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

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I. Length of Authorization [20]

Coverage will be provided for 6 months and may be renewed annually thereafter (unless otherwise specified).

- Ventral Hernia: Initial coverage will be provided for 6 months and may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

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
Ventral Hernia	500	N/A

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria [1]

- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**

- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB, daxibotulinumtoxinA, etc.); **AND**

Cervical Dystonia † [1,2]

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

Blepharospasms † [1]

Spastic Conditions [1]

- Patient has one of the following:
    - Upper Limb spasticity in adults (i.e., used post-stroke for spasms) **†**
    - Pediatric upper limb spasticity in patients aged 2 years to 17 years of age, excluding spasticity caused by cerebral palsy **†**

Prophylaxis for Chronic Migraines ‡ [3,8,10,23-25,27]

- Patient is utilizing prophylactic intervention modalities (i.e., avoiding migraine triggers, pharmacotherapy, behavioral therapy, physical therapy, etc.); **AND**
- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months; **AND**
    - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)**§**; **AND**
    - On at least 8 days per month for > 3 months:
        - Headaches have characteristics and symptoms consistent with migraine**§**; **OR**
        - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- One of the following apply:
    - Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of migraine-prophylactic medications below for examples **±**); **OR**
    - Patient had previous treatment with a CGRP antagonist used for prevention of migraines

Incontinence due to Neurogenic Detrusor Overactivity ‡ [7,9,19,28]

- 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 (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

Overactive Bladder (OAB) ‡ [7,9,19,28]

- 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 (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

Severe Primary Axillary Hyperhidrosis ‡ [4-6,26]

- Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, 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.)

Chronic Sialorrhea † [1,13,22]

- Patient has a history of troublesome sialorrhea for at least a 3 month period; **AND**
    - Patient has Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury **†**; **OR**
    - Patient has a severe developmental delay **‡**; **OR**
    - Patient has cerebral palsy, other genetic or congenital disorders, or traumatic brain injury **†**; **AND**
        - Patient is at least 2 years of age

Ventral Hernia ‡ [20,21]

- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

† FDA Approved Indication(s); **‡** Literature Supported Indication; **Φ** Orphan Drug

± Migraine-Prophylaxis Oral Medications *(list not all-inclusive)* [11,12,16,27]
• Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)

§ Migraine Features § [16,23,24]

Migraine without aura
• At least five attacks have the following:
  ○ Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
  ○ Headache has at least two of the following characteristics:
  – 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:
  – Nausea and/or vomiting
  – Photophobia and phonophobia

Migraine with aura
• At least two attacks have the following:
  ○ One or more of the following fully reversible aura symptoms:
  – Visual
  – Sensory
  – Speech and/or language
  – Motor
  – Brainstem
  – Retinal; **AND**
  ○ At least three of the following characteristics:
  – At least one aura symptom spreads gradually over ≥5 minutes
  – Two or more symptoms occur in succession
  – Each individual aura symptom lasts 5 to 60 minutes
  – At least one aura symptom is unilateral
  – At least one aura symptom is positive (e.g., scintillations and pins and needles)
  – The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific criteria as identified in section III; **AND**
- Duration of authorization has not been exceeded (refer to Section I); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reactions (e.g., anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea, etc.), corneal exposure/ulceration, ectropion in patients treated for blepharospasm, etc.; **AND**
- Disease response as evidenced by the following:

Blepharospasms [1]

- Improvement of severity and/or frequency of eyelid spasms

Cervical Dystonia [1]

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

- Improvement of abnormal head positioning

Upper Limb Spasticity [1]

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

Severe Primary Axillary Hyperhidrosis [4-6]

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

Prophylaxis for Chronic Migraines [10,16,23]

- 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 [9]

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

Overactive Bladder (OAB) [9]

- 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

Chronic Sialorrhea [1,13,22]

- Significant decrease in saliva production

V. Dosage/Administration [1-23]

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	The recommended initial dose for treatment naïve patients is 50 units (25 units per eye). Subsequent doses in patients previously treated with Xeomin should not exceed the maximum dose of 100 units per treatment session (50 units per eye), every 12 weeks or longer, as necessary.

Upper Limb Spasticity	The dosage, frequency, and number of injection sites should be tailored to the individual patient based on the size, number, and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, patient's response to previous treatment, and adverse event history with Xeomin. Localization of the involved muscles with electromyographic guidance, nerve stimulation, or ultrasound techniques is recommended. Adults Up to 400 units total, repeated no sooner than every 12 weeks Pediatrics 8 units/kg, divided among affected muscles, up to a maximum dose of 200 units per single upper limb. If both upper limbs are treated, total Xeomin dosage should not exceed 16 Units/kg, up to a maximum of 400 units, repeated 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	Adults: 30 units per parotid gland and 20 units per submandibular gland (50 units per each side of the face for a total recommended dose of 100 units per treatment session), repeated no sooner than every 16 weeks Pediatrics: Dosing is based on body weight as noted below and is repeated no sooner than every 16 weeks – 12 kg to <15 kg: 6 units per parotid gland and 4 units per submandibular gland (10 units per each side of the face for a total recommended dose of 20 units per treatment session) – 15 kg to <19 kg: 9 units per parotid gland and 6 units per submandibular gland (15 units per each side of the face for a total recommended dose of 30 units per treatment session) – 19 kg to <23 kg: 12 units per parotid gland and 8 units per submandibular gland (20 units per each side of the face for a total recommended dose of 40 units per treatment session) – 23 kg to <27 kg: 15 units per parotid gland and 10 units per submandibular gland (25 units per each side of the face for a total recommended dose of 50 units per treatment session) – 27 kg to <30 kg: 18 units per parotid gland and 12 units per submandibular gland (30 units per each side of the face for a total recommended dose of 60 units per treatment session)

	– 30 kg or more: 22.5 units per parotid gland and 15 units per submandibular gland (37.5 units per each side of the face for a total recommended dose of 75 units per treatment session)
Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. *May not be renewed.*
Note: *- The recommended maximum cumulative dose for any indication should not exceed 400 Units in a treatment session (unless used for Ventral Hernia).* *- Units of Xeomin are specific to the preparation and assay method utilized and are not interchangeable with other preparations of botulinum toxin products and cannot be compared to or converted into units of any other botulinum toxin products*	

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Xeomin 50 unit powder for injection; single-dose vial: 00259-1605-xx
- Xeomin 100 unit powder for injection; single-dose vial: 00259-1610-xx
- Xeomin 200 unit powder for injection; single-dose vial :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
K43.6	Other and unspecified ventral hernia with obstruction, without gangrene
K43.7	Other and unspecified ventral hernia with gangrene
K43.9	Ventral hernia without obstruction or gangrene
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

Dual coding requirements:

- Primary G and M codes require a secondary G or I code in order to be payable

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6 & K	A52848	National Government Services, Inc. (NGS)
F	A57186	Noridian Healthcare Solutions, LLC
E	A57185	Noridian Healthcare Solutions, LLC
5 & 8	A57474	Wisconsin Physicians Service Insurance Corp (WPS)
15	A56472	CGS Administrators, LLC
J & M	A56646	Palmetto GBA
N	A57715	First Coast Service Options, Inc.
H & L	A58423	Novitas Solutions, Inc.

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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