

Xeomin® (incobotulinumtoxinA) (Intramuscular/Intradetrusor/Intradermal)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Xeomin 50 unit Injection: 1 vial per 84 day supply
- Xeomin 100 unit Injection: 1 vial per 84 day supply (*per 112 days for severe primary axillary hyperhidrosis*)
- Xeomin 200 unit Injection: 2 vials per 84 day supply

B. Max Units (per dose and over time) [Medical Benefit]:

Indication	Billable Units	Per # days
Cervical dystonia	200	84
Blepharospasms	100	84
Upper limb spasticity	400	84
Prophylaxis for chronic migraines	200	84
Incontinence due to neurogenic detrusor overactivity	200	84
Overactive bladder (OAB)	100	84
Severe primary axillary hyperhidrosis	100	112
Sialorrhea	100	112

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient aged 18 or greater; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**

Cervical Dystonia †

- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
 - Patient has sustained head tilt; **OR**
 - Patient has abnormal posturing with limited range of motion in the neck

Blepharospasms †

Upper Limb Spasticity †

Prophylaxis for Chronic Migraines ‡

- Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g. erenumab, etc.); **AND**
- Patient is utilizing prophylactic intervention modalities (i.e. pharmacotherapy, behavioral therapy, or physical therapy, etc); **AND**
- Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of prophylactic medications below for examples); **AND**
- Patient has 15 or more migraine-like headache days per month for at least 3 months; **AND**
 - Headaches have diagnostic migraine-features, on at least 8 days per month for at least 3 months (see list of diagnostic migraine features with and without aura below) §; **OR**
 - Patient suspected migraines are relieved by a triptan or ergot derivative medication

Incontinence due to neurogenic detrusor overactivity ‡

- Patient has detrusor overactivity associated with a neurologic condition (i.e., spinal cord injury, multiple sclerosis, etc.) that is confirmed by urodynamic testing; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.

Overactive Bladder (OAB) ‡

- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.

Severe Primary Axillary Hyperhidrosis ‡

- Patient has tried and failed \geq 1 month trial of a topical agent (e.g., aluminum chloride, glycopyrronium, etc); **AND**
 - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**

- Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc)

Sialorrhea

- Duration of condition is 3 months or more; **AND**
- Patient has tried and failed, is unable to tolerate or has a contraindication to an adequate trial of oral therapy (e.g., glycopyrrolate, benztropine, atropine, etc.); **AND**
 - Patient has Parkinson’s disease, atypical Parkinsonism, stroke, or traumatic brain injury †; **OR**
 - Patient has a severe developmental delay ‡

† FDA Approved Indication(s); ‡ Literature Supported Indication

Migraine-Prophylaxis Oral Medications (<i>list not all-inclusive</i>)
<ul style="list-style-type: none"> • Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc)
Migraine Features
<p><u>Migraine without aura</u></p> <ul style="list-style-type: none"> • At least five attacks have the following: <ul style="list-style-type: none"> ○ Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) ○ Headache has at least two of the following characteristics: <ul style="list-style-type: none"> – Unilateral location – Pulsating quality – Moderate or severe pain intensity – Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); AND ○ During headache at least one of the following: <ul style="list-style-type: none"> – Nausea and/or vomiting – Photophobia and phonophobia
<p><u>Migraine with aura</u></p> <ul style="list-style-type: none"> • At least two attacks have the following: <ul style="list-style-type: none"> ○ One or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> – Visual – Sensory – Speech and/or language – Motor – Brainstem – Retinal; AND ○ At least two of the following characteristics: <ul style="list-style-type: none"> – At least one aura symptom spreads gradually over ≥5 minutes, and/or two or more symptoms occur in succession – Each individual aura symptom lasts 5 to 60 minutes – At least one aura symptom is unilateral – The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g. asthenia, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties, etc.), corneal ulceration, etc; **AND**
- Disease response as evidenced by the following:

Blepharospasms

- Improvement of severity and/or frequency of eyelid spasms

Cervical dystonia

- Improvement in the severity and frequency of pain; **AND**
- Improvement of abnormal head positioning

Upper Limb Spasticity

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g. Ashworth Scale, etc.)

Severe primary axillary hyperhidrosis

- Significant reduction in spontaneous axillary sweat production; **AND**
- Patient has a significant improvement in activities of daily living

Prophylaxis for chronic migraines

- Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Improvement in function; **AND**
- Patient continues to utilize prophylactic intervention modalities (i.e. pharmacotherapy, behavioral therapy, physical therapy, etc.)

Incontinence due to detrusor overactivity

- Significant improvements in weekly frequency of incontinence episodes; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Overactive bladder (OAB)

- Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

Sialorrhea associated with neurological disorders (Parkinson's disease, atypical Parkinsonism, stroke, traumatic brain injury, or severe developmental delay)

- Significant decrease in saliva production

V. Dosage/Administration

Indication	Dose
Cervical Dystonia	The recommended initial total dose for cervical dystonia is 120 Units. Initial dose is divided among the affected muscles every 12 weeks or longer, as necessary
Blepharospasm	1.25-5.6 units per injection site, not to exceed 50 units per eye (maximum of 35 units per eye for initial dose), every 12 weeks or longer, as necessary
Upper limb spasticity	Up to 400 units total no sooner than every 12 weeks
Chronic Migraine	Up to 200 units divided among the affected muscles every 12 weeks
Severe primary axillary hyperhidrosis	50 Units intradermally per axilla every 16 weeks
Neurogenic bladder/ Detrusor overactivity	Up to 200 units per treatment divided among the affected muscles every 12 weeks.
Overactive Bladder (OAB)	Up to 100 units per treatment divided among the affected muscles every 12 weeks
Sialorrhea	30 Units per parotid gland and 20 Units per submandibular gland (total recommended dose is 100 Units per treatment session), repeated no sooner than every 16 weeks

Note: The recommended maximum cumulative dose for any indication should not exceed 400 Units in a treatment session.

VI. Billing Code/Availability Information

Jcode:

- J0588 – Injection, incobotulinumtoxinA, 1 unit; 1 billable unit = 1 unit

NDC:

- Xeomin 50 unit Injection: 00259-1605-xx
- Xeomin 100 unit Injection: 00259-1610-xx
- Xeomin 200 unit Injection: 00259-1620-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G24.3	Spasmodic torticollis
G24.5	Blepharospasm
G25.89	Other specified extrapyramidal and movement disorders
G35	Multiple sclerosis
G37.0	Diffuse sclerosis of central nervous system
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus

G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G82.53	Quadriplegia, C5-C7, complete
G82.54	Quadriplegia, C5-C7, incomplete
G83.0	Diplegia of upper limbs, Diplegia (Upper), Paralysis of both upper limbs
G83.20	Monoplegia of upper limb affecting unspecified side
G83.21	Monoplegia of upper limb affecting right dominant side
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side

I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified site
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side

I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side
K11.7	Disturbances of salivary secretion
M43.6	Torticollis
N31.0	Uninhibited neuropathic bladder, not elsewhere classified
N31.1	Reflex neuropathic bladder, not elsewhere classified
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
L74.510	Primary focal hyperhidrosis, axilla

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 15	NCD/LCD Document (s): L33949
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33949&bc=gAAAAAAAAAAAAAAAAA==	

Jurisdiction(s): N	NCD/LCD Document (s): L33274
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33274&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): J, M	NCD/LCD Document (s): L33458
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33458&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): 6; K	NCD/LCD Document (s): L33646
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33646&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): F	NCD/LCD Document (s): L35172
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35172&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): E	NCD/LCD Document (s): L35170
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35170&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34635
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34635&bc=gAAAAAAAAAAAAAA==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC