

# Policy Key: Botulinum Toxins

## TriWest Clinical Operations – TRICARE West

### SCOPE

This Policy Key provides criteria to use during medical necessity reviews for the injectable medication botulinum toxin, used in treating approved conditions.

Brand names include:

- Botox (onabotulinumtoxinA)
- Daxxify (daxibotulinumtoxinA)
- Dysport (abobotulinumtoxinA)
- Myobloc (rimabotulinumtoxinB)
- Xeomin (incobotulinumtoxinA)

### NOT COVERED

- Cosmetic indications (e.g., frown lines and brow furrows). [\[2\]](#) [\[3\]](#)
- Botulinum Toxin Type A injections used for:
  - Lower back pain/lumbago, [\[1\]](#)
  - Episodic migraine, chronic daily headache, cluster headache, cervicogenic headache, and tension-type headache, medication overuse headache (MOH), hemicrania continua, new daily persistent headache (NDPH), [\[1\]](#) [\[4\]](#)
  - Treatment of myofascial pain dysfunction syndrome, also known as temporomandibular joint (TMJ) syndrome
- Botox for treating muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis. [\[1\]](#)
- Any condition or indication not listed in the coverage criteria.

### COVERAGE CRITERIA

#### General Information

- Authorizations may be approved for 365 days unless otherwise specified.
- Pharmaceutical agents supplied by physicians and other appropriate clinicians, and pharmaceutical agents provided in supporting home health care (e.g., home infusion therapy) are processed under the medical benefit. [\[1\]](#)
- If preauthorized, pharmaceutical agents (e.g., injectables) not appropriate for self-administration may be obtained through the TRICARE Pharmacy benefit and administered by the physician, other appropriate clinician, or in the home if it is an appropriate setting. [\[1\]](#)

- May be considered for **off-label treatment** of any of the following indications when they meet criteria [2]:
  - Botox (OnabotulinumtoxinA) for treating chronic anal fissure unresponsive to conservative therapeutic measures;
  - Botox (OnabotulinumtoxinA) injections for laryngeal dystonia (adductor spasmodic dysphonia) and oromandibular dystonia (jaw-closing dystonia);
  - Botox (OnabotulinumtoxinA) injections for treating palmar hyperhidrosis that is refractory to topical and pharmacological therapies;
  - Botox (OnabotulinumtoxinA) and Myobloc® (RimabotulinumtoxinB) injections for treating sialorrhea associated with Parkinson's disease patients who are refractory to, or unable to tolerate, systemic anticholinergics;
  - Botulinum toxin A injections for spasticity resulting from Cerebral Palsy (CP).

### **Botox [2] [3]**

#### **Initial Therapy**

- **Initial Level of Review** may approve for **any** of the following indications when prescribed by, or in consultation with a provider specializing in treating the condition and meets criteria [3]:
  - **Achalasia**
    - Tried and failed or poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy.
  - **Anal fissures, chronic**
    - No response to first line therapy such as topical calcium channel blockers or topical nitrates.
  - **Blepharospasm**
    - Including blepharospasm associated with dystonia, benign essential blepharospasm, or VII nerve disorder; **and**
    - 12 years of age or older.
  - **Cervical dystonia** (e.g., torticollis)
    - Abnormal head placement to reduce severity of abnormal head position or neck pain; **and**
    - 18 years of age and older.
  - **Chronic Migraine** may authorize the first injection and two subsequent injections for up to six months, if the following conditions are met: [4]
    - Definition of Chronic Migraine, please refer to Definition section,
    - 15 days or more per month, 4 hours or longer on at least 8 days per month
    - 18 years of age or older,
    - Documentation of failure at least one first line drug OR prior use of Botox for migraine:
      1. Antidepressants (e.g., amitriptyline, venlafaxine);
      2. Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium);
      3. Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol).
  - **Chronic Sialorrhea (excessive salivation or ptyalism)**
    - Associated with Parkinson's disease

- Has been refractory to pharmacotherapy (e.g., anticholinergics).
- **Essential tremor**
  - Treatment of essential tremor.
- **Facial myokymia**
  - Treatment of facial myokymia.
- **First bite syndrome**
  - Failed relief from analgesics, antidepressants or anticonvulsants.
- **Focal hand dystonia**
  - Treatment of focal hand dystonia.
- **Hirschsprung disease with internal sphincter achalasia**
  - Treatment following endorectal pull through and the beneficiary is refractory to laxative therapy;
- **Orofacial tardive dyskinesia**
  - Tried and failed conventional therapies (e.g., benzodiazepines, clozapine, or tetrabenazine); and
- **Oromandibular dystonia**
  - Treatment of oromandibular dystonia.
- **Overactive bladder with urinary incontinence, urgency, and frequency**
  - Has had an inadequate response or experienced intolerance to:
    1. Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]); and
  - 5 years of age or older [5].
- **Painful bruxism**
  - Inadequate response to a night guard (**occlusal splints**), and
  - Inadequate response to pharmacologic therapy such as diazepam or behavioral interventions.
- **Palatal myoclonus**
  - Disabling symptoms (e.g., intrusive clicking tinnitus) with an inadequate response to clonazepam, lamotrigine, carbamazepine, or valproate.
- **Primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis**
  - Significant disruption of professional and/or social life has occurred because of excessive sweating; and
  - Topical aluminum chloride or other extra-strength antiperspirants (Drysol, Sofpironium, Glycopyrronium tosylate) are ineffective or result in a severe rash; and
  - 18 years of age or older.
- **Recurrent cricopharyngeal dysfunction (R-CPD), inability to belch syndrome**
  - Inability to burp leading to bloating, chest and abdominal discomfort, gurgling sounds, and excessive flatulence
- **Spasmodic dysphonia (laryngeal dystonia)**
  - Treatment of spasmodic dysphonia (laryngeal dystonia).
- **Strabismus**
  - Interference with normal visual system development is likely to occur and spontaneous recovery is unlikely; and

- 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**
  - 2 years of age or older; **and**
  - 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)**
  - Tried and failed behavioral therapy; **and**
  - Inadequate response or experienced intolerance to one agent from **either** of the following classes:
    1. Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]); or
    2. Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron]); **and**
  - 5 years of age or older.

### Continuation Therapy [3]

- **Initial Level of Review** may approve:
  - If therapy is medically necessary, meets all initial authorization criteria, and experiencing benefit from therapy.
  - For **chronic migraines**, approve if there is documented clinical benefit, e.g. improvement from prior to initiation of therapy or maintenance of benefit.

### Daxxify (daxibotulinumtoxinA) [3]

#### Initial Therapy

- **Initial Level of Review** may approve for cervical dystonia (e.g., torticollis) when prescribed by, or in consultation with a provider specializing in treating the condition and meets criteria:
  - 18 years or older; **and**
  - There is abnormal head placement with limited range of motion in the neck.

#### Continuation Therapy

- **Initial Level of Review** may approve:
  - If therapy is medically necessary, meets all initial authorization criteria, and experiencing benefit from therapy;

### Dysport (abobotulinumtoxinA) [3]

#### Initial Therapy

- **Initial Level of Review** may approve for any of the following indications when prescribed by, or in consultation with a provider specializing in treating the condition and meets criteria:
  - **Blepharospasm**
    - Including blepharospasm associated with dystonia and benign essential blepharospasm.
  - **Cervical dystonia with cervical dystonia** (e.g., torticollis)

- 18 years of age or older; **and**
- Abnormal head placement with limited range of motion in the neck.
- **Chronic anal fissures**
  - No response to first-line therapy such as topical calcium channel blockers or topical nitrates.
- **Chronic sialorrhea (excessive salivation)**
  - Refractory to pharmacotherapy (e.g., anticholinergics).
- **Hemifacial spasm**
  - Treatment of hemifacial spasm.
- **Primary axillary hyperhidrosis**
  - 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**
  - 2 years of age or older; **and**
  - 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).

### Continuation Therapy

- **Initial Level of Review** may approve:
  - If therapy is medically necessary, meets all initial authorization criteria, and experiencing benefit from therapy,

### Myobloc (rimabotulinumtoxinb) [3]

#### Initial Therapy

- **Initial Level of Review** may approve for any of the following indications when prescribed by, or in consultation with a provider specializing in treating the condition and when meets criteria:
  - **Cervical dystonia with cervical dystonia (e.g., torticollis)**
    - 18 years of age or older; **and**
    - Abnormal head placement with limited range of motion in the neck.
  - **Chronic Sialorrhea (excessive salivation)**
    - 18 years of age or older; **and**
    - Refractory to pharmacotherapy (e.g., anticholinergics).
  - **Primary axillary and palmar hyperhidrosis**
    - 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 limb spasticity**
  - As a primary diagnosis or as a symptom of a condition causing limb spasticity.

### Continuation Therapy

- **Initial Level of Review** may approve:

- If therapy is medically necessary, meets all initial authorization criteria, and experiencing benefit from therapy,

### **Xeomin (incobotulinumtoxinA) [3]**

#### **Initial Therapy**

- **Initial Level of Review** may approve for any of the following indications when prescribed by, or in consultation with a provider specializing in treating the condition and meets criteria:
  - **Blepharospasm**
    - Including benign essential blepharospasm or blepharospasm associated with dystonia; **and**
    - 18 years of age or older.
  - **Cervical dystonia** with cervical dystonia (e.g., torticollis)
    - 18 years of age or older; **and**
    - Abnormal head placement with limited range of motion in the neck.
  - **Chronic sialorrhea (excessive salivation)**
    - 2 years of age or older; **and**
    - Refractory to pharmacotherapy (e.g., anticholinergics).
  - **Upper limb spasticity**
    - As a primary diagnosis or as a symptom of a condition causing limb spasticity; **and**
    - 18 years of age or older; or 2 to 17 years of age and the spasticity is not caused by cerebral palsy.

#### **Continuation Therapy**

- **Initial Level of Review** may approve:
  - If therapy is medically necessary, meets all initial authorization criteria, and experiencing benefit from therapy,
  - For chronic migraine prophylaxis when reduction in monthly headache frequency has been achieved or maintained since starting therapy.

## **DEFINITIONS**

### **Chronic Migraine is defined by: [4]**

- Headache occurring on 15 or more days per month for more than 3 months, with at least 8 days of the month fulfilling the criteria for a migraine attack (i.e., throbbing pain, nausea/vomiting, sensitivity to light and sound).
- The individual must have a history of migraine without aura or migraine with aura.
- The headaches must have characteristics that meet the usual definition of a migraine, such as:
  - Pulsating, moderate-to-severe pain.
  - Associated symptoms like nausea, photophobia, phonophobia.
  - Headaches are often unilateral, though they can occur on both sides of the head.

A diagnosis of Chronic Migraine (not Episodic Migraine or Chronic Daily Headache) documented in the medical record will meet the requirement for Chronic Migraine.

## **CODES**



CPT: 46505, 64611 - 64615, 64640, 64653, 67345  
HCPCS: J0585 - J0588

## REFERENCES

- [1] TRICARE Policy Manual 6010.63-M, April 2021, Change 25 (November 7, 2024), Chapter 8 , Section 9.1, Pharmacy Benefits Program, [https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S9\\_1.html](https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S9_1.html)
- [2] TRICARE Policy Manual 6010.63-M, April 2021, Change 25 (November 7, 2024), Chapter 7, Section 27.1, Botulinum Toxin Injections [https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-10-31/AsOf/TPT5/C7S27\\_1.html](https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-10-31/AsOf/TPT5/C7S27_1.html)
- [3] Aetna Clinical Policy Bulletin, Botulinum Toxin, Retrieved November 18, 2024 [https://www.aetna.com/cpb/medical/data/100\\_199/0113.html](https://www.aetna.com/cpb/medical/data/100_199/0113.html)
- [4] Ailani J, Burch RC, Robbins MS; the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021–1039. <https://doi.org/10.1111/head.14153>
- [5] U.S. Food and Drug Administration. (2024). BOTOX® Cosmetic (onabotulinumtoxinA) for injection, for intramuscular use: Prescribing information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/103000s5316s5319s5323s5326s5331lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103000s5316s5319s5323s5326s5331lbl.pdf)

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