VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxins – Myobloc Utilization Management Medical Policy
- Myobloc® (rimabotulinumtoxinB injection – Solstice Neurosciences)

REVIEW DATE: 01/11/2023

OVERVIEW

Myobloc (rimabotulinumtoxinB) is indicated for the following uses:[1]
- **Cervical Dystonia** in adults.
- **Sialorrhea, chronic** in adults.

Other Uses with Supportive Evidence

Spasticity, Upper Limb: In 2016 American Academy of Neurology guidelines (reaffirmed 2022), Myobloc is supported for use in upper limb spasticity (Level B; probably effective).[2] Of note, evidence is insufficient for Myobloc in the setting of lower limb spasticity (Level U).

Dosing Considerations

Definitive dosing has not been established for off-label uses of botulinum toxins, including Myobloc. Recommendations for maximum dosing and frequency for Myobloc are based on a suggested relative conversion of 50:1 between Myobloc and Botox units.[3] For **Spasticity, Upper Limb**, dosing is based on the Botox prescribing information, which states that in a 3-month interval, adults should not exceed a total dose of 400 units.[4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Myobloc. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the dosing interval is provided in months, 1 month is equal to 30 days.

Medical benefit coverage is not recommended for cosmetic conditions.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Myobloc is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Cervical Dystonia**. Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 5,000 units, administered not more frequently than once every 12 weeks.

2. **Sialorrhea, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 3,500 units (1,750 units per side), administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

3. **Spasticity, Upper Limb.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 20,000 units, administered not more frequently than once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Myobloc is not recommended in the following situations:

1. **Cosmetic Uses.** Note: Examples of cosmetic uses include facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, or rejuvenation of the periorbital region. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; September 2020.
2. 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.
3. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. *Clin Aesthet Dermatol*. 2014;7(21):31-39.
4. Botox® injection [prescribing information]. Madison, NJ: Allergan; August 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Bladder Dysfunction:** This Other Use with Supportive Evidence was removed from the policy. **Myofascial Pain:** This Other Use with Supportive Evidence was removed from the policy.	07/13/2022
Early Annual Revision	**Cervical Dystonia:** An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Sialorrhea, Chronic:** An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. **Hyperhidrosis, Palmar or Primary Axillary:** This Other Use with Supportive Evidence was removed from the policy. **Spasticity, Upper Limb:** This Other Use with Supportive Evidence was reworded as listed; previously the indication was listed as "Spasticity (i.e., spasticity due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm)". Additionally, an age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. With this change, pediatric dosing was removed from the dosing section.	01/11/2023