

Dysport® (abobotulinumtoxinA) (Intramuscular/Intradetrusor/Intradermal)

Document Number: OHSU HEALTHSERVICES-0239

Last Review Date: 12/02/2025

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, 05/2022, 05/2023, 12/2024, 06/2025, 12/2025

I. Length of Authorization ³⁶

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter, unless otherwise specified.
 - Ventral Hernia: Prior authorization validity may NOT be renewed.
 - Chronic Anal Fissures: Prior authorization may be renewed every 6 months thereafter.

II. Dosing Limits

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 |
| Lower Limb Spasticity | 300 | 84 |
| Neurogenic Detrusor Overactivity/OAB | 160 | 84 |
| Severe Primary Axillary Hyperhidrosis | 100 | 84 |
| Palmar Hyperhidrosis | 100 | 168 |
| Hemifacial Spasms | 60 | 84 |
| Ventral Hernia | 100 | N/A |

III. Initial Approval Criteria ¹

Prior authorization validity 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 any of the following:
 - Hypersensitivity to any botulinum toxin product
 - Hypersensitivity to cow's milk protein
 - Active infection at the proposed injection site
 - Any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin; **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

Spastic Conditions † ‡ ^{1,2,12-14,20,21,39}

- Patient has one of the following:
 - Upper/Lower Limb Spasticity in adults † ‡
 - Upper/Lower Limb Spasticity in pediatric patients at least 2 years of age † ‡
 - Hemifacial Spasm ‡

Blepharospasms ‡ ^{2,9-11}

Prophylaxis for Chronic Migraines ‡ ^{3,22,38,40,41,43-45}

- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Patient is utilizing prophylactic intervention modalities (i.e. avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, physical therapy, etc.); **AND**
- Other causes of headaches have been ruled out; **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**
- On at least 8 days per month for > 3 months, headaches have characteristics and symptoms consistent with migraine

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**
 - 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 ‡^{15-17,23,35}

- 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 (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

Overactive Bladder (OAB) ‡^{15-17,23,35,44}

- 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 ‡^{18,19,42,46}

- Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, sofipironium, 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.)

Severe Palmar Hyperhidrosis ‡^{47,48}

- Patient has tried and failed ≥ 1 month trial of a topical agent (i.e., 20% aluminum chloride, etc.); **AND**
- Patient has failed with iontophoresis; **AND**
 - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
 - Patient has had a significant impact to activities of daily living due to condition

Ventral Hernia ‡^{36,37}

- 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); ‡ Compendia Recommended Indications(s); ◊ Orphan Drug

IV. Renewal Criteria¹⁻³⁷

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

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reactions (e.g., anaphylaxis, serum sickness, urticaria, soft tissue edema, dyspnea, etc.); **AND**
- Disease response as evidenced by the following:

Blepharospasms^{2,9-11}

- Improvement of severity and/or frequency of eyelid spasms

Cervical Dystonia¹

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

Upper/Lower Limb Spasticity¹

- 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

Severe Palmar Hyperhidrosis ^{47,48}

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

Prophylaxis for Chronic Migraines ^{24,29,38}

- Significant decrease in the number, frequency, and/or intensity of headaches compared to baseline on an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Improvement in function; **AND**
- Patient continues to utilize prophylactic intervention modalities (i.e., avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, 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 ^{20,21}

- 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

V. Dosage/Administration ^{1-4,6-8,15-17,19,20,36,47}

| 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 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 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. <i>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.</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> 1000-1500 units divided among the affected muscles every 12-16 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, 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. <i>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.</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 |

| | |
|--|---|
| Severe Palmar Hyperhidrosis | 100 to 240 Units per hand, repeated every 6 months (24 weeks), as needed. |
| 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>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.</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; September 2023. Accessed November 2025.
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 (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, 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. 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.
23. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. *J Urol*. Published online April 23, 2024. doi:10.1097/JU.0000000000003985. Available from: <https://www.auajournals.org/doi/10.1097/JU.0000000000003985>
24. Schwedt TJ. Chronic Migraine. *BMJ*. 2014;348:g1416.
25. Hein HA, Gonzalez A. Migraine Headache Prophylaxis. *Am Fam Physician*. 2019 Jan 1; 99(1):17-24.
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. 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
29. 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.
30. Haider A, Solish N. Focal hyperhidrosis: diagnosis and management. *CMAJ*. 2005;172(1):69-75.
31. 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.
32. 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
33. 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.
34. Stewart DB, Gaertner W, Glasgow S, et al. Clinical Practice Guideline for the Management of Anal Fissures. *Dis Colon Rectum* 2017; 60: 7–14.

35. 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
36. 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.
37. 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.
38. 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.
39. 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.
40. 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.
41. Garza I, Schwedt TJ. (2025) Chronic Migraine. In Robertson CE (Ed). *UpToDate*. Last updated October 3, 2024. Accessed on November 7, 2025. Available from <https://www.uptodate.com/contents/chronic-migraine>
42. 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>
43. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024; 64: 333-341. doi:10.1111/head.14692
44. Puledda F, Sacco S, Diener HC, et al. International Headache Society Global Practice Recommendations for Preventive Pharmacological Treatment of Migraine. *Cephalalgia*. 2024;44(9):3331024241269735. doi:10.1177/03331024241269735.
45. Sacco S, Ashina M, Diener HC, et al. Setting higher standards for migraine prevention: A position statement of the International Headache Society. *Cephalalgia*. 2025;45(2):3331024251320608. doi:10.1177/03331024251320608
46. Odat RM, Yousef Aldalati A, Hammadeh BM, et al. Efficacy and safety of sofpironium in treatment of primary hyperhidrosis: a systematic review. *J Dermatolog Treat*. 2025 Dec;36(1):2441258. doi: 10.1080/09546634.2024.2441258. Epub 2024 Dec 13. PMID: 39668771.
47. Weinberg T, Solish N, Murray C. Botulinum neurotoxin treatment of palmar and plantar hyperhidrosis. *Dermatol Clin*. 2014 Oct; 32(4):505-15. Epub 2014 Jul 24

48. Smith CC, Pariser MD. (2024) Primary focal hyperhidrosis. In Dellavalle RP, Owen C (Eds). *UpToDate*. Last updated: May 13, 2024. Accessed on November 5, 2025. Available from <https://www.uptodate.com/contents/primary-focal-hyperhidrosis>
49. National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848). Centers for Medicare & Medicaid Services, Inc. Updated on 09/17/2025 with effective date 10/01/2025. Accessed November 2025.
50. 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 10/23/2025 with effective date 10/01/2025. Accessed November 2025.
51. 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 09/17/2025 with effective date 10/01/2025. Accessed November 2025.
52. CGS, Administrators, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxins (A56472). Centers for Medicare & Medicaid Services, Inc. Updated on 09/17/2025 with effective date 10/01/2025. Accessed November 2025.
53. 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 10/23/2025 with effective date 10/01/2025. Accessed November 2025.
54. Palmetto GBA. Local Coverage Article: Billing and Coding: Chemodenervation (A56646). Centers for Medicare & Medicaid Services, Inc. Updated on 08/21/2025 with effective date 10/01/2025. Accessed November 2025.
55. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 09/19/2025 with effective date 11/09/2025. Accessed November 2025.
56. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A58423). Centers for Medicare & Medicaid Services, Inc. Updated on 09/19/2025 with effective date 11/09/2025. Accessed November 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

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

| Factor | Conclusion |
|------------|----------------------|
| Indication | Yes: Consider for PA |

| | |
|----------------------------|-----------------------|
| Safety and efficacy | Yes: Consider for PA |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---------|--|
| G11.4 | Hereditary spastic paraplegia |
| G24.3 | Spasmodic torticollis |
| G24.5 | Blepharospasm |
| G35.A | Relapsing-remitting multiple sclerosis |
| G35.B0 | Primary progressive multiple sclerosis, unspecified |
| G35.B1 | Active primary progressive multiple sclerosis |
| G35.B2 | Non-active primary progressive multiple sclerosis |
| G35.C0 | Secondary progressive multiple sclerosis, unspecified |
| G35.C1 | Active secondary progressive multiple sclerosis |
| G35.C2 | Non-active secondary progressive multiple sclerosis |
| G35.D | Multiple sclerosis, unspecified |
| G37.0 | Diffuse sclerosis of central nervous system |
| G43.701 | Chronic migraine without aura, not intractable, with status migrainosus |
| G43.709 | Chronic migraine without aura, not intractable, without status migrainosus |
| G43.711 | Chronic migraine without aura, intractable, with status migrainosus |
| G43.719 | Chronic migraine without aura, intractable, without status migrainosus |
| G43.E01 | Chronic migraine with aura, not intractable, with status migrainosus |
| G43.E09 | Chronic migraine with aura, not intractable, without status migrainosus |
| G43.E11 | Chronic migraine with aura, intractable, with status migrainosus |
| G43.E19 | Chronic migraine with aura, intractable, without status migrainosus |
| 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 |
| G80.3 | Athetoid cerebral palsy |

| | |
|---------|---|
| G80.4 | Ataxic cerebral palsy |
| G80.8 | Other cerebral palsy |
| G80.9 | Cerebral palsy, unspecified |
| 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 |

| | |
|---------|--|
| 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 |
| 169.051 | 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 |
| 169.141 | 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 |
| 169.151 | 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 |
| 169.241 | 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 |
| 169.251 | 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 |
| 169.341 | 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 |
| 169.351 | 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 |
| 169.841 | 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 |
| 169.851 | 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 |
| 169.941 | 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 |

| | |
|---------|--|
| I69.949 | Monoplegia of lower limb following unspecified cerebrovascular disease affecting unspecified side |
| I69.951 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side |
| I69.952 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side |
| I69.953 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side |
| I69.954 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side |
| I69.959 | Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side |
| K11.7 | Disturbances of salivary 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 |
| L74.512 | Primary focal hyperhidrosis, palms |
| 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)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

| Medicare Part B Covered Diagnosis Codes | | |
|---|--------------------------|---|
| Jurisdiction | NCD/LCA/LCD Document (s) | Contractor |
| 5 & 8 | A57474 | Wisconsin Physicians Service Insurance Corp (WPS) |
| N | A57715 | First Coast Service Options, Inc. |
| 6 & K | A52848 | National Government Services, Inc. (NGS) |
| 15 | A56472 | CGS Administrators, LLC |
| F | A57186 | Noridian Healthcare Solutions, LLC |
| E | A57185 | Noridian Healthcare Solutions, LLC |
| J & M | A56646 | Palmetto GBA |
| H & L | A58423 | Novitas Solutions, Inc. |

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