Policy:	**Botulinum Toxins – Myobloc Utilization Management Medical Policy** • Myobloc® (rimabotulinumtoxinB injection – Solstice Neurosciences)
Date:	06/23/2026
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States/Territories:	Noridian JE: California, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada Noridian JF: Alaska, Idaho, Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah, Wyoming
Applicable NCDs, LCDs, and/or LCAs	L35172, A57186, L35170, A57185

SUMMARY OF EVIDENCE

Myobloc (rimabotulinumtoxinB), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

- **Cervical dystonia,** to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.
- **Sialorrhea, chronic** in adults.

Other Uses with Supportive Evidence

Spasticity, Upper Limb(s): In the 2016 American Academy of Neurology guidelines (reaffirmed 2022), Myobloc is supported for use in adult upper limb spasticity (Level B; probably effective).[2] Of note, evidence is insufficient for Myobloc in the setting of lower limb spasticity (Level U). Botulinum toxin type B was shown to be effective in reducing spasticity in a randomized, double-blind, placebo-controlled study (n = 24) in hemiparetic patients with disabling elbow flexor overactivity after stroke or traumatic brain injury.[3] 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.[4]

Dosing Information

Toxin distribution varies between the commercially available botulinum toxin products.[1] Labeling for the botulinum toxin products states there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity.

- 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.[5] For **Spasticity, Upper Limb**, the Botox prescribing information states that in a 3-month interval, an adult should not exceed a total dose of 400 units.[6]

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

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 Sources of Information 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 Sources of Information 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.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. **Cervical Dystonia.** ^
   Note: Cervical dystonia is also known as spasmodic torticollis.

   Criteria. Approve for 1 year if the patient is ≥ 18 years of age. [IC-L]

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

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2. **Sialorrhea, Chronic.** ^

   Criteria. Approve for 1 year if the patient is ≥ 18 years of age. [IC-L]

   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

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3. **Spasticity, Upper Limb(s).** [@]

   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.

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.

SOURCES OF INFORMATION

1. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; August 2025.
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. Gracies JM, Bayle N, Goldberg S, et al. Botulinum toxin type B in the spastic arm: a randomized, double-blind, placebo-controlled, preliminary study. *Arch Phys Med Rehabil.* 2014;95:1303-1311.
4. Brashear A, McAfee AL, Kuhn ER, et al. Botulinum toxin type B in upper-limb poststroke spasticity: a double-blind, placebo-controlled trial. *Arch Phys Med Rehabil*. 2004;85(5):705-709.
5. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. *Clin Aesthet Dermatol*. 2014;7(21):31-39.
6. Botox® injection [prescribing information]. Madison, NJ: Allergan; November 2023.
7. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Determination: Botulinum Toxin Types A and B (L35172) (Original effective date 10/1/2015; revision effective date 2/22/2026). Accessed on June 23, 2026.

8. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186) (Original effective date 10/1/2019; revision effective date 4/9/26). Accessed on June 23, 2026.
9. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Determination: Botulinum Toxin Types A and B Policy (L35170) (Original effective date 10/1/2015; revision effective date 2/22/26). Accessed on June 23, 2026.
10. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B Policy (A57185) (Original effective date 10/1/2019; revision effective date 4/9/26). Accessed on June 23, 2026.

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	04/15/2020
Policy revision	"Sialorrhea (Salivary Hypersecretion), Chronic" updated to "Sialorrhea, Chronic."	06/09/2020
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. **Spasticity** – Added indication for coverage **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.	08/02/2021
Policy revision	**Bladder Dysfunction:** This Other Use with Supportive Evidence was removed from the policy.	08/01/2022
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, Palmar or Primary Axillary:** This Other Use with Supportive Evidence was removed from the policy. **Spasticity, Upper Limb:** An age requirement of ≥ 18 years was added to criteria. Previously there was not an age requirement in place. Updated dosing. **Spasticity (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis:** Removed hemifacial spasm from examples.	02/24/2023
Policy review	No criteria changes (based on review of commercial policy review)	02/22/2024
Policy revision	**Cervical Dystonia**: The following Note was added: Cervical dystonia is also known as spasmodic torticollis.	10/01/2024
Policy revision	No criteria changes. Formatting and notation updates.	06/18/2025
Policy review	No criteria changes, based on commercial policy review	10/01/2025
Policy review	No criteria changes, review of LCD/LCA surveillance	10/23/2025
Policy revision	Removed the following indications from the policy: spasticity, speech/voice disorder.	02/04/2026, effective 02/22/2026
Policy review	No criteria changes, CMS surveillance review	04/02/2026
Policy review	No criteria changes, CMS surveillance review	06/23/2026