

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Dysport (abobotulinumtoxinA)
BILLING CODE	J0586
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office, Outpatient
STATUS	Prior Authorization Required

Dysport is a neurotoxin produced from Clostridium botulinum serotype A. It works through the inhibition of acetylcholine release from peripheral nerve endings, causing neuromuscular blockage and muscle paralysis. Dysport was initially approved by the FDA in 2009 for the treatment of adults with cervical dystonia. Cervical dystonia (also known as spasmodic torticollis) involves the involuntary contractions of the neck that cause abnormal movements and postures of the neck and head. Dysport is the first botulinum toxin approved for both upper and lower spasticity in pediatric patients.

Dysport (abobotulinumtoxinA) will be considered for coverage when the following criteria are met:

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist or other specialist experienced with treating cervical dystonia; AND
3. Member has a documented diagnosis of moderate to severe cervical dystonia as evidenced by involuntary contractions of neck muscles, leading to abnormal movements or postures; AND
4. Symptoms affect quality of life and daily functions.
5. **Dosage allowed:** Up to 1000 units every 12 weeks, divided among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. severity of abnormal head position, neck pain).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SPASTICITY

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist or other specialist experienced with treating spasticity (e.g., PM&R); AND

3. Member has a documented diagnosis of upper or lower limb spasticity that affects daily functioning and quality of life; AND
4. Spasticity is secondary to a neurologic condition such as cerebral palsy, stroke, or brain or spinal cord injury; AND
5. Member has tried or is unable to try one conventional treatment modality such as physical therapy or oral medication (e.g. baclofen, tizanidine).
6. **Dosage allowed:** Adult: Not to exceed 1500 total units every 12 weeks (given intramuscularly as a divided dose among affected muscles). Pediatric: Not to exceed 1000 total units or 30 units per kg (whichever is lower) every 3 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. decrease in severity of increased muscle tone).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Dysport (abobotulinumtoxinA) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/06/2018	New policy for Dysport created. Diagnoses of Blepharospasm and Upper extremity dystonia (e.g. writer's cramp) are no longer covered. Diagnoses of Spasticity and Lower Limb spasticity combined, patient weight and age are no longer required. Criterion "no infection at proposed injection site" removed from Cervical Dystonia diagnosis. Age limitation removed from Cervical Dystonia; pain and abnormal head position requirements clarified and medications trial added.
08/17/2020	<u>Cervical dystonia</u> : Added age limit and specialist requirement. Re-worded the diagnosis requirement. Removed trial of oral medication. Removed exclusions. Corrected the dose. Extended re-auth duration. Updated references. <u>Spasticity</u> : Add age and specialist. Update to match latest drug label. Relaxed list of co-existing conditions. Added trial of conventional treatment. Extended initial auth duration. Added reference.
08/10/2021	Transferred to new template. Allowing additional specialists for cervical dystonia and spasticity indications.

References:

1. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; 2020.
2. MCG 20th Edition, 2016.
3. U.S. Drug and Food Administration Safety Data.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/125036s044lbl.pdf (March 6, 2011).
4. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2011. (March 6, 2011).
5. Brashear A, Lew MF, Dykstra DD, et al, "Safety and Efficacy of NeuroBloc (Botulinum Toxin Type B) in Type A-Responsive Cervical Dystonia," Neurology, 1999, 53(7):1439-46.
6. Clinical Use of Botulinum Toxin," Arch Neurol, 1991, 48(12):1294-8.
7. Benecke R, Jost WH, Kanovsky P, et al, "A New Botulinum Toxin Type A Free of Complexing Proteins for Treatment of Dystonia," Neurology, 2005, 64(11):1949-51.
8. Borodic GE and Pearce LB, "New Concepts in Botulinum Toxin Therapy," Drug Saf, 1994, 11(3):145-52. Jankovic J and Brin MF, "Therapeutic Uses of Botulinum Toxin," N Engl J Med, 1991, 324(17):1186-94.
9. Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," Curr Med Res Opin, 2004, 20(7):981-90.

10. Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, *Muscle Nerve Suppl* 1997; 6:S181.
11. Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome *Am J Phys Med Rehabil*. 2002 Dec;81(12):936-42.
12. Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. <http://www.guideline.gov/content.aspx?id=12942>(March 11 2011).
13. Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70(19):1699-706.
14. Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70:1707-14.
15. Keam SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. *Drugs* 2011;71(8):1043-58.
16. Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. *Neurology*. 2004;62(1):37-40.
17. Cervical Dystonia. NORD (National Organization for Rare Disorders). <https://rarediseases.org/rare-diseases/cervical-dystonia/>. Published July 19, 2019. Accessed July 17, 2020.
18. 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. *Neurology*. 2016;86(19):1818-1826. doi:10.1212/wnl.0000000000002560
19. Dressler D, Altenmueller E, Bhidayasiri R, et al. Strategies for treatment of dystonia. *Journal of Neural Transmission*. 2015;123(3):251-258. doi:10.1007/s00702-015-1453-x
20. Lindsay C, Kouzouna A, Simcox C, Pandyan AD. Pharmacological interventions other than botulinum toxin for spasticity after stroke. *Cochrane Database of Systematic Reviews* 2016, Issue 10. Art. No.: CD010362. DOI: 10.1002/14651858.CD010362.pub2.

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