IOWA Health and Human Services

Botulinum Toxins

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

PAM – 001

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2008
Revision Number	14	**Last Reviewed**	04/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	04/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	03/12/2020

Overview

For a complete list of indications, dosage, and limits, refer to Appendix A.

Pharmacologic Category	Benefit Category
Neuromuscular blocker agent, toxin	Medical

FDA-Approved Indications [Ages Expressed in **Years** – Adults (18+), Pediatrics (as indicated)]					
FDA-Approved Indication	Botox® [1] (OnaA)	Daxxify® [2] (DaxiA)	Dysport® [3] (AboA)	Myobloc® [4] (RimaB)	Xeomin® [5] (IncoA)
Overactive Bladder	Adults (18+)				
Neurogenic detrusor overactivity	Adults (18+) Peds (5+)				
Chronic Migraine	Adults (18+)				
Spasticity, Lower Limb	Adults (18+) Peds (2+)		Adults (18+) Peds (2+)		
Spasticity, Upper Limb	Adults (18+) Peds (2+)		Adults (18+) Peds (2+)		Adults (18+) Peds (2+)
Cervical Dystonia	Adults (18+)	Adults (18+)	Adults (18+)	Adults (18+)	Adults (18+)
Primary Axillary Hyperhidrosis	Adults (18+)				
Blepharospasm					Adults (18+)
Blepharospasm associated with Dystonia	Adults (18+) Peds (12+)				
Strabismus associated with Dystonia	Adults (18+) Peds (12+)				
Chronic Sialorrhea				Adults (18+)	Adults (18+) Peds (2+)

- OnaA: onabotulinumtoxinA [Botox®]
- AboA: abobotulinumtoxinA [Dysport®]
- IncoA: incobotulinumtoxinA [Xeomin®]
- DaxiA: daxibotulinumtoxinA-lanm [Daxxify®]
- RimaB: rimabotulinumtoxinB [Myobloc®]

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, five preparations of botulinum are available, produced by two different strains of bacteria:

- Type A: OnabotulinumtoxinA (Botox®), daxibotulinumtoxinA-lanm (Daxxify®), 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 (Ach) 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.

Those 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 ACh 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®, Daxxify®, 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.[6]

Guidelines

The American Urological Association/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (AUA/SUFU) Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder (2024).[7]

Detrusor overactivity associated with a neurologic condition (adults): Neurogenic Lower Urinary Tract Dysfunction: AUA/SUFU Guidelines (2021).[8]

Practice guideline update summary: Botulinum neurotoxin (BoNT) for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology (2016). Reaffirmed on April 30, 2022.[9]

American Headache Society position statement update on use of CGRP therapies for migraine prevention (referenced list of first-line oral agents for prevention of chronic migraine).[10]

Criteria

Prior authorization is required. Off-label indications and corresponding dosage regimens (when available) obtained from American Hospital Formulary Service Clinical Drug Information (AHFS-CDI).[11]

1. 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 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 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.

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

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 or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of detrusor overactivity associated with a neurological condition; **AND**
3. Member is between 5 and 17 years of age*; **AND**
4. Documentation of positive clinical response to therapy; **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.

* If member is 18 years of age or older, refer to continuation criteria for "Detrusor Overactivity Associated with a Neurological Condition in Adults."

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 or more 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. The member has tried and failed at least two of the following oral migraine preventative therapies, each for at least 8 weeks and from different therapeutic classes *(unless clinically significant adverse effects are experienced or all are contraindicated)*:
    a. Antiepileptic (e.g., divalproex sodium, topiramate, valproate); **AND/OR**
    b. Beta-blocker (e.g., metoprolol, propranolol, timolol); **AND/OR**
    c. Candesartan; **AND/OR**
    d. Tricyclic antidepressant (e.g., amitriptyline, nortriptyline); **AND/OR**
    e. Serotonin-norepinephrine reuptake inhibitor (e.g., venlafaxine, duloxetine); **AND**
5. Botulinum toxin therapy is not prescribed concurrently with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec ODT®, Qulipta®, Vyepti®, Zavzpret®, etc.); **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 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 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.

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 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 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 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.

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6. Cervical Dystonia in Adults (Botox®, Daxxify®, 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 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 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.

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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 or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of primary axillary hyperhidrosis (excessive underarm sweating); **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 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.

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.

8. 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 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 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.

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®*).

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9. Blepharospasm Associated with Dystonia (12+ years of age) (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 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 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.

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.

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10. Strabismus Associated with Dystonia (12+ years of age) (Botox®)

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

1. Diagnosis of strabismus associated with dystonia; **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):
        i. Horizontal strabismus less than 20 prism diopters; **OR**
        ii. Horizontal strabismus 20 to 50 prism diopters; **OR**
    c. Persistent sixth cranial nerve (VI; abducens nerve) palsy lasting one month or longer and 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 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 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.

11. 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 or b):
    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 physiatry 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 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 physiatry 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.

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.

12. 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 or b):
    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 between 2 and 17 years of age; **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 physiatry 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 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. Member is between 2 and 17 years of age*; **AND**
5. Prescribed by, or in consultation with, a physiatry or neurology 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.

* If member is 18 years of age or older, refer to continuation criteria for “Chronic Sialorrhea in Adults.”

Criteria (off-label indications)

Prior authorization is required.

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

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

1. Member is currently receiving medication through the Iowa Medicaid benefit 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 when **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 when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit 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 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.

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

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

1. Clinical documentation supports **ONE** of the following (a, b, c, d, or e):
    a. Diagnosis of hemifacial spasm (Botox®, Myobloc®); **AND**
        i. Member is 18 years of age or older; **AND**
        ii. If Myobloc ® therapy is prescribed, member has previously responded to treatment with onabotulinumtoxinA (Botox®); **AND**
        iii. 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**
        i. Member is 18 years of age or older; **AND**
        ii. Medical records document that condition causes persistent pain, interferes with nutritional intake, and/or causes significant speech impairment; **AND**
        iii. 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**
        i. Member is 18 years of age or older; **AND**
        ii. Medical records document moderate to severe difficulty in the production of speech sounds; **AND**
        iii. 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**
        i. Member is 2 years of age or older; **AND**
        ii. 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**
        i. Member is 18 years of age or older; **AND**
        ii. Initial dose does not exceed 5-30 units of Botox® per muscle (depending on muscle being treated), no sooner than once every 12 weeks;[12] **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 when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit 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 when **ALL** of the following are met:

1. Diagnosis of **ONE** of the following (a or b):
    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 when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of Hirschsprung disease or 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 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.

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

Botulinum toxin is considered medically necessary when **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 a 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 240 units of Botox® (120 units per palm) or 18,000 units of Myobloc® (9,000 units per palm) 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 when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Current clinical documentation supports diagnosis of primary palmar 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 240 units of Botox® (120 units per palm) or 18,000 units of Myobloc® (9,000 units per palm) 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.

* Injection of botulinum toxin into the palm may cause a decrease in muscle strength in the hand, thumb, and/or fingers, and so some providers treat the palms sequentially (e.g., 3 weeks apart) rather than simultaneously. If this regimen is followed, dose should not exceed 120 units of Botox® or 9,000 units of Myobloc® every 12 weeks per palm.

Non-Covered

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

Coverage is not provided for non-FDA approved indications which are not addressed in this document, unless there is sufficient documentation of efficacy and safety (supporting clinical documentation must be provided with request).

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)
Spasticity – upper limb (peds)	24 weeks (2 sessions)	OnaA: 48 weeks (4 sessions) AboA: 48 weeks (3 sessions) IncoA: 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)

Diagnosis († indicates off-label)	Approval Duration	
	Initial Authorization	Continuation Therapy
Chronic sialorrhea	24 weeks (2 sessions)	RimaB: 48 weeks (4 sessions) IncoA: 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)
Palmar hyperhidrosis †	24 weeks (2 sessions)	48 weeks (4 sessions)
Focal dystonia and essential tremor †	24 weeks (2 sessions)	48 weeks (4 sessions)

- **OnaA:** onabotulinumtoxinA [Botox®]
- **AboA:** abobotulinumtoxinA [Dysport®]
- **IncoA:** incobotulinumtoxinA [Xeomin®]
- **DaxiA:** daxibotulinumtoxinA-lanm [Daxxify®]
- **RimaB:** rimabotulinumtoxinB [Myobloc®]

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®
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	Daxxify®

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. (an AbbVie company) (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 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.

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.

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**

WARNING: DISTANT SPREAD OF TOXIN EFFECT
Postmarketing reports indicate that the effects of BOTOX and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

Daxxify (daxibotulinumtoxinA-lanm) HCPCS: J0589

- J0589: Injection, daxibotulinumtoxina-lanm, 1 unit
- Labeler: Revance Therapeutics, Inc. (72960)

Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Daxxify 50 units (powder, SDV)	72960-0111-01	1 unit	1	EA	50
Daxxify 100 units (powder, SDV)	72960-0112-01	1 unit	1	EA	100

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

1) Treatment of cervical dystonia in adult patients.

Cervical dystonia – Adults (18 years of age and older) – Dose, Limits, & Frequency
- 125 to 250 units given intramuscularly as a divided dose among affected muscles
- Retreat no sooner than every 12 weeks (3 months)

WARNING: DISTANT SPREAD OF TOXIN EFFECT

The effects of all botulinum toxin products, including DAXXIFY, may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, an unapproved use for DAXXIFY, but symptoms can also occur in adults, particularly in those patients who have an underlying condition that would predispose them to these symptoms.

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 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) Spasticity (2 years of age and older)
a. Treatment of spasticity in patients 2 years of age and older.

Spasticity (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 1,500 units
- Retreat no sooner than every 12 weeks (3 months)

Spasticity (Adults – 18 years of age and older) – Dose, Limits, & Frequency
- Upper limb: 500 – 1,000 units divided among selected muscles
- Lower limb: 1,000 to 1,500 units divided among selected muscles
- Maximum total dose in a single treatment session for spasticity is 30 units/kg or 1,000 units,
- Repeat treatment should be administered when the effect of a previous injection has diminished, but no sooner than every 12 weeks (3 months)

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of DYSPORT and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

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® 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.

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

- Initial dose (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 dose: 5,000 to 10,000 units per treatment session
- Retreat no sooner than every 12 – 16 weeks (3 – 4 months)

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 (3 months)

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of MYOBLOC and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

Xeomin (incobotulinumtoxinA) HCPCS: J0588

- HCPCS: description 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 a neuromuscular blocking agent indicated for:

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

- Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per session)
- Dosing is weight-based; 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

- Retreat no sooner than every 16 weeks (4 months)

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

- Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per 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 total units	20 units per side	40 total units	100 units total

- Retreat no sooner than every 16 weeks (4 months)

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

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 adults patients.

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

- Excludes upper limb spasticity caused by cerebral palsy
- Divide among affected muscles:
  - 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

- 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

- 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

- Initial dose: 50 units (25 units per eye)
- Maximum dose of 100 units per treatment session (50 units per eye)
- Retreat no sooner than every 12 weeks (3 months)

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including lower limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Compliance

1. Should conflict exist between the 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] Myobloc® prescribing information (03/2021). Solstice Neurosciences, LLC: Rockville, MD. Available online: www.myoblochcp.com. Accessed February 24, 2025.

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[6] Choudhury S, Baker MR, Chatterjee S, Kumar H. Botulinum Toxin: An Update on Pharmacology and Newer Products in Development. Toxins (Basel). 2021 Jan 14;13(1):58. doi: 10.3390/toxins13010058. PMID: 33466571; PMCID: PMC7828686.

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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.
Available online at www.auanet.org/guidelines/guidelines/adult-neurogenic-lower-urinary-tract-dysfunction.

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American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26. Epub 2016 Apr 18. PMID: 27164716. Reaffirmed on April 30, 2022.

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

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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.

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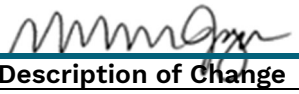
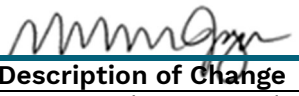
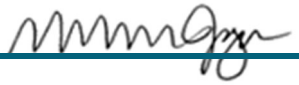
Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
[mm/dd/yyyy]	CAC		
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
04/18/2025	CAC	Annual review. DaxibotulinumtoxinA-lanm (Daxxify®) now eligible for rebate under the Medicaid Drug Rebate Program; added to Overview table, Descriptive Narrative, Cervical Dystonia criteria, and Appendix A. Updated AUA/SUFU Guidelines for overactive bladder (2024). Chronic migraine criteria: added additional first-line oral therapy options (candesartan, amitriptyline, nortriptyline, venlafaxine, and duloxetine) to align with recommendations for migraine prevention from the American Headache Society (AHS, 2024). Added Nurtec ODT®, Qulipta®, and Zavzpret® to list of prophylactic CGRP inhibitors. Primary palmar hyperhidrosis: updated Botox® dose from 200 to 240 units per session (120 units per palm). Added optional alternative dosing schedules for indication. Non-Covered Conditions section: added statement "Coverage is not provided for non-FDA approved indications which are not addressed in this document, unless there is sufficient documentation of efficacy and safety (supporting clinical documentation must be provided with request)." Appendix A: removed information on non-covered indication for glabellar lines (Dysport, Xeomin). Added boxed warnings regarding distant spread of toxin effect. Updated references.	14
Signature William (Bill) Jagiello, DO			
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 overactivity "associated with a neurologic condition such as spinal cord injury, multiple sclerosis" & 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"; 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