

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
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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 <u>Appendix A</u>.

Pharmacologic Category	Benefit Category
Neuromuscular blocker agent, toxin	Medical

FDA-Approved Indic	ations [Ages Ex	xpressed in Yea r	s – Adults (18+)	, Pediatrics (as i	ndicated)]
FDA-Approved Indication	Botox ^{® 1} (OnaA)	Daxxify ^{® 2} (DaxiA)	Dysport ^{® 3} (AboA)	Myobloc ^{® 4} (RimaB)	Xeomin ^{® ₅} (IncoA)
<u>Overactive Bladder</u>	Adults (18+)				
Neurogenic detrusor overactivity	<u>Adults (18+)</u> <u>Peds (5+)</u>				
<u>Chronic Migraine</u>	Adults (18+)				
<u>Spasticity, Lower Limb</u>	Adults (18+) Peds (2+)		Adults (18+) Peds (2+)		
Spasticity, Upper Limb	Adults (18+) Peds (2+)		Adults (18+) Peds (2+)		Adults (18+) Peds (2+)
<u>Cervical Dystonia</u>	Adults (18+)	Adults (18+)	Adults (18+)	Adults (18+)	Adults (18+)
<u>Primary Axillary</u> <u>Hyperhidrosis</u>	Adults (18+)				
<u>Blepharospasm</u>					Adults (18+)
<u>Blepharospasm</u> <u>associated with Dystonia</u>	Adults (18+) Peds (12+)				
<u>Strabismus associated</u> with Dystonia	Adults (18+) Peds (12+)				
Chronic Sialorrhea				<u>Adults (18+)</u>	<u>Adults (18+)</u> <u>Peds (2+)</u>

OnaA: <u>onabotulinumtoxinA [Botox[®]]</u>

DaxiA: daxibotulinumtoxinA-lanm [Daxxify®]

AboA: <u>abobotulinumtoxinA [Dysport®]</u>
 IncoA: <u>incobotulinumtoxinA [Xeomin®]</u>

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 <u>ALL</u> of the following are met:

- 1. Diagnosis of overactive bladder; **<u>AND</u>**
- Documentation of symptoms of urinary incontinence, urgency, and frequency; <u>AND</u>
- 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; <u>AND</u>
- 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 FDAapproved 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; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> 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; <u>AND</u>
- 4. Prescribed by, or in consultation with, a neurology or urology specialist; **<u>AND</u>**
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of detrusor overactivity associated with a neurological condition; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> of the following are met:

- 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); <u>AND</u>
- 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; <u>AND</u>
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of detrusor overactivity associated with a neurological condition; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> 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); **<u>AND/OR</u>**
 - c. Candesartan; **AND/OR**
 - d. Tricyclic antidepressant (e.g., amitriptyline, nortriptyline); AND/OR
 - e. Serotonin-norepinephrine reuptake inhibitor (e.g., venlafaxine, duloxetine); <u>AND</u>
- 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.); <u>AND</u>
- 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 FDAapproved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

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

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

Botulinum toxin is considered medically necessary when <u>ALL</u> of the following are met:

- 1. Diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; <u>AND</u>
- 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; <u>AND</u>
- 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); <u>AND</u>
- 5. Documentation indicates that contractions are causing pain and functional impairment; <u>AND</u>
- 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 FDAapproved 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; <u>AND</u>
- Current clinical documentation supports diagnosis of cervical dystonia; <u>AND</u>
- 3. Documentation of positive clinical response to therapy; **AND**
- 4. Prescribed by, or in consultation with, a neurology, orthopedic, or physiatry specialist; <u>AND</u>
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved 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 <u>ALL</u> of the following are met:

- Diagnosis of primary axillary hyperhidrosis (excessive underarm sweating); <u>AND</u>
- 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; <u>AND</u>
- 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; <u>AND</u>
- 5. Medical records document that condition significantly interferes with activities of daily living <u>AND</u> condition is causing chronic skin irritations; <u>AND</u>
- 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 FDAapproved 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; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of primary axillary hyperhidrosis (excessive underarm sweating); <u>AND</u>
- 3. Documentation of positive clinical response to therapy; **AND**
- 4. Prescribed by, or in consultation with, a dermatology or neurology specialist; <u>AND</u>
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved 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 <u>ALL</u> 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; <u>AND</u>
- 4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; <u>AND</u>
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved 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; <u>AND</u>
- Current clinical documentation supports diagnosis of blepharospasm; <u>AND</u>
- 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 FDAapproved 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[®]*).

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

Botulinum toxin is considered medically necessary when <u>ALL</u> 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; <u>AND</u>
- 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 FDAapproved 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; <u>AND</u>
- Current clinical documentation supports diagnosis of blepharospasm; <u>AND</u>
- 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 FDAapproved 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.

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

Botulinum toxin is considered medically necessary when <u>ALL</u> 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; <u>AND</u>
- 4. Prescribed by, or in consultation with, an ophthalmology or neurology specialist; **<u>AND</u>**
- 5. Treatment plan details number of units per indication and treatment session and does not exceed dosing and frequency indicated in FDAapproved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of strabismus associated with dystonia; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> 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 FDAapproved 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; <u>AND</u>
- Current clinical documentation supports diagnosis of chronic sialorrhea; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> 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 FDAapproved labeling for the medication being administered. If botulinum toxin is being used for multiple indications, total cumulative dosage does not exceed FDA-approved limitations.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- Current clinical documentation supports diagnosis of chronic sialorrhea; <u>AND</u>
- 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 FDAapproved 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 <u>ALL</u> 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 **<u>EACH</u>** 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); <u>AND</u>
 - b. Topical nitroglycerin ointment; **AND**
- 4. Prescribed by, or in consultation with, a colorectal or gastroenterology specialist; **<u>AND</u>**
- 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.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 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 <u>ALL</u> 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; <u>AND</u>
- 4. Prescribed by, or in consultation with, a gastroenterology specialist; **AND**
- 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 FDAapproved 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; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of esophageal achalasia; <u>AND</u>
- 3. Documentation of positive clinical response to therapy; **AND**
- 4. Prescribed by, or in consultation with, a gastroenterology specialist; **<u>AND</u>**
- 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 FDAapproved limitations.

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

Botulinum toxin is considered medically necessary when <u>ALL</u> of the following are met:

- 1. Clinical documentation supports **<u>ONE</u>** of the following (a, b, c, d, or e):
 - a. Diagnosis of hemifacial spasm (Botox[®], Myobloc[®]); <u>AND</u>
 - 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[®]); <u>AND</u>
 - 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; <u>OR</u>
 - 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; <u>OR</u>
 - c. Diagnosis of laryngeal dystonia involving the adductor muscles (Botox[®]); <u>AND</u>
 - i. Member is 18 years of age or older; AND
 - ii. Medical records document moderate to severe difficulty in the production of speech sounds; <u>AND</u>
 - iii. Treatment plan does not exceed 30 units of Botox[®] per treatment session no sooner than once every 12 weeks; <u>OR</u>
 - d. Diagnosis of upper extremity dystonia (Botox[®]); **<u>AND</u>**
 - 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; <u>AND</u>
- 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; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of focal dystonia and/or essential tremor; <u>AND</u>
- 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; <u>AND</u>
- 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 <u>ALL</u> of the following are met:

- 1. Diagnosis of **<u>ONE</u>** 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; <u>AND</u>
- 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.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of Hirschsprung disease or internal anal sphincter achalasia; <u>AND</u>
- 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 <u>ALL</u> 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; <u>AND</u>
- 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; <u>AND</u>
- 5. Medical records document that condition significantly interferes with activities of daily living <u>AND</u> condition is causing chronic skin irritations; <u>AND</u>
- 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 FDAapproved limitations.

- 1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; <u>AND</u>
- 2. Current clinical documentation supports diagnosis of primary palmar hyperhidrosis; <u>AND</u>
- 3. Documentation of positive clinical response to therapy; **AND**
- Prescribed by, or in consultation with, a dermatology or neurology specialist; <u>AND</u>
- 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 FDAapproved 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); <u>**OR**</u>
- 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 <u>Appendix A</u>.

Diagnasis (+ indiantan off label)	Approval Duration			
Diagnosis († indicates off-tabet)	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)		

Clinical Criteria – PAM–001 – Botulinum Toxins

Diagnasis (+ indiantas off label)	Approval Duration			
Diagnosis (1 indicates off-tabet)	Initial Authorization	Continuation Therapy		
Chronic cialorrhoa	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[®]]
- DaxiA: daxibotulinumtoxinA-lanm [Daxxify®]
- ◆ AboA: abobotulinumtoxinA [Dysport[®]]
- ◆ IncoA: incobotulinumtoxinA [Xeomin®]
- DaxIA: daxidotulinumtoxinA-lanm [Daxxity
 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

<u>Botox (</u>	onabotulinumtoxinA)				HC	PCS: J0585
J0585:Labeler	Injection, onabotulinumtoxinA, 1 unit : Allergan USA, Inc. (an AbbVie compan	y) (00023)				
	Product (SDV = single-dose vial)	NDC	Dosage	Pkg Size	Pkg Otv	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 a	an acetylcholine release inhibitor and n	euromuscular blocki	ng agent inc	licated for:		
1) Overact	ive Bladder (18 years of age and older)					
a. Trea	tment of overactive bladder with symp	toms of urge urinary	incontinend	ce, urgency,	and freque	ncy, in adults
who	have an inadequate response to or are	e intolerant of an ant	icholinergic	medication	•	
	Overactive Bladder – Adults (18 years	of age and older) – D	ose, Limits	, & Frequen	су	
	 100 units total per treatment, inject 	ed across 20 sites int	to the detru	sor		
	 Maximum cumulative dose for all in 	dications is 400 units	s in a 3-mor	nth period		
	• Retreat no sooner than every 12 wee	eks (3 months)				
2) Detruso	r Overactivity associated with a Neurola	naical Condition (18 ve	ears of age	and older)		
a. Trea	tment of urinary incontinence due to c	letrusor overactivity a	associated v	vith a neuro	logic condit	tion (e.g.,
SCI,	MS) in adults who have an inadequate	response to or are ir	ntolerant of	an antichol	inergic med	lication.
	Detrusor Overactivity associated with	neurological condition	on – Adults	(18 years of	age and old	ler) – Dose,
		, <u> </u>				
	• 200 units total per treatment, inject	ed across 30 sites in	to the detru	isor		
	• Maximum cumulative dose for all in	dications is 400 units	s in a 3-mor	nth period		
	 Retreat no sooner than every 12 wee 	eks (3 months				
3) Pediatri	c Detrusor Overactivity associated with	a Neurological Condi	tion (5 years	s of age and	l older)	
a. Trea	tment of neurogenic detrusor overactiv	vity (NDO) in pediatric	c patients 5	years of ag	e and older	who have
an i	nadequate response to or are intoleran	t of anticholinergic m	nedication.	-		
	Detrusor Overactivity associated with Limits, & Frequency	neurological conditio	on – Pediatr	ics (5 years	of age & old	der) – Dose,
	 Injections across 20 sites into the d weight (less than 34 kg: 6 units/kg 	etrusor. Total dose pe 34 kg or greater: 200	er treatmen [.]) units)	t is based o	n patient	
	• Maximum cumulative dose for all in is lower	dications in a 3-mon	th period: 10) units/kg o	r 340 units,	whichever
	• Retreat no sooner than every 12 wee	eks (3 months)				
4) Chronic	Migraine (18 years of age and older)					
a. Proj	phylaxis of headaches in adult patients	with chronic migrain	e (≥15 days	per month	with headad	che
last	$\log \geq 4$ hours a day).			4 h h l		!!
D. LIM	itations of Use: Safety and effectivenes	s nave not been esta	iblished for	the prophyl	axis of epis	odic
iiig	Chronic Migraine Adulta (19 years of	ontin) in seven placer		Fragues.		
	Chronic Migraine – Adults (18 years of	age and older) - Dos	se, Limits, &	Frequency		>
	• 155 units total per treatment (5-unit	injections per site, o	ivided acro	ss / nead/n	eck muscle	s)
	• Maximum cumulative dose for all in	dications is 400 units	s in a 3-mor	nth period		
	 Retreat no sooner than every 12 wee 	eks (3 months)				
5) Spastic	ty (2 years of age and older)					
a. Trea	tment of spasticity in patients 2 years	of age and older.		с., · · ,		
b. Lim	itations of Use: Botox [®] has not been sr	iown to improve uppe	er extremity	functional	abilities, or	range of
mot	Constinition Dedictoire (Oursens to loss	the set 10 second of a second				
	Spasticity – Pediatrics (2 years to less	inan is years of age) – Dose, Li	mits, & Fred	luency	
	• Upper limb: 3 – 6 units/kg, divided a	among affected muse	cles, or 300	units, which	never is low	ver
	 Lower limb: 4 – 8 units/kg, divided 	among attected muse	cles, or 200	units, whic	hever is low	/er
	 Maximum cumulative dose, all indic 	ations (3-mos. period	1): 10 units/l	kg or 340 ui	nits, whiche	ver is lower
	 Retreat no sooner than every 12 wee 	eks (3 months)				
	Spasticity - Adults (18 years of age an	d older) – Dose, Lim	its, & Freque	ency		
	• Upper limb: 75 to 400 units divided	among the selected	muscles			
	• Lower limb: 300 to 400 units divide	d among 5 muscles				
	Maximum cumulative dose for all in	dications is 400 units	s in a 3-mor	oth neriod		
	Retreat no sooner than every 12 woo	ake (3 monthe)	5 11 a 5-11101	iai periou		
	included no sooner than every 12 wee					

<u>Botox (onabotulinumtoxinA) (co<i>ntinued)</i></u>	HCPCS: J0585
<i>Cervical Dystonia (18 years of age and older)</i> a. Treatment to reduce the severity of abnormal head position and neck pain associated w	vith 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) 	
 Primary Axillary Hyperhidrosis (18 years of age and older) a. Treatment of severe primary axillary hyperhidrosis that is inadequately managed with to b. Limitations of Use: The safety and effectiveness of Botox[®] for hyperhidrosis in other both been established. Weakness of hand muscles and blepharoptosis may occur in patients for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated accurses of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment without the diagnosis and/or treatment of the underlying disease. 	ppical agents. dy areas have not who receive Botox® lated for potential ent of hyperhidrosis
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 effection diminishes, but no sooner than every 12 weeks (3 months). 	ect of the previous
a. Treatment of blepharospasm associated with dystonia (12 years of age and older) disorders in patients 12 years of age and older.	arospasm or VII nerve
Blepharospasm associated with dystonia (12 years of age and older) – Dose, Limits	s, & 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, increased up to two-fold if response from the initial treatment is insufficient. 	, the dose may be
Strabismus associated with dystonia (12 years of age and older) a. Treatment of strabismus and associated with dystonia, including benign essential bleph disorders in patients 12 years of age and older.	arospasm or VII nerve
Strabismus associated with dystonia (12 years of age and older) – Dose, Limits, & I	Frequency
 Initial doses (use lower dose small deviations and use larger dose only for large For vertical muscles and for horizontal strabismus of less than 20 prism did in any one muscle For horizontal strabismus of 20 to 50 prism diopters: 2.5 – 5 units in any on o For persistent VI nerve palsy ≥ 1 month duration: 1.25 – 2.5 units in the med Subsequent doses for residual or recurrent strabismus: Patient should be re-examined 7-14 days after each injection to assess the Patients experiencing adequate paralysis of the target muscle that requires should receive a dose comparable to the initial dose. Subsequent doses for patients experiencing incomplete paralysis of the tar increased up to two-fold compared to the previously administered dose. Subsequent injections should not be administered until the effects of the patients dose (single injection for any one muscle): 25 units Maximum dose (single injection for any one muscle): 25 units Adults: 400 units Ages 12-17: 10 units/kg or 340 units, whichever is lower 	deviations): opters: 1.25 – 2.5 units ne muscle Jial rectus muscle effect of that dose. subsequent injections get muscle may be orevious dose have
ARNING: DISTANT SPREAD OF TOXIN EFFECT ostmarketing reports indicate that the effects of BOTOX and all botulinum toxin products m f injection to produce symptoms consistent with botulinum toxin effects. These may include nuscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and hese symptoms have been reported hours to weeks after injection. Swallowing and breathin preatening and there have been reports of death. The risk of symptoms is probably greatest pasticity but symptoms can also occur in adults treated for spasticity and other conditions,	ay spread from the area e asthenia, generalized I breathing difficulties. g difficulties can be life in children treated for particularly in those

Daxxify (daxibotulinumtoxinA-lanm)

HCPCS: J0589

HCPCS: J0586

- 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.

<u>Dysport (abobotulinumtoxinA)</u>

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.

 JOSR' injection, imabculinumtoxinB, 100 units Labeler: Solitics Neurosciences, LLC (10454) <u>Product (SDV = single-dose vial) NDC Dosase Pkg Size Pkg Qty Units/Pkg</u> <u>Myobloc 2,500 units/Dm (SDV) 10454-0711-0 100 units 1 EA 50</u> Myobloc 2,500 units/Dm (SDV) 10454-0711-0 100 units 1 EA 50 Myobloc 2,500 units/Dm (SDV) 10454-0711-0 100 units 1 EA 50 Myobloc 2,500 units/Dm (SDV) 10454-0711-0 100 units 1 EA 50 Myobloc 2,500 units/Dm (Indicated for: 1) Cervical Dystonia (Aduts - 18 years of age and older) - Dose, Limits, 3 Frequency Intertament to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Testament to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Attraat no sooner than every 12 - 16 weeks (3 - 4 months) Chronic Saloforbe (18 years of age and older) Attraat no sooner than every 12 - 16 weeks (3 - 4 months) Chronic Saloforbe (18 years of age and older) Attraat no sooner than every 12 weeks (3 months) Wathinko: DistAM SPREAD OF DXNH EFFECT Postmarkeling reports indicate that the effect of MYOSLOC and all botulinum toxin products may spread from the postmarkeling reports indicate that the effect of MYOSLOC and all botulinum toxin products may spread from the reating difficulties. These may include asthenia, generalized muscle wakness, diplopia, burred vision, ptosis, dysphagi, dysphonia, dysarthria, urinay incontinence, and breathing difficulties rease or spaticity and other conditions that would predispose them to these other cervical dystonia and at lower doses. Vectori CiscobultumotxinA) VECCS: JOSE30 Vectori CiscobultumotxinA, 1 unit Labeler: Merz Pharmaceuticals, LLC (00259) Vectori CiscobultumotxinA) tolds: Solitonia discober associated for: Ortoni	<u>Myoblo</u>	<u>c (rimabotulinumtoxin</u>	<u>3)</u>				HCF	PCS: J0587
• Labeler: Solatice Neurosciences, LU: (10434) Wobice 2500 units/0.5 mi, (SDV) 10454-0710-10 00 units 1 1 EA 25 Wybloe? is an acetylcholine release inhibitor indicated for: 0. Cervicel Dystonic (8) geors of age and alder) a. Treatment to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Cervical Dystonic (8) geors of age and alder) a. Treatment to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Cervical Dystonic (8) geors of age and alder) a. Treatment to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. Cervical Dystonic (8) geors of age and alder) - Dose, Limits, & Frequency • Initial dose (for patients with a prior history of tolerating botulinum toxins): 2,500 to 5,000 units divided among fracted muscles. Patients without a prior history should receive a lower initial dosage. • Arrent neos common the end off. a. Treatment of offic salarines in alder) a. Treatment of offic salarines in alder. Chronic Solarine (8) dosing the general dider) - Dose, Limits, & Frequency • (1500 to 5,000 units per gland a. Treatment of offic salarines in alder. Chronic Solarine (8) dosing divide arrent general dider) - Dose, Limits, & Frequency • (1500 to 5,000 units per gland • Bertating solarine than every 12 weeks (3 months) WARNING: DISTANT SPREAD OF TONIN EFFECT Postmandeling pools. Survey division, Dosis, dysphala, dysp	• J0587:	Injection, rimabotulinumtoxi	nB, 100 units	;				
Product (SDV) = single-dose via) Nuc. Dosage Pig Size Piz	 Labeler 	: Solstice Neurosciences, LL	C (10454)					
Importance show of its factor in the start of t		Product (SDV = single-dos	e vial)	NDC	Dosage	Pkg Size	Pkg Qty	Units/Pkg
Myoblac ⁴ is an acetylcholine release inhibitor indicated for: 1. Control Dystonic (By 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 bodylumum toxins, 2.000 to 5,000 units, and the prior history of tolerating bodylumum toxins, 2.000 to 5,000 units, and the prior history of tolerating bodylumum toxins, 2.000 to 5,000 units, and 2.000 to 10,000 units per treatment session; Amatemance dose: 5,000 to 10,000 units per treatments; Chronic Sidorrhea (Adults - 18 years of age and older) - Dose, Limits, & Frequency Amatemance dose: 5,000 to 10,000 units per gland Submandibular: 200 units, divide among the paroid and submandibular glands Submandibular: 200 units per gland Retreat no sooner than every 12 weeks (3 months) WARNING: DisTAIN SPREAD OF TOXIN EFFECT Postmarketing difficulties: here symptoms can also occur in allos of passicity and other and abuts reset of passicity and other and abuts and allot for spassicity and other and abuts mated for spassicity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms in an also occur in audits treated for spassicity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms in a subaproved uses, including spasticity in child		Myobloc 5,000 units/0.5 m		10454-0710-10	100 units	1	EA FA	25 50
 Interment of the part of age multicular of the severity of admormal head position and neck pain associated with cervical dystonia. Creatment to reduce the severity of admormal 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 bothulinum toxin; 2.500 to 5.000 units divided among affected muscles. Patients without a prior history should receive a lower initial dosage. Retreat no sconer than every 12 - 16 weeks (3 - 4 months) Othomic Silourhea (18 years of age and older) - Dose, Limits, & Frequency 1.500 to 3,500 units, divided among the parotid and submandibular glands 	Muchloo®		bibitor india	10404-0111-10	100 011123		LA	50
 a. Treatment to reduce the severity of abnormal head position and neck pain associated with envical dystonia. a. Treatment to reduce the severity of abnormal head position and neck pain associated with envical dystonia. e. Revisal Dystonia (Adults – 18 years of age and older) – Dose, Limits, & Frequency e. Initial dose (for patients with a prior bistory should receive a lower initial dosage. Maintenance dose: 5:000 to 10.000 units per treatment session e. Retreat no sooner than every 12 – 16 weeks (3 – 4 months) 2) Chronic Sidorrhea (Adults – 18 years of age and older) – Dose, Limits, & Frequency e. Toratment of chronic sidorrhe in adults. Chronic Sidorrhea (Adults – 18 years of age and older) – Dose, Limits, & Frequency e. Stomandibular: 250 units, per gland e. Retreat no sooner than every 12 weeks (3 months) Chronic Sidorrhea (Adults – 18 years of age and older) – Dose, Limits, & Frequency e. Stomandibular: 250 units per gland e. Retreat no sooner than every 12 weeks (3 months) Chronic Sidorrhea (Adults – 18 years of age aported hours to weeks date injection. Swallowing and breathing eports indicates that the effects of MVOBLOC and all botulinum toxin products may spread from the Free and injection spaticity and burner vision, prosis, dysphaja, dysphonia, dysarthria, urinary incontinence, and breathing difficulties: can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in childer and adults, and in approved indications, acaes of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses. Yeomin Si units (SDV) 00259-1600-01 1 unit 1 EA 100 Yeomin Si ounits (SDV) 00259-1600-01 1 unit 1 EA 100 Yeomin Si ounits (SDV) 00259-1600-01 1 unit 1 EA 100 Yeomin Si ounits (SDV)	1) Cervical	I Dystonia (18 years of gae ar	nibitor indic nd older)	ated for:				
Cervical Dystonia (Adults – 16 years of age and older) – Dose, Limits, & Frequency Initial dose (for patients with a prior history of tolerating brulinum toxine): 2,500 to 5,500 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 sonner than every 12 – 16 weeks (3 – 4 months) 20 Chronic Silorizenta (May Env Pares of age and older) – Dose, Limits, & Frequency Initial to a stress (300 units, divided among the parotid and submandibular glands	a. Trea	atment to reduce the severity	y of abnorma	al head position	and neck pair	associated	with cervical	dystonia.
 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) Chronic Silorchea (Mults - 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 Retreat no sooner than every 12 weeks (3 months) WARNING: DISTANT SPREAD OF TOXIN EFFECT Postmarkeing 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, burred vision, ptosis, dysphaja, dysphonia, dysanthria, urinary inontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and there have been reports of death. The risk of symptoms is probably breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and there have been reported hours to weeks after injection. Swallowing and submarking and there have been reported hours to weeks after injection. Swallowing and submarking and there have been reported hours to weeks after injection. Swallowing and to be specifyin (hidder and adults, and in approved indications, case of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses. Vecomin flocobotulinumtoxinA, 1 unit LECPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit Lebel: Merz Pharmaceuticals, LLC (00259) Lecronis folorites (S0V) 00259-160-01 1 unit 1 exert of chonic isoloren an patents 2		Cervical Dystonia (Adults -	- 18 years of	age and older)	- Dose, Limits	& Frequenc	v	<u> </u>
 divided among äffected muscles. Patients without a prior history should receive a lower initial dosage. Maintenance dose: 5,000 to 10,000 units per graament session Retreat no sooner than every 12 - 16 weeks (3 - 4 months) 2) Chronic Silorines (<i>B</i> yeors of <i>age</i> and older) Treatment of chronic silorines (Aduts - 18 years of <i>age</i> and older) - Osse, Limits. & Frequency 1,500 to 3,500 units, divided among the parotid and submandibular glands Parotici 500 - 1,500 units per gland Submandibular: 250 units per gland Submandibular: 250 units per gland Submandibular: 250 units per gland Busch and the affects of MVOBLOC and all botulinum toxin products may spread from the generalized muscle weakness, diplopia, buitred vision, probasis, dysphajad, dysphonia, dysanthria, 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 aduts, 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. HCPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit Labeler: Merz Pharmaceuticals, LLC (00259) Acomin 500 units (50V) 00259-160-01 1 unit		• Initial dose (for patients	with a prior	history of toler	ating botulinu	m toxins): 2,	500 to 5,000	units
 Maintenance dose: 5,000 to 10,000 units per treatment session Retreat no sooner than every 12 – 16 weeks (3 – 4 months) Chronic Sialorrhea (78 years of age and older) Treatment of chronic sialorrhea in adults. Chronic Sialorrhea (Adults – 18 years of age and older) – Dose, Limits, & Frequency 1,500 to 3,500 units, divide among the parotid and submandibular glands Submandibular: 250 units per gland Retreat no sooner than every 12 Weeks (3 months) WARNING: DISTANT SPREAD OF TOXIN EFFECT Postmarkeling reports indicate that the effects of MVOBLOC and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, incenting and injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, incenting and intere have been reports of death. The risk of symptoms is probably greatest 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. Yeomin (10 coloculinumtoxinA) HCPCS: JO588 HCPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit Labeler: Merz Pharmaceuticals, LLC (00259) Yeomin Vis (SDV) 00259-1605-01 1 unit 1 EA 100 Xeomin 90 units (SDV) 00259-1605-01 1 unit 1 EA 100 Xeomin 90 units (SDV) 00259-1605-01 1 unit 1 EA 100 Xeomin 90 units (SDV) 00259-1605-01 1 unit 1 EA 100 Xeomin 90 units (SDV)<		divided among affected	muscles. Pa	tients without a	a prior history	should recei	ve a lower in	itial dosage.
 Netreat no sconer than every 12 - 16 weeks (3 - 4 months) Chronic Sialorrhea (18 years of age and older) Treatment of 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 Parotid 500 - 1,500 units per gland Parotid 500 - 1,500 units per gland Submandibular: 250 units per gland Parotid 500 - 1,500 units per gland Submandibular: 250 units per gland Submandibular: 250 units per gland Bertrat no sconer 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, gland breathing difficulties incess on protoms have been reports of death. The risk of symptoms is probably greaded in dilleran treated to see satistick with mystoms or pain acodifies it that would predispose the probably gread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses. Xeomin (incobotulinumtoxinA) HCPCS: description J0588: injection, incobotulinumtoxinA, 1 unit Labeler: Merra Pharmaceuticals, LLC (00259) Product (SDV = single-dose vial) NDC Dosage Pkg Size Pkg Qty Units/Pkg Xeomin 50 units (SDV) 00259-1600-01 1 unit 1 EA 100 Xeomin 700 units (SDV) 00259-1600-01 1 unit 1 EA 100 Xeomin 700 units (SDV) 00259-1600-01 1 unit 1 EA 100 Xeomin 700 units (SDV) 00259-1600-01 1 unit 1 EA 100 Xeomin 700 units (SDV) 00259-1600-01 1 unit 1 EA 100 Xeomin 100 units (SDV) <p< td=""><td></td><td>• Maintenance dose: 5,00</td><td>0 to 10,000 u</td><td>inits per treatm</td><td>ent session</td><td></td><td></td><td></td></p<>		• Maintenance dose: 5,00	0 to 10,000 u	inits per treatm	ent session			
 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 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, potsis, dysphaig, dysphoin, dysarthria, urinary incontinence, 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 undreyling 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 dosse comparable to those used to treat cervical dystonia and at lower doses. VECOS: description J0588: Injection, incobotulinumtoxinA, 1 unit Labeler: Mar Zharmaceuticals, LLC (00259) Product (SDV = single-dose vial) <u>NDC Dosage Pkg Size Pkg Qty Units/Pkg Xeomin 300 units (SDV) 00258-1680-01 1 unit 1 EA 200</u> Xeomin 300 units (SDV) 00258-1680-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00258-1680-01 1 unit 1 EA 200 Xeomin 300 units (SDV) 00258-1680-01 1 unit 1 EA 200 Xeomin 300 units (SDV) 00258-1680-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00258-1680-01 1 u		Retreat no sooner than	every 12 – 16	5 weeks (3 – 4 n	nonths)			
a. IPredifient of chronic Slaturmea In Boults. Pronic Slaturmea (Adults – 18 years of age and older) – Dose, Limits, & Frequency • 1.500 to 3.500 units, divided among the parotid and submandibular glands • Parotid Sto0 – 1.500 units per gland • Retreat no sooner than every 12 weeks (B months) VMANING: DISTANT SPEEAD OF TOXIN EFFECT Postmarkeing reports indicate that the effects of MVOBLOC and all botulinum toxin products may spread from the generalized muscle weakness, diplopia, Burred vision, posis, dysphaidia, dysphnia, undude asthenia, emeralized muscle weakness, diplopia, Burred vision, posis, dysphaidia, dysphnia, upravi pincontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties. These symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions. Paroticularly 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. Yeomin 10 units (SDV) 00259-160-01 1 unit 1 EA 100 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 100 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 200 Yeomin 50 units (2) Chronic	Sialorrhea (18 years of age o	ind older)					
Chronic Slatormea (Adults - 18 years of age and older) - Dose, Limits, & Frequency Protid: 500 - 1,500 units, per gland Submanibular: 320 units, per gland Submanibular: 320 units, per gland Partid: 500 - 1,500 units, per gland Submanibular: 320 units, per gland Partid: 500 or 500 units, divided among the partid and submandibular: gland Partid: 500 or 5,500 units, divided among the partid: and submandibular: gland Partid: 500 or 5,500 units, divided among the partid: and units, divided atter injection. Swallowing and diversiting difficulties can be life threatening and there have been reports induce to weeks after injections, avallowing and breating 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 nated 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. PArotid (SDV) 00259-1600-01 1 unit 1 EA 1 EA 500 PArotid (SDV) 00259-1610-01 1 unit 1 EA	a. Trea	atment of chronic slatorrhea	in adults.					
Provid: 500 - 1,500 units, per gland Submandibular: 250 units per gland Retreat no sooner than every 12 weeks (a months) VARNING: DISTANT SPEAD OF TOXIN EFFECT Postmarkeling reports indicate that the effects of WOBLOC 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, dyspaia, dysphonia, dysathria, urinary incontinence, and breathing difficulties can be life threatening and there have been reports of death. The rick 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 toose 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: JO588 + CPCS: description JO588: injection, incobotulinumtoxinA, 1 unit Labele:: Kerz Pharmaceuticals, LLC (00259) Product (SDV = single-dose vial) NDC Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 50 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 unit 1 EA 200 Xeomin 90 units (SDV) 00259-1600-01 1 u		Chronic Sialorrhea (Adults	- 18 years of	t age and older)	– Dose, Limit	s, & ⊢requer	icy	
• o Submandibular: 250 units per gland • Retreat no sconer 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 breating difficulties can be life threatening and there have been reported hours to weeks after injection. Swallowing and breating 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 indicatons, 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 1 EA 50 ×eomin 50 units (SDV) 00259-1610-01 1 unit 1 EA 50 ×eomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 50 ×eomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 200		• $1,500 \text{ to } 3,500 \text{ units, alv}$	laed among In units per c	the parotio and aland	submandibuta	ir glands		
● 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, eigeneralized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphagia		 Submandibular: 25 	50 units per a	gland				
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 can be life threatening and there 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 prodiscates the 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 Keomin 50 units (SDV) 00259-160-01 10 chronic Sialorrhea (veors of age and older) Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per session) 0 chronic Sialorrhea (Pediatrics – 2 years to less than 18 years of age) – Dose, Limits, & Frequency 10 chronic Sialorrhea (Pediatrics – 2 years to less than		Retreat no sooner than	every 12 wee	ks (3 months)				
Variational US INFORMOUT Destmarketing 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, dysph			FFFFOT	• •				
The set of the product symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, unnary incontinence, and breathing difficulties can be life threatening and there 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 9. HCPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit 1 EA 1. Labeler: Merz Pharmaceuticals, LLC (00259) Product (SDV) 00259-1605-01 1 unit 1 EA 100 2. Coronic Sialorrhea (years of age and older. 1 1 EA 100 3. Coronic Sialorrhea (years of age and older. 1 1 EA 200 3. Coronic Sialorrhea (years of age and older. 1 1 1 20 100 4. Coronic Sialorrhea (years of age and older. 1 1 1 20 10 10<	Postmarke	ting reports indicate that the	EFFECT	MYOBLOC and a	ll botulinum te	vin product	s may spread	from the
generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, 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) 00259-1600-01 1 unit 1 EA 100 Xeomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 50 units (SDV) 00259-1620-01	area of inie	ection to produce symptoms	consistent v	with botulinum	toxin effects.	These may i	nclude asthe	nia.
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 Oty Units/Pkg Xeomin 50 units (SDV) Q0259-1610-01 1 unit 1 EA 50 Xeomin 00 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 00 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 00 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 100 .a. Treatment of chronic sialorrhea in patients 2 years of age and older.	generalize	d muscle weakness, diplopia	, blurred visi	ion, ptosis, dysp	hagia, dyspho	nia, dysarthr	ia, urinary ind	continence,
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 thickness 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 100 Xeomin 00 units (SDV) 00259-1605-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1605-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1605-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1605-01 1 unit 1 EA 200 Xeomin 50 units (SDV) 00259-1605-01 1 unit 1 EA 200 Xeomin 50 units (SDV) 00259-1605-01 1 unit 1 EA 200 10 chro	and breath	ning difficulties. These sympt	oms have be	een reported ho	urs to weeks a	fter injectio	n. Swallowing	g and
greatest in children treated to spasticity but symptoms can also occur in adults treated to 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 100 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 100 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 100 Xeomin® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: 1) Chronic Sialorrhea (Pediatrics – 2 years of age and older. 0 Units (SDV) 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. 0 Mody Weight* Parotid gland Submandibular glands, b	breathing	difficulties can be life threat	ening and th	iere have been r	eports of deat	h. The risk c	of symptoms	is probably
Conductors particity in children and adults, and in approved indictions, 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 • • EA 50 • HCPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit • • EA 50 • HCPCS: description J0588: Injection, incobotulinumtoxinA, 1 unit • EA 50 • Keomin 50 units (SDV) 00259-1605-01 1 unit 1 EA 50 × Reomin 50 units (SDV) 00259-1602-01 1 unit 1 EA 100 × Reomin 100 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 100 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 100 units (SDV) <td>greatest in</td> <td>children treated for spastic</td> <td>ity but symp</td> <td>toms can also o</td> <td>ditions that we</td> <td>treated for</td> <td>spasticity an</td> <td>d otner</td>	greatest in	children treated for spastic	ity but symp	toms can also o	ditions that we	treated for	spasticity an	d otner
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) • Yeomin 100 units (SDV) 00259-1605-01 1 unit 1 EA 50 Xeomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 50 Xeomin 200 units (SDV) 00259-1620-01 1 unit 1 EA 50 Yeomin 200 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 6: Salorrhea (2 years of age and older) a. Treatment of chronic sialorrhea in patients 2 years of age and older. • • 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 Gose per side) (both glands, both sides) ≥ 12 kg to <15 kg	symptoms	s, particularly in those patients includ	ing snasticity	v in children and	d adults and i	n approved i	ndications c	ases of
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 00 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 00 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 200 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin 200 units (SDV) 00259-1620-01 1 unit 1 EA 100 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1602-01 1 unit 1 EA 200 Xeomin 6 is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: 1) Infectionsites per session) 0 Dosing is weight-based; is divided wita ratoio 03:2 between the partid and submandi	spread of	effect have occurred at dose	s comparabl	le to those used	d to treat cervi	cal 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) • Vecomin 50 units (SDV) 00259-1605-01 1 unit 1 EA 50 Xeomin 100 units (SDV) 00259-1610-01 1 unit 1 EA 100 Xeomin® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: 1) 1) Chronic Siatorrhea (2 years of age and older) a. Treatment of chronic siatorrhea in patients 2 years of age and older. Chronic Siatorrhea (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 Total dose ≥ 12 kg to <15 kg			•			•		
Accommut (incodorumine (xinA)) HCPCS: 30988 • HCPCS: description J0588: injection, incobotulinuttoxinA, 1 unit • Labeler: Merz Pharmaceuticals, LLC (00259) Product (SDV = single-dose vial) NDC Dosage Pkg Size Pkg Qty Units/Pkg Xeomin 100 units (SDV) 00259-1600-01 1 unit 1 EA 50 Xeomin 100 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 200 units (SDV) 00259-1620-01 1 unit 1 EA 200 Xeomin 6: a an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: 1) Chronic Sialorrhea (Pediatrics - 2 years of age and older. • 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 Total dose (dose per side) (dose per side) (both glands, both sides) ≥ 12 kg to <15 kg								
 HCPCS: description J0583: 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 6 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) (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 ≥13 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 × 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 Ounits per side 60 total units 20 units per side 40 total units 100 units total 	Vaanain	(in a chatulin unstavin A)						
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Product (SDV = single-dose vial)NDCDosagePkg SizePkg QtyUnits/PkgXeomin 50 units (SDV)00259-160-011 unit1EA50Xeomin 100 units (SDV)00259-1620-011 unit1EA100Xeomin 200 units (SDV)00259-1620-011 unit1EA200Xeomin 6 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.• 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 glandsBody Weight*Parotid gland (dose per side)21 kg to <15 kg	Xeomin • HCPCS:	(incobotulinumtoxinA) description J0588: Injection	, incobotulin	umtoxinA, 1 uni	t		НСР	CS: J0588
Xeomin 50 units (SDV)00259-16105-011 unit1EA50Xeomin 00 units (SDV)00259-1620-011 unit1EA100Xeomin® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:1) Chronic Sidorrhea (2 years of age and older)a. Treatment of chronic sialorrhea in patients 2 years of age and older.Chronic Sidorrhea (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 glandsBody Weight*Parotid gland (dose per side)(dose per side)(both glands, both sides) $\geq 12 kg$ to <15 kg	Xeomin • HCPCS: • Labeler	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC	, incobotulin (00259)	umtoxinA, 1 uni	t		НСР	CS: J0588
Attention Control of the second s	Xeomin • HCPCS: • Labeler	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dos	, incobotulin (00259) e vial) NE	umtoxinA, 1 uni	t Dosage	Pkg Size	HCP Pkg Qty	CS: J0588
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Acception Is an acception of the an acception with a neuromuscular blocking agent indicated for: 1) Chronic Sidorrhea (2 years of age and older) a. Treatment of chronic sialorrhea in patients 2 years of age and older. Chronic Sidorrhea (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 Submandibular gland Total dose (both glands, both sides) ≥ 12 kg to <15 kg 6 units 4 units 20 units ≥ 19 kg to <23 kg 12 units 8 units 10 units 50 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 sconer 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.	Xeomin • HCPCS: • Labeler	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV)	, incobotulin (00259) e vial) NE 00 00	umtoxinA, 1 uni DC 1259-1605-01 1259-1610-01	t Dosage 1 unit 1 unit	Pkg Size 1 1	HCP Pkg Qty EA EA	CS: J0588 Units/Pkg 50 100
a. Treatment of chronic sialorrhea in patients 2 years of age and older. A. Treatment of 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 Submandibular gland Total dose (both glands, both sides) ≥ 12 kg to < 15 kg	Xeomin HCPCS: Labeler	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC <u>Product (SDV = single-dose</u> Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV)	, incobotulin (00259) e vial) NE 00 00 00	umtoxinA, 1 uni 0C 0259-1605-01 0259-1610-01 0259-1620-01	t Dosage 1 unit 1 unit 1 unit	Pkg Size 1 1 1	HCP Pkg Qty EA EA EA	Units/Pkg 50 100 200
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) (dose per side) (both glands, both sides) ≥ 12 kg to <15 kg 6 units 4 units 20 units ≥ 15 kg to <19 kg 9 units 6 units 4 units 20 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 10 units 50 units ≥ 27 kg to <30 kg 18 units 12 units 10 units 50 units ≥ 27 kg to <30 kg 18 units 12 units 15 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)	Xeomin • HCPCS: • Labeler Xeomin [®] is 1) Chronic	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) s an acetylcholine release inf	, incobotulin (00259) e vial) NE 00 00 00 00 nibitor and older)	umtoxinA, 1 uni 0259-1605-01 0259-1610-01 0259-1620-01 neuromuscular	t Dosage 1 unit 1 unit 1 unit blocking agen	Pkg Size 1 1 1 t indicated 1	HCP Pkg Qty EA EA EA Tor:	Units/Pkg 50 100 200
 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) 2 kg to < 15 kg 6 units 4 units 2 0 units 2 ls g to < 15 kg 9 units 6 units 30 units 2 ls g to < 27 kg 12 units 10 units 2 lnits 10 units 2 lnits 10 units 2 lnits 10 units 2 lnits 10 units 30 kg or more 22.5 units 15 units 15 units 15 units 16 units 75 units 16 units 75 units A kg or more 22.5 units 15 units 16 units 175 units A keomin 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) – D	Xeomin • HCPCS: • Labeler Xeomin [®] is 1) Chronic a. Trea	i (incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) Sean acetylcholine release inf Sialorrhea (2 years of age of atment of chronic sialorrhea	, incobotulin (00259) e vial) NE 00 00 00 nibitor and a <i>nd older</i>) in patients 2	00000000000000000000000000000000000000	t Dosage 1 unit 1 unit 1 unit blocking agen d older.	Pkg Size 1 1 1 t indicated 1	HCP Pkg Qty EA EA EA or:	Units/Pkg 50 100 200
 Dosing is weight-based; is divided with a ratio of 3:2 between the parotid and submandibular glands Body Weight* Parotid gland Submandibular gland 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 21 kg to < 30 kg 18 units 12 units 8 units 40 units 23 kg to < 27 kg 15 units 10 units 50 units 30 kg or more 22.5 units 15 units 75 units 8 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 100 units total 100 units total Parotid gland Submandibular gland 100 units total 100 u	Xeomin • HCPCS: • Labeler Xeomin® is 1) Chronic a. Trea	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) San acetylcholine release inf Sialorrhea (2 years of age an atment of chronic sialorrhea Chronic Sialorrhea (Pediati	, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 vics – 2 vears	00000000000000000000000000000000000000	t Dosage 1 unit 1 unit 1 unit blocking agen d older.	Pkg Size 1 1 t indicated 1 – Dose, Lim	HCP Pkg Qty EA EA EA or:	CS: J0588
Body Weight* Parotid gland (dose per side) Submandibular gland (dose per side) Total dose (both glands, both sides) ≥ 12 kg to < 15 kg	Xeomin • HCPCS: • Labeler Xeomin® is 1) Chronic a. Trea	 (incobotulinumtoxinA) description J0588: Injection Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) San acetylcholine release infection Sialorrhea (2 years of age of atment of chronic sialorrhea Chronic Sialorrhea (Pediation) Inject into the parotid a 	, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 rics – 2 years nd submand	00000000000000000000000000000000000000	t Dosage 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) both sides (i.	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio	HCP Pkg Qty EA EA Tor: its, & Freque n sites per se	CS: J0588 Units/Pkg 50 100 200
Body Weight*(dose per side)(dose per side)(both glands, both sides) $\geq 12 \text{ kg to } < 15 \text{ kg } = 6 \text{ units}$ 4 units20 units $\geq 15 \text{ kg to } < 19 \text{ kg}$ 9 units6 units30 units $\geq 19 \text{ kg to } < 23 \text{ kg}$ 12 units8 units40 units $\geq 23 \text{ kg to } < 27 \text{ kg}$ 15 units10 units50 units $\geq 27 \text{ kg to } < 30 \text{ kg}$ 18 units12 units60 units 30 kg or more 22.5 units15 units75 units 30 kg or more 22.5 units15 units75 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 $20 units per side 60 total units 20 units per side 40 total units 100 units total• Parotid glandSubmandibular gland• Date per value (4 months)$	Xeomin • HCPCS: • Labeler Xeomin® is 1) Chronic a. Trea	 (incobotulinumtoxinA) description J0588: Injection Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) xeomin 200 units (SDV) xeomin 200 units (SDV) an acetylcholine release inl Sialorrhea (2 years of age and the sialorrhea Chronic Sialorrhea (Pediational et al. 100 and 100 an	, incobotulin (00259) e vial) NE 00 00 00 00 00 00 00 00 00 00 00 00 00	00000000000000000000000000000000000000	t Dosage 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) n both sides (i. 2 between the	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and	HCP Pkg Qty EA EA Tor: its, & Freque n sites per se submandibu	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands
$ \begin{array}{ c c c c c } \hline \geq 12 \ kg \ to < 15 \ kg & 6 \ units & 4 \ units & 20 \ units \\ \hline \geq 15 \ kg \ to < 19 \ kg & 9 \ units & 6 \ units & 30 \ units \\ \hline \geq 19 \ kg \ to < 23 \ kg & 12 \ units & 8 \ units & 40 \ units \\ \hline \geq 23 \ kg \ to < 27 \ kg & 15 \ units & 10 \ units & 50 \ units \\ \hline \geq 27 \ kg \ to < 30 \ kg & 18 \ units & 12 \ units & 60 \ units \\ \hline 30 \ kg \ or \ more & 22.5 \ units & 15 \ units & 75 \ units \\ \hline 30 \ kg \ or \ more & 22.5 \ units & 15 \ units & 75 \ units \\ \hline \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	Xeomin • HCPCS: • Labeler Xeomin® is 1) Chronic a. Trea	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) San acetylcholine release inf Sialorrhea (2 years of age of atment of chronic sialorrhea Chronic Sialorrhea (Pediati Inject into the parotid a Dosing is weight-based;	, incobotulin (00259) e vial) NE 00 00 00 00 00 00 00 00 00 00 00 00 00	DC DC D259-1605-01 D259-1610-01 D259-1620-01 neuromuscular s to less than 18 ibular glands or ith a ratio of 3:2 d gland	t <u>Dosage</u> 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) both sides (i. 2 between the Submandibula	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and	HCP Pkg Qty EA EA EA or: its, & Freque n sites per se submandibu Total d	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands
$\frac{\geq 15 \text{ kg to} < 19 \text{ kg}}{\geq 19 \text{ kg to} < 23 \text{ kg}} \qquad 9 \text{ units} \qquad 6 \text{ units} \qquad 30 \text{ units}}{\geq 19 \text{ kg to} < 23 \text{ kg}} \qquad 12 \text{ units} \qquad 8 \text{ units} \qquad 40 \text{ units}}{\geq 23 \text{ kg to} < 27 \text{ kg}} \qquad 15 \text{ units} \qquad 10 \text{ units} \qquad 50 \text{ units}}{\geq 27 \text{ kg to} < 30 \text{ kg}} \qquad 18 \text{ units} \qquad 12 \text{ units} \qquad 60 \text{ units}}{\geq 27 \text{ kg to} < 30 \text{ kg}} \qquad 18 \text{ units} \qquad 12 \text{ units} \qquad 60 \text{ units}}{\leq 27 \text{ kg to} < 30 \text{ kg}} \qquad 18 \text{ units} \qquad 15 \text{ units} \qquad 75 \text{ units}}{\leq 30 \text{ kg or more}} \qquad 22.5 \text{ units} \qquad 15 \text{ units} \qquad 75 \text{ units}}{\leq 30 \text{ kg or more}} \qquad 22.5 \text{ units} \qquad 15 \text{ units} \qquad 75 \text{ units}}{\leq 75 \text{ units}} \qquad 15 \text{ units} \qquad 75 \text{ units}}{\leq 75 \text{ units}}{\leq 75 \text{ units}} \qquad 10 \text{ units} \qquad 12 \text{ kg}}{\leq 8 \text{ Retreat no sooner than every 16 weeks (4 months)}}$	Xeomin [®] is 1) Chronic a. Trea	in constant in the second seco	, incobotulin (00259) e vial) NE 00 00 00 00 00 00 00 00 00 00 00 00 00	DemovinA, 1 uni DC D259-1605-01 D259-1610-01 D259-1620-01 neuromuscular s to less than 18 ibular glands or ith a ratio of 3:2 d gland per side)	t <u>Dosage</u> 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) both sides (i. 2 between the Submandibula (dose per s	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and r gland de) (HCP Pkg Qty EA EA EA or: its, & Freque n sites per se submandibu Total d poth glands,	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides)
$\frac{\geq 19 \text{ kg to} < 23 \text{ kg}}{\geq 23 \text{ kg to} < 27 \text{ kg}} 12 \text{ units} \\ 8 \text{ units} \\ 40 \text{ units} \\ 23 \text{ kg to} < 27 \text{ kg} \\ 15 \text{ units} \\ 10 \text{ units} \\ 50 \text{ units} \\ 27 \text{ kg to} < 30 \text{ kg} \\ 18 \text{ units} \\ 12 \text{ units} \\ 60 \text{ units} \\ 30 \text{ kg or more} \\ 22.5 \text{ units} \\ 15 \text{ units} \\ 75 \text{ units} \\ 75 \text{ units} \\ 8 \text{ chronic Sialorrhea (Adults - 18 years of age and older) - Dose, Limits, & Frequency} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{Chronic Sialorrhea (Adults - 18 years of age and older) - Dose, Limits, & Frequency} \\ \hline \text{ Inject into the parotid and submandibular glands on both sides (i.e., 4 injection sites per session)} \\ \hline \text{ Total dose per treatment session of 100 units; divided with a ratio of 3:2 between the parotid and submandibular glands} \\ \hline \text{ Parotid gland} \text{ Submandibular gland} \text{ Total for both glands} \\ \hline 30 \text{ units per side} \text{ 60 total units} \text{ 20 units per side} \text{ 40 total units} \text{ 100 units total} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Parotid gland} \text{ Submandibular gland} \text{ Total for both glands} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \text{ Retreat no sooner than every 16 weeks (4 months)} \\ \hline \end{tabular submandibular gland} \\ \hline tabular subma$	Xeomin [®] is 1) Chronic a. Trea	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) San acetylcholine release inf Sialorrhea (2 years of age and the chronic sialorrhea Chronic Sialorrhea (Pediation) • Dosing is weight-based; Body Weight* ≥ 12 kg to < 15 kg	, incobotulin (00259) e vial) NE 00 00 00 00 00 00 00 00 00 00 00 00 00	oumtoxinA, 1 uni 0C 0259-1605-01 0259-1610-01 0259-1620-01 neuromuscular s to less than 18 ibular glands or ith a ratio of 3:2 d gland per side) nits	t <u>Dosage</u> 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) both sides (i. 2 between the Submandibula (dose per s 4 units	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and r gland de) (HCP Pkg Qty EA EA EA Total do poth glands, 20 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its
$ \begin{array}{ c c c c c } \hline \geq 23 \ \text{kg to} < 27 \ \text{kg} & 15 \ \text{units} & 10 \ \text{units} & 50 \ \text{units} \\ \hline \geq 27 \ \text{kg to} < 30 \ \text{kg} & 18 \ \text{units} & 12 \ \text{units} & 60 \ \text{units} \\ \hline 30 \ \text{kg or more} & 22.5 \ \text{units} & 15 \ \text{units} & 75 \ \text{units} \\ \hline 30 \ \text{kg or more} & 22.5 \ \text{units} & 15 \ \text{units} & 75 \ \text{units} \\ \hline & \text{Xeomin has not been studied in children weighing less than 12 \ \text{kg}} \\ \hline \text{Retreat no sooner than every 16 weeks (4 months)} \\ \hline \hline \begin{array}{c} \text{Chronic Sialorrhea} \ (\text{Adults} - 18 \ \text{years of age and older}) - \text{Dose, Limits, \& Frequency} \\ \hline \text{Inject into the parotid and submandibular glands on both sides (i.e., 4 \ \text{injection sites per session})} \\ \hline \text{Total dose per treatment session of 100 units; divided with a ratio of 3:2 between the parotid and submandibular glands} \\ \hline \hline \begin{array}{c} Parotid \ \text{gland} & Submandibular \ \text{gland} & Total \ \text{for both glands} \\ \hline 30 \ \text{units per side} & 60 \ \text{total units} & 20 \ \text{units per side} & 40 \ \text{total units} & 100 \ \text{units total} \\ \hline \end{array} $	Xeomin [®] is 1) Chronic a. Trea	(incobotulinumtoxinA) description J0588: Injection : Merz Pharmaceuticals, LLC Product (SDV = single-dose Xeomin 50 units (SDV) Xeomin 100 units (SDV) Xeomin 200 units (SDV) Xeomin 200 units (SDV) San acetylcholine release info Sialorrhea (2 years of age on atment of chronic sialorrhea Chronic Sialorrhea (Pediati • Inject into the parotid a • Dosing is weight-based; Body Weight* ≥ 12 kg to < 15 kg	, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 rics – 2 years nd submand is divided w Parotic (dose p 6 u 9 u	oumtoxinA, 1 uni 0C 0259-1605-01 0259-1610-01 0259-1620-01 neuromuscular s to less than 18 ibular glands or ith a ratio of 3:2 d gland per side) nits nits	t Dosage 1 unit 1 unit 1 unit blocking agen d older. 3 years of age) both sides (i. 2 between the Submandibula (dose per s 4 units 6 units	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and r gland de) (HCP Pkg Qty EA EA EA Total do poth glands, 20 un 30 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its
≥ 27 kg to < 30 kg	Xeomin [®] is 1) Chronic a. Trea	$\begin{array}{c} (incobotulinumtoxinA)\\ (incobotulinumtoxinA)\\ (description J0588: Injection)\\ (modeline in the second secon$, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 rics – 2 years nd submand is divided w Parotic (dose p 6 u 9 u	December 2012 Control of the second s	t <u>Dosage</u> 1 unit 1 unit 1 unit blocking agen dolder. 3 years of age) both sides (i. 2 between the Submandibula (dose per s 4 units 6 units 8 units	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and r gland de) (HCP Pkg Qty EA EA EA Total do toth glands, 20 un 30 un 40 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its its
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 30 units per side 60 total units 20 units per side 40 total units 0 units total 100 units total	Xeomin [®] is 1) Chronic a. Trea	$\begin{array}{c} (incobotulinumtoxinA)\\ (incobotulinumtoxinA)\\ (description J0588: Injection)\\ (modeline in the second secon$, incobotulin (00259) e vial) NE 00 00 00 nibitor adder) in patients 2 rics – 2 years nd submand is divided w Parotic (dose p 6 u 9 u 9 u	aumtoxinA, 1 uni DC D259-1605-01 2259-1610-01 2259-1620-01 neuromuscular s to less than 18 ibular glands or ith a ratio of 3:2 d gland Ser side) side nits nits nits units nits	t <u>Dosage</u> 1 unit 1 unit 1 unit blocking agen dolder. 3 years of age) both sides (i. 2 between the Submandibula (dose per s 4 units 6 units 8 units 10 units	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and r gland de) (HCP Pkg Qty EA EA EA Tor: its, & Freque n sites per se submandibu Total d poth glands, 20 un 30 un 40 un 50 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its its its its
* 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 Ounits per side 60 total units 20 units per side 40 total units 100 units total Patreat no sooner than every 16 weeks (4 months)	Xeomin [®] is 1) Chronic a. Trea	$\begin{array}{r} \textbf{(incobotulinumtoxinA)}\\ \textbf{(incobotulinumtoxinA)}\\ \textbf{(description J0588: Injection)}\\ \textbf{: Merz Pharmaceuticals, LLC}\\ \hline \textbf{Product (SDV = single-dose)}\\ \textbf{(xeomin 50 units (SDV))}\\ \textbf{(xeomin 100 units (SDV))}\\ \textbf{(xeomin 100 units (SDV))}\\ \textbf{(xeomin 200 units (SDV))}\\ \textbf{(seomin 200 units (SDV))}\\ $, incobotulin (00259) e vial) NE 00 00 00 nibitor and older) in patients 2 rics – 2 years nd submand is divided w Parotic (dose p 6 u 9 u 12 u 15 u	aumtoxinA, 1 uni DC D259-1605-01 2259-1610-01 2259-1620-01 neuromuscular 2 years of age ar s to less than 18 ibular glands or rith a ratio of 3:2 d gland Ser side) ser nits nits units nits units nits units nits	t Dosage 1 unit 1 unit 1 unit blocking agen d older. years of age) both sides (i. between the Submandibula (dose per s 4 units 6 units 8 units 10 units 12 units	Pkg Size 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and f gland de) (HCP Pkg Qty EA EA EA Tor: its, & Freque n sites per se submandibu Total d poth glands, 20 un 30 un 40 un 50 un 60 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its its its its its its
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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 30 units per side 60 total units 20 units per side 40 total units • Patreat no scoper than every 16 weeks (4 months)	Xeomin [®] is 1) Chronic a. Trea	$\begin{array}{c} (incobotulinumtoxinA)\\ (incobotulinumtoxinA)\\ (description J0588: Injection)\\ (Herz Pharmaceuticals, LLC)\\ \hline Product (SDV = single-dose)\\ (Xeomin 50 units (SDV))\\ (Xeomin 100 units (SDV))\\ (Xeomin 100 units (SDV))\\ (Xeomin 200 units (SDV))\\ (Xeo$, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 rics - 2 years nd submand is divided w Parotic (dose p 6 u 9 u 12 u 15 u 18 u	aumtoxinA, 1 uni DC 2259-1605-01 2259-1610-01 2259-1620-01 neuromuscular 2 years of age ar s to less than 18 ibular glands or ith a ratio of 3:: d gland per side) nits nits units units units units units units units	t Dosage 1 unit 1 unit 1 unit blocking agen d older. years of age) both sides (i. between the Submandibula (dose per s 4 units 6 units 8 units 10 units 12 units 15 units	Pkg Size 1 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and gland de) (12 kg	HCP Pkg Qty EA EA EA Tor: its, & Freque n sites per se submandibu Total d poth glands, 20 un 30 un 40 un 50 un 60 un 75 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its its its its its its its its
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 30 units per side 60 total units 20 units per side 40 total units • Retreat no scoper than every 16 weeks (4 months)	Xeomin [®] is 1) Chronic a. Trea	$\begin{array}{c} (incobotulinumtoxinA)\\ (incobotulinumtoxinA)\\ (description J0588: Injection)\\ (Herz Pharmaceuticals, LLC)\\ \hline Product (SDV = single-dose)\\ (Xeomin 50 units (SDV))\\ (Xeomin 100 units (SDV))\\ (Xeomin 100 units (SDV))\\ (Xeomin 200 units (SDV))\\ (Xeomin 100 units (SDV))\\ (Xeomin 400 units (SDV))\\ (Xeo$, incobotulin (00259) e vial) NE 00 00 00 nibitor and a nd older) in patients 2 rics - 2 years nd submand is divided w Parotic (dose p 6 u 9 u 12 u 15 u 18 u 22.5 een studied	aumtoxinA, 1 uni DC 2259-1605-01 2259-1610-01 2259-1620-01 neuromuscular 2 years of age ar s to less than 18 ibular glands or ith a ratio of 3:: d gland per side) nits units units units units units in children weig ks (4 months)	t Dosage 1 unit 1 unit 1 unit blocking agen d older. years of age) both sides (i. between the Submandibula (dose per s 4 units 6 units 8 units 10 units 12 units 15 units ghing less than	Pkg Size 1 1 1 t indicated 1 - Dose, Lim e., 4 injectio parotid and gland de) ((12 kg	HCP Pkg Qty EA EA EA Tor: its, & Freque n sites per se submandibu Total d poth glands, 20 un 30 un 40 un 50 un 60 un 75 un	CS: J0588 Units/Pkg 50 100 200 ncy ession) lar glands lose both sides) its its its its its its its its
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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 spastic cerebral palsy. b. Treatment of upper limb spasticity in adults patients. 	city caused by
 Upper Limb Spasticity (Pediatrics – 2 years to less than 18 years of age) – Dose, Limits. 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) 	, & Frequency
 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 muscle Retreat no sooner than every 12 weeks (3 months) 	Jscles
 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 Betreat 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 s of injection to produce symptoms consistent with botulinum toxin effects. These may include asth muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontin difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and bic can be life threatening and there have been reports of death. The risk of symptoms is probably gre treated for spasticity but symptoms can also occur in adults treated for spasticity and other condit those patients who have underlying conditions that would predispose them to these symptoms. In including lower limb spasticity in children, and in approved indications, cases of spread of effect h at doses comparable to those used to treat cervical dystonia and at lower doses.	pread from the area nenia, generalized nence and breathing reathing difficulties vatest in children itions, particularly in nunapproved uses, nave been reported

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.

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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 <u>www.auanet.org/guidelines/guidelines/adult-neurogenic-</u> lower-urinary-tract-dysfunction.

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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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	Signature William (Bill) J	agiello, DO	Mmgm				

Criteria Change History <i>(continued)</i>					
Change Date	Changed By	Description of Change	Version		
04/15/2022	CAC	Annual review. Rewrite.	11		
Signature William (Bill) J	agiello, DO	Mmgm			
Change Date	Changed By	Description of Change	Version		
01/15/2021	CAC	Annual review.	10		
Signature William (Bill) J	agiello, DO	Mmgm			
Change Date	Changed By	Description of Change	Version		
03/13/2018	CAC	Added narrative under Description regarding Botox [®] an Xeomin [®] being equipotent and having similar biologic a	d 9 Ictivity.		
Signature	CN				
C. David Smith	i, MD Cha	- Kn K K, D. William (Bill) Jagiello, DO //////	NOm		
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	7		
		neurologic condition such as spinal cord injury, multipl sclerosis" & added "or well-documented overactive bla	.e Idder".		
Signature					
Change Date	Changed By	Description of Change	Version		
Change Date 01/15/2015	Changed By CAC	Description of Change Removed criterion #1q as was duplicate of #1n. Under r	Version		
Change Date 01/15/2015	Changed By CAC	Description of Change Removed criterion #1q as was duplicate of #1n. Under r covered removed "wrinkles"; included in "cosmetic cor	Version non- 6 nditions".		
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CAC = Medicaid Clinical Advisory Committee