

Reference number
2249-A

SPECIALTY GUIDELINE MANAGEMENT

MYOBLOC (rimabotulinumtoxin B)

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 to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
2. Treatment of chronic sialorrhea in adults

B. Compendial Uses

1. Primary axillary and palmar hyperhidrosis
2. Upper limb spasticity

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

II. PRESCRIBER SPECIALTIES

The medication must be prescribed by, or in consultation with the following for each indication:

- A. Cervical dystonia and upper limb spasticity: neurologist, orthopedist or physiatrist
- B. Chronic sialorrhea: neurologist or otolaryngologist
- C. Primary axillary and palmar hyperhidrosis: neurologist, internist or dermatologist

III. EXCLUSIONS

Coverage will not be provided for cosmetic use.

IV. 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. **Chronic Sialorrhea (excessive salivation)**

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when all of the following are met:

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1. Member is 18 years of age or older
2. Member is refractory to pharmacotherapy (e.g., anticholinergics)

C. Primary axillary and palmar hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary or palmar 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.

D. Upper limb spasticity

Authorization of 12 months may be granted for treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

V. 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.

VI. REFERENCES

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4. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. <http://online.lexi.com/>. Accessed July 28, 2023.
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 (19) 1818-1826.
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 July 28, 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.