VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 06/30/2021

OVERVIEW

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

Other Uses with Supportive Evidence

Botulinum toxins, including Myobloc, have been studied in a variety of indications outside of FDA-approved uses. Literature is available to support use of Myobloc in the following conditions:
- **Bladder Dysfunction:** Botulinum toxin type B was shown to be effective in improving symptoms of overactive bladder in one small randomized, double-blind, placebo-controlled study (formulation not specified) in patients unresponsive to oral antimuscarinic agents.[3] Oral pharmacologic therapy with antimuscarinic agents is the mainstay of drug therapy in the treatment of overactive bladder.[4,5]
- **Hyperhidrosis, Palmar or Primary Axillary:** Myobloc was shown to be effective in treating palmar hyperhidrosis in one small, randomized, double-blind, placebo-controlled study and a second prospective, open, single-blind, multicenter study.[6,7] Botulinum toxin type B was shown to be effective in treating axillary hyperhidrosis in one randomized, double-blind, placebo-controlled trial (using Myobloc) and one small, open-label study (using Neurobloc [a European formulation of Myobloc]).[8,9] There was no significant difference between Botox and Myobloc/Neurobloc in duration of effect in one small comparative study in patients with axillary hyperhidrosis.[10] In a small (n = 10), single-blind, comparative study, botulinum toxin type B (Neurobloc) was significantly more effective than Botox in decreasing sweat weight and area.[11] Topical antiperspirants (e.g., topical aluminum chloride) are recommended first-line therapies for the treatment of primary hyperhidrosis.[12-14] In the setting of primary axillary hyperhidrosis, Qbrexza® (glycopyrronium cloth 2.4% for topical use), a topical anticholinergic, may also be used first-line.[15] The American Academy of Neurology (AAN) notes that botulinum toxin therapy is established safe and effective in axillary hyperhidrosis (Level A).[16] AAN guidelines state that botulinum toxins are probably safe and effective and should be considered for palmar hyperhidrosis (Level B).
- **Myofascial Pain:** Myobloc was effective in reducing myofascial pain associated with piriformis syndrome in a small open-label study; 95% of patients reported fair to excellent improvement in pain.[17]
- **Spasticity (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm):** Botulinum toxin type B was shown to be effective in reducing spasticity in one open-label study (formulation not specified) in children with spastic or dystonic movement disorders[18] and in a randomized, double-blind, placebo-controlled study (n = 24) in hemiparetic patients with disabling elbow flexor overactivity after stroke or traumatic brain injury.[19] In one small, randomized, double-blind, placebo-controlled study in patients with upper-limb post-stroke spasticity (n = 15), Myobloc reduced spasticity at 2 weeks but was not statistically significant at other follow-up visits.[20] Botulinum toxin type B was shown to be effective in treating hemifacial spasm in one small open-label study (formulation not specified).[21] Per AAN guidelines, botulinum toxin is possibly effective and may be considered for hemifacial spasm (Level C).

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.[22] Specific dosing considerations by indication are noted below. For other indications addressed in this policy, specific dosing guidance is not available. In these cases, 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.[23] Per Botox labeling, pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval. Of note, while Myobloc prescribing information does not include pediatric labeling, some data in pediatric patients are available.[18,24]

- **Bladder Dysfunction:** Botox is indicated for urinary incontinence associated with neurological conditions, up to a maximum dose of 200 units administered not more frequently than once every 12 weeks.[23]
- **Hyperhidrosis, Palmar or Primary Axillary:** Botox is indicated for primary axillary hyperhidrosis at a dose of 50 units per axilla, administered not more frequently than once every 3 months.[23] Dosing is not established for palmar hyperhidrosis.

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 1 year in duration. 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

FDA-Approved Indications

1. Cervical Dystonia. Approve for 1 year.

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.

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. Bladder Dysfunction. Approve for 1 year if the patient meets the following criteria (A and B):
A) Patient has tried at least one other pharmacologic therapy; AND

Note: Examples of other pharmacologic therapies include a beta-3 adrenergic agonist or an anticholinergic medication.

B) Myobloc is being prescribed by or after consultation with a urologist.

Dosing. Approve up to a maximum dose of 10,000 units, administered not more frequently than once every12 weeks.

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4. Hyperhidrosis, Palmar or Primary Axillary. Approve for 1 year if the patient meets the following criteria (A and B):

A) Patient has tried at least one topical agent; AND
Note: Examples of topical agents include topical aluminum chloride or Qbrexza (glycopyrronium cloth 2.4% for topical use).

B) Patient has tried Botox (onabotulinumtoxinA injection).

Dosing. Approve the following regimens (A or B):

A) Primary axillary hyperhidrosis: Approve a maximum dose of 2,500 units per axilla, administered not more frequently than once every 3 months.

B) Palmar hyperhidrosis: Approve one of the following regimens (i or ii):

i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 20,000 units, administered not more frequently than once every 3 months.

ii. Patient is < 18 years of age: Approve up to a maximum dose of 500 units/kg (not to exceed 17,000 units), administered not more frequently than once every 3 months.

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5. Myofascial Pain. Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 20,000 units, administered not more frequently than once every 3 months.

B) Patient is < 18 years of age: Approve up to a maximum dose of 500 units/kg (not to exceed 17,000 units), administered not more frequently than once every 3 months.

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6. Spasticity (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm). Approve for 1 year.

Dosing. Approve one of the following regimens (A or B):

A) Patient is ≥ 18 years of age: Approve up to a maximum dose of 20,000 units, administered not more frequently than once every 3 months.

B) Patient is < 18 years of age: Approve up to a maximum dose of 500 units/kg (not to exceed 17,000 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.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Sialorrhea, Chronic:** The approval condition was updated to as listed; previously it was listed as "Sialorrhea (Salivary Hypersecretion), Chronic."	06/03/2020

	Anal Fissure: This Other Use with Supportive Evidence was removed from the policy. **Blepharospasm:** This Other Use with Supportive Evidence was removed from the policy. **Migraine Headache Prophylaxis in Patients with Chronic Migraine:** This Other Use with Supportive Evidence was removed from the policy. **Spasticity:** Hemifacial spasm was rolled into the approval condition. **Speech/Voice Disorder (spasmodic dysphonia):** This Other Use with Supportive Evidence was removed from the policy.	
Annual Revision	**Cervical Dystonia:** The phrase "spasmodic torticollis" was removed from the approval condition. **Bladder Dysfunction:** Examples of pharmacologic therapies were moved from criteria into a Note. The examples were updated to "a beta-3 adrenergic agonist or an anticholinergic medication". Specific medication names were removed from the examples. **Hyperhidrosis, Palmar or Primary Axillary:** Examples of topical agents were moved into a Note. **Cosmetic Uses:** Examples of cosmetic uses were moved from the approval condition into a Note. The example list was updated for alignment with other botulinum toxin policies. **Dosing:** In the following Other Uses with Supportive Evidence, the dosing was updated such that the maximum dose for patients < 18 years of age is the lesser of 500 units/kg or 17,000 units in 3 months (adult maximum dosing remains unchanged at 20,000 units in 3 months): Hyperhidrosis, Palmar; Myofascial Pain; and Spasticity. Under the condition of Spasticity, the dosing specific to hemifacial spasm was removed from the policy; the same dosing is now applied to hemifacial spasm as for other forms of spasticity.	06/30/2021