

Botulinum Toxins

Botox® (onabotulinumtoxinA)
 Dysport® (abobotulinumtoxinA)
 Myobloc® (rimabotulinumtoxinB)
 Xeomin® (incobotulinumtoxinA)

PAM-001

Iowa Medicaid Program:	Prior Authorization	Effective Date:	07/01/2008
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Overview

For complete list of indications, dosage, and limits, refer to [Appendix A](#).*

Pharmacologic Category	Benefit Category
Neuromuscular blocker agent, toxin	Medical

FDA-Approved Indication	OnabotulinumtoxinA (Botox®) ¹	AbobotulinumtoxinA (Dysport®) ²	RimabotulinumtoxinB (Myobloc®) ³	IncobotulinumtoxinA (Xeomin®) ⁴
Overactive Bladder	Adults, age 18+ years			
Neurogenic detrusor overactivity	Adults, age 18+ years Pediatrics, age 5+ years			
Chronic Migraine	Adults, age 18+ years			
Spasticity, Lower Limb	Adults, age 18+ years Pediatrics, age 2+ years	Adults, age 18+ years Pediatrics, age 2+ years		
Spasticity, Upper Limb	Adults, age 18+ years Pediatrics, age 2+ years	Adults, age 18+ years Pediatrics, age 2+ years		Adults, age 18+ years Pediatrics, age 2+ years
Cervical Dystonia	Adults, age 18+ years	Adults, age 18+ years	Adults, age 18+ years	Adults, age 18+ years
Primary Axillary Hyperhidrosis	Adults, age 18+ years			
Blepharospasm				Adults, age 18+ years
Blepharospasm associated with Dystonia	Adults and Pediatrics, age 12+ years			
Strabismus associated with Dystonia	Adults and Pediatrics, age 12+ years			
Chronic Sialorrhea			Adults, age 18+ years	Adults, age 18+ years Pediatrics, age 2+ years

* NOTE: On September 7, 2022, the FDA approved daxibotulinumtoxinA-lanm (Daxxify™), manufactured by Revance Therapeutics, Inc. (labeler code 72960). This product is not included in the Botulinum Toxins policy as the labeler is not a participant in the Medicaid Drug Rebate Program.

Descriptive Narrative

Botulinum toxins are neurotoxins produced by the bacterium *Clostridium botulinum* and are used to treat various disorders of focal muscle spasm and excessive muscle contractions. There are seven distinct botulinum neurotoxin serotypes (labeled A to G) which cleave specific SNARE* proteins. In the United States, four preparations of botulinum are available, produced by two different strains of bacteria:

- Type A: OnabotulinumtoxinA (Botox[®]), abobotulinumtoxinA (Dysport[®]), and incobotulinumtoxinA (Xeomin[®]).
- Type B: RimabotulinumtoxinB (Myobloc[®]).

The botulinum neurotoxins derived from Type A block neuromuscular transmission via the following activity sequence upon injection:

1. Neurotoxin binds to acceptor sites on motor or autonomic nerve terminals.
2. Neurotoxin enters the nerve terminals and cleaves SNAP25[†], leading to inhibition of the release of acetylcholine from vesicles situated within the nerve endings.
3. Recovery of transmission occurs gradually as the neuromuscular junction recovers from SNAP25 cleavage and as new nerve endings are formed.

The botulinum neurotoxins derived from Type B block cholinergic transmission at the neuromuscular and salivary neuroglandular junction via the following activity sequence:

1. Upon injection, the neurotoxin binds to cholinergic nerve terminals.
2. Neurotoxin enters the nerve terminals and cleaves VAMP[‡], leading to inhibition of the release of acetylcholine from vesicles situated within the nerve endings.
3. In both muscles and glands, impulse transmission is reestablished by the formation of new nerve endings.

Although all are produced by the same strain of bacteria, Botox[®], Dysport[®], and Myobloc[®] are chemically, pharmacologically, and clinically distinct products that are not interchangeable. While the clinical evidence suggests that Botox[®] and Xeomin[®] have similar biologic activity (and studies have shown that they are equipotent), each product's FDA-approved labeling states:

“Units of biological activity cannot be converted into units of any other botulinum toxin or any other toxin assessed with any other specific assay method.”

* **SNARE** proteins (soluble N-ethylmaleimide sensitive factor attachment protein receptor): a complex group of proteins involved in regulation of a fusion of the synaptic vesicle with the plasma membrane.

† **SNAP25** (synaptosome associated protein 25), a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings.

‡ **VAMP** (vesicle-associated membrane protein), a presynaptic target protein essential for the release of acetylcholine.⁵

Guidelines

Overactive bladder (adults): Diagnosis and Treatment of Non-neurogenic Overactive Bladder in Adults: an AUA/SUFU Guideline (2019).⁶

Detrusor overactivity associated with a neurologic condition (adults):

- Neurogenic Lower Urinary Tract Dysfunction: AUA/SUFU Guideline (2021).⁷

Chronic migraine (adult), spasticity (adult), blepharospasm, cervical dystonia:

- Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology (2016).⁸

Criteria

Prior authorization is required. Off-label indications and corresponding dosage regimens (when available) obtained from AHFS Clinical Drug Information.⁹

I. Overactive Bladder In Adults (Botox[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of overactive bladder; **AND**
2. Documentation of symptoms of urinary incontinence, urgency, and frequency; **AND**
3. Member is 18 years of age or older; **AND**
4. Documentation of inadequate clinical response after at least a 30-day trial each of two anticholinergic agents (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine tartrate, trospium), unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
5. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
6. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of overactive bladder; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

2. Detrusor Overactivity in Adults Associated with a Neurological Condition (Botox®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of urinary incontinence and member's history is positive for a causative neurological condition (e.g., multiple sclerosis, spinal cord injury, intracranial lesion, cerebrovascular accident); **AND**
2. Member is 18 years of age or older; **AND**
3. Documentation of inadequate clinical response after at least a 30-day trial each of two anticholinergic agents (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine tartrate, trospium), unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
4. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of detrusor overactivity associated with a neurological condition; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

3. Detrusor Overactivity Associated with a Neurological Condition in Pediatrics (Botox®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of urinary incontinence and member's history is positive for a causative neurological condition (e.g., cerebrovascular accident, dysraphic malformations, intracranial lesion, multiple sclerosis, spinal cord injury); **AND**
2. Member is between 5 and 17 years of age; **AND**
3. Documentation of inadequate clinical response after at least a 30-day trial each of two anticholinergic agents (e.g., oxybutynin, solifenacin, tolterodine), unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
4. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of detrusor overactivity associated with a neurological condition; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology or urology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

4. Chronic Migraine in Adults (Botox[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of chronic migraine; **AND**
2. Documentation (in medical record) that member is experiencing ≥ 15 headache days per month, with headache lasting 4 hours or longer, for more than 3 months (not for treatment of episodic migraines, defined as 14 or fewer headache days per month); **AND**
3. Member is 18 years of age or older; **AND**
4. Documentation of inadequate clinical response after a minimum 8-week trial (**each**) of at least two of the following oral therapies (must trial at least one from each of the two therapeutic classes), or has a contraindication to all of the following:
 - a. Antiepileptics: divalproex, topiramate, or valproate; **AND**
 - b. Beta-blockers: metoprolol, propranolol, or timolol; **AND**
5. Botulinum toxin therapy is not prescribed concurrently with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor (e.g., Aimovig[®], Ajovy[®], Emgality[®], Vyepti[®]); **AND**
6. Prescribed by, or in consultation with, a neurology specialist; **AND**
7. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of chronic migraine; **AND**
3. Documentation of positive clinical response to therapy (i.e., member has achieved or maintained a 30 percent reduction in headaches from baseline); **AND**
4. Prescribed by, or in consultation with, a neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

5. Spasticity – Lower Limb (Botox[®], Dysport[®]) and/or Upper Limb (Botox[®], Dysport[®], Xeomin[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of upper and/or lower limb spasticity; **AND**
2. Documentation that spasticity is associated with either (a or b):
 - a. Paralysis; **OR**
 - b. A central nervous system (CNS)-demyelinating disease such as multiple sclerosis, cerebral palsy, or stroke; **AND**
3. Member is 2 years of age or older; **AND**
4. Prescribed by, or in consultation with, a neurology, orthopedic, or physiatry specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for both upper and lower limb spasticity, or is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of lower and/or upper limb spasticity; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology, orthopedic, or physiatry specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for both upper and lower limb spasms, or is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

6. Cervical Dystonia in Adults (Botox[®], Dysport[®], Myobloc[®], Xeomin[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
2. Member is 16 years of age or older; **AND**
3. Member has sustained head torsion and/or tilt with limited range of motion in neck; **AND**
4. Member is experiencing clonic and/or tonic involuntary contractions of neck and/or shoulder muscles (e.g., sternocleidomastoid, splenius, trapezius, and/or posterior cervical muscles); **AND**
5. Documentation indicates that contractions are causing pain and functional impairment; **AND**
6. Prescribed by, or in consultation with, a neurology, orthopedic, or physiatry specialist; **AND**
7. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of cervical dystonia; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology, orthopedic, or physiatry specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

7. Primary Axillary Hyperhidrosis (Severe) in Adults (Botox®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of primary axillary hyperhidrosis (excessive underarm sweating); **AND**
2. Member is 18 years of age or older; **AND**
3. Documentation that topical aluminum chloride or other extra-strength antiperspirants are ineffective after a minimum 3-month trial, unless clinically significant adverse effects are experienced or therapy is contraindicated; **AND**
4. Documentation of failure after minimum 3-month trial of oral pharmacotherapy prescribed for excessive sweating (e.g., anticholinergic agents, alpha-adrenergic agonists), unless clinically significant adverse effects are experienced or therapy is contraindicated; **AND**
5. Medical records document that condition significantly interferes with activities of daily living **AND** condition is causing chronic skin irritations; **AND**
6. Prescribed by, or in consultation with, a dermatology or neurology specialist; **AND**
7. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of primary axillary hyperhidrosis; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a dermatology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Off-Label: Off-label use of Myobloc for severe axillary hyperhidrosis is supported in compendia (AHFS). May follow above criteria if using Myobloc for this indication, with dose of 2,000 units per axilla, distributed among 25 sites about 2 cm apart.

8a. Blepharospasm in Adults (Xeomin®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of blepharospasm; **AND**
2. Member is 18 years of age or older; **AND**
3. Member is experiencing significant disability in daily functional activities due to interference with vision; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of blepharospasm; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Off-Label: Off-label use of Dysport (DrugDex) and Myobloc (AHFS) for blepharospasm in adult patients is supported in compendia. May follow above criteria if using Dysport or Myobloc for this indication (*with the caveat that Myobloc should only be used in patients who have previously responded to Botox*).

8b. Blepharospasm Associated with Dystonia (12 years of age or older) (Botox®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of blepharospasm; **AND**
2. Member is 12 years of age or older; **AND**
3. Member is experiencing significant disability in daily functional activities due to interference with vision; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of blepharospasm associated with dystonia; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Off-Label: Off-label use of Myobloc (AHFS) or Xeomin (AHFS) for blepharospasm associated with dystonia in patients 12 years of age or older is supported in compendia *for patients who have been previously responded to Botox*. May follow above criteria if using Myobloc or Xeomin for this indication.

9. Strabismus Associated with Dystonia (12 years of age or older) (Botox[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of strabismus; **AND**
2. Member is 12 years of age or older; **AND**
3. Strabismus meets one of the following (a, b, or c):
 - a. Vertical strabismus (superior and inferior rectus muscles, superior and inferior oblique muscles); **OR**
 - b. Horizontal strabismus (medial and lateral rectus muscles):
 - 1) Horizontal strabismus <20 prism diopters; **OR**
 - 2) Horizontal strabismus 20 to 50 prism diopters; **OR**
 - c. Persistent sixth cranial nerve (VI; abducens nerve) palsy of ≥ 1 month involving the lateral rectus muscle; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of strabismus associated with dystonia; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

10. Chronic Sialorrhea in Adults (Myobloc[®], Xeomin[®])

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of chronic sialorrhea for at least the past 3 months due to one of the following:
 - a. Underlying neurologic disorder (e.g., amyotrophic lateral sclerosis, atypical parkinsonism, cerebral palsy, Parkinson disease, stroke, traumatic brain injury); **OR**
 - b. Craniofacial abnormality (e.g., Goldenhar syndrome); **AND**
2. Member is 18 years of age or older; **AND**
3. Documentation of inadequate clinical response after a trial of at least one anticholinergic agent (e.g., benztropine, glycopyrrolate), unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
4. Prescribed by, or in consultation with, a psychiatry or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of chronic sialorrhea; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a psychiatry or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Off-Label: Off-label use of Botox (DrugDex) in adults for excessive salivation in advanced Parkinson's disease is supported in compendia. May follow above criteria if using Botox for this indication.

I I. Chronic Sialorrhea in Pediatrics (Xeomin®)

Botulinum toxin is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of chronic sialorrhea for at least the past 3 months due to one of the following:
 - a. Underlying neurologic disorder (e.g., amyotrophic lateral sclerosis, atypical parkinsonism, cerebral palsy, Parkinson disease, stroke, traumatic brain injury); **OR**
 - b. Craniofacial abnormality (e.g., Goldenhar syndrome); **AND**
2. Member is 2 years of age or older; **AND**
3. Documentation of inadequate clinical response after a trial of at least one anticholinergic agent (e.g., benzotropine, glycopyrrolate), unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
4. Prescribed by, or in consultation with, a psychiatry or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of chronic sialorrhea; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a psychiatry or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed FDA-approved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Criteria (off-label indications)

Prior authorization is required.

A. Chronic Anal Fissure (off-label) (Botox®)

Botulinum toxin is considered medically necessary if **ALL** of the following are met:

1. Diagnosis of chronic anal fissure; **AND**
2. Member is 18 years of age or older; **AND**
3. Documentation of failure after a trial of **EACH** of the following (unless clinically significant adverse effects are experienced or therapy is contraindicated):
 - a. Oral or topical calcium channel blockers (e.g., nifedipine or diltiazem); **AND**
 - b. Topical nitroglycerin ointment; **AND**
4. Prescribed by, or in consultation with, a colorectal or gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy if **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of chronic anal fissure; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a colorectal or gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

B. Esophageal Achalasia (off-label) (Botox[®])

Botulinum toxin is considered medically necessary if **ALL** of the following are met:

1. Diagnosis of esophageal achalasia; **AND**
2. Member is 18 years of age or older; **AND**
3. Member has tried and failed, or is not a candidate for conventional therapy such as pneumatic dilation and surgical myotomy; **AND**
4. Prescribed by, or in consultation with, a gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 80-100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy if **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of esophageal achalasia; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

C. Focal Dystonia and Essential Tremor (off-label) (Botox[®]) (*Myobloc[®] for hemifacial spasm only*)

Botulinum toxin is considered medically necessary if **ALL** of the following are met:

1. Clinical documentation supports **ONE** of the following criteria (a, b, c, d, or e):
 - a. Diagnosis of hemifacial spasm (Botox[®], Myobloc[®]); **AND**
 - 1) Member is 18 years of age or older; **AND**
 - 2) If Myobloc[®] therapy is prescribed, member has previously responded to treatment with onabotulinumtoxinA (Botox[®]); **AND**

- 3) Treatment plan does not exceed 25 units of Botox[®] or 10,000 units of Myobloc[®] per treatment session no sooner than once every 12 weeks; **OR**
- b. Diagnosis of oromandibular dystonia (Botox[®]); **AND**
 - 1) Member is 18 years of age or older; **AND**
 - 2) Medical records document that condition causes persistent pain, interferes with nutritional intake, and/or causes significant speech impairment; **AND**
 - 3) Treatment plan does not exceed 160 units (80 units per side) of Botox[®] per treatment session no sooner than once every 12 weeks; **OR**
- c. Diagnosis of laryngeal dystonia involving the adductor muscles (Botox[®]); **AND**
 - 1) Member is 18 years of age or older; **AND**
 - 2) Medical records document moderate to severe difficulty in the production of speech sounds; **AND**
 - 3) Treatment plan does not exceed 30 units of Botox[®] per treatment session no sooner than once every 12 weeks; **OR**
- d. Diagnosis of upper extremity dystonia (Botox[®]); **AND**
 - 1) Member is 2 years of age or older; **AND**
 - 2) Treatment plan does not exceed 400 units of Botox[®] per treatment session (for adults) or 10 units/kg or 340 units, whichever is lower, for patients 2 to 17 years of age, retreating no sooner than once every 12 weeks; **OR**
- e. Diagnosis of upper extremity essential tremor (Botox[®]); **AND**
 - 1) Member is 18 years of age or older; **AND**
 - 2) Initial dose does not exceed 5-30 units¹⁰ of Botox[®] per muscle (depending on muscle being treated), no sooner than once every 12 weeks; **AND**
2. Prescribed by, or in consultation with, a neurology, orthopedic, physiatry, or ear/nose/throat (ENT) specialist; **AND**
3. Treatment plan details number of units per indication and treatment session. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy if **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of focal dystonia and/or essential tremor; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a neurology, orthopedic, physiatry, or ear/nose/throat (ENT) specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed the dosing limits indicated in the initial authorization criteria. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

D. Hirschsprung Disease, Internal Anal Sphincter Achalasia (off-label) (Botox®)

Botulinum toxin is considered medically necessary if **ALL** of the following are met:

1. Diagnosis of **ONE** of the following:
 - a. Hirschsprung disease with a subtype known as ultra-short segment and Botox® is prescribed for constipation post-surgery; **OR**
 - b. Internal anal sphincter achalasia; **AND**
2. Member is 2 years of age or older; **AND**
3. Documentation of inadequate clinical response after a trial of stool softeners and laxatives, unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
4. Prescribed by, or in consultation with, a colorectal or gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy if **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of Hirschsprung disease, internal anal sphincter achalasia; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a colorectal or gastroenterology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 100 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

E. Primary Palmar Hyperhidrosis (off-label) (Botox®, Myobloc®)

Botulinum toxin is considered medically necessary if **ALL** of the following are met:

1. Diagnosis of primary palmar hyperhidrosis; **AND**
2. Member is 18 years of age or older; **AND**
3. Documentation that topical aluminum chloride or other extra-strength antiperspirants are ineffective after a minimum 3-month trial, unless clinically significant adverse effects are experienced or therapy is contraindicated; **AND**
4. Documentation of failure after minimum 3-month trial of oral pharmacotherapy prescribed for excessive sweating (e.g., anticholinergic agents, alpha-adrenergic agonists), unless clinically significant adverse effects are experienced or therapy is contraindicated; **AND**
5. Medical records document that condition significantly interferes with activities of daily living **AND** condition is causing chronic skin irritations; **AND**
6. Prescribed by, or in consultation with, a dermatology or neurology specialist; **AND**
7. Treatment plan details number of units per indication and treatment session and does not exceed 200 units of Botox® or 18,000 units of Myobloc® per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Botulinum toxin is considered medically necessary for continuation of therapy if **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit and/or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis; **AND**
3. Documentation of positive clinical response to therapy; **AND**
4. Prescribed by, or in consultation with, a dermatology or neurology specialist; **AND**
5. Treatment plan details number of units per indication and treatment session and does not exceed 200 units per treatment session no sooner than once every 12 weeks. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

Non-Covered

Botulinum toxins are considered not medically necessary for members who do not meet the criteria set forth above.

Non-covered indications for the use of botulinum toxins due to being investigational, experimental, or unproven include (but are not limited to):

1. Atypical facial pain; **OR**
2. Carpel tunnel syndrome; **OR**
3. Chronic neck pain; **OR**
4. Headache: tension, chronic daily headache; **OR**
5. Low back pain; **OR**
6. Myofascial pain; **OR**
7. Temporomandibular joint disorders or chronic orofacial pain; **OR**
8. Tourette's syndrome (including tics associate with Tourette's syndrome); **OR**
9. Voiding dysfunction associated with any of the following:
 - a. Benign prostatic hyperplasia; **OR**
 - b. Urge incontinence refractory to anticholinergic therapy; **OR**
10. Paralytic scoliosis; **OR**
11. Diabetic gastroparesis; **OR**
12. Cosmetic conditions.

Approval Duration and Quantity Limits

Approval duration below. For quantity limits, reference dosage and administration in [Appendix A](#).

Diagnosis († indicates off-label)	Approval Duration	
	Initial Authorization	Continuation Therapy
Overactive bladder	24 weeks (2 sessions)	48 weeks (4 sessions)
Neurogenic overactive bladder (including NDO in peds)	24 weeks (2 sessions)	48 weeks (4 sessions)
Chronic migraine	24 weeks (2 sessions)	48 weeks (4 sessions)
Spasticity – lower or upper limb (adults)	24 weeks (2 sessions)	48 weeks (4 sessions)
Spasticity – lower limb (peds)	24 weeks (2 sessions)	48 weeks (4 sessions)

Diagnosis († indicates off-label)	Approval Duration	
	Initial Authorization	Continuation Therapy
Spasticity – upper limb (peds)	24 weeks (2 sessions)	Botox [®] : 48 weeks (4 sessions) Dysport [®] : 48 weeks (3 sessions) Xeomin [®] : 48 weeks (4 sessions)
Cervical dystonia	24 weeks (2 sessions)	48 weeks (4 sessions)
Axillary hyperhidrosis	24 weeks (2 sessions)	48 weeks (4 sessions)
Blepharospasm	24 weeks (2 sessions)	48 weeks (4 sessions)
Strabismus	24 weeks (2 sessions)	48 weeks (4 sessions)
Chronic sialorrhea	24 weeks (2 sessions)	Myobloc [®] : 48 weeks (4 sessions) Xeomin [®] : 48 weeks (3 sessions)
Chronic anal fissure †	24 weeks (2 sessions)	48 weeks (4 sessions)
Esophageal hyperplasia †	24 weeks (2 sessions)	48 weeks (4 sessions)
Palmer hyperhidrosis †	24 weeks (2 sessions)	48 weeks (4 sessions)
Focal dystonia and essential tremor †	24 weeks (2 sessions)	48 weeks (4 sessions)

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description	Proprietary Name
J0585	Injection, onabotulinumtoxinA, 1 unit	Botox [®]
J0586	Injection, abobotulinumtoxinA, 5 units	Dysport [®]
J0587	Injection, rimabotulinumtoxinB, 100 units	Myobloc [®]
J0588	Injection, incobotulinumtoxinA, 1 unit	Xeomin [®]

ICD-10	Description
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G35	Multiple sclerosis
G43.001-G43.919	Migraine
G51.31-G51.39	Clonic hemifacial spasm
G80.0-G80.9	Cerebral palsy
G81.10-G81.14	Spastic hemiplegia
H49.00-H49.9	Paralytic strabismus
H50.00-H50.9	Other strabismus
J38.5	Laryngeal spasm
K11.7	Disturbances of salivary secretion
K22.0	Achalasia of cardia
K60.1	Chronic anal fissure
L74.510	Primary focal hyperhidrosis, axilla
L74.512	Primary focal hyperhidrosis, palms
N31.0-N31.9	Neuromuscular dysfunction of bladder
N32.81	Overactive bladder
N39.3	Stress incontinence
N39.41-N39.498	Other specified urinary incontinence
Q43.1	Hirschsprung's disease
R25.1	Tremor, unspecified
R32	Unspecified urinary incontinence
R49.8-R49.9	Other and unspecified voice and resonance disorders

Appendix A: Product-specific indications, dosing, categories, and packaging

Botox® (onabotulinumtoxinA)

HCPCS: J0585

- J0585: Injection, onabotulinumtoxinA, 1 unit
- Labeler: Allergan USA, Inc. (00023)

Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Botox 100 units (powder, SDV)	00023-1145-01	1 unit	1	EA	100
Botox 200 units (powder, SDV)	00023-3921-02	1 unit	1	EA	200

Botox® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

1) *Overactive Bladder (18 years of age and older)*

- a. 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.

Overactive Bladder – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 100 units total per treatment, injected across 20 sites into the detrusor.
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Retreat no sooner than every 12 weeks (3 months).

2) *Detrusor Overactivity associated with a Neurological Condition (18 years of age and older)*

- a. Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Detrusor Overactivity associated with neurological condition – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 200 units total per treatment, injected across 30 sites into the detrusor.
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Retreat no sooner than every 12 weeks (3 months).

3) *Pediatric Detrusor Overactivity associated with a Neurological Condition (5 years of age and older)*

- a. 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.

Detrusor Overactivity associated with neurological condition – Pediatrics (5 years of age & older) – Dose, Limits, & Frequency

- Injections across 20 sites into the detrusor. Total dose per treatment is based on patient weight (less than 34 kg: 6 units/kg | 34 kg or greater: 200 units)
- Maximum cumulative dose for all indications in a 3-month period: 10 units/kg or 340 units, whichever is **lower**.
- Retreat no sooner than every 12 weeks (3 months).

4) *Chronic Migraine (18 years of age and older)*

- a. Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting ≥ 4 hours a day).
- b. Limitations of Use: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.

Chronic Migraine – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 155 units total per treatment (5-unit injections per site, divided across 7 head/neck muscles).
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Retreat no sooner than every 12 weeks (3 months).

5) *Spasticity (2 years of age and older)*

- a. Treatment of spasticity in patients 2 years of age and older.
- b. Limitations of Use: Botox® has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

Spasticity – Pediatrics (2 years to less than 18 years of age) – Dose, Limits, & Frequency

- Upper limb: 3 – 6 units/kg, divided among affected muscles, or 300 units, whichever is **lower**.
- Lower limb: 4 – 8 units/kg, divided among affected muscles, or 200 units, whichever is **lower**.
- Maximum cumulative dose, all indications (3-mos. period): 10 units/kg or 340 units, whichever is **lower**.
- Retreat no sooner than every 12 weeks (3 months).

Spasticity – Adults (18 years of age and older) – Dose, Limits, & Frequency

- Upper limb: 75 to 400 units, divided among the selected muscles.
- Lower limb: 300 to 400 units, divided among 5 muscles.
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Retreat no sooner than every 12 weeks (3 months).

6) Cervical Dystonia (18 years of age and older)

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

Cervical Dystonia – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 198 to 300 units, divided among affected muscles.
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Retreat no sooner than every 12 weeks (3 months).

7) Primary Axillary Hyperhidrosis (18 years of age and older)

- a. Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
- b. Limitations of Use: The safety and effectiveness of Botox® for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox® for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease.
- c. Safety and effectiveness of Botox® have not been established for the treatment of axillary hyperhidrosis in patients under age 18.

Primary Axillary Hyperhidrosis – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 50 units per axilla.
- Maximum cumulative dose for all indications is 400 units in a 3-month period.
- Repeat injections for hyperhidrosis should be administered when the clinical effect of the previous injection diminishes, but no sooner than every 12 weeks (3 months).

8) Blepharospasm associated with dystonia (12 years of age and older)

- a. Treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.

Blepharospasm associated with dystonia – 12 years of age and older – Dose, Limits, & Frequency

- 1.25 to 2.5 units into each of 3 sites per affected eye.
- Cumulative dose for blepharospasm in a 30-day period not to exceed 200 units.
- Maximum cumulative dose for all indications in a 3-month period:
 - Ages 18 years and over: 400 units.
 - Ages 12 to 17 years of age: 10 units/kg or 340 units, whichever is **lower**.
- Retreat no sooner than every 12 weeks (3 months). At repeat treatment sessions, the dose may be increased up to two-fold if response from the initial treatment is insufficient.

9) Strabismus associated with dystonia (12 years of age and older)

- a. Treatment of strabismus and associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.

Strabismus associated with dystonia – 12 years of age and older – Dose, Limits, & Frequency

- Initial doses (use lower dose small deviations and use larger dose only for large deviations):
 - For vertical muscles and for horizontal strabismus of less than 20 prism diopters: 1.25 – 2.5 units in any one muscle.
 - For horizontal strabismus of 20 to 50 prism diopters: 2.5 – 5 units in any one muscle.
 - For persistent VI nerve palsy ≥ 1 month duration: 1.25 – 2.5 units in the medial rectus muscle.
- Subsequent doses for residual or recurrent strabismus:
 - Patient should be re-examined 7-14 days after each injection to assess the effect of that dose.
 - Patients experiencing adequate paralysis of the target muscle that require subsequent injections should receive a dose comparable to the initial dose.
 - Subsequent doses for patients experiencing incomplete paralysis of the target muscle may be increased up to two-fold compared to the previously administered dose.
 - Subsequent injections should not be administered until the effects of the previous dose have dissipated, and no sooner than every 12 weeks (3 months).
- Maximum dose (single injection for any one muscle): 25 units.
- Maximum cumulative dose for all indications in a 3-month period:
 - Adults: 400 units.
 - Ages 12-17: 10 units/kg or 340 units, whichever is **lower**.

Dysport® (abobotulinumtoxinA)**HCPCS: J0586**

- J0586: Injection, abobotulinumtoxinA, 5 units
- Labeler: Ipsen Biopharmaceuticals, Inc. (15054)

Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Dysport 500 units (freeze-dried; 1 SDV)	15054-0500-01	5 units	1	EA	100
Dysport 500 units (freeze-dried; 2 SDV)	15054-0500-02	5 units	1	EA	200
Dysport 300 units (freeze-dried; 1 SDV)	15054-0530-06	5 units	1	EA	60

Dysport® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- 1) *Cervical dystonia (18 years of age and older)*
 - a. Treatment of cervical dystonia in adults.

Cervical Dystonia – Adults (18 years of age and older) – Dose, Limits, & Frequency

- Initial dose: 500 units divided among affected muscles.
- Maximum dose of 1,000 units per treatment session.
- Retreat no sooner than every 12 weeks (3 months).

- 2) *Glabellar lines [cosmetic – not a covered indication; including for informational purposes only]*
 - a. Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults less than 65 years of age.
- 3) *Spasticity (2 years of age and older)*
 - a. Treatment of spasticity in patients 2 years of age and older.

Pediatrics (2 years to less than 18 years of age) – Dose, Limits, & Frequency

- Upper limb: 8 – 16 units/kg per limb. Maximum dose per treatment session is 16 units/kg or 640 units, whichever is **lower**.
- Lower limb: 10 – 15 units/kg per limb. Maximum dose per treatment session:
 - for unilateral limb injections = 15 units/kg or 1,000 units, whichever is **lower**;
 - for bilateral limb injections = 30 units/kg or 1,000 units, whichever is **lower**.
- Maximum total dose in a single treatment session for spasticity is 30 units/kg or 1,000 units, whichever is **lower**.
- Retreat no sooner than every 12 weeks (3 months).

Adults (18 years of age and older) – Dose, Limits, & Frequency

- Upper limb: 500 to 1,000 units
- Lower limb: 1,000 to 1,500 units
- Maximum total dose per treatment session is 1,500 units.
- Retreat no sooner than every 12 weeks (3 months).

Myobloc® (rimabotulinumtoxinB)**HCPCS: J0587**

- J0587: Injection, rimabotulinumtoxinB, 100 units
- Labeler: Solstice Neurosciences, LLC (10454)

Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Myobloc 2,500 units/0.5 mL (SDV)	10454-0710-10	100 units	1	EA	25
Myobloc 5,000 units/mL (SDV)	10454-0711-10	100 units	1	EA	50
Myobloc 10,000 units/2 mL (SDV)	10454-0712-10	100 units	1	EA	200

Myobloc® is an acetylcholine release inhibitor indicated for:

- 1) *Cervical Dystonia (18 years of age and older)*
 - a. Treatment to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.

Cervical Dystonia – Adults (18 years of age and older) – Dose, Limits, & Frequency

- Initial dosage (for patients with a prior history of tolerating botulinum toxins): 2,500 to 5,000 units divided among affected muscles.
- Patients without a prior history should receive a lower initial dosage.
- Maintenance: 5,000 to 10,000 units every 12 to 16 weeks.

- 2) *Chronic Sialorrhea (18 years of age and older)*
 - a. Treatment of chronic sialorrhea in adults.

Chronic Sialorrhea – Adults (18 years of age and older) – Dose, Limits, & Frequency

- 1,500 to 3,500 units, divided among the parotid and submandibular glands.
 - Parotid: 500 – 1,500 units per gland. Submandibular: 250 units per gland.
- Retreat no sooner than every 12 weeks.

Xeomin® (incobotulinumtoxinA)**HCPCS: J0588**

- J0588: Injection, incobotulinumtoxinA, 1 unit
- Labeler: Merz Pharmaceuticals, LLC (00259)

Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Xeomin 50 units (SDV)	00259-1605-01	1 unit	1	EA	50
Xeomin 100 units (SDV)	00259-1610-01	1 unit	1	EA	100
Xeomin 200 units (SDV)	00259-1620-01	1 unit	1	EA	200

Xeomin® is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment or improvement of:

1) *Chronic Sialorrhea (2 years of age and older)*

- a. Treatment of chronic sialorrhea in patients 2 years of age and older.

Chronic Sialorrhea – Pediatrics (2 years to less than 18 years of age) – Dose, Limits, & Frequency			
<ul style="list-style-type: none"> • Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per treatment session). • Dosing is weight-based and is divided with a ratio of 3:2 between the parotid and submandibular glands. 			
Body Weight*	Parotid gland (dose per side)	Submandibular gland (dose per side)	Total dose (both glands, both sides)
≥ 12 kg to < 15 kg	6 units	4 units	20 units
≥ 15 kg to < 19 kg	9 units	6 units	30 units
≥ 19 kg to < 23 kg	12 units	8 units	40 units
≥ 23 kg to < 27 kg	15 units	10 units	50 units
≥ 27 kg to < 30 kg	18 units	12 units	60 units
30 kg or more	22.5 units	15 units	75 units

* Xeomin has not been studied in children weighing less than 12 kg.

Chronic Sialorrhea – Adults (18 years of age and older) – Dose, Limits, & Frequency		
<ul style="list-style-type: none"> • Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per treatment session). • Total dose per treatment session of 100 units, divided with a ratio of 3:2 between the parotid and submandibular glands. 		
Parotid gland	Submandibular gland	Total for both glands
30 units per side; 60 units total	20 units per side; 40 units total	100 units total

2) *Upper Limb Spasticity (2 years of age and older)*

- a. Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
b. Treatment of upper limb spasticity in adult patients.

Upper Limb Spasticity – Pediatrics (2 years to less than 18 years of age) – Dose, Limits, & Frequency
<ul style="list-style-type: none"> • Excludes upper limb spasticity caused by cerebral palsy. • Divide among affected muscles: <ul style="list-style-type: none"> ○ 8 units/kg (up to a maximum of 200 units) per single upper limb. ○ 16 units/kg (up to a maximum of 400 units) in both upper limbs. • Retreat no sooner than every 12 weeks (3 months).

Upper Limb Spasticity – Adults (18 years of age and older) – Dose, Limits, & Frequency
<ul style="list-style-type: none"> • Dose varies depending on muscle being treated (range is 5 to 100 units per muscle). • Maximum total dose per treatment session is 400 units, divided among affected muscles. • Retreat no sooner than every 12 weeks (3 months).

3) *Cervical Dystonia (18 years of age and older)*

- a. Treatment of cervical dystonia in adults.

Cervical Dystonia – Adults (18 years of age and older) – Dose, Limits, & Frequency
<ul style="list-style-type: none"> • Initial dose: 120 units, divided among affected muscles. • Maximum dose of 400 units per treatment session. • Retreat no sooner than every 12 weeks (3 months).

4) *Blepharospasm (18 years of age and older)*

- a. Treatment of blepharospasm in adult patients.

Blepharospasm – Adults (18 years of age and older) – Dose, Limits, & Frequency
<ul style="list-style-type: none"> • Initial dose: 50 units (25 units per eye). • Maximum 100 units per treatment session (50 units per eye). • Retreat no sooner than every 12 weeks (3 months).

5) *Glabella Lines [cosmetic – not a covered indication; including for informational purposes only]*

- a. Temporary improvement in the appearance of moderate to severe glabella lines associated with procerus and corrugator muscle activity in adult patients.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

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⁴ Xeomin prescribing information (09/2023). Merz Pharmaceuticals, LLC: Raleigh, NC. Available online at www.xeomin.com/healthcare-professionals. Accessed February 8, 2024.

⁵ Tambasco N, Filidei M, Nigro P, Parnetti L, Simoni S. Botulinum Toxin for the Treatment of Hemifacial Spasm: An Update on Clinical Studies. *Toxins* (Basel). 2021 Dec 9;13(12):881. doi: [10.3390/toxins13120881](https://doi.org/10.3390/toxins13120881). PMID: 34941718; PMCID: PMC8706367.

⁶ Lightner DJ, Gomelsky A, Souter L et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. *J Urol* 2019; 202: 558.

Gormley EA, Lightner DJ, Burgio KL et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. *J Urol* 2012; 188: 2455.

Available online at [www.auanet.org/guidelines/guidelines/overactive-bladder-\(oab\)-guideline](http://www.auanet.org/guidelines/guidelines/overactive-bladder-(oab)-guideline).

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Ginsberg DA, Boone TB, Cameron AP et al: The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up. J Urol 2021; 206: 1106.



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⁸ Simpson DM, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26. Epub 2016 Apr 18. PMID: 27164716.

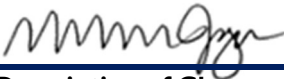
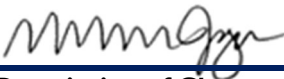


⁹ Off-label indications and corresponding dosage regimens (when available) obtained from: AHFS Clinical Drug Information. Bethesda, MD: American Society of Health-System Pharmacists, Inc. www.ahfscdi.com. Accessed February 27, 2024.

¹⁰ Kamel JT, Cordivari C, Catania S. Treatment of Upper Limb Tremor With Botulinum Toxin: An Individualized Approach. Mov Disord Clin Pract. 2019 Sep 9;6(8):652-655. PMID: 31745472.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History			
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]			
Signature			
Change Date	Changed By	Description of Change	Version
04/19/2024	CAC	Annual review. Added note to Overview section: "NOTE: On September 7, 2022, the FDA approved daxibotulinumtoxinA-lanm (Daxxify™), manufactured by Revance Therapeutics, Inc. (labeler code 72960). This product is not included in the Botulinum Toxins policy as the labeler is not a participant in the Medicaid Drug Rebate Program." Updated references.	13
Signature			
William (Bill) Jagiello, DO			
Change Date	Changed By	Description of Change	Version
04/21/2023	CAC	New template. Moved detailed list of indications, dosing, and quantity limitations to Appendix A. Updated Dysport dosing recommendations for pediatric spasticity to include maximum dose per treatment session.	12
Signature			
William (Bill) Jagiello, DO			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
04/15/2022	CAC	Annual review. Rewrite.	11
Signature			
William (Bill) Jagiello, DO			
Change Date	Changed By	Description of Change	Version
01/15/2021	CAC	Annual review.	10
Signature			
William (Bill) Jagiello, DO			
Change Date	Changed By	Description of Change	Version
03/13/2018	CAC	Added narrative under Description regarding Botox® and Xeomin® being equipotent and having similar biologic activity.	9
Signature			
C. David Smith, MD		William (Bill) Jagiello, DO	
Change Date	Changed By	Description of Change	Version
05/01/2017	Policy	Formatting changes.	8
Signature			
Change Date	Changed By	Description of Change	Version
01/20/2017	CAC	Criterion #1n removed over activity “associated with a neurologic condition such as spinal cord injury, multiple sclerosis” and added “or well-documented overactive bladder”.	7
Signature			
Change Date	Changed By	Description of Change	Version
01/15/2015	CAC	Removed criterion #1q as was duplicate of #1n. Under non-covered removed “wrinkles” and included in “cosmetic conditions”.	6
Signature			
Change Date	Changed By	Description of Change	Version
01/16/2015	CAC	Added paragraph in References.	5
Signature			
Change Date	Changed By	Description of Change	Version
01/30/2014	Medical Director	HCPCS Codes Added	4
Signature			
Change Date	Changed By	Description of Change	Version
01/17/2014	CAC	Criterion #1”o” - remove > 15 days per month with headache lasting four hours a day or longer.	3
Signature			
Change Date	Changed By	Description of Change	Version
01/30/2014	Medical Director	Clarification and addition of information on incobotulinumtoxinA.	2
Signature			
Change Date	Changed By	Description of Change	Version
11/02/2010	Medical Director	New FDA criteria.	1
Signature			

CAC = Medicaid Clinical Advisory Committee