

# Dysport® (abobotulinumtoxinA)

(Intramuscular/Intradetrusor/Intradermal)

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

- Coverage will be provided for 6 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 single-dose vial for injection: 1 vial per 84 day supply
- Dysport 500 unit single-dose vial for injection: 3 vials per 84 day supply
- Dysport 500 unit single-dose vial for 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         |
| Adult Upper Limb Spasticity           | 200            | 84         |
| Pediatric Upper Limb Spasticity       | 160            | 112        |
| Adult Lower Limb Spasticity           | 300            | 84         |
| Pediatric Lower Limb Spasticity       | 200            | 84         |
| Neurogenic Detrusor Overactivity/OAB  | 160            | 84         |
| Severe Primary Axillary Hyperhidrosis | 100            | 84         |
| Hemifacial Spasms                     | 60             | 84         |
| Ventral Hernia                        | 100            | 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 1

- 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.);

## Cervical Dystonia † Φ 1,28

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

## **Spastic Conditions** † ‡ 1,2,12-14,28,40

- 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 ‡ Φ <sup>2,9-11</sup>

## **Prophylaxis for Chronic Migraines** ‡ 3,22,39,41,42

- Patient is utilizing prophylactic intervention modalities (i.e. avoiding migraine triggers, pharmacotherapy, behavioral therapy, or physical therapy, etc.); **AND**
- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months; AND
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; AND
  - On at least 8 days per month for > 3 months:
    - Headaches have characteristics and symptoms consistent with migraine§; OR
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication;
       AND



 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 abobotulinumtoxinA

### Sialorrhea associated with Neurological Disorders ‡ 4,5

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

#### Chronic Anal Fissure ‡ 6-8

- 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 ≥ 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 ‡ 15-17,23,36

- 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) ‡ 15-17,23,36

- 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 ‡ 18,19,43

- 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.)



## Hemifacial Spasms ‡ 20,21

#### Ventral Hernia ‡ 37,38

- 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 (list not all-inclusive) 25,26,30

- 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 30,39,41

#### Migraine without aura

- At least five attacks have the following:
  - 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
  - During headache at least one of the following:
    - Nausea and/or vomiting
    - Photophobia and phonophobia

#### Migraine with aura

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

## IV. Renewal Criteria 1-38

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, dyspnea, etc.); AND
- Disease response as evidenced by the following:

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

• Improvement of severity and/or frequency of eyelid spasms

#### Cervical Dystonia 1

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

#### Upper/Lower 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 18,19

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

#### Prophylaxis for Chronic Migraines <sup>24,30,39</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.)

#### Sialorrhea associated with Neurological Disorders 4,5

• Significant decrease in saliva production

## Incontinence due to Detrusor Overactivity 15-17,23

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

## Overactive Bladder (OAB) 15-17.23

- 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 <sup>20,21</sup>

• 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 6-8

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

## Ventral Hernias 37,38

• May not be renewed

# V. Dosage/Administration <sup>1-4,6-8,15-17,19,20,37</sup>

| Indication                      | Dose  |
|---------------------------------|---|
| Cervical Dystonia               | Initial dose: 500 units divided among the affected muscles.   |
|                                 | Re-treatment: 250-1000 units every 12 weeks or longer as necessary  |
| Upper Limb                      | Adults  |
| Spasticity                      | 500-1000 units divided among the affected muscles every 12-16 weeks or longer, as necessary.  |
|                                 | Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.   |
|                                 | <u>Pediatrics</u>   |
|                                 | Up to 8-16 units/kg divided among the affected muscles every 16 weeks, or longer, as necessary. Maximum dose per treatment session for upper limb spasticity is 16 units/kg or 640 units, whichever is lower.   |
|                                 | Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units in a 3-month interval, whichever is lower.   |
| Chronic Migraine<br>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                      | <u>Adults</u>   |
| Spasticity                      | 1000-1500 units divided among the affected muscles every 12-16 weeks.   |
|                                 | Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.   |
|                                 | Pediatrics  |
|                                 | Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks, or longer, as necessary. 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. |



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|   | Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units in a 3-month interval, whichever is lower.       |
|---|---|
| Blepharospasms  | Up to 120 units per affected eye every 12 weeks   |
| Neurogenic Detrusor<br>Overactivity/<br>Overactive Bladder<br>(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> .   |
| Note: Units of Dysport a  | re specific to the preparation and assay method utilized and are not interchangeable with   |

Note: Units of Dysport 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:**

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; January 2023. Accessed April 2023.
- 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, Poungvarin N, et al. Prophylactic botulinum type A toxin complex (DYSPORT®) 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. DYSPORT®' 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, placebocontrolled, 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. Ausg. 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.
- 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 Jneurol 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. Safarpour Y, Mousavi T, Jabbari B. Botulinum Toxin Treatment in Multiple Sclerosis-a Review. Curr Treat Options Neurol. 2017 Aug 17;19(10):33. doi: 10.1007/s11940-017-0470-5.
- 41. 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.
- 42. Garza I, Schwedt TJ. (2022) Chronic Migraine. In Swanson JW (Ed). *UpToDate*. Accessed on April 11, 2022). Available from <a href="https://www.uptodate.com/contents/chronic-migraine?search=chronic%20migraine&source=search\_result&selectedTitle=1~68&usage\_type=default&display\_rank=1.">https://www.uptodate.com/contents/chronic-migraine?search=chronic%20migraine&source=search\_result&selectedTitle=1~68&usage\_type=default&display\_rank=1.</a>
- 43. 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
- 44. 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.



- 45. 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.
- 46. 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.
- 47. 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 12/01/2022. Accessed April 2023.
- 48. 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.
- 49. 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.
- 50. 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.
- 51. 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   |
|---------|--|
| 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  |
| 169.031 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side     |
| 169.032 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side      |
| 169.033 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side |
| 169.034 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side  |
| 169.039 | Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side        |



| 169.051 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side           |
|---------|---|
| 169.052 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side            |
| 169.053 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side       |
| 169.054 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side        |
| 169.059 | Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side              |
| 169.131 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side            |
| 169.132 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side             |
| 169.133 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side        |
| 169.134 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side         |
| 169.139 | Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site               |
| 169.151 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side          |
| 169.152 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side           |
| 169.153 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side      |
| 169.154 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side       |
| 169.159 | Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side             |
| 169.231 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side       |
| 169.232 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side        |
| 169.233 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side   |
| 169.234 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side    |
| 169.239 | Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site          |
| 169.251 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side     |
| 169.252 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side      |
| 169.253 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side |
| 169.254 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side  |
| 169.259 | Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side        |
| 169.331 | Monoplegia of upper limb following cerebral infarction affecting right dominant side                              |
| 169.332 | Monoplegia of upper limb following cerebral infarction affecting left dominant side                               |
| 169.333 | Monoplegia of upper limb following cerebral infarction affecting right non-dominant side                          |
| 169.334 | Monoplegia of upper limb following cerebral infarction affecting left non-dominant side                           |
| 169.339 | Monoplegia of upper limb following cerebral infarction affecting unspecified site                                 |
| 169.351 | Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side                            |



| 169.352 | Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side                      |
|---------|--|
| 169.353 | Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side                 |
| 169.354 | Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side                  |
| 169.359 | Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side                        |
| 169.831 | Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side             |
| 169.832 | Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side              |
| 169.833 | Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side         |
| 169.834 | Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side          |
| 169.839 | Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site                |
| 169.851 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side           |
| 169.852 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side            |
| 169.853 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side       |
| 169.854 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side        |
| 169.859 | Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side              |
| 169.931 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side       |
| 169.932 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side        |
| 169.933 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side   |
| 169.934 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side    |
| 169.939 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side          |
| 169.951 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side     |
| 169.952 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side      |
| 169.953 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side |
| 169.954 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side  |
| 169.959 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side        |
| 169.041 | Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right dominant side      |
| 169.042 | Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left dominant side       |
| 169.043 | Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side  |
| 169.044 | Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side   |
| 169.049 | Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage affecting unspecified side         |
| 169.141 | Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right dominant side     |
| 169.142 | Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left dominant side      |
| 169.143 | Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side |
| 169.144 | Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side  |
| 169.149 | Monoplegia of lower limb following nontraumatic intracerebral hemorrhage affecting unspecified site        |



| 169.241 | Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right dominant side     |
|---------|---|
| 169.242 | Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left dominant side      |
| 169.243 | Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side |
| 169.244 | Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side  |
| 169.249 | Monoplegia of lower limb following other nontraumatic intracranial hemorrhage affecting unspecified site        |
| 169.341 | Monoplegia of lower limb following cerebral infarction affecting right dominant side                            |
| 169.342 | Monoplegia of lower limb following cerebral infarction affecting left dominant side                             |
| 169.343 | Monoplegia of lower limb following cerebral infarction affecting right non-dominant side                        |
| 169.344 | Monoplegia of lower limb following cerebral infarction affecting left non-dominant side                         |
| 169.349 | Monoplegia of lower limb following cerebral infarction affecting unspecified site                               |
| 169.841 | Monoplegia of lower limb following other cerebrovascular disease affecting right dominant side                  |
| 169.842 | Monoplegia of lower limb following other cerebrovascular disease affecting left dominant side                   |
| 169.843 | Monoplegia of lower limb following other cerebrovascular disease affecting right non-dominant side              |
| 169.844 | Monoplegia of lower limb following other cerebrovascular disease affecting left non-dominant side               |
| 169.849 | Monoplegia of lower limb following other cerebrovascular disease affecting unspecified site                     |
| 169.939 | Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side               |
| 169.941 | Monoplegia of lower limb following unspecified cerebrovascular disease affecting right dominant side            |
| 169.942 | Monoplegia of lower limb following unspecified cerebrovascular disease affecting left dominant side             |
| 169.943 | Monoplegia of lower limb following unspecified cerebrovascular disease affecting right non-dominant side        |
| 169.944 | Monoplegia of lower limb following unspecified cerebrovascular disease affecting left non-dominant side         |
| 169.949 | 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: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. 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): 5 & 8  | NCD/LCD/LCA Document (s): A57474 |  |
|---|----------------------------------|--|
| https://www.cms.gov/medicare-coverage-database/new-search/search-                       |                                  |  |
| results.aspx?keyword=a57474&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6% |                                  |  |
| 2C3%2C5%2C1%2CF%2CP   |                                  |  |
|   |                                  |  |
| Jurisdiction(s): N  | NCD/LCD/LCA Document (s): A57715 |  |
|   |                                  |  |

https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57715&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP

| Jurisdiction(s): 6 & K  | NCD/LCD/LCA Document (s): A52848 |  |
|---|----------------------------------|--|
| https://www.cms.gov/medicare-coverage-database/new-search/search-                       |                                  |  |
| results.aspx?keyword=a52848&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6% |                                  |  |
| 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&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6% |                                  |  |
| 2C3%2C5%2C1%2CF%2CP   |                                  |  |

| Jurisdiction(s): F  | NCD/LCD/LCA Document (s): A57186 |
|---|----------------------------------|
| https://www.cms.gov/medicare-coverage-database/new-search/search- results.aspx?keyword=a57186&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6% 2C3%2C5%2C1%2CF%2CP |                                  |

| Jurisdiction(s): E | NCD/LCD/LCA Document (s): A57185 |
|--------------------|----------------------------------|
|--------------------|----------------------------------|



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

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

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%2C6% 2C3%2C5%2C1%2CF%2CP

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=aIl&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6% 2C3%2C5%2C1%2CF%2CP

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |  |
|---|---|---|--|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |  |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |  |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |  |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |  |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |  |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |  |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |  |
| J (10)  | TN, GA, AL  | Palmetto GBA, 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  | кү, он  | CGS Administrators, LLC                           |  |