

Clinical Policy: IncobotulinumtoxinA (Xeomin)

Reference Number: CP.PHAR.231

Effective Date: 07.01.16

Last Review Date: 05.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

IncobotulinumtoxinA (Xeomin[®]) is an acetylcholine release inhibitor and a neuromuscular blocking agent.

FDA Approved Indication(s)

| Indication | Adults | Pediatrics | Treatment | Prophylaxis |
|-------------------------------------------------|--------|------------|-----------|-------------|
| Sialorrhea | X | X | X | |
| Upper limb spasticity | X | X | X | |
| Cervical dystonia (focal dystonia) | X | | X | |
| Blepharospasm (focal dystonia) | X | | X | |
| Upper facial lines [<i>benefit exclusion</i>] | X | | X | |
| <i>Off-Label Uses</i> | | | | |
| Lower limb spasticity* | X | | X | |
| Overactive bladder | X | | X | |
| Urinary incontinence | X | | X | |
| Migraine | X | | | X |
| Axillary hyperhidrosis | X | | X | |
| Laryngeal dystonia** | X | | X | |
| Oromandibular dystonia** | X | | X | |
| Upper extremity dystonia** | X | | X | |
| Upper extremity essential tremor** | X | | X | |

*See criteria set entitled *Upper and Lower Limb Spasticity*

**See criteria set entitled *Focal Dystonia and Essential Tremor*

Xeomin is indicated for the treatment or improvement of:

- Chronic sialorrhea in patients 2 years of age and older
- Upper limb spasticity in adults
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Cervical dystonia in adults
- Blepharospasm in adults
- The appearance of upper facial lines in adults [*benefit exclusion*]:
 - Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
 - Moderate to severe horizontal forehead lines associated with frontalis muscle activity

- Moderate to severe lateral canthal lines associated with orbicularis oculi muscle activity

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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It is the policy of health plans affiliated with Centene Corporation[®] that Xeomin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Sialorrhea (must meet all):

1. Diagnosis of chronic sialorrhea for at least the last three months due to one of the following (a or b):
 - a. Underlying neurologic disorder (e.g., Parkinson disease, atypical parkinsonism, stroke, traumatic brain injury, cerebral palsy, amyotrophic lateral sclerosis);
 - b. Craniofacial abnormality (e.g., Goldenhar syndrome);
 2. Prescribed by or in consultation with a neurologist or physiatrist;
 3. Age \geq 2 years;
 4. Failure of at least one anticholinergic drug (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;*
- * For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
5. Xeomin is not prescribed concurrently with other botulinum toxin products;
 6. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 16 weeks;

7. Treatment plan provided detailing number of Units per indication and treatment session;
8. Request is for one of the following (a or b):
 - a. For age ≥ 18 years, dose does not exceed 30 Units per parotid gland, 20 Units per submandibular gland, 100 Units per treatment session;
 - b. For age ≥ 2 years, dose does not exceed any of the following (i, ii, iii, iv, v, or vi):
 - i. For body weight 12 kg to < 15 kg, 6 Units per parotid gland, 4 Units per submandibular gland, 20 Units per treatment session;
 - ii. For body weight 15 kg to < 19 kg, 9 Units per parotid gland, 6 Units per submandibular gland, 30 Units per treatment session;
 - iii. For body weight 19 kg to < 23 kg, 12 Units per parotid gland, 8 Units per submandibular gland, 40 Units per treatment session;
 - iv. For body weight 23 kg to < 27 kg, 15 Units per parotid gland, 10 Units per submandibular gland, 50 Units per treatment session;
 - v. For body weight 27 kg to < 30 kg, 18 Units per parotid gland, 12 Units per submandibular gland, 60 Units per treatment session;
 - vi. For body weight ≥ 30 kg, 22.5 Units per parotid gland, 15 Units per submandibular gland, 75 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member's renewal date, whichever is longer

B. Upper and Lower Limb Spasticity (*includes cerebral palsy*) (must meet all):

1. Diagnosis of upper limb spasticity or lower limb spasticity (e.g., associated with paralysis, central nervous system demyelinating diseases such as multiple sclerosis, cerebral palsy, stroke);
2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
3. Member meets one of the following (a or b):
 - a. For upper limb spasticity, age ≥ 2 years;
 - b. For lower limb spasticity, age ≥ 18 years (off-label);
4. Failure of Botox[®] and Dysport[®], unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
5. Xeomin is not prescribed concurrently with other botulinum toxin products;
6. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
7. Treatment plan provided detailing number of Units per indication and treatment session;
8. Dose does not exceed 400 Units per treatment session.

* For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member's renewal date, whichever is longer

C. Cervical Dystonia (must meet all):

1. Diagnosis of CD;

2. Prescribed by or in consultation with a neurologist, orthopedist, or physiatrist;
 3. Age \geq 18 years;
 4. Member is experiencing involuntary contractions of the neck and shoulder muscles (e.g., splenius, sternocleidomastoid, levator scapulae, scalene, trapezius, semispinalis capitis) resulting in abnormal postures or movements of the neck, shoulder, or head;
 5. Contractions are causing pain and functional impairment;
 6. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
- * For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
7. Xeomin is not prescribed concurrently with other botulinum toxin products;
 8. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
 9. Treatment plan provided detailing number of Units per indication and treatment session;
 10. Dose does not exceed one of the following (a or b):
 - a. Treatment-naïve: 120 Units per treatment session;
 - b. Treatment-experienced: 300 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

D. Blepharospasm (*focal dystonia - abnormal eyelid muscle contraction*) (must meet all):

1. Diagnosis of blepharospasm;
 2. Prescribed by or in consultation with a neurologist or ophthalmologist;
 3. Age \geq 18 years;
 4. Member is experiencing significant disability in daily functional activities due to interference with vision;
 5. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
- * For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Xeomin is not prescribed concurrently with other botulinum toxin products;
 7. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
 8. Treatment plan provided detailing number of Units per indication and treatment session;
 9. Dose does not exceed 50 Units per eye per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

E. Overactive Bladder and Urinary Incontinence (off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. OAB, and member’s history is positive for urinary urgency, frequency, and nocturia with or without incontinence;

- b. Urinary incontinence, and member's history is positive for an associated neurologic condition (e.g., spinal cord injury, multiple sclerosis);
2. Prescribed by or in consultation with a neurologist or urologist;
3. Age \geq 18 years;
4. Failure of a trial of both of the following (a and b), each used for at least 30 days, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
 - a. Two anticholinergic agents;
 - b. Oral beta-3 agonist medication;
5. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
** For Illinois HIM requests, the step therapy requirements above do not apply to Dysport as of 1/1/2026 per IL HB 5395*
6. Xeomin is not prescribed concurrently with other botulinum toxin products;
7. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
8. Treatment plan provided detailing number of Units per indication and treatment session;
9. Dose does not exceed 200 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member's renewal date, whichever is longer

F. Chronic Migraine (off-label) (must meet all):

1. Diagnosis of chronic migraine (i.e., \geq 15 headache days per month for at least 3 months with headache lasting 4 hours a day or longer);
2. Prescribed by or in consultation with a neurologist or pain specialist;
3. Age \geq 18 years;
4. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, or c):*
** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
 - a. Antiepileptics (e.g., divalproex sodium, sodium valproate, topiramate);
 - b. Beta-blockers (e.g., metoprolol, propranolol, timolol);
 - c. Antidepressants (e.g., amitriptyline, venlafaxine);
5. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
** For Illinois HIM requests, the step therapy requirements above do not apply to Dysport as of 1/1/2026 per IL HB 5395*
6. Xeomin is not prescribed concurrently with injectable calcitonin gene-related peptide (CGRP) inhibitors (e.g., Aimovig[®], Ajovy[®], Emgality[®]);
7. Xeomin is not prescribed concurrently with other botulinum toxin products;
8. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
9. Treatment plan provided detailing number of Units per indication and treatment session;

10. Dose does not exceed 155 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

G. Primary Axillary Hyperhidrosis (*excessive underarm sweating*) (off-label) (must meet all):

1. Diagnosis of primary axillary hyperhidrosis;
 2. Prescribed by or in consultation with a neurologist or dermatologist;
 3. Age \geq 18 years;
 4. Failure of a 6-month trial of topical aluminum chloride, unless contraindicated or clinically significant adverse effects are experienced;
 5. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
- * For Illinois HIM requests, the step therapy requirements below do not apply to Dysport as of 1/1/2026 per IL HB 5395*
6. Xeomin is not prescribed concurrently with other botulinum toxin products;
 7. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
 8. Treatment plan provided detailing number of Units per indication and treatment session;
 9. Dose does not exceed 100 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

H. Focal Dystonia and Essential Tremor (off-label) (must meet all):

1. Diagnosis of one of the following (a, b, c, or d):
 - a. Laryngeal dystonia;
 - b. Oromandibular dystonia (OMD);
 - c. Upper extremity (UE) dystonia;
 - d. UE essential tremor;
 2. Prescribed by or in consultation with a neurologist, ENT specialist, orthopedist, orofacial pain specialist, or physiatrist;
 3. Age meets one of the following (a or b):
 - a. For upper extremity dystonia: Age \geq 2 years;
 - b. For all other indications: Age \geq 18 years;
 4. For upper extremity dystonia: Failure of a trial of carbidopa/levodopa or trihexyphenidyl (*see Appendix B*), unless clinically significant adverse effects are experienced or both are contraindicated;*
- * For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
5. Failure of Botox and Dysport, unless clinically significant adverse effects are experienced or both are contraindicated (*see Appendix B*);*
- * For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Xeomin is not prescribed concurrently with other botulinum toxin products;

7. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
8. Treatment plan provided detailing number of Units per indication and treatment session;
9. Request meets one of the following (a or b):
 - a. Laryngeal dystonia: Dose does not exceed 25 Units per treatment session;
 - b. UE dystonia, UE essential tremor, OMD: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use and member age (*prescriber must submit supporting evidence; Units per treatment session does not exceed 400 Units per treatment session*).

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

I. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Approval

A. Chronic Migraine (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. If receipt of ≥ 2 Xeomin treatment sessions, member has experienced and maintained a 30% reduction in monthly migraine headache frequency from baseline;
3. Xeomin is not prescribed concurrently with injectable CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality);
4. Xeomin is not prescribed concurrently with other botulinum toxin products;

5. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 weeks;
6. Treatment plan details number of Units per indication and treatment session;
7. If request is for a dose increase, new dose does not exceed 155 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member's renewal date, whichever is longer

B. All Other Indications in Section I (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Xeomin is not prescribed concurrently with other botulinum toxin products;
4. Botulinum toxin therapy for cosmetic or medical conditions has not been administered within the last 12 week (16 weeks if sialorrhea);
5. If request is for a dose increase, new dose does not exceed the following indication-specific maximums (a, b, c, d, e, f, or g):
 - a. Chronic sialorrhea (i or ii):
 - i. For age \geq 18 years, dose does not exceed 30 Units per parotid gland, 20 Units per submandibular gland, 100 Units per treatment session;
 - ii. For age \geq 2 years, dose does not exceed any of the following (a, b, c, d, e, or f):
 - a) For body weight 12 kg to $<$ 15 kg, 6 Units per parotid gland, 4 Units per submandibular gland, 20 Units per treatment session;
 - b) For body weight 15 kg to $<$ 19 kg, 9 Units per parotid gland, 6 Units per submandibular gland, 30 Units per treatment session;
 - c) For body weight 19 kg to $<$ 23 kg, 12 Units per parotid gland, 8 Units per submandibular gland, 40 Units per treatment session;
 - d) For body weight 23 kg to $<$ 27 kg, 15 Units per parotid gland, 10 Units per submandibular gland, 50 Units per treatment session;
 - e) For body weight 27 kg to $<$ 30 kg, 18 Units per parotid gland, 12 Units per submandibular gland, 60 Units per treatment session;
 - f) For body weight \geq 30 kg, 22.5 Units per parotid gland, 15 Units per submandibular gland, 75 Units per treatment session;
 - b. Upper/lower limb spasticity, UE dystonia, UE essential tremor: 400 Units per treatment session;
 - c. Focal dystonia and essential tremor (i and ii):
 - i. Laryngeal dystonia: 25 Units per treatment session;
 - ii. UE dystonia, UE essential tremor, OMD: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use and member age

(prescriber must submit supporting evidence; Units per treatment session does not exceed 400 Units per treatment session);

- d. CD (i or ii):
 - i. Treatment-naïve: 120 Units per treatment session;
 - ii. Treatment-experienced: 300 Units per treatment session;
- e. Blepharospasm: 50 Units per eye per treatment session;
- f. OAB/urinary incontinence: 200 Units per treatment session;
- g. Axillary hyperhidrosis: 100 Units per treatment session.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to member’s renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents;
- B.** Cosmetic treatment of hyperfunctional wrinkles of the upper face including glabellar frown lines, deep forehead wrinkles and periorbital wrinkles (crow’s feet);
- C.** Episodic migraine (\leq 14 headache days per month): Safety and efficacy have not been established per the package insert;
- D.** Total treatment dose per session does not exceed 400 Units.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CD: cervical dystonia

CGRP: calcitonin gene-related peptide

ER: extended release

FDA: Food and Drug Administration

IR: immediate release

MS: multiple sclerosis

OAB: overactive bladder
OMD: oromandibular dystonia

SCI: spinal cord injury
UE: upper extremity

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <i>Sialorrhea: examples of anticholinergic drugs</i> | | |
| glycopyrrolate (Glycate [®] oral tablets, Cuvposa [®] oral solution) | <ul style="list-style-type: none"> Adults: 1 mg PO TID <i>(Off-label: Lakraj 2013)</i> Pediatrics: chronic drooling: children \geq 3 years and adolescents \leq 16 years: oral solution (Cuvposa): 20 mcg/kg/dose 3 times daily, titrate in increments of 20 mcg/kg/dose every 5 to 7 days as tolerated to response up to a maximum dose of 100 mcg/kg/dose 3 times daily; not to exceed 1,500 to 3,000 mcg/dose. <i>(FDA labeled)</i> | See regimen information |
| benztropine mesylate (oral tablets– 0.5 mg, 1 mg, 2 mg) | Mean doses of 3.8 mg/day have been used in adults and pediatrics \geq 4 years. Benztropine typically is administered in divided doses titrating up as needed. <i>(Off-label– Sridharan 2018, Lakraj 2013; Micromedex, package insert)</i> | See regimen information |
| <i>Overactive bladder, urinary incontinence</i> | | |
| oxybutynin (Ditropan [®] /XL, Gelnique [®]) <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> Immediate-release (IR) tablets: 5 mg PO two to three times daily Extended-release tablets: 5-10 mg PO QD Topical gel: Apply contents of one sachet topically QD | <ul style="list-style-type: none"> IR: 20 mg/day ER: 30 mg/day Gel: one sachet/day |
| tolterodine tartrate (Detrol [®] /LA) <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> IR tablets: 2 mg PO QD ER tablets: 4 mg PO QD | 4 mg/day |
| fesoterodine (Toviaz [®]) <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> Pediatrics: 4 mg PO QD. If needed, dosage may be increased to 8 mg PO QD Adults: 4 mg PO QD | 8 mg/day |
| solifenacin (Vesicare [®]) <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> Adults and children weighing more than 60 kg: 5 mg PO QD | 10 mg/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| | <ul style="list-style-type: none"> • Children weighing between 46 to 60 kg: 4 mg PO QD • Children weighing between 16 to 45 kg: 3 mg PO QD • Children weighing between 9 to 15 kg: 2 mg QD | |
| darifenacin <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> • 7.5 mg PO QD | 15 mg/day |
| trospium (Sanctura [®] , Sanctura [®] XR) <i>(anticholinergic agent)</i> | <ul style="list-style-type: none"> • IR: 20 mg PO BID • ER: 60 mg PO QD | 60 mg/day |
| Myrbetriq [®] (mirabegron) <i>(beta-3 agonist)</i> | 25 mg PO QD | 50 mg/day |
| Gemtesa [®] (vibegron) <i>(beta-3 agonist)</i> | 75 mg PO QD | 75 mg/day |
| Botox [®] (OnabotulinumtoxinA) | <p><u>OAB:</u> Up to 5 Units IM per injection across up to 20 injection sites in the detrusor muscle for a total of up to 100 Units per treatment session</p> <p><u>Urinary incontinence associated with neurologic condition:</u> Up to approximately 6.7 Units IM per injection across up to 30 injection sites in the detrusor muscle for a total of up to 200 Units per treatment session</p> | <p>See dosing regimens for maximum dose</p> <p>Frequency: One treatment session every 12 weeks</p> |
| Dysport [®] (abobotulinumtoxinA) | <p>Up to 250 Units IM in the detrusor muscle per treatment session. <i>(Off-label– Irwin 2013)</i></p> | <p>See dosing regimens for maximum dose</p> <p>Frequency: One treatment session every 12 weeks</p> |
| Chronic migraine | | |
| <p><i>Examples of oral migraine preventive therapies–</i></p> <ul style="list-style-type: none"> • Anticonvulsants: divalproex (Depakote[®]), topiramate (Topamax[®]) | <p><i>Refer to prescribing information for dosing regimens.</i></p> | <p><i>Refer to prescribing information</i></p> |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Beta blockers: propranolol (Inderal[®]), metoprolol (Lopressor[®]), timolol • Antidepressants/tricyclic antidepressants: amitriptyline (Elavil[®]), venlafaxine (Effexor[®]) | | |
| Botox (OnabotulinumtoxinA) | Up to 5 Units IM per injection across up to 7 head/neck muscles for a total of up to 155 Units per treatment session | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| Dysport (abobotulinumtoxinA) | Up to 250 Units IM per treatment session. <i>(Off-label– Alipour 2016, Menezes 2007)</i> | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| <i>Primary axillary hyperhidrosis</i> | | |
| Drysol [®] (aluminum chloride) | Apply topically once daily | One application/day |
| Botox (OnabotulinumtoxinA) | Up to 50 Units IM per axilla per treatment session | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| Dysport (abobotulinumtoxinA) | Up to 200 Units IM per treatment session. <i>(Off-label– Clinical Pharmacology, Heckmann 2001)</i> | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| <i>Dystonia</i> | | |
| carbidopa/levodopa (Sinemet [®] , Duopa [®] , Rytary [®]) | 25 mg/100 mg PO QD, and increase by 1 tablet every 3 to 5 days. | 1,200 mg/day of levodopa |
| trihexyphenidyl | 30 mg PO QD | 30 mg/day |
| <i>Upper and lower limb spasticity</i> | | |
| Botox (OnabotulinumtoxinA) | <u>Adult:</u> Up to 50 Units IM per injection and up to 400 Units per treatment session <u>Pediatric:</u> <ul style="list-style-type: none"> • Upper limb spasticity: Up to the lower of 6 Units/kg or 200 Units IM per treatment session • Lower limb spasticity: Up to the lower of 8 Units/kg or 300 Units IM per treatment session • Upper and lower limb spasticity: Up to the lower of 10 Units/kg or 340 Units IM per treatment session | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| Dysport (abobotulinumtoxinA) | <u>Adult:</u> Divided among affected muscles every 12 weeks: <ul style="list-style-type: none"> • Upper limb: Up to 1,000 Units IM • Lower limb: Up to 1,500 Units IM Upper and lower limbs: Up to 1,500 Units IM staying within per limb guidelines <u>Pediatric:</u> Divided among affected muscles every 12 weeks: <ul style="list-style-type: none"> • Upper limb: Up to the lowr of 16 Units/kg/limb IM or 640 Units IM • Lower limb: Up to the lower of 15 Units/kg/limb IM or 1,000 Units IM • Bilateral lower limb: Up to the lower of 30 Units IM or 1,000 Units IM Upper and lower limbs: Up to the lower of 30 Units IM or 1,000 Units IM staying within per limb guidelines | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <i>Cervical Dystonia</i> | | |
| Botox [®] (OnabotulinumtoxinA) | Up to 50 Units IM per injection, 100 Units total in the sternocleidomastoid (SCM) muscle, and 300 Units per treatment session | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| Dysport (abobotulinumtoxinA) | Divided among affected muscles every 12 weeks: Up to 1,000 Units IM | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| <i>Blepharospasm</i> | | |
| Botox [®] (OnabotulinumtoxinA) | <ul style="list-style-type: none"> • Botox naive: Up to 2.5 Units IM per muscle, 7.5 Units per eye, and 15 Units per treatment session • Botox experienced: Up to 5 Units IM per muscle, 15 Units per eye, and 30 Units per treatment session | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |
| Dysport (abobotulinumtoxinA) | Up to 120 Units SC per treatment session. <i>(Off-label - Hallet 2009, Micromedex, Truong 2008)</i> | See dosing regimens for maximum dose Frequency: One treatment session every 12 weeks |

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Known hypersensitivity to the active substance botulinum neurotoxin type A or to any of the excipients
 - Infection at the proposed injection sites
- Boxed warning(s): Distant spread of toxin effect

Appendix D: Botulinum Toxin Product Interchangeability

- Potency Units of Xeomin are not interchangeable with other botulinum toxin product preparations (e.g., Dysport[®], Botox[®], Myobloc[®]).

Appendix E: Guideline Support for Botulinum Toxin Use

| Indication | Guideline |
|-----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Focal Dystonia* and Essential Tremor, and Headache</i> | |
| Blepharospasm, cervical dystonia, adult spasticity, and headache | Academy of Neurology (2016) |
| Migraine prevention | American Academy of Neurology and the American Headache Society (Neurology 2012, Headache 2021) |
| Laryngeal dystonia | American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNS, 2018) |
| Oromandibular dystonia | American Academy of Oral Medicine (2018) |
| Focal limb dystonia - UE** | American Academy of Neurology (2008) |
| Essential tremor - UE | American Academy of Neurology (2011) |
| Sialorrhea | American Academy of Cerebral Palsy and Developmental Medicine (AACPD, 2018); International Parkinson and Movement Disorder Society (2018) |
| OAB/urinary incontinence | American Urological Association Society of Urodynamics (2019) |
| <i>Gastrointestinal Conditions (see guidelines for required oral medication information)</i> | |
| Esophageal achalasia | American College of Gastroenterology (2020) |
| HD and IAS achalasia | American Pediatric Surgical Association (2017) |
| Chronic anal fissure | American College of Gastroenterology (2021) |

*American Academy of Neurology (AAN) classifies Botox use for hemifacial spasm and motor tics as category C, and notes that data are inadequate to make a recommendation for lower limb dystonia. All other AAN Botox recommendations above are classified as category B - probably effective.

**Policy criteria requiring failure of oral medication for dystonias are limited to dystonias affecting the limbs (see Cloud and Jinnah, 2010).

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| Chronic sialorrhea | <ul style="list-style-type: none"> • Adults: up to 30 Units IM per parotid gland, 20 Units IM per submandibular gland, and 100 Units IM per treatment session every 16 weeks. • Pediatrics (by body weight): <ul style="list-style-type: none"> ○ 12 kg to < 15 kg, 6 Units per parotid gland, 4 Units per submandibular gland, 20 Units per treatment session; ○ 15 kg to < 19 kg, 9 Units per parotid gland, 6 Units per submandibular gland, 30 Units per treatment session; | Adults: 100 Units/16 weeks Pediatrics: 75 Units/16 weeks |

| Indication | Dosing Regimen | Maximum Dose |
|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| | <ul style="list-style-type: none"> ○ 19 kg to < 23 kg, 12 Units per parotid gland, 8 Units per submandibular gland, 40 Units per treatment session; ○ 23 kg to < 27 kg, 15 Units per parotid gland, 10 Units per submandibular gland, 50 Units per treatment session; ○ 27 kg to < 30 kg, 18 Units per parotid gland, 12 Units per submandibular gland, 60 Units per treatment session; ○ ≥ 30 kg, 22.5 Units per parotid gland, 15 Units per submandibular gland, 75 Units per treatment session. | |
| CD | Up to 120 Units IM per treatment session every 12 weeks for treatment-naïve patients. Up to 300 Units IM per treatment session every 12 weeks for treatment-experienced patients. | 300 Units/12 weeks |
| Blepharospasm | Up to 50 Units IM per eye per treatment session every 12 weeks. | 100 Units/12 weeks |
| Upper limb spasticity | Up to 400 Units IM per treatment session every 12 weeks. | 400 Units/12 weeks |
| Off-label uses | | |
| Lower limb spasticity | Up to 400 Units IM per treatment session every 12 weeks. <i>(Off-label - Bensmail 2020, Santamato 2013)</i> | 400 Units/12 weeks |
| OAB/urinary incontinence associated with neurologic condition | Up to 200 Units IM in the detrusor muscle per treatment session every 12 weeks. <i>(Off-label - Asafu-Adjei 2020)</i> | 200 Units/12 weeks |
| Chronic migraine | Up to 155 Units IM per treatment session every 12 weeks. <i>(Off-label - Salazar 2014, Ion 2018)</i> | 155 Units/12 weeks |
| Axillary hyperhidrosis | Up to 100 Units IM per treatment session every 12 weeks. <i>(Off-label - Dressler 2010, Rosell 2013)</i> | 100 Units/12 weeks |
| Laryngeal Dystonia | Up to 25 Units IM per treatment session <i>(off-label – Kohli 2022)</i> | 25 Units/12 weeks |
| UE dystonia, UE essential tremor, OMD | Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use and member age (prescriber must submit supporting evidence; number of Units per treatment session does not exceed 400 Units IM per treatment session every 12 weeks). | 400 Units/12 weeks |

VI. Product Availability

Vials: 50 Units, 100 Units, 200 Units

VII. References

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Overactive Bladder, Urinary Incontinence

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Migraine, Spasticity, Dystonia, Tremor

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|-------------|----------------------------------------|
| J0588 | Injection, incobotulinumtoxinA, 1 unit |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------------|
| 2Q 2022 annual review: no significant changes; removal of the statement “*The treatment of hyperhidrosis is a benefit exclusion for HIM;” revised commercial approval duration from "6 months" (or whatever it is now) to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; references reviewed and updated. | 02.07.22 | 05.22 |
| Template changes applied to other diagnoses/indications and continued therapy section. | 10.07.22 | |
| 2Q 2023 annual review: Per February SDC and prior clinical guidance, added redirection requirement to co-prefer Botox and Dysport for all indications except chronic sialorrhea; references reviewed and updated. | 02.21.23 | 05.23 |
| 2Q 2024 annual review: added max dose for laryngeal dystonia (off-label); revised max dose for OMD from “25 units” to standard language “Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use and member age (prescriber must submit supporting evidence; number of Units per treatment session does not exceed 400 Units IM per treatment session every 12 weeks)”; references reviewed and updated. | 01.18.24 | 05.24 |
| RT4: updated FDA approved indications to include horizontal forehead lines and lateral canthal lines per PI with no clinical changes to the criteria as coverage is not authorized for cosmetic usage. | 07.18.24 | |
| 2Q 2025 annual review: for focal dystonia and essential tremor, added prescriber option for orofacial pain specialist; updated Appendix B with additional agents for OAB; references reviewed and updated. | 01.16.25 | 05.25 |
| Added step therapy bypass for IL HIM per IL HB 5395. | 06.27.25 | |
| 2Q 2026 annual review: extended Medicaid and HIM approval durations to 12 months; references reviewed and updated. Added ICHRA line of business. | 04.24.26 | 05.26 |

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

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