

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

Approved Off-label Compensial Uses

- Blepharospasm
- Hemifacial spasm
- Anal fissure
- Chronic sialorrhea

Coverage Guidelines

The individual must have one of the following indications for the approval:

- Cervical dystonia
- Upper and lower limb spasticity
- Blepharospasm
- Hemifacial spasm
- Anal fissure
- Chronic sialorrhea

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. The

maximum recommended total dose per treatment session (upper and lower limb combined) is 1500 units with re-treatment 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 not more frequently than once every 12 weeks.

Hemifacial Spasm

The recommended maximum dose is 220 units per treatment session, administered subcutaneously not more frequently than once every 3 months.

Anal Fissure

The recommended maximum dose is 1,200 units, administered not more frequently than once every 3 months.

Chronic Sialorrhea

The recommended maximum dose is 300 units (150 units per side), administered not more frequently than once every 16 weeks.

References

1. Dysport® for injection [prescribing information]. Cambridge, MA and Fort Worth, TX: Ipsen/Galderma; January 2023.
2. Smith CP, Chancellor MB. Emerging role of botulinum toxin in the management of voiding dysfunction. *J Urol.* 2004;17(6 Pt 1):2128-2137.
3. Brisinda G, Bentivoglio AR, Maria G, et al. Treatment with botulinum neurotoxin of gastrointestinal smooth muscles and sphincters spasms. *Mov Disord.* 2004;19(Suppl 8):S146-S156.
4. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol.* 2014;109(8):1141-57. Available at: <http://gi.org/guideline/management-of-benign-anorectal-disorders/>. Accessed on May 27, 2020.
5. 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.

6. 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.
7. 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.
8. 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. Available at: <http://www.neurology.org/content/86/19/1818.full>. Accessed on May 27, 2020.
9. Naumann M, So Y, Argoff AE, et al. Assessment: botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1707-1714. Available at: <http://neurology.org/content/70/19/1707.full>. Accessed on May 29, 2020.
10. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci*. 2005;235(1-2):1-9.
11. Tan EK. Botulinum toxin treatment of sialorrhea: comparing different therapeutic preparations. *Eur J Neurol*. 2006;13 (Suppl 1):60-64.
12. Sheffield JK, Jakovic J. Botulinum toxin in the treatment of tremors, dystonias, sialorrhea and other symptoms associated with Parkinson's disease. *Expert Rev Neurotherapeutics*. 2007;7(6):637-647.
13. Pathak MS, Nguyen HT, Graham HK, et al. Management of spasticity in adults: practical application of botulinum toxin. *Eur J Neurol*. 2006;13 Suppl 1:42-50.
14. Bakheit AM, Pittock S, Moore AP, et al. A randomized, double-blind, placebo-controlled study of the efficacy and safety of botulinum toxin type A in upper limb spasticity in patients with stroke. *Eur J Neuro*. 2001;8:559-565.
15. Ubhi T, Bhakta BB, Ives HL, et al. Randomised double-blind placebo-controlled trial of the effect of botulinum toxin on walking in cerebral palsy. *Arch Dis Childhood*. 2000;83:481-487.
16. Park ES, Rha DW. Botulinum toxin type A injection for management of upper limb spasticity in children with cerebral palsy: a literature review. *Yonsei Med J*. 2006;47(5):589-603.
17. Frei K, Truong DD, Dressler D. Botulinum toxin therapy of hemifacial spasm: comparing different therapeutic preparations. *Eur J Neurol*. 2006;13(Suppl 1):30-35.
18. Kollewe K, Mohammadi B, Dengler R, et al. Hemifacial spasm and reinnervation synkinesias: long-term treatment with either Botox or Dysport. *J Neural Transm*. 2010;117:759-763.
19. Stewart DB Sr, Gaertner W, Glasgow S, Migaly J, Feingold D, Steele SR. Clinical practice guideline for the management of anal fissures. *Dis Colon Rectum*. 2017;60(1):7-14.
20. Vashishta R, Nguyen SA, White DR, Gillespie MB. Botulinum toxin for the treatment of sialorrhea: a meta-analysis. *Otolaryngol Head Neck Surg*. 2013;148(2):191-196.
21. AbobotulinumtoxinA (Dysport®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Updated; December 13, 2020; Accessed April 18, 2023.
22. AbobotulinumtoxinA (Dysport®). Micromedex. Available at: <https://www.micromedexsolutions.com/> Accessed on April 18, 2023.