Medicare Advantage (MA) Medical Utilization Review Policy

Policy:	**Botulinum Toxins – Myobloc Utilization Management Medical Policy** • Myobloc® (rimabotulinumtoxinB injection – Solstice Neurosciences)
Date:	02/24/2023
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

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 indication(s). 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.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the

exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Cervical Dystonia.

Criteria. 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.

Criteria. 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. Urinary Incontinence Associated with a Neurological Condition.[5]

Criteria.[20] Approve for 1 year if the patient meets both of the following (A and B):
A) The patient uses clean intermittent self-catheterization (CIC) to empty the bladder; AND
B) The patient has tried at least one oral anticholinergic agent for incontinence episodes that occur between catheterizations.

Dosing. Approve up to a maximum dose of 10,000 units, administered not more frequently than once every 12 weeks.

4. Hyperhidrosis, Primary Axillary.

Criteria. Approve for 1 year if patient has tried at least one topical agent.
Note: Examples of topical agents include topical aluminum chloride or Qbrexza (glycopyrronium cloth 2.4% for topical use).

Dosing. Approve a maximum dose of 2,500 units per axilla, administered not more frequently than once every 3 months.

5. Spasticity (i.e., spasticity secondary to spastic hemiplegia,[5] hemiparesis)[5].

Criteria. 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, Upper Limb.

Criteria. 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.

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7. Speech/Voice Disorder (e.g., spasmodic dysphonias, laryngeal spasm).[5]

Criteria. Approve for 1 year.

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 under the Medicare 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.
5. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination: Botulinum Toxins (LCD L33646) (Original effective date 10/1/2015; revision effective date 05/01/2021). Accessed on February 21, 2023.
6. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848) (Original effective date 10/1/2015; revision effective date 1/5/2023). Accessed on February 21, 2023.

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	07/11/2018
Policy revision	Statement added to dosing to allow for approval of doses that are below the recommended maximum daily dose for each indication.	n/a
Policy revision	Removed the following criterion: "For all approvable indications, failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype/product used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype." L33646 provides this verbiage and it has since been interpreted as optional criterion because of the 'could' language. Not required to issue approval or denial but can be used when considering an appeal.	n/a
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Determination L33646	08/28/2019
Policy revision	Reviewed and revised policy.	9/4/2019
Policy revision	Non-clinical update to policy to add the statement "This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage."	1/30/2020
Policy revision	*Added the following note: "Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles." *Updated dosing for upper limb spasticity *Removed additional criteria requirements for Sialorrhea and Speech/Voice disorder	4/15/2020
Policy 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. **Added coverage for the following indications**: Myofasical pain, Spasticity **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.	08/17/2021

	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.	
Policy 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. **Urinary Incontinence Associated with a Neurological Condition.** Added this indication with the following criteria: The patient uses clean intermittent self-catheterization (CIC) to empty the bladder; AND The patient has tried at least one oral anticholinergic agents for incontinence episodes that occur between catheterizations.	08/17/2022
Policy 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, Primary Axillary:** Reworded as listed. Palmar hyperhidrosis was removed from the policy. **Spasticity, Upper Limb:** This indication was added to Other Uses with Supportive Evidence **Spasticity (i.e., spasticity secondary to spastic hemiplegia, hemiparesis:** examples of spastic hemiplegia and hemiparesis were added and following examples were removed – cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, and hemifacial spasm.	02/24/2023