

PHARMACY POLICY STATEMENT

Arkansas PASSE

DRUG NAME	Dysport (abobotulinumtoxinA)
BENEFIT TYPE	Medical
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 and is approved for the treatment of adults with cervical dystonia and for the treatment of spasticity in patients 2 years of age and older.

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

Cervical Dystonia

For **initial** authorization:

1. Member is at least 18 years of age; 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 with dystonic symptoms localized to the head, neck, shoulder areas.
4. **Dosage allowed/Quantity limit:** Up to 1000 units every 12 weeks, divided among affected muscles.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show improved severity, disability, or pain compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Spasticity

For **initial** authorization:

1. Member is at least 2 years of age; 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/Quantity limit:** 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 all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes show improved signs and symptoms (e.g., decrease in severity of increased muscle tone).

If all the above requirements are met, 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.
03/04/2022	Annual review; no changes
11/14/2023	Cervical dystonia: removed "Symptoms affect quality of life and daily functions." Updated references and clarified renewal criteria.

References:

1. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; 2023.
2. MCG 20th Edition, 2016.
3. Clinical use of botulinum toxin. National Institutes of Health Consensus Development Conference Statement, November 12-14, 1990. *Arch Neurol.* 1991;48(12):1294-1298.
4. 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.
5. Borodic GE and Pearce LB, "New Concepts in Botulinum Toxin Therapy," *Drug Saf*, 1994, 11(3):145-52.
6. Jankovic J and BrinMF, "Therapeutic Uses of Botulinum Toxin," *N Engl J Med*, 1991, 324(17):1186-94.
7. 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.
8. 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-S193.
9. Fishman LM, Anderson C, Rosner B. BOTOX and physical therapy in the treatment of piriformis syndrome. *Am J Phys Med Rehabil.* 2002;81(12):936-942. doi:10.1097/00002060-200212000-00009.
10. Simpson DM, Gracies JM, Graham HK, et al. 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. *Neurology.* 2008;70(19):1691-1698. doi:10.1212/01.wnl.0000311391.00944.c4.
11. 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.

12. 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.
13. Keam SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. *Drugs* 2011;71(8):1043-58.
14. 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
15. 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
16. 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.
17. Dashtipour K, Mari Z, Jankovic J, Adler CH, Schwartz M, Brin MF. Minimal clinically important change in patients with cervical dystonia: Results from the CD PROBE study. *J Neurol Sci*. 2019;405:116413. doi:10.1016/j.jns.2019.07.031
18. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. *J Neural Transm (Vienna)*. 2021;128(4):531-537. doi:10.1007/s00702-020-02266-z
19. Rodrigues FB, Duarte GS, Marques RE, et al. Botulinum toxin type A therapy for cervical dystonia. *Cochrane Database Syst Rev*. 2020;11(11):CD003633. Published 2020 Nov 12. doi:10.1002/14651858.CD003633.pub4

Effective date: 04/01/2024

Revised date: 11/14/2023