

SPECIALTY GUIDELINE MANAGEMENT

DYSPORE (abobotulinumtoxin A)

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 there is 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 either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

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. Member is unresponsive or unable to tolerate oral pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines); and
2. Significant disruption of professional and/or social life has occurred because of excessive sweating; and
3. 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.

V. REFERENCES

1. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; July 2020.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com>. Accessed August 10, 2020.
3. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. <http://online.lexi.com/>. Accessed August 10, 2020.
4. Clinical Pharmacology. Tampa (FL): Elsevier. 2019. Available from: <http://www.clinicalpharmacology-ip.com>. Accessed August 10, 2020.
5. 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.
6. 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.
7. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. *Toxins* 2013, 5, 1010-1031
8. 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 23, 2019.
9. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. *Degener Neurol Neuromuscul Dis*. 2019; 9: 19–26.