

# Dysport® (abobotulinumtoxinA)

## (Intramuscular/Intradetrusor/Intradermal)

Document Number: SHP-0239

Last Review Date: 05/03/2021

Date of Origin: 06/21/2011

Dates Reviewed: 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 02/2013, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 03/2015, 06/2015, 08/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018, 04/2019, 09/2019, 10/2019, 01/2020, 05/2020, 08/2020, 05/2021

### I. Length of Authorization <sup>37</sup>

- Coverage will be provided for six 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]:

- Dysport 300 unit Injection: 1 vial per 84 day supply
- Dysport 500 unit Injection: 3 vials per 84 day supply
- Dysport 500 unit Injection: 1 vial once (for Ventral Hernia only)

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

Indication	Billable Units	Per # days
Cervical Dystonia	200	84
Chronic Migraine Prophylaxis	60	84
Sialorrhea	100	84
Chronic Anal Fissure	60	84
Blepharospasms	60	84
Upper Limb Spasticity	200	84
Upper Limb Spasticity (Pediatric)	160	84
Lower Limb Spasticity	300	84
Lower Limb Spasticity (Pediatric)	200	84
Neurogenic detrusor overactivity/OAB	160	84
Severe Primary Axillary Hyperhidrosis	100	84
Hemifacial Spasms	60	84
Ventral Hernia	500	N/A

### III. Initial Approval Criteria <sup>1</sup>

Xeomin is the preferred botulinum product for the overlapping indications which includes: Cervical Dystonia, Blepharospasms, Upper Limb Spasticity, Prophylaxis for chronic migraines, Incontinence due to neurogenic detrusor overactivity, Overactive bladder, Severe Primary Axillary Hyperhidrosis, and Sialorrhea. Patients must have failed, or have a contraindication, or intolerance to Xeomin prior to consideration of Dysport.

Coverage is provided in the following conditions:

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

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

- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., incobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB, etc.); **AND**

#### Cervical Dystonia † <sup>1</sup>

- 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

#### Spastic Conditions † ‡ <sup>1,2,12-14,28</sup>

- Patient has one of the following:
  - Upper/Lower Limb Spasticity in adults (i.e., spasticity post-stroke, traumatic brain or spinal cord injuries) †
  - Upper/Lower Limb Spasticity in pediatric patients at least 2 years of age †
  - Spasticity of the lower limbs due to multiple sclerosis or Schilder's disease ‡

#### Blepharospasms ‡ <sup>2,9-11</sup>

#### Prophylaxis for Chronic Migraines ‡ <sup>3,22,39</sup>

- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g., eptinezumab, erenumab, galcanezumab, fremanezumab, etc.) [*NOTE: This does not include CGRP inhibitors used for acute treatment (e.g., ubrogepant)*]; **AND**

- 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)

#### **Sialorrhea associated with neurological disorders ‡<sup>4,5</sup>**

- Patient has a history of troublesome sialorrhea for at least a 3-month period; **AND**
  - Patient has Parkinson’s disease; **OR**
  - Patient has severe developmental delays; **OR**
  - Patient has cerebral palsy

#### **Chronic Anal Fissure ‡<sup>6-8</sup>**

- Other causes of disease have been ruled out (i.e., Crohn’s Disease, etc.); **AND**
- Patient has failed on non-pharmacologic supportive measures (i.e., sitz baths, psyllium fiber, bulking agents, etc.); **AND**
- Patient has tried and failed a  $\geq 1$  month trial of conventional pharmacologic therapy (e.g. oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.)

#### **Incontinence due to neurogenic detrusor overactivity ‡<sup>15-17,23,36</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>15-17,23,36</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 (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.

#### **Severe Primary Axillary Hyperhidrosis ‡<sup>18,19</sup>**

- Patient has tried and failed  $\geq 1$  month trial of a topical agent (e.g., aluminum chloride, glycopyrronium, etc.); **AND**
  - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)

#### Hemifacial Spasms †<sup>20,21</sup>

#### Ventral Hernia †<sup>37,38</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)

† FDA approved indication(s); ‡ Literature Supported Recommendation; Ⓟ Orphan Drug

Migraine-Prophylaxis Oral Medications ( <i>list not all-inclusive</i> ) <sup>25,26,30</sup>
<ul style="list-style-type: none"> <li>• Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.)</li> <li>• Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.)</li> <li>• Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.)</li> <li>• Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)</li> <li>• Calcium channels blockers (e.g., verapamil, etc.)</li> </ul>
Migraine Features § <sup>39</sup>
<p><b>Migraine without aura</b></p> <ul style="list-style-type: none"> <li>• At least five attacks have the following: <ul style="list-style-type: none"> <li>○ Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)</li> <li>○ Headache has at least two of the following characteristics: <ul style="list-style-type: none"> <li>– Unilateral location</li> <li>– Pulsating quality</li> <li>– Moderate or severe pain intensity</li> <li>– Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); <b>AND</b></li> </ul> </li> <li>○ During headache at least one of the following: <ul style="list-style-type: none"> <li>– Nausea and/or vomiting</li> <li>– Photophobia and phonophobia</li> </ul> </li> </ul> </li> </ul>
<p><b>Migraine with aura</b></p> <ul style="list-style-type: none"> <li>• At least two attacks have the following: <ul style="list-style-type: none"> <li>○ One or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> <li>– Visual</li> <li>– Sensory</li> <li>– Speech and/or language</li> <li>– Motor</li> <li>– Brainstem</li> <li>– Retinal; <b>AND</b></li> </ul> </li> <li>○ At least three of the following characteristics: <ul style="list-style-type: none"> <li>– At least one aura symptom spreads gradually over <math>\geq 5</math> minutes</li> <li>– Two or more symptoms occur in succession</li> <li>– Each individual aura symptom lasts 5 to 60 minutes</li> <li>– At least one aura symptom is unilateral</li> <li>– At least one aura symptom is positive (e.g., scintillations and pins and needles)</li> <li>– The aura is accompanied, or followed within 60 minutes, by headache</li> </ul> </li> </ul> </li> </ul>

#### IV. Renewal Criteria <sup>1-38</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, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties, 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/Lower 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**

- 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.)

##### **Sialorrhea associated with neurological disorders**

- Significant decrease in saliva production

##### **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

### Hemifacial Spasms

- Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face

### Chronic Anal Fissure

- Complete healing of anal fissure; **OR**
- Symptomatic improvement of persistent fissures

### Ventral Hernias

- May not be renewed

## V. Dosage/Administration <sup>1,3,4,6,9,15-17,19,20,37</sup>

Indication	Dose
Cervical Dystonia	Initial dose: 500 units divided among the affected muscles. Re-treatment: 250-1000 units every 12-16 weeks or longer as necessary
Upper Limb Spasticity	<u>Adults</u> 500-1000 units divided among the affected muscles every 12-16 weeks or longer, as necessary. <i>Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.</i>  <u>Pediatrics</u> Up to 8-16 units/kg per limb every 12 weeks. Maximum dose per treatment session for upper limb spasticity is 16 units/kg or 640 units, whichever is lower. <i>Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower.</i>
Chronic Migraine Prophylaxis	Up to 240 units divided among the affected muscles every 12 weeks
Sialorrhea	Up to 450 units divided among the affected muscles every 12 weeks
Chronic Anal Fissure	Up to 150 units divided among the affected muscles every 12 weeks
Lower Limb Spasticity	<u>Adults</u> Up to 1500 units divided among the affected muscles every 12 weeks. <i>Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.</i>  <u>Pediatrics</u> Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks. Maximum dose per treatment session for lower limb spasticity is 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1000 units, whichever is lower. <i>Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower.</i>

Blepharospasms	Up to 120 units per affected eye every 12 weeks
Neurogenic Detrusor Overactivity/ Overactive Bladder (OAB)	Up to 750 units divided among the affected muscles every 12 weeks
Severe Primary Axillary Hyperhidrosis	Up to 200 units per axilla not more often than every 12 weeks
Hemifacial Spasms	Up to 220 units per treatment session based on sites and severity of the spasm. Subsequent injections administered upon recurrence of spasm, every 12 weeks, if needed.
Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. <i>May not be renewed.</i>

## VI. Billing Code/Availability Information

### HCPCS Code:

- J0586 – Injection, abobotulinumtoxinA, 5 units; 1 billable unit = 5 units

### NDC(s):

- Dysport 300 unit powder for injection; single-dose vial: 15054-0530-xx
- Dysport 500 unit powder for injection; single-dose vial: 15054-0500-xx

## VII. References

1. Dysport [package insert]. Wrexham, UK; Ipsen Biopharm Ltd; July 2020. Accessed April 2021.
2. 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. Chankrachang S, Arayawichanont A, Pongvarin N, et al. Prophylactic botulinum type A toxin complex (DYSPOORT®) for migraine without aura. *Headache* 2011; 51(1):52-63.
4. Mancini F, Zangaglia R, Cristina S, et al. Double-blind, placebo-controlled study to evaluate the efficacy and safety of botulinum toxin type A in the treatment of drooling in parkinsonism. *Move Disord*, 2003; 18(6): 685-688
5. Pal PK, Calne DB, Calne S, Tsui JK. Botulinum toxin A as treatment for drooling saliva in PD. *Neurology* 2000; 54:244–247.
6. Brisinda G, Albanese A, Cadeddu F, et al. Botulinum neurotoxin to treat chronic anal fissure: results of a randomized ‘Botox vs. DYSPOORT®’ controlled trial. *Aliment Pharmacol Ther.* 2004; 19:695-701.

7. Brisinda G, Cadeddu F, Brandara F, Marniga G, and Maria G. Randomized clinical trial comparing botulinum toxin injections with 0.2 percent nitroglycerin ointment for chronic anal fissure. *Br J Surg*. 2007; 94:162-167.
8. Jost W.H. and Schrank B. Chronic anal fissures treated with botulinum toxin injections: a dose-finding study with DYSPORT®. *Colorectal Disease*. 1999; 1:26-28.
9. Truong D, Comella C, Fernandez HH, et al. Efficacy and safety of purified botulinum toxin type A (Dysport®) for the treatment of benign essential blepharospasm: A randomized, placebo-controlled, phase II trial. *Parkinsonism & Related Disorders* Volume 14, Issue 5, July 2008, Pages 407–414. doi:10.1016/j.parkreldis.2007.11.003.
10. Bentivoglio AR, Fasano A, Ialongo T, et al. Fifteen-Year Experience in Treating Blepharospasm with Botox or Dysport: Same Toxin, Two Drugs. *Neurotoxicity Research* April 2009, Volume 15, Issue 3, pp 224-231. DOI 10.1007/s12640-009-9023-3
11. Ching-Piao Tsai, Ming-Chang Chiu, Der-Jen Yen, Yuh-Cherng Guo, Chih-Lun Yuan, and Tzu-Chi Lee. Quantitative Assessment of Efficacy of Dysport Botulinum Toxin Type A) in the Treatment of Idiopathic Blepharospasm and Hemifacial Spasm. *Acta Neurologica Taiwanica* Vol 14 No 2 June 2005
12. Hyman N, Barnes M, Bhakta B, et al. Botulinum toxin (Dysport) treatment of hip adductor spasticity in multiple sclerosis: a prospective, randomised, double blind, placebo controlled, dose ranging study. *J Neurol Neurosurg Psychiatry* 2000; 68:707–712.
13. Pittock SJ, Moore AP, Hardiman O, et al. A double-blind randomised placebo-controlled evaluation of three doses of botulinum toxin type A (Dysport) in the treatment of spastic equinovarus deformity after stroke. *Cerebrovasc Dis* 2003; 15:289–300.
14. Gusev YI, Banach M, Simonow A, et al. Efficacy and safety of botulinum type A toxin in adductor spasticity due to multiple sclerosis. *J Musculoskel Pain* 2008; 16:175-188.
15. Ravindra P, Jackson BL, Parkinson RJ. Botulinum toxin type A for the treatment of non-neurogenic overactive bladder: does using onabotulinumtoxinA (Botox®) or abobotulinumtoxinA (Dysport®) make a difference? *BJU International* Volume 112, Issue 1, pages 94–99, July 2013. DOI: 10.1111/bju.12028
16. Frohme C, Varga Z, Olbert P, Schrader AJ, Hofmann R, Hegele A. [Effects of botulinum toxin type A in the single and repeated treatment of overactive bladder. A prospective analysis]. *Der Urologe. Aug. A*[2010, 49(5):639-644] DOI:10.1007/s00120-009-2208-9
17. Abeywickrama L, Arunkalaivanan A, Quinlan M. Repeated botulinum toxin type A (Dysport®) injections for women with intractable detrusor overactivity: a prospective outcome study. *International Urogynecology Journal*. May 2014, Volume 25, Issue 5, pp 601-605
18. Montaser-Kouhsari L, Zartab H, Fanian F, et al. Comparison of intradermal injection with iontophoresis of abobotulinum toxin A for the treatment of primary axillary hyperhidrosis: A randomized, controlled trial. *Journal of Dermatological Treatment*. Volume 25, Issue 4, 2014. DOI: 10.3109/09546634.2012.739679.
19. Heckmann M, Ceballos-Baumann AO, Plewig G. Botulinum toxin A for axillary hyperhidrosis (excessive sweating). *N Engl J Med* 2001; 344:488-493.



20. Jitpimolmard S, Tiamkao S, & Laopaiboon M: Long term results of botulinum toxin type A (Dysport) in the treatment of hemifacial spasm: a report of 175 cases. *J Neurol Neurosurg Psychiatry* 1998; 64(6):751-757.
21. Van Den Bergh P, Francart J, Mourin S, et al: Five-year experience in the treatment of focal movement disorders with low-dose Dysport botulinum toxin. *Muscle Nerve* 1995; 18(7):720-729.
22. 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.
23. Gormley EA, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline. April 2019.
24. Schwedt TJ. Chronic Migraine. *BMJ*. 2014;348:g1416.
25. Modi S, Lowder DM. Medications for migraine prophylaxis. *Am Fam Physician*. 2006 Jan 1; 73(1):72-8.
26. Pringheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012 Mar; 39(2 Suppl 2):S1-S9.
27. 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.
28. 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
29. 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
30. 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.
31. Haider A, Solish N. Focal hyperhidrosis: diagnosis and management. *CMAJ*. 2005;172(1):69-75.
32. 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.
33. American Society for Gastrointestinal Endoscopy (ASGE): Standards of practice for the role of endoscopy in patients with anorectal disorders. *Gastro Endo*. Volume 72, No. 6 : 2010
34. Wald A, Bharucha AE, Cosman BC, et al. American Gastroenterological Association. American Gastroenterological Association medical position statement: Diagnosis and care of patients with anal fissure. *Gastroenterology*. 2003;124(1):233.

35. Stewart DB, Gaertner W, Glasgow S, et al. Clinical Practice Guideline for the Management of Anal Fissures. *Dis Colon Rectum* 2017; 60: 7–14.
36. 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
37. 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.0000000000004856.
38. 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.
39. 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.
40. National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848). Centers for Medicare & Medicaid Services, Inc. Updated on 10/25/2019 with effective date 10/31/2019. Accessed April 2021.
41. 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 12/16/2020 with effective date 10/01/2020. Accessed April 2021.
42. 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 03/21/2021 with effective date 04/01/2021. Accessed April 2021.
43. CGS, Administrators, LLC. Local Coverage Article: Billing and Coding: Billing and Coding for Botulinum Toxins (A56472). Centers for Medicare & Medicaid Services, Inc. Updated on 11/16/2020 with effective date 11/21/2020. Accessed April 2021.
44. 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 12/16/2019 with effective date 10/01/2020. Accessed April 2021.
45. Palmetto GBA. Local Coverage Article: Billing and Coding: Chemodenervation (A56646). Centers for Medicare & Medicaid Services, Inc. Updated on 01/29/2021 with effective date 01/01/2021. Accessed April 2021.
46. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 01/29/2021 with effective date 03/21/2021. Accessed April 2021.
47. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A58423). Centers for Medicare & Medicaid Services, Inc. Updated on 01/29/2021 with effective date 03/21/2021. Accessed April 2021.
48. Xeomin [package insert]. Dessau-Rosslau, Germany; Merz Group Services GmbH; July 2018. Accessed September 2018.

49. 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
50. Pastorelli F, Michelucci R, Plasmati R. A Randomized Controlled Trial Comparing Botulinum Toxin Type A Xeomin® and Dysport® for Treatment Of Primary Axillary Hyperhidrosis (P3.021). Neurology April 8, 2014 vol. 82 no. 10 Supplement P3.021
51. 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 double-blind 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
52. 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

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G11.4	Hereditary spastic paraplegia
G24.3	Spasmodic torticollis
G24.5	Blepharospasm
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
G51.3	Clonic hemifacial spasm
G51.31	Clonic hemifacial spasm, right
G51.32	Clonic hemifacial spasm, left
G51.33	Clonic hemifacial spasm, bilateral
G51.39	Clonic hemifacial spasm, unspecified
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
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
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
G83.10	Monoplegia of lower limb affecting unspecified side
G83.11	Monoplegia of lower limb affecting right dominant side
G83.12	Monoplegia of lower limb affecting left dominant side
G83.13	Monoplegia of lower limb affecting right nondominant side
G83.14	Monoplegia of lower limb affecting left nondominant side
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
I69.041	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.042	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.043	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.044	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.141	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.142	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.143	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side

I69.144	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.241	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.242	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.243	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.244	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side
I69.349	Monoplegia of lower limb following cerebral infarction affecting unspecified site
I69.841	Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side
I69.842	Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side
I69.843	Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side
I69.844	Monoplegia of lower limb following other cerebrovascular disease affecting left non-dominant side
I69.849	Monoplegia of lower limb following other cerebrovascular disease affecting unspecified site
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side
I69.941	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side
I69.942	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side
I69.943	Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.944	Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side
K11.7	Disturbances of salivary secretions
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
K60.1	Chronic anal fissure
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
M43.6	Torticollis

**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: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

<b>Jurisdiction(s):</b> 5 & 8	<b>NCD/LCD/LCA Document (s):</b> A57474
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> N	<b>NCD/LCD/LCA Document (s):</b> A57715
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57715&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57715&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> 6 & K	<b>NCD/LCD/LCA Document (s):</b> A52848
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> 15	<b>NCD/LCD/LCA Document (s):</b> A56472
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56472&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56472&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> F	<b>NCD/LCD/LCA Document (s):</b> A57186
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57186&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57186&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> E	<b>NCD/LCD/LCA Document (s):</b> A57185
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57185&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57185&amp;bc=gAAAAAAAAAAAA</a>	



<b>Jurisdiction(s):</b> J & M	<b>NCD/LCD/LCA Document (s):</b> A56646
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56646&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56646&amp;bc=gAAAAAAAAAAAA</a>	

<b>Jurisdiction(s):</b> H & L	<b>NCD/LCD/LCA Document (s):</b> A58423
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A58423&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A58423&amp;bc=gAAAAAAAAAAAA</a>	

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