Medical Benefit Drug Policy

Botulinum Toxins (Botox®, Daxxify®, Dysport®, Myobloc®, and Xeomin®)

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Related Policies

- n/a

Coverage Rationale

Cosmetic Use

For coverage requests for Botox, Daxxify, Dysport, and Xeomin for Cosmetic Use:

- Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

Achalasia

For initial coverage of Botox for the treatment of achalasia, the following will be required:

- Diagnosis of achalasia **and**
- One of the following:
  - Contraindication to, or failure of one of the following:
    - Pneumatic dilation
    - Myotomy **or**
  - Prior dilation caused esophageal perforation **or**
  - Patient has an increased risk of dilation-induced perforation due to one of the following:
    - Epiphrenic diverticulum
    - Hiatal hernia

For reauthorization coverage of Botox for the treatment of achalasia, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., improvement or reduction in symptoms of dysphagia, aspiration, regurgitation, chest pain) **and**

- At least 6 months have or will have elapsed since the last series of injections

Adult Bladder Dysfunction OR Neurogenic Detrusor Overactivity

For initial coverage of Botox for the treatment of adult bladder dysfunction or neurogenic detrusor overactivity (NDO), the following will be required:

- One of the following conditions:
  - Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
  - Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency)
  - Neurogenic detrusor overactivity (NDO) **and**
- Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/ scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)] **and**
- Patient is routinely performing clean intermittent self-catheterization (CIC) or is willing/able to perform CIC if he/she has post-void residual (PVR) urine volume greater than 200 mL **and**
- Prescribed by or in consultation with a urologist

For reauthorization coverage of Botox for the treatment of adult bladder dysfunction or neurogenic detrusor overactivity (NDO), the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

Blepharospasm, Strabismus, Cranial Nerve VII (facial) Disorders

For initial coverage of Botox for the treatment of blepharospasm, strabismus, and cranial nerve VII disorders, the following will be required:

- Diagnosis of blepharospasm associated with dystonia (e.g., benign essential blepharospasm) **and**
- Patient is 12 years of age or older **or**
- Diagnosis of strabismus **or**
- Diagnosis of cranial nerve VII disorders (hemifacial spasms)

For initial coverage of Xeomin for the treatment of blepharospasm the following will be required:

- Diagnosis of blepharospasm

For reauthorization coverage of Botox and Xeomin for the treatment of blepharospasm, strabismus, VII cranial nerve disorders, the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

Cervical Dystonia (Spasmodic Torticollis)

For initial coverage of Botox, Daxxify, Dysport, Myobloc and Xeomin for the treatment of cervical dystonia (also known as spasmodic torticollis), the following will be required:

- Diagnosis of cervical dystonia

For reauthorization coverage of Botox, Daxxify, Dysport Myobloc, and Xeomin for the treatment of cervical dystonia, the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

Chronic Anal Fissure

For initial coverage of Botox for the treatment of chronic anal fissure, the following will be required:

- Diagnosis of chronic anal fissure **and**
- At least 2 months of one of the following symptoms:
    - Nocturnal pain and bleeding
    - Post-defecation pain **and**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
    - Topical nitrates (e.g. Glyceryl trinitrate (Nitroglycerin))
    - Topical calcium channel blockers (CCBs) (e.g., diltiazem, nifedipine)

For reauthorization coverage of Botox for the treatment of chronic anal fissure, the following will be required:

- One of the following:
    - Incomplete healing of fissure
    - Recurrence of fissure **and**
- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

Chronic Migraine

For initial coverage of Botox for the treatment of chronic migraine, the following will be required:

- Diagnosis of chronic migraines **and**
- Patient has greater than or equal to 8 migraine days per month **and**
- Patient is 18 years of age or older **and**
- Medication overuse headache has been considered and potentially offending medication(s) have been discontinued **and**
- History of failure (after at least a two-month trial), contraindication or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action:
    - Elavil [amitriptyline] or Effexor [venlafaxine]
    - Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
    - Atenolol, propranolol, nadolol, timolol, metoprolol
    - Candesartan
    - Lisinopril **and**
- Trial and failure, contraindication, or intolerance to one calcitonin gene-related peptide (CGRP) for migraine **and**
- Prescribed by or in consultation with one of the following:
    - Neurologist
    - Pain specialist
    - Headache specialist

For reauthorization coverage of Botox for the treatment of chronic migraine, the following will be required:

- Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines) **and**
- Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of therapy **and**
- At least 3 months have or will have elapsed since the last treatment **and**

- Patient continues to be monitored for medication overuse headache (MOH) **and**
- Trial and failure, contraindication, or intolerance to calcitonin gene-related peptide (CGRP) for migraine **and**
- Prescribed by or in consultation with one of the following:
    - Neurologist
    - Pain specialist
    - Headache specialist

Chronic Sialorrhea

For initial coverage of Myobloc for the treatment of chronic sialorrhea the following will be required:

- Diagnosis of chronic sialorrhea

For reauthorization coverage of Myobloc for the treatment of chronic sialorrhea, the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

For initial coverage of Xeomin for the treatment of chronic sialorrhea the following will be required:

- Diagnosis of chronic sialorrhea **and**
- Patient is 2 years of age or older

For reauthorization coverage of Xeomin for the treatment of chronic sialorrhea, the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 4 months have or will have elapsed since the last treatment

Primary Axillary Hyperhidrosis

For initial coverage of Botox for the treatment of primary axillary hyperhidrosis, the following will be required:

- Diagnosis of primary axillary hyperhidrosis **and**
- One of the following:
    - Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) **or**
    - Skin maceration with secondary infection **and**
- Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]

For reauthorization coverage of Botox for the treatment of primary axillary hyperhidrosis, the following will be required:

- At least a 2-point improvement in HDSS **and**
- At least 3 months have or will have elapsed since the last treatment

Spasticity

For initial coverage of Botox for the treatment of spasticity the following will be required:

- Diagnosis of upper limb spasticity **or**
- Diagnosis of lower limb spasticity

For initial coverage of Dysport for the treatment of spasticity the following will be required:

- Diagnosis of spasticity **and**
- Patient is 2 years of age or older

For initial coverage of Xeomin for the treatment of upper limb spasticity the following will be required:

- Diagnosis of upper limb spasticity **and**
- Patient is 2 years of age or older

For reauthorization coverage of Botox, Dysport, and Xeomin for the treatment of spasticity, the following will be required:

- Patient demonstrates positive clinical response to therapy **and**
- At least 3 months have or will have elapsed since the last treatment

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0585	Injection, onabotulinumtoxina, 1 Unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxina, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

ICD-10 Code	Description
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
D33.0	Benign neoplasm of brain, supratentorial
D33.1	Benign neoplasm of brain, infratentorial

ICD-10 Code	Description
D33.2	Benign neoplasm of brain, unspecified
D33.3	Benign neoplasm of cranial nerves
D33.4	Benign neoplasm of spinal cord
D33.7	Benign neoplasm of other specified parts of central nervous system
D33.9	Benign neoplasm of central nervous system, unspecified
D43.0	Neoplasm of uncertain behavior of brain, supratentorial
D43.1	Neoplasm of uncertain behavior of brain, infratentorial
D43.2	Neoplasm of uncertain behavior of brain, unspecified
D43.3	Neoplasm of uncertain behavior of cranial nerves
D43.4	Neoplasm of uncertain behavior of spinal cord
D43.8	Neoplasm of uncertain behavior of other specified parts of central nervous system
D43.9	Neoplasm of uncertain behavior of central nervous system, unspecified
D49.6	Neoplasm of unspecified behavior of brain
G04.1	Tropical spastic paraplegia
G11.4	Hereditary spastic paraplegia
G24.09	Other drug induced dystonia
G24.1	Genetic torsion dystonia
G24.2	Idiopathic nonfamilial dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0	Essential tremor
G35	Multiple sclerosis
G36.0	Neuromyelitis optica [Devic]
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migraine with aura, intractable, without status migrainosus
G51.0	Bell's palsy

ICD-10 Code	Description
G51.1	Geniculate ganglionitis
G51.2	Melkersson's syndrome
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
G51.4	Facial myokymia
G51.8	Other disorders of facial nerve
G51.9	Disorder of facial nerve, unspecified
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.4	Ataxic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G83.4	Cauda equina syndrome
H49.881	Other paralytic strabismus, right eye
H49.882	Other paralytic strabismus, left eye
H49.883	Other paralytic strabismus, bilateral
H49.889	Other paralytic strabismus, unspecified eye
H49.9	Unspecified paralytic strabismus
H50.21	Vertical strabismus, right eye
H50.22	Vertical strabismus, left eye
H50.60	Mechanical strabismus, unspecified
H50.69	Other mechanical strabismus
H50.9	Unspecified strabismus
H50.89	Other specified strabismus
H51.0	Palsy (spasm) of conjugate gaze
I60.10	Nontraumatic subarachnoid hemorrhage from unspecified middle cerebral artery

ICD-10 Code	Description
I60.11	Nontraumatic subarachnoid hemorrhage from right middle cerebral artery
I60.12	Nontraumatic subarachnoid hemorrhage from left middle cerebral artery
I61.0	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical
I61.2	Nontraumatic intracerebral hemorrhage in hemisphere, unspecified
I61.3	Nontraumatic intracerebral hemorrhage in brain stem
I61.4	Nontraumatic intracerebral hemorrhage in cerebellum
I61.5	Nontraumatic intracerebral hemorrhage, intraventricular
I61.6	Nontraumatic intracerebral hemorrhage, multiple localized
I61.8	Other nontraumatic intracerebral hemorrhage
I61.9	Nontraumatic intracerebral hemorrhage, unspecified
I63.00	Cerebral infarction due to thrombosis of unspecified precerebral artery
I63.011	Cerebral infarction due to thrombosis of right vertebral artery
I63.012	Cerebral infarction due to thrombosis of left vertebral artery
I63.013	Cerebral infarction due to thrombosis of bilateral vertebral arteries
I63.019	Cerebral infarction due to thrombosis of unspecified vertebral artery
I63.02	Cerebral infarction due to thrombosis of basilar artery
I63.031	Cerebral infarction due to thrombosis of right carotid artery
I63.032	Cerebral infarction due to thrombosis of left carotid artery
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries
I63.039	Cerebral infarction due to thrombosis of unspecified carotid artery
I63.09	Cerebral infarction due to thrombosis of other precerebral artery
I63.10	Cerebral infarction due to embolism of unspecified precerebral artery
I63.111	Cerebral infarction due to embolism of right vertebral artery
I63.112	Cerebral infarction due to embolism of left vertebral artery
I63.113	Cerebral infarction due to embolism of bilateral vertebral arteries
I63.119	Cerebral infarction due to embolism of unspecified vertebral artery
I63.12	Cerebral infarction due to embolism of basilar artery
I63.131	Cerebral infarction due to embolism of right carotid artery
I63.132	Cerebral infarction due to embolism of left carotid artery
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries
I63.139	Cerebral infarction due to embolism of unspecified carotid artery
I63.19	Cerebral infarction due to embolism of other precerebral artery
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral artery

ICD-10 Code	Description
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral artery
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral artery
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar artery
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid artery
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery
I63.323	Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery
I63.333	Cerebral infarction due to thrombosis of bilateral posterior cerebral arteries
I63.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery
I63.341	Cerebral infarction due to thrombosis of right cerebellar artery
I63.342	Cerebral infarction due to thrombosis of left cerebellar artery
I63.343	Cerebral infarction due to thrombosis of bilateral cerebellar arteries
I63.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery
I63.39	Cerebral infarction due to thrombosis of other cerebral artery
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery
I63.411	Cerebral infarction due to embolism of right middle cerebral artery
I63.412	Cerebral infarction due to embolism of left middle cerebral artery
I63.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries
I63.419	Cerebral infarction due to embolism of unspecified middle cerebral artery
I63.421	Cerebral infarction due to embolism of right anterior cerebral artery
I63.422	Cerebral infarction due to embolism of left anterior cerebral artery
I63.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries

ICD-10 Code	Description
I63.429	Cerebral infarction due to embolism of unspecified anterior cerebral artery
I63.431	Cerebral infarction due to embolism of right posterior cerebral artery
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery
I63.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries
I63.439	Cerebral infarction due to embolism of unspecified posterior cerebral artery
I63.441	Cerebral infarction due to embolism of right cerebellar artery
I63.442	Cerebral infarction due to embolism of left cerebellar artery
I63.443	Cerebral infarction due to embolism of bilateral cerebellar arteries
I63.449	Cerebral infarction due to embolism of unspecified cerebellar artery
I63.49	Cerebral infarction due to embolism of other cerebral artery
I63.50	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.519	Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.529	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior cerebral arteries
I63.539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries
I63.549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I63.6	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery
I63.89	Other cerebral infarction
I63.9	Cerebral infarction, unspecified
J38.5	Laryngeal spasm
K11.7	Disturbances of salivary secretion
K22.0	Achalasia of cardia

ICD-10 Code	Description
K60.1	Chronic anal fissure
L74.510	Primary focal hyperhidrosis, axilla
L74.511	Primary focal hyperhidrosis, face
L74.512	Primary focal hyperhidrosis, palms
L74.513	Primary focal hyperhidrosis, soles
L74.519	Primary focal hyperhidrosis, unspecified
L74.52	Secondary focal hyperhidrosis
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
N36.44	Muscular disorders of urethra
N39.41	Urge incontinence
N39.46	Mixed incontinence
R13.12	Dysphagia, oropharyngeal phase
R49.0	Dysphonia
R49.9	Unspecified voice and resonance disorder
R61	Generalized hyperhidrosis
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue
Z87.820	Personal history of traumatic brain injury

Background

Botulinum toxin or botulinum neurotoxin (BoNT) is a protein neurotoxin produced by *Clostridium botulinum*, the bacterium responsible for botulism. Through the inhibition of neurotransmission between peripheral nerve endings and muscle fibers, BoNT weakens or paralyzes skeletal muscle (Carruthers 2025). The effects of BoNT are transient; muscular function typically returns to baseline within a few months.

There are several Food and Drug Administration (FDA)-approved preparations of BoNT: onabotulinumtoxinA (onaBoNT-A) (Botox, Botox Cosmetic), abobotulinumtoxinA (aboBoNT-A) (Dysport), incobotulinumtoxinA (incoBoNT-A) (Xeomin), daxibotulinumtoxinA-lanm (daxiBoNT-A) (Daxxify), rimabotulinumtoxinB (rimaBoNT-B) (Myobloc), and prabotulinumtoxinA-xvfs (Jeuveau). Cosmetic indications and products only approved for cosmetic use (e.g., Botox Cosmetic, Jeuveau) are outside the scope of this policy. The different products available in the market vary in terms of chemical properties and biological activities; they are not interchangeable (Samizadeh & De Boulle 2018).

The BoNT products are indicated for various conditions including treatment of cervical dystonia (CD), overactive bladder (OAB), primary axillary hyperhidrosis, detrusor overactivity associated with a neurologic condition, spasticity, blepharospasm, strabismus, sialorrhea, and prophylaxis of chronic migraine (see Table 1 for the FDA-approved indications for each product).

Table 1: FDA-approved indications for BoNTs (does not include cosmetic indications)

Indication	Botox (onaBoNT-A)	Daxxify (daxiBoNT-A)	Dysport (aboBoNT-A)	Myobloc (rimaBoNT-B)	Xeomin (incoBoNT-A)
Blepharospasm	✓†				✓
Strabismus	✓†				
Cervical dystonia	✓	✓	✓	✓	✓
Chronic migraine prophylaxis	✓				
Chronic sialorrhea				✓	✓*
Lower limb spasticity	✓*		✓*		
Upper limb spasticity	✓*		✓*		✓*
OAB‡	✓				
Detrusor overactivity associated with a neurologic condition‡	✓‖				
Primary axillary hyperhidrosis§	✓				

*Patients aged ≥ 2 years

†Patients aged ≥ 12 years

‡In patients who have an inadequate response to or are intolerant of an anticholinergic medication

§Inadequately managed with topical agents

‖Patients aged ≥ 5 years

Clinical Evidence

Blepharospasm

BoNT-A has demonstrated efficacy for treatment of blepharospasm.

- A technology assessment of 13 studies (N = 1523) conducted by the American Academy of Ophthalmology (AAO) to evaluate the efficacy of various BoNT preparations in the treatment of benign essential blepharospasm (BEB) and hemifacial spasm (HFS) found Level I evidence supporting the efficacy of onaBoNT-A and incoBoNT-A for the treatment of BEB. Although aboBoNT-A appeared to have efficacy similar to onaBoNT-A for BEB and HFS, any definitive conclusions from the included studies were limited by differences in the methodologies used (Bilyk et al 2018).
- A Cochrane systematic review of 3 double-blind (DB), randomized, placebo-controlled (PC) trials (N = 313) was conducted to evaluate the efficacy and safety of BoNT-A (2 studies with incoBoNT-A, 1 study with aboBoNT-A) vs placebo in patients with blepharospasm. Compared to placebo, BoNT-A resulted in a moderate to large improvement in blepharospasm-specific severity, disability, and involuntary movements. Although BoNT-A did not show a risk of adverse events (AEs), it increased the risk of vision complaints and eyelid ptosis (Duarte et al 2020).

Cervical Dystonia

Data support the use of BoNT-Afor the treatment of CD.

- A DB, randomized, PC trial (ASPEN-1) (N = 301) in adults with CD found that both daxiBoNT-A dose groups (125 U and 250 U) were statistically significantly superior to placebo in terms of change from baseline in the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score over weeks 4 and 6 (Daxxify Prescribing Information 2023).

- A Cochrane systematic review of 3 randomized controlled trials (RCTs) (N = 270) found that single treatment sessions of BoNT-A (specifically onaBoNT-A) and BoNT-B (rimaBoNT-B) were equally effective in the treatment of adults with certain types of CD (Duarte et al 2016).
    - No difference was found between the 2 types of BoNTs in terms of overall efficacy, with a mean difference (MD) of -1.44 (95% confidence interval [CI], -3.58 to 0.70) points lower on the TWSTRS for BoNT-B-treated patients.
    - The most frequently reported AEs were sore throat/dry mouth and dysphagia; treatment with BoNT-B was associated with an increased risk of sore throat/dry mouth in comparison with BoNT-A.

Migraine

Data support the use of BoNT-A for the treatment of prevention of chronic migraine.

- A Cochrane systematic review of 28 DB, RCTs (N = 4190) was conducted to evaluate the effects of BoNT vs placebo or active treatments for the prevention or reduction in frequency of chronic or episodic migraine in adults. The majority of trials evaluated onaBoNT-A, while a few included aboBoNT-A. BoNT-A reduced the number of chronic migraine days per month by 2 days (95% CI, -2.8 to -1.1) compared with placebo, while a single trial of patients with episodic migraine showed no difference between groups for number of migraine days per month (p = 0.49) (Herd et al 2018).

Neurogenic Detrusor Overactivity

OnaBoNT-A has demonstrated efficacy for the treatment of neurogenic detrusor overactivity (NDO) in pediatric and adult patients.

- A DB, randomized trial in 113 pediatric patients aged 5 to 17 years with NDO found that onaBoNT-A resulted in a reduction in urinary incontinence episodes from baseline to week 6 for all dose groups (50 U, 100 U, and 200 U). The 200 U dose demonstrated statistically significant improvements in bladder capacity and maximum detrusor pressure vs the 50 U dose (Austin et al 2021).
- A meta-analysis of 5 DB, PC, RCTs found that compared to placebo, treatment with onaBoNT-A led to significantly fewer urinary incontinence episodes per day at week 2 and per week at week 6, increased maximum cystometric capacity at week 6, and decreased maximum detrusor pressure at week 6 in adult patients with NDO. OnaBoNT-A was often associated with higher rates of AEs such as urinary tract infections (UTIs) compared with placebo (Wu et al 2019).

Overactive bladder

Study data support the efficacy of BoNT vs placebo and other drugs for the treatment of OAB.

- In a Cochrane systematic review of 19 RCTs, all studies demonstrated superiority of intravesical BoNT (BoNT-A and BoNT-B) vs placebo in terms of outcomes such as urinary frequency and incontinence episodes (Duthie et al 2011).
- A systematic review and network meta-analysis of 56 RCTs compared the efficacy of onaBoNT-A, mirabegron, and various anticholinergics (e.g., darifenacin, fesoterodine, oxybutynin, propiverine, solifenacin, tolterodine, and trospium) vs each other or placebo for treatment of patients with idiopathic OAB (Drake et al 2017).
    - All treatments were more effective than placebo in reducing urinary incontinence episodes, urgency episodes, and micturition.
    - MDs favored onaBoNT-A vs all comparators for urinary incontinence episodes and urgency episodes, and all but 2 comparators (solifenacin and oxybutynin controlled-release) for micturition frequency. OnaBoNT-A was also associated with higher odds of achieving a 100% decrease in the number of urinary incontinence episodes/day vs all other treatments as well as a ≥ 50% decrease in urinary incontinence episodes/day vs most other treatments except for darifenacin.

Primary Hyperhidrosis

BoNTs have demonstrated efficacy for treatment of primary hyperhidrosis.

- A systematic review of 50 studies (32 RCTs, 17 non-randomized trials, 1 case series) was conducted to evaluate the efficacy of treatments for the management of primary hyperhidrosis. Most of the 23 BoNT studies used BoNT-A, while 2 used BoNT-B. Although the available evidence was limited overall, meta-analyses showed a large and clinically significant effect of BoNT for axillary hyperhidrosis; benefits were largely sustained at 16 weeks of follow-up. The most common treatment-related AEs were injection-site pain and compensatory sweating (Wade et al 2018).

Sialorrhea

BoNTs have demonstrated efficacy for treatment of sialorrhea.

- A DB, randomized, PC trial evaluated incoBoNT-A (weight-based doses of 20 U to 75 U) in pediatric patients with chronic sialorrhea associated with cerebral palsy, other genetic or congenital disorders, or traumatic brain injury. At week 4, a significant difference between incoBoNT-A and placebo was seen in mean unstimulated salivary flow rate (uSFR) decrease and the carers' Global Impression of Change Scale (GICS) rating, in favor of active treatment (Berweck et al 2021).
- A meta-analysis of 8 PC, RCTs (N = 181) was conducted to evaluate the efficacy of BoNT in the treatment of sialorrhea. Five studies used BoNT-B (rimaBoNT-B) while 3 studies used BoNT-A (onaBoNT-A, aboBoNT-A) (Vashishta et al 2013).
    - Compared with placebo control at 4 weeks, BoNT was found to decrease the severity of drooling in patients with sialorrhea (standardized mean difference [SMD] -1.54; 95% CI, -2.05 to -1.04; p = 0.06; I2 = 48%). Both BoNT-A (SMD -1.53; 95% CI, -2.27 to -0.79) and BoNT-B (SMD -1.56; 95% CI, -2.32 to -0.79) produced similar effects.
- A network meta-analysis of 21 RCTs evaluating the efficacy of various pharmacological interventions (BoNT types A and B, glycopyrrolate, benztropine) for treatment of sialorrhea found that there was a statistically significant reduction in the total drooling scores with benztropine (Cohen's SMD [Cohen's d] -6.04; 95% CI, -8.20 to -3.88), BoNT-A (Cohen's d -1.25; 95% CI, -2.17 to -0.32), and BoNT-B (Cohen's d -1.88; -2.75 to -0.80) compared to placebo; the reduction in drooling score with glycopyrrolate was not statistically significant (Sridharan et al 2018).

Upper and lower limb spasticity

Study data support the efficacy of BoNT for treatment of upper and lower limb spasticity in adult and pediatric patients.

- A systematic review and meta-analysis of 37 RCTs was conducted to evaluate the efficacy of BoNT-A vs placebo or no treatment on spasticity and pain in the upper/lower limb in adults. Moderate-quality evidence for spasticity found significant effects of BoNT in the upper limb (weighted mean difference [WMD] 0.88; 95% CI, 0.63 to 1.14; Z = 6.86, p < 0.00001) and the lower limb (risk ratio [RR] 2.42; 95% CI, 1.60 to 3.65; Z = 4.18; p < 0.0001). However, low- to very low-quality evidence for pain did not find any significant effects of BoNT in the upper or lower limb (Baker & Pereira 2013).
- A Cochrane systematic review of 10 RCTs evaluating the efficacy of BoNT-A (i.e., onaBoNT-A) alone or with occupational therapy for treatment of the upper limb in children with spastic cerebral palsy found that the combination of BoNT-A and occupational therapy was more effective than occupational therapy alone in reducing impairment, improving activity level outcomes and goal achievement, but not for improving quality of life or perceived self-competence. However, there was moderate evidence that BoNT-A alone was not effective compared to placebo or no treatment (Hoare et al 2010).
- A systematic review and Bayesian network meta-analysis of 10 RCTs evaluating the relative efficacy and tolerability of BoNT-A for treatment of lower limb spasticity in children with cerebral palsy found that aboBoNT-A offered efficacy advantages vs onaBoNT-A on tone (Modified Ashworth Scale) and functional outcomes (Goal Attainment Scale) and comparable efficacy on the Tardieu Scale spasticity grade. However, the authors cautioned

that these results should be interpreted in the context of heterogeneity and sparsity of the evidence (Guyot et al 2019).

- A Cochrane systematic review of 31 RCTs (N = 1508) was conducted to evaluate the safety and efficacy of BoNT-A (onaBoNT-A and aboBoNT-A) compared to other treatments (usual care or physiotherapy, placebo/sham, serial casting, orthoses) in the management of lower limb spasticity in children with cerebral palsy (Blumetti et al 2019).
    - Limited evidence found that BoNT-A was more effective than placebo or a non-placebo control at improving gait, joint range of motion, satisfaction, and lower limb spasticity in children with cerebral palsy; however, the results for function were conflicting.
    - BoNT-A was not more effective than ankle serial casting to treat ankle contractures for any of the assessed outcomes, but was more effective than orthotics at improving range of motion and spasticity.
- A Phase 3, DB, randomized, dose-ranging trial (N = 350) evaluated incoBoNT-A in pediatric patients aged 2 to 17 years with unilateral or bilateral spastic cerebral palsy. Patients received weight-based doses of incoBoNT-A 2 U/kg, 6 U/kg, or 8 U/kg per upper limb, with optional lower limb injections. At week 4, all dose groups demonstrated improvement from baseline in Ashworth Scale scores; the 8 U/kg dose demonstrated a statistically significantly greater improvement in the upper limb main clinical target pattern compared with the 2 U/kg dose. Improvements were also observed on investigator, child/adolescent, and parent/caregiver Global Impression of Change Scale ratings, and treatment benefits were sustained over additional treatment cycles in the open-label extension. The incidence of adverse events did not increase with higher dose or repeated treatment (Dabrowski et al 2021).

Strabismus

- A Cochrane systematic review of 4 RCTs evaluating the efficacy of BoNT therapy (onaBoNT-A) for the treatment of strabismus compared with alternative conservative or surgical treatment options found low-certainty evidence that patients treated with surgery may be more likely to improve or correct strabismus compared with those treated with BoNT. There was also low-certainty evidence suggesting BoNT may have little to no effect on achievement of sensory fusion and stereopsis compared with surgery in children with acquired or infantile esotropia. Reported complications with BoNT therapy included partial transient ptosis and transient vertical deviation (Bort-Martí et al 2023).

Clinical Guidelines

- A guideline issued in 2016 (retired April 7, 2025, not yet replaced) by the American Academy of Neurology (AAN), (Simpson et al 2016) considered BoNT therapy as a first-line treatment for blepharospasm and cervical dystonia. It is also a treatment option for spasticity in adults and for chronic migraine prophylaxis. A consensus statement by the American Headache Society (AHS) (Ailani et al 2021) lists onaBoNT-A as an option for prevention of chronic migraine that has established efficacy.
- According to the AAN practice parameter (Delgado et al 2010; reaffirmed by the AAN Guidelines Subcommittee on July 19, 2025), BoNT-A should be offered as an effective and generally safe treatment option for localized/segmental spasticity in the upper and lower extremities of children with cerebral palsy that warrants treatment.
- Several guidelines support the use of BoNT therapy for treatment of axillary hyperhidrosis.
    - The American Academy of Family Physicians (AAFP) (McConaghy & Fosselman 2018) states that topical 20% aluminum chloride should be used first-line for most cases of primary hyperhidrosis regardless of severity and location; onaBoNT-A may be considered first- or second-line for many cases of primary hyperhidrosis involving the axillae, palms, soles, or face.
    - According to the International Hyperhidrosis Society (IHhS) primary axillary hyperhidrosis treatment algorithm (2025) (IHhS Website), first-line treatment options include topical antiperspirant therapy

(aluminum and zirconium salts) or if there is an inadequate response, onaBoNT-A, glycopyrronium cloth, sofpironium gel, TAT patch, or microwave thermolysis should be considered.
    - An evidence-based review of BoNT for treatment of secretory disorders (Naumann et al 2013), which used the AAN classification scale, gave a Level A recommendation for BoNT-A, Level B recommendations for onaBoNT-A and aboBoNT-A individually, and a Level U recommendation (insufficient data) for rimaBoNT-B and incoBoNT-A for the treatment of axillary hyperhidrosis.
- An evidence-based review of BoNT for treatment of secretory disorders (Naumann et al 2013), which used the AAN classification scale, gave Level B recommendations for rimaBoNT-B, onaBoNT-A, and aboBoNT-A, and a Level U recommendation (insufficient data) for incoBoNT-A for treatment of sialorrhea.
    - Note: Since this review was published, incoBoNT-A has been FDA-approved for sialorrhea.
- According to the joint guidelines from the American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) on the treatment of OAB in adults (Cameron et al 2024), options include non-invasive therapies, (e.g., incontinence management strategies such as pads, bladder training, behavioral therapies), pharmacotherapy (with oral anti-muscarinics or β3-adrenoceptor agonists), and minimally invasive therapies (BoNT, tibial nerve stimulation and sacral neuromodulation).
- An evidence-based review of BoNT for treatment of urologic conditions (Chancellor et al 2013), which used the AAN classification scale, gave a Level A recommendation for BoNT-A as well as for both onaBoNT-A and aboBoNT-A in the treatment of NDO; incoBoNT-A and rimaBoNT-B were given a Level U recommendation (insufficient data).
- According to the AAO preferred practice pattern for treatment of adult strabismus (Dagi et al 2023), chemodenervation with BoNT is a nonsurgical treatment option for various conditions including sensory strabismus, abducens palsy (also known as sixth nerve palsy), and oculomotor palsy (also known as third nerve palsy).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

BOTOX (onabotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients 12 years of age and older
- Treatment of strabismus in patients 12 years of age and older

DAXXIFY (botulinum toxin type A injection) is an acetylcholine release inhibitor and neuromuscular-blocking agent indicated for:

- Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients
- The treatment of cervical dystonia in adult patients

DYSPORT (botulinum toxin type A injection) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for:

- The treatment of cervical dystonia in adults
- The temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age
- The treatment of spasticity in patients 2 years of age and older

MYOBLOC (rimabotulinumtoxinB injection) is an acetylcholine release inhibitor indicated for:

- Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults
- Treatment of chronic sialorrhea in adults

XEOMIN (incobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment or improvement of:

- Chronic sialorrhea in patients 2 years of age and older
- Upper limb spasticity in patients 2 years of age and older
- Cervical dystonia in adults
- Blepharospasm in adults
- The appearance of upper facial lines in adults:
    - Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
    - Moderate to severe horizontal forehead lines associated with frontalis muscle activity
    - Moderate to severe lateral canthal lines associated with orbicularis oculi muscle activity

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Policy History/Revision Information

Date	Summary of Changes
9/17/2025	Approved by OptumRx P&T Committee
10/21/2026	Annual Review. Updated Xeomin indication to reflect expanded FDA approval. Updated Clinical Evidence section to include an additional study. Formatting updates and corrections. Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
N/A		

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

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- Qualified sign language interpreters.
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Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

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Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

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Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

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Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

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