Coverage Policy/Guideline			
Name:	Myobloc	Page:	1 of 2
Effective Date:	1/6/2025	Last Review Date:	11/2024
Applies to:	☒Arizona		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Myobloc 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 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.

Applicable Drug List:

Myobloc

Policy/Guideline:

Prescriber Specialty:
The medication must be prescribed by or in consultation with a provider specialized in 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

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:

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 palmer 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.

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. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com. Accessed August 14, 2024.
3. AHFS Drug Information. http://online.lexi.com/lco. Accessed August 14, 2024.
4. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. http://online.lexi.com/. Accessed August 14, 2024.
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 August 14, 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.