

Policy:	082204 (MRx 05-23)	Initial Effective Date: 08/30/2022
Code(s):	HCPCS J0587	Annual Review Date: 05/18/2023
SUBJECT:	Xeomin® (incobotulinumtoxinA)	Last Revised Date: 05/18/2023

□Subject to Site of Care

### Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

### I. Length of Authorization <sup>20</sup>

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

### II. Dosing Limits

## A. Quantity Limit (max daily dose) [NDC Unit]:

- Xeomin 50 unit single-dose vial for injection: 1 vial per 84 day supply
- Xeomin 100 unit single-dose vial for injection: 1 vial per 84 day supply (*per 112 days for severe primary axillary hyperhidrosis*)
- Xeomin 100 unit single-dose vial for injection: 5 vials once (for Ventral Hernia only)
- Xeomin 200 unit single-dose vial injection: 2 vials per 84 day supply

### B. 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
<b>Prophylaxis for Chronic Migraines</b>	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<sup>1</sup>

Coverage is provided in the following conditions:

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

### Universal Criteria<sup>1</sup>

- 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, 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 †<sup>1</sup>

### **Spastic Conditions**<sup>1</sup>

- 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 ‡ <sup>3,8,10,23-25</sup>

- 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

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-



- 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
- 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 ±) prior to initiation of incobotulinumtoxinA

## Incontinence due to Neurogenic Detrusor Overactivity ‡<sup>7,9,19</sup>

- 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)** ‡ <sup>7,9,19</sup>

- 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 †<sup>1,13,22</sup>

- 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

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-and



## Ventral Hernia <sup>20,21</sup>

- 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)

 $\dagger$  FDA Approved Indication(s);  $\ddagger$  Literature Supported Indication;  $\Phi$  Orphan Drug

## ± Migraine-Prophylaxis Oral Medications (list not all-inclusive)<sup>11,12,16</sup>

- 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 § <sup>16,23,24</sup>

### 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  $\geq 5$  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<sup>1</sup>

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, 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<sup>1</sup>

• Improvement of severity and/or frequency of eyelid spasms

### Cervical Dystonia<sup>1</sup>

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

## Upper Limb Spasticity<sup>1</sup>

• 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**<sup>10,16,23</sup>

- 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 <sup>9</sup>

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

### **Overactive Bladder (OAB)**<sup>9</sup>

- 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<sup>1,13,22</sup>

• Significant decrease in saliva production

## Ventral Hernias<sup>20,21</sup>

• May not be renewed.

### V. Dosage/Administration<sup>1-23</sup>

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 <u>Pediatrics:</u> 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
	<ul> <li>units per treatment session)</li> <li>-15 kg to &lt;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)</li> </ul>
	-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)
	<ul> <li>-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)</li> </ul>
Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. <i>May not be renewed</i> .

### 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

- Xeomin [package insert]. Dessau-Rosslau, Germany; Merz Group Services GmbH; August 2021. Accessed April 2023.
- Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2016: 86:1-9
- 3. Grogan P, Robinson A, Chao W, Ford A. Incobotulinumtoxin A for the Preventive Treatment of Chronic Migraine Headaches. Neurology April 8, 2014 vol. 82 no. 10 Supplement P7.188
- 4. Lakraj AA<sup>1</sup>, Moghimi N, Jabbari B. Hyperhidrosis: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxins. Toxins (Basel). 2013 Apr 23; 5(4):821-40. doi: 10.3390/toxins5040821.

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-and



- Pastorelli F, Michelucci R, Plasmati R. A Randomized Controlled Trial Comparing Botulinum Toxin Type A Xeomin 
   <sup>®</sup> and Dysport 
   <sup>®</sup> for Treatment Of Primary Axillary Hyperhidrosis (P3.021). Neurology April 8, 2014 vol. 82 no. 10 Supplement P3.021
- Dressler D. Routine use of Xeomin in patients previously treated with Botox: long term results. Eur J Neurol. 2009 Dec; 16 Suppl 2:2-5. doi: 10.1111/j.1468-1331.2009.02877.x.
- Hampel C, D'Andrea D, Gillitzer R, et al. Comparison of two different Botulinumtoxin A products (Xeomin, Botox) used for detrusor injection in patients with bladder overactivity (BO) – a prospective randomized doubleblind study. Paper presented at: the 27th Annual European Association of Urology (EAU) Congress - February 24 - 28, 2012 - Le Palais des Congrès de Paris, Paris, France
- 8. The International Classification of Headache Disorders, 3rd edition (beta version).Headache Classification Committee of the International Headache Society (IHS) Cephalalgia. 2013 Jul;33(9):629-808.
- Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. 2019 Sep;202(3):558-563. doi: 10.1097/JU.000000000000309.
- 10. Schwedt TJ. Chronic Migraine. BMJ. 2014;348:g1416.
- 11. Modi S, Lowder DM. Medications for migraine prophylaxis. Am Fam Physician. 2006 Jan 1; 73(1):72-8.
- 12. Pringheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. Can Jneurol Sci. 2012 Mar; 39(2 Suppl 2):S1-S9.
- Blitzer A, Friedman A, Michel O, et al. SIAXI: IncobotulinumtoxinA for Sialorrhea in Parkinson's Disease, Stroke, and Other Etiologies-Phase III results. Archives of Physical Medicine and Rehabilitation, 2017 Dec. Volume 98, Issue 12, e161.
- 14. Jost W, Friedman A, Michel O, et al. SIAXI: Efficacy and safety of Xeomin (incobotulinumtoxinA) for the treatment of sialorrhea in Parkinson's disease (PD) and other neurological conditions: Results of a Phase III, placebo-controlled, randomized, double-blind study (S2.007). Neurology Apr 2018, 90 (15 Supplement) S2.007;
- 15. Glaser DA, Hebert AA, Nast A, et al. Topical glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials. J Am Acad Dermatol. 2019;80(1):128. Epub 2018 Jul 10
- 16. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18. doi: 10.1111/head.13456. Epub 2018 Dec 10.
- 17. Haider A, Solish N. Focal hyperhidrosis: diagnosis and management. CMAJ. 2005;172(1):69-75.
- Nawrocki S, Cha J. The Etiology, Diagnosis and Management of Hyperhidrosis: A Comprehensive Review. Part II. Therapeutic Options. J Am Acad Dermatol. 2019 Jan 30. pii: S0190-9622(19)30167-7.

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx</a>



- Kuo HC, Chen SL, Chou CL, et al. Taiwanese Continence Society clinical guidelines for diagnosis and management of neurogenic lower urinary tract dysfunction. Urological Science, Volume 25, Issue 2, 2014, pp. 35-41
- 20. Motz BM, Schlosser KA, Heniford BT. Chemical Components Separation: Concepts, Evidence, and Outcomes. Plast Reconstr Surg. 2018 Sep;142(3 Suppl):58S-63S. doi: 10.1097/PRS.000000000004856.
- 21. Elstner KE, Read JW, Saunders J, et al. Selective muscle botulinum toxin A component paralysis in complex ventral hernia repair. Hernia. 2019 Apr 4. doi: 10.1007/s10029-019-01939-3.
- 22. Merz Pharmaceuticals. Clinical Study to Investigate the Efficacy and Safety of NT 201 Compared to Placebo in the Treatment of Chronic Troublesome Drooling Associated With Neurological Disorders and/or Intellectual Disability (SIPEXI). Available from: https://clinicaltrials.gov/ct2/show/NCT02270736?cond=incobotulinumtoxinA+for+sialorrhea&draw=2&rank=3. NLM identifier: NCT02270736. Accessed December 22, 2020
- 23. The International Classification of Headache Disorders, 3rd edition (beta version).Headache Classification Committee of the International Headache Society (IHS) Cephalalgia. 2018 Jan;38(1):1-211.
- 24. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039. doi: 10.1111/head.14153.
- 25. Garza I, Schwedt TJ. (2022) Chronic Migraine. In Swanson JW (Ed). UpToDate. Accessed on April 11, 2022). Available from <u>https://www.uptodate.com/contents/chronic-</u> <u>migraine?search=chronic%20migraine&source=search\_result&selectedTitle=1~68&usage\_type=default&display</u> <u>\_rank=1</u>.
- 26. Mcconaghy J, Fosselma D. Hyperhidrosis: Management Options. Am Fam Physician. 2018;97(11):729-734. https://www.aafp.org/pubs/afp/issues/2018/0601/p729.html#afp20180601p729-b4
- National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848). Centers for Medicare & Medicaid Services, Inc. Updated on 12/29/2022 with effective date 01/05/2023. Accessed April 2023.
- Noridian Administrative Services, LLC Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186). Centers for Medicare & Medicaid Services, Inc. Updated on 01/16/2023 with effective date 01/01/2023. Accessed April 2023.
- 29. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article: Billing and Coding: Botulinum Toxin Type A & Type B (A57474). Centers for Medicare & Medicaid Services, Inc. Updated on 10/18/2022 with effective date 10/27/2022. Accessed April 2023.

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx</a>



- CGS, Administrators, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxins (A56472). Centers for Medicare & Medicaid Services, Inc. Updated on 12/29/2022 with effective date 12/29/2022. Accessed April 2023.
- Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B Policy (A57185). Centers for Medicare & Medicaid Services, Inc. Updated on 01/16/2023 with effective date 01/01/2023. Accessed April 2023.
- Palmetto GBA. Local Coverage Article: Billing and Coding: Chemodenervation (A56646). Centers for Medicare & Medicaid Services, Inc. Updated on 01/17/2023 with effective date 01/01/2023. Accessed April 2023.
- 33. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 02/04/2022 with effective date 02/10/2022. Accessed April 2023.
- Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A58423). Centers for Medicare & Medicaid Services, Inc. Updated on 02/04/2022 with effective date 02/10/2022. Accessed April 2023.

### **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

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx</a>



	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting
I69.139	unspecified site
	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right
I69.151	dominant side
	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left
I69.152	dominant side
T 60 1 70	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right
I69.153	non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non- dominant side
109.134	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting
I69.159	unspecified side
107.107	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right
I69.231	dominant side
	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left
I69.232	dominant side
	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right
I69.233	non-dominant side
160 224	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left
I69.234	non-dominant side Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting
I69.239	unspecified site
107.237	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting
I69.251	right dominant side
	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left
I69.252	dominant side
	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting
I69.253	right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
109.234	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting
I69.259	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	
107.332	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

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx</a>



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 adding requirements:	

**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)

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): J & M	NCD/LCD/LCA Document (s): A56646	
https://www.cms.gov/medicare-coverage-database/new-search/search-		
results.aspx?keyword=a56646&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2		
<u>C6%2C3%2C5%2C1%2CF%2CP</u>		

**Jurisdiction(s):** 5 & 8

NCD/LCD/LCA Document (s): A57474

https://www.cms.gov/medicare-coverage-database/new-search/searchresults.aspx?keyword=a57474&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2 C6%2C3%2C5%2C1%2CF%2CP

Jurisdiction(s): 6& K NCD/LCD/LCA Document (s): A52848	
--	--



https://www.cms.gov/medicare-coverage-database/new-search/searchresults.aspx?keyword=a52848&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2 C6%2C3%2C5%2C1%2CF%2CP

Jurisdiction(s): 15	NCD/LCD/LCA Document (s): A56472
https://www.cms.gov/medicare-coverage-database/new-search/search-	
results.aspx?keyword=a56472&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2	
<u>C6%2C3%2C5%2C1%2CF%2CP</u>	

Jurisdiction(s): F	NCD/LCD/LCA Document (s): A5/186
https://www.cms.gov/medicare-coverage-database/new-search/search-	
$\underline{results.aspx?keyword=a57186\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD\%2}$	
<u>C6%2C3%2C5%2C1%2CF%2CP</u>	

. . .

1 57100

	Jurisdiction(s): E	NCD/LCD/LCA Document (s): A57185	
https://www.cms.gov/medicare-coverage-database/new-search/search-			
regular come la come la come de come de come de come NCA 0/ 2CCAL 0/ 2CNCD0/ 2CMEDCA			

results.aspx?keyword=a57185&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2 C6%2C3%2C5%2C1%2CF%2CP

Jurisdiction(s): N	NCD/LCD/LCA Document (s): A57715
https://www.cms.gov/medicare-coverage-database/new-search/search-	
<pre>results.aspx?keyword=a57715&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2</pre>	
<u>C6%2C3%2C5%2C1%2CF%2CP</u>	

Jurisdiction(s): H & L

NCD/LCD/LCA Document (s): A58423

https://www.cms.gov/medicare-coverage-database/new-search/search-

results.aspx?keyword=a58423&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2 C6%2C3%2C5%2C1%2CF%2CP



Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdictio	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,	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 &	Novitas Solutions, Inc.	
K (13 & 14)	Fairfax counties and the city of Alexandria in NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)	
15	KY, OH	CGS Administrators, LLC	

#### **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

### FOR MEDICAL BENEFIT COVERAGE REQUESTS:

### Prior approval is required for HCPCS Codes J0588.

This document is subject to the disclaimer found at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> and is subject to change. Always verify with the most current version at <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx">https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx</a> or <a href="https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-and