Effective Date: 01/01/2022
Reviewed: 10/2021, 1/2022, 3/2023, 12/2023 Pharmacy Scope: Medicaid (Pharmacy Benefit ONLY) Medical Scope: Commercial, Medicare-Medicaid Plan (MMP)

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

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)**

****Effective 01/01/2022: Medication will only be covered on the Pharmacy Benefit for Medicaid Members**

I. Length of Authorization

- Coverage will be provided for six months and may be renewed for 12 months.
- Preoperative use in Ventral Hernia may NOT be renewed.

II. Dosing Limits

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

- Xeomin 50-unit Injection: 1 vial per 90 day supply
- Xeomin 100-unit Injection: 1 vial per 90 day supply (*per 112 days for severe primary axillary hyperhidrosis*)
- Xeomin 100-unit Injection: 5 vials once (for Ventral Hernia only)
- Xeomin 200-unit Injection: 2 vials per 90 day supply
- **Max Units (per dose and over time) [HCPCS Unit]:**

Indication	Billable Units	Per # days
Cervical dystonia	200	90
Blepharospasms	100	90
Upper limb spasticity	400	90
Prophylaxis for chronic migraines	200	90
Incontinence due to neurogenic detrusor overactivity	200	90
Overactive bladder (OAB)	100	90
Severe primary axillary hyperhidrosis	100	112
Sialorrhea	100	112
Ventral Hernia	500	N/A

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

- Xeomin 1 fill per 90 days

III. Initial Approval Criteria[1]

Coverage is provided in the following conditions:

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

Universal Criteria

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

Spastic Conditions

- 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] ‡

- Patient is utilizing prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, or physical therapy, etc.); **AND**
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 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 at least 3 months:
        - Headaches have characteristics and symptoms consistent with migraine§; **OR**
        - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- 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)

Incontinence due to neurogenic detrusor overactivity [7,9,19] ‡

- 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) [7,9,19] ‡

- 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 [4,5,6] ‡

- Patient has tried and failed ≥ 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.)

Chronic Sialorrhea [1,13] †

- 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

Migraine-Prophylaxis Oral Medications *(list not all-inclusive)*
• 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 (e.g., lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) • Calcium channels blockers (e.g., verapamil, etc.)
Migraine Features §

Migraine without aura
• At least five attacks have the following:
  o Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
  o 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**
  o 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:
  o One or more of the following fully reversible aura symptoms:
  – Visual
  – Sensory
  – Speech and/or language
  – Motor
  – Brainstem
  – Retinal; **AND**
  o At least two 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 universal and indication-specific criteria as 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, Physician Global Assessment, Clinical Global Impression (CGI), 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[10]

- 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

Ventral Hernias

- May not be renewed.

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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 (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
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).	

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- 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
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