic use such as, but not limited to reduce skin wrinkling.

Criteria for Initial Approval

Curative considers incobotulinumtoxinA (Xeomin) medically necessary for the treatment of *any* of the following indications:

- **Blepharospasm**

Treatment of blepharospasm, including blepharospasm when *all* of the following criteria are met:

- Member has a diagnosis of blepharospasm including benign essential blepharospasm or blepharospasm associated with dystonia; *and*
- Member is 18 years of age or older;

- **Cervical dystonia**

Treatment of adults with cervical dystonia (e.g., torticollis) when *all* of the following criteria are met:

- **Member is 18 years of age or older; *and***
 - There is abnormal placement of the head with limited range of motion in the neck;

- **Chronic sialorrhea (excessive salivation)**

Treatment of chronic sialorrhea (excessive salivation) when *all* of the following criteria are met:

- Member is 2 years of age or older; *and*
- Member has been refractory to pharmacotherapy (e.g., anticholinergics);

- **Upper limb spasticity**

Treatment of upper limb spasticity when *all* of the following are met:

- Member has a diagnosis of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity; *and*
- Member meets *one* of the following criteria:
 - Member is 18 years of age or older; or
 - Member is 2 to 17 years of age and the spasticity is not caused by cerebral palsy.

Curative considers all other indications as experimental and investigational

Curative considers continuation of incobotulinumtoxinA (Xeomin) therapy medically necessary for all members (including new members) who meet all initial authorization criteria and are experiencing benefit from therapy.

EMG Guidance

Curative considers the use of electromyographic (EMG) guidance of botulinum toxin injections medically necessary for *any* of the following indications:

- Cervical dystonia
- Hand dystonia
- Limb spasticity
- Strabismus.

Curative considers the use of EMG guidance of botulinum toxin injections experimental and investigational for the following indications (not an all-inclusive list):

- Treatment of bladder dysfunction
- Treatment of blepharospasm
- Treatment of hyperhidrosis
- Treatment of migraines.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical and Pharmacy associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

11.1. Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
Charles, Brandon	3/25/2024	<small>DocuSigned by:</small> <i>Charles, Brandon</i>
(Printed Name)	(Date)	(Signature)

REVISION HISTORY			
Date	Author	Version	Comments
			Initial Version

APPENDICES

N/A