

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

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| DRUG NAME   | Dysport (abobotulinumtoxinA)   |
| BILLING CODE  | J0586  |
| BENEFIT TYPE  | Medical  |
| SITE OF SERVICE ALLOWED                                     | Office, Outpatient   |
| COVERAGE REQUIREMENTS                                       | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT— vary per diagnosis |
| LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY | <a href="#">Click Here</a>   |

Dysport (abobotulinumtoxinA) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:

1. Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
2. Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
3. Member does **not** have any of the following:
  - a) Fixed contractures causing decreased neck range of motion;
  - b) Neuromuscular disease (e.g., myasthenia gravis);
  - c) Prior surgical treatment.
4. **Dosage allowed:** 500 Units given intramuscularly as a divided dose 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 have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.***

### SPASTICITY

For **initial** authorization:

1. Chart notes submitted with documentation of abnormal muscle tone that is interfering with functional ability (or that is expected to affect joint contracture in future growth); AND
2. Medication is being requested to improve function or allow additional therapeutic modality to be employed; AND
3. One of the following:
  - a) Member is a child with cerebral palsy;
  - b) Member has hereditary spastic paraplegia;

- c) Member has limb spasticity due to multiple sclerosis or other demyelinating diseases of the central nervous system;
  - d) Member is adult and has upper extremity spasticity due to stroke or brain injury.
4. **Dosage allowed:** 500-1500 Units given intramuscularly as a divided dose among affected muscles.

***If member meets all the requirements listed above, the medication will be approved for 3 months.***

For **reauthorization:**

- 1. Member must be in compliance with all other initial criteria; AND
- 2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Glabellar Lines (considered cosmetic)
- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease
- Sialorrhea due to Parkinson's disease

| 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. |

References:

- 1. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; 2009.
- 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](http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/125036s044lbl.pdf) (March 6, 2011).
- 4. Wolters Kluwer. Facts & Comparisons. [www.factsandcomparisons.com](http://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 BrinMF, "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. Kean 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.

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