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

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I. Length of Authorization [20]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter, unless otherwise specified.
  - Ventral Hernia: Prior authorization validity 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]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria [1]

- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., hypersensitivity to any botulinum toxin product or any of its excipients, active infection at the proposed injection site); **AND**
- Member is not on concurrent treatment with another botulinum toxin; **AND**

Cervical Dystonia † [1,2,32]

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

Blepharospasms † [1]

Spastic Conditions [1]

- Member has one of the following:
  - Upper Limb spasticity in adults **† ‡**
  - Pediatric upper limb spasticity in members aged 2 years to 17 years of age, excluding spasticity caused by cerebral palsy **†**

Prophylaxis for Chronic Migraines ‡ [3,8,10,23-25,27,29,30]

- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Member is utilizing prophylactic intervention modalities (e.g., avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, physical therapy, etc.); **AND**
- Other causes of headaches have been ruled out; **AND**
- Member 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**
- On at least 8 days per month for > 3 months, headaches have one of the following features consistent with migraine:
  - Headache is relieved by triptans or ergot derivatives; **OR**
  - Headache is presenting as migraine with aura; **OR**
  - Headache is without aura but has characteristics of a migraine as determined by the provider (e.g., unilateral, pulsating, nausea/vomiting, photophobia/phonophobia, etc.)

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

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

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

- Member has symptoms of urge urinary incontinence, urgency, and frequency; **AND**

- Member has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

Severe Primary Axillary Hyperhidrosis ‡ [4-6,26,31]

- Member has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, sofpironium, etc.); **AND**
  - Member has a history of medical complications such as skin infections or significant functional impairments; **OR**
  - Member 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]

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

Ventral Hernia ‡ [20,21]

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

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member 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, dyspnea, etc.), corneal exposure/ulceration, ectropion in members 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**
- Member 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 compared to baseline on an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Improvement in function; **AND**
- Member continues to utilize prophylactic intervention modalities (e.g., avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, physical therapy, etc.)

Incontinence due to Neurogenic Detrusor Overactivity [9]

- Significant improvements in weekly frequency of incontinence episodes; **AND**
- Member'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**
- Member'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 members is 50 units (25 units per eye). Subsequent doses in members 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 member based on the size, number, and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, member'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.
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, incobotulinumtoxin a, 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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B1	Active primary progressive multiple sclerosis
G35.B2	Non-active primary progressive multiple sclerosis
G35.C0	Secondary progressive multiple sclerosis, unspecified
G35.C1	Active secondary progressive multiple sclerosis
G35.C2	Non-active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified
G37.0	Diffuse sclerosis of central nervous system
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migraine with aura, intractable, without 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
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
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	A59707	National Government Services, Inc. (NGS)
F	A57186	Noridian Healthcare Solutions, LLC
E	A57185	Noridian Healthcare Solutions, LLC

5 & 8	A59809	Wisconsin Physicians Service Insurance Corp (WPS)
15	A59726	CGS Administrators, LLC
J & M	A59714	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