



Medical Policy Manual **Approved Rev: Do Not Implement until 7/2/24**

Abobotulinumtoxin A (Dysport®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

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.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. 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.

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)

Medical Policy Manual **Approved Rev: Do Not Implement until 7/2/24**

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.

IV. 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; **January 2023**.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com>. Accessed August 2, 2023.
3. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. <http://online.lexi.com/>. Accessed August 2, 2022.
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.



Medical Policy Manual **Approved Rev: Do Not Implement until 7/2/24**

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 2, 2023.
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.

EFFECTIVE DATE

7/2/2024

ID_CHS