

Dysport® (abobotulinumtoxinA)

When requesting Dysport® (abobotulinumtoxinA), the individual requiring treatment must be diagnosed with one of the following approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

- Cervical dystonia in adults
- Upper and lower limb spasticity in patients 2 years of age and older

Approved Off-label Compensial Uses

- Blepharospasm
- Hemifacial spasm
- Chronic anal fissure
- Chronic sialorrhea
- Oromandibular dystonia

Coverage Guidelines

The individual must be 18 years of age or older for approval of the following indications:

- Cervical dystonia (Spasmodic torticollis)
- Blepharospasm
- Hemifacial spasm
- Chronic anal fissure
- Chronic sialorrhea
- Oromandibular dystonia

The individual must be 2 years of age or older for approval of the following indications:

- Upper limb spasticity
- Lower limb spasticity

Approval Duration: 12 months

Dosing Recommendations

Cervical Dystonia

The recommended initial dose is 500 units administered intramuscularly. Dose adjustment can be made in 250 unit steps up to a maximum dose of 1000 units according to the individual patient's response, with re-treatment every 12 weeks or longer.

Adult Spasticity (upper and lower)

The recommended dosing for upper limb spasticity is between 500 units and 1000 units and for lower limb spasticity is up to 1500 units, administered intramuscularly every 12 weeks or longer.

Pediatric Upper Limb Spasticity

The recommended dosing for upper limb spasticity is 8 units/kg to 16 units/kg per limb, administered intramuscularly. The maximum recommended total dose administered per treatment session must not exceed 16 units/kg or 640 units, whichever is lower. The re-treatment should occur no sooner than 16 weeks after the previous injection

Pediatric Lower Limb Spasticity

The recommended dosing for lower limb spasticity is 10 units/kg to 15 units/kg per limb, administered intramuscularly. Total dose per treatment session must not exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral injections, or 1000 units, whichever is lower. The re-treatment should occur no sooner than 12 weeks after the previous injection.

Blepharospasm

The recommended maximum dose is 120 units per eye, administered subcutaneously no more frequently than every 12 weeks.

Hemifacial Spasm

The recommended maximum dose is 220 units per treatment session, administered subcutaneously no more frequently than every 12 weeks.

Chronic Anal Fissure

The recommended dose is a maximum of 100 units, administered no more frequently than every 12 weeks.

Chronic Sialorrhea

The recommended dose is a maximum of 300 units (150 units per side), administered no more frequently than every 16 weeks.

Oromandibular Dystonia

The recommended dose is up to a maximum of 1,200 units administered not more frequently than once every 12 weeks.

References

1. Dysport® for injection [prescribing information]. Cambridge, MA and Fort Worth, TX: Ipsen/Galderma; September 2023.
2. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: management of benign anorectal. *Am J Gastroenterol*. 2021;116(10):1987-2008.
3. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 1. *Am J Health Syst Pharm*. 2006;63(2): 145–152.
4. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 2. *Am J Health Syst Pharm*. 2006;63(3):225-232.
5. Truong D, Comella C, Fernandez HH, et al.; Dysport Benign Essential Blepharospasm Study Group. 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 Relat Disord*. 2008;14(5):407-14.
6. Kollewe K, Mohammadi B, Köhler S, et al. Blepharospasm: long-term treatment with either Botox®, Xeomin® or Dysport®. *J Neural Transm*. 2015;122(3):427-31.
7. 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;86:1818-1826.
8. Simpson DM, Blitzer A, Brashear A, et al. Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1699-1706.
9. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci*. 2005;235(1-2):1-9.
10. Müller J, Wenning GK, Wissel J, Seppi K, Poewe W. Botulinum toxin treatment in atypical parkinsonian disorders associated with disabling focal dystonia. *J Neurol*. 2002;249(3):300-304.
11. Jankovic J, Orman J. Botulinum A toxin for cranial-cervical dystonia: a double-blind, placebo-controlled study. *Neurology*. 1987;37(4):616-623.
12. France K, Stoopler ET. The American Academy of Oral Medicine Clinical Practice Statement: Oromandibular dystonia. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2018;125(4):283-285.
13. Van den Bergh P, Francart J, Mourin S, Kollmann P, Laterre EC. Five-year experience in the treatment of focal movement disorders with low-dose Dysport botulinum toxin. *Muscle Nerve*. 1995;18(7):720-729.
14. Hassell TJW, Charles D. Treatment of Blepharospasm and Oromandibular Dystonia with Botulinum Toxins. *Toxins (Basel)*. 2020;12(4):269. Published 2020 Apr 22.
15. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxin. *Toxins*. 2013;5:1010-1031.
16. Botox® injection [prescribing information]. Madison, NJ: Allergan; August 2022.
17. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.
18. Scaglione F. Conversion ratio between Botox®, Dysport®, and Xeomin® in clinical practice. *Toxins (Basel)*. 2016;8(3):65.
19. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on September 17, 2024. Search terms: Dysport.
20. Hallett M, Albanese A, Dressler D, Segal KR, Simpson DM, Truong D, Jankovic J. Evidence-based review, and assessment of botulinum neurotoxin for the treatment of movement disorders. *Toxicon*. 2013 Jun 1;67:94-114.
21. Berkel AE, Rosman C, Koop R, van Duijvendijk P, van der Palen J, Klaase JM. Isosorbide dinitrate ointment vs botulinum toxin A (Dysport) as the primary treatment for chronic anal fissure: a randomized multicentre study. *Colorectal Dis*. 2014 Oct;16(10):O360-6. doi: 10.1111/codi.12615. PMID: 24629060.
22. 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 Jun;64(6):751-7. doi: 10.1136/jnnp.64.6.751. PMID: 9647304; PMCID: PMC2170133.