



Coverage Policy/Guideline

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Effective Date:	1/6/2025	Last Review Date:	11/2024
Applies to:	<input checked="" type="checkbox"/> Arizona		

**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Dysport under the patient’s prescription drug benefit.

**Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Treatment of cervical dystonia in adults
2. Treatment of spasticity in patients 2 years of age and older

B. Compendial Uses

1. Blepharospasm
2. Hemifacial spasm
3. Chronic anal fissures
4. Excessive salivation
5. Primary axillary hyperhidrosis

All other indications are considered experimental/investigational and not medically necessary.

**Applicable Drug List:**

Dysport

**Policy/Guideline:**

**Prescriber Specialty:**

The medication must be prescribed by or in consultation with a provider specialized in the treating the member’s condition.

**Exclusions:**

Coverage will not be provided for cosmetic use.

**Criteria for Initial Approval:**

**A. Cervical dystonia**

Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:

1. Member is 18 years of age or older
2. Member has abnormal placement of the head with limited range of motion in the neck.



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**B. Upper or lower limb spasticity**

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity when all of the following are met:

1. Member is 2 years of age or older
2. Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition (including focal spasticity or equinus gait due to cerebral palsy)

**C. Blepharospasm**

Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

**D. Hemifacial spasm**

Authorization of 12 months may be granted for treatment of hemifacial spasm.

**E. Chronic anal fissures**

Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first-line therapy such as topical calcium channel blockers or topical nitrates.

**F. Excessive salivation**

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

**G. Primary axillary hyperhidrosis**

Authorization of 12 months may be granted for treatment of primary axillary hyperhidrosis when all of the following criteria are met:

1. Significant disruption of professional and/or social life has occurred because of excessive sweating; and
2. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

**Continuation of Therapy:**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria and be experiencing benefit from therapy.

**Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

**References:**

1. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; September 2023.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com>. Accessed August 15, 2024.
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4. 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.
5. Dashtipour K, Chen JJ, Frei K, et al. Systemic Literature Review of AbobotulinumtoxinA in Clinical Trials for Blepharospasm and Hemifacial Spasm. *Tremor Other Hyperkinet Mov (NY)*. 2015;5:338.
6. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. *Toxins* 2013, 5, 1010-1031
7. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. American Academy for Cerebral Palsy and Developmental Medicine Care Pathways. <https://www.aacpdm.org/publications/care-pathways/sialorrhea>. Accessed August 15, 2024.
8. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. *Degener Neurol Neuromuscul Dis*. 2019; 9: 19–26.