

Effective Date: 01/01/2022

Reviewed: 10/2021, 1/2022, 3/2023, 12/2023, 01/2024

Pharmacy Scope: Medicaid**(Pharmacy Benefit ONLY)

Medical Scope: Commercial, Medicare-Medicaid Plan (MMP)

Myobloc® (rimabotulinumtoxinB) (Intramuscular/Intradermal)

****Effective 01/01/2022: Medication will only be covered on the Pharmacy Benefit for Medicaid Members**

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Medical Benefit]:

- Myobloc 2,500 unit/0.5 mL solution for injection: 1 vial per 84 days
- Myobloc 5,000 unit/mL solution for injection: 1 vial per 84 days
- Myobloc 10,000 unit/2 mL solution for injection: 1 vial per 84 days
- **Max Units (per dose and over time) [HCPCS Unit]:**

Cervical Dystonia

- 100 billable units per 12 weeks (84 days)

Upper Limb Spasticity

- 150 billable units per 12 weeks (84 days)

Chronic Migraine Prophylaxis

- 100 billable units per 12 weeks (84 days)

Chronic Sialorrhea

- 50 billable units per 12 weeks (84 days)

Severe Primary Axillary Hyperhidrosis

- 100 billable units per 12 weeks (84 days)

B. Quantity Limit (max daily dose) [Medicaid Pharmacy Benefit]:

- Myobloc 1 fill per 84 days

III. Summary of Evidence

Myobloc is an acetylcholine release inhibitor indicated for cervical dystonia and chronic sialorrhea. In randomized controlled trials and open-label studies, Myobloc injections have been shown to improve symptoms of cervical dystonia, including reduced severity of neck pain, muscle spasms, and abnormal head postures. Similarly, in clinical trials evaluating chronic sialorrhea, Myobloc injections have led to significant reductions in saliva production and improvements in quality of life for patients.

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IV. Initial Approval Criteria ¹⁻²⁶

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA, daxibotulinumtoxina-lanm, etc.); **AND**

Cervical Dystonia ^{1,2} † Φ

- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck and upper shoulders; **AND**
 - Patient has sustained head tilt, **OR**
 - Patient has abnormal posturing with limited range of motion in the neck

Chronic Sialorrhea ^{1,13,14,15,16,17,18} †

- Patient has a history of troublesome sialorrhea for at least a 3-month period

Upper Limb Spasticity ^{2,3,4,5,6} ‡

Prophylaxis for Chronic Migraines ^{7,8,9,10,19,20,21,22,24} ‡

- Patient is utilizing prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, or physical therapy, etc.); **AND**
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months; **AND**
 - Patient has had at least five attacks with features consistent with migraine (with and/or without aura) §; **AND**
 - On at least 8 days per month for at least 3 months:
 - Headaches have characteristics and symptoms consistent with migraine§; **OR**
 - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of migraine-prophylactic medications below for examples)

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Severe Primary Axillary Hyperhidrosis ^{1,11,12,25,26} †

- Patient has tried and failed ≥ 1 month trial of a topical agent* (i.e., aluminum chloride, glycopyrronium, etc.); **AND**
 - Patient has a history of medical complications such as skin infections or significant functional impairments, **OR**
 - Patient has had a significant burden of disease or impact to activities of daily living due to condition (i.e., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)

* **This requirement does not apply to MMP members**

† FDA approved indication(s); ‡ Literature Supported Indication; Ⓢ Orphan Drug

Migraine-Prophylaxis Oral Medications <i>(list not all-inclusive)</i>
<ul style="list-style-type: none"> • Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.) • Calcium channels blockers (e.g., verapamil, etc.)
Migraine Features §
<p><u>Migraine without aura</u></p> <ul style="list-style-type: none"> • At least five attacks have the following: <ul style="list-style-type: none"> ○ Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) ○ Headache has at least two of the following characteristics: <ul style="list-style-type: none"> – Unilateral location – Pulsating quality – Moderate or severe pain intensity – Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); AND ○ During headache at least one of the following: <ul style="list-style-type: none"> – Nausea and/or vomiting – Photophobia and phonophobia
<p><u>Migraine with aura</u></p> <ul style="list-style-type: none"> • At least two attacks have the following: <ul style="list-style-type: none"> ○ One or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> – Visual – Sensory – Speech and/or language – Motor – Brainstem – Retinal; AND ○ At least three of the following characteristics: <ul style="list-style-type: none"> – At least one aura symptom spreads gradually over ≥5 minutes – Two or more symptoms occur in succession – Each individual aura symptom lasts 5 to 60 minutes – At least one aura symptom is unilateral – At least one aura symptom is positive (e.g., scintillations and pins and needles)

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– The aura is accompanied, or followed within 60 minutes, by headache

V. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal, and indication specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (i.e., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reactions, etc.; **AND**
- Disease response as evidenced by the following:

Cervical Dystonia

- Improvement in the severity and frequency of pain; **AND**
- Improvement of abnormal head positioning

Upper Limb Spasticity

- Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (i.e. Ashworth Scale, Physician Global Assessment, Clinical Global Impression (CGI), etc.)

Prophylaxis for Chronic Migraines ²⁰

- Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Improvement in function; **AND**
- Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.)

Chronic Sialorrhea

- Significant decrease in saliva production

Severe Primary Axillary Hyperhidrosis

- Significant reduction in spontaneous axillary sweat production; **AND**
- Patient has a significant improvement in activities of daily living

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VI. Dosage/Administration

Indication	Dose
Cervical Dystonia	Initial dose: 2,500 – 5,000 units divided among the affected muscles. Re-treatment: 2,500-10,000 units every 12 -16 weeks or longer, as necessary
Upper Limb Spasticity	Up to 15,000 units divided among the affected muscles every 12 weeks
Chronic Migraine Prophylaxis	Up to 8,250 units divided among the affected muscles every 12 weeks
Chronic Sialorrhea	Recommended dose: 1,500 – 3,500 units (500 – 1,500 units per parotid gland and 250 units per submandibular gland) every 12 weeks. Maximum dose: 3500 units divided among the affected muscles every 12 weeks.
Severe Primary Axillary Hyperhidrosis	Up to 4,000 units per axilla every 12 weeks

VII. Billing Code/Availability Information

HCPCS Code:

- J0587 – Injection, rimabotulinumtoxinB, 100 units; 1 billable unit = 100 units

NDC:

- Myobloc 2,500 unit/0.5 mL Solution for Injection: 10454-0710-xx
- Myobloc 5,000 unit/mL Solution for Injection: 10454-0711-xx
- Myobloc 10,000 unit/ 2mL Solution for Injection: 10454-0712-xx

VIII. References

1. Myobloc [package insert]. South San Francisco, CA; Solstice Neurosciences, Inc.; October 2022. Accessed March 2023.
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; 86:1-9
3. Gracies JM, Bayle N, Goldberg S, Simpson DM. 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 A, Kuhn E, et al. Botulinum Toxin Type B in Upper-Limb Poststroke Spasticity: A Double-Blind, Placebo-Controlled Trial, *Arch Phys Med Rehabil* 2004;85:705-9.
5. Brashear A, McAfee A, Kuhn E, et al. Treatment with botulinum toxin type B for upper-limb spasticity. *Arch Phys Med Rehabil* 2003; 84:103-7.

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6. Hecht J, Preston L, McPhee S. Effects of botulinum toxin type B on shoulder pain, hypertonia, and function in adults with spastic hemiparesis. Poster presented at the 63rd Annual Assembly of the American Academy of Physical Medicine and Rehabilitation; November 21-24, 2002; Orlando, Florida.
7. Gwynn, MW, English, JB, Baker, TS. Double-blind, placebo-controlled study of Myobloc (botulinum toxin type B) for preventing chronic headache. Poster presented at 45th Annual Scientific Meeting of the American Headache Society; June 19-22, 2003, Chicago, Illinois.
8. Lake AE III, Saper JR. Botulinum toxin type B for migraine prophylaxis: a 4-month, open-label, prospective outcome study. Poster presented at the 22nd Annual Scientific Meeting of the American Pain Society; March 20-23, 2003, Chicago, Illinois.
9. Opida CL. Open-label study of Myobloc (botulinum toxin type B) in the treatment of patients with transformed migraine headaches. Poster presented at the International Conference 2002: Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins; June 8-11, 2002, Hannover, Germany
10. Alvarez M, Grogan P. Effectiveness of botulinum toxin type-A and type-B in exploding, imploding, and ocular migraine headache. Presented at the 5th World Congress of the World Institute of Pain; March 13-16, 2009, New York, New York.
11. Dressler D, Saberi FA, Benecke R. Botulinum toxin type B for treatment of axillary hyperhidrosis. *J Neurol* (2002) 249:1729-1732. DOI 10.1007/s00415-002-0929-4.
12. Baumann L, Slezinger A, Halem M et al. Pilot study of the safety and efficacy of Myobloc™ (botulinum toxin type B) for treatment of axillary hyperhidrosis. *International Journal of Dermatology*, 44: 418–424. doi: 10.1111/j.1365-4632.2004.02531.x
13. Chinnapongse R, Gullo K, Nemeth P, Zhang Y, Griggs L. Safety and Efficacy of Botulinum Toxin Type B for Treatment of Sialorrhea in Parkinson’s Disease: A Prospective Double-Blind Trial. *Mov Disord*. 2012; 27:219-226.
14. Lagalla G, Millevolte M, Capecci M, Provinciali L, Ceravolo M. Long Lasting Benefits of botulinum toxin type B in Parkinson’s disease-related drooling. *J Neurol*. 2009;256:563-567
15. Costa J, Rocha ML, Ferreira J, Evangelista T, Coelho M, de Carvalho M. Botulinum toxin type-B improves sialorrhea and quality of life in bulbar-onset amyotrophic lateral sclerosis. *J Neurol*. 2008; 255:545-550.
16. Guidubaldi A, Fasano A, Ialongo T, Piano C, Pompili M, Masciana R, Siciliani L, Sabatelli M, Bentivoglio A. Botulinum Toxin A versus B in Sialorrhea: A Prospective, Randomized, Double-Blind Crossover Pilot Study in Patients with Amyotrophic Lateral Sclerosis or Parkinson’s Disease. *Mov Disord*. 2011; 26:313-319.
17. Basciani M, Di Rienzo F, Fontana A, Copetti M, Pellegrini F, Intiso D. Botulinum toxin type B for Sialorrhea in Children with Cerebral Palsy: a randomized trial comparing three doses. *Dev Med & Child Neurol*. 2011; 53:559-564.
18. Wright E. Botulinum toxin type B (Myobloc®) for treatment of pediatric sialorrhea. Poster presented at: 63rd Annual Assembly of the American Academy of Physical Medicine and Rehabilitation; November 21- 24, 2002; Orlando, Florida.

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19. The International Classification of Headache Disorders, 3rd edition (beta version).Headache Classification Committee of the International Headache Society (IHS) Cephalalgia. 2013 Jul;33(9):629-808.
20. Schwedt TJ. Chronic Migraine. BMJ. 2014;348:g1416.
21. Modi S, Lowder DM. Medications for migraine prophylaxis. Am Fam Physician. 2006 Jan 1; 73(1):72-8.
22. Pringheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. Can Jneurol Sci. 2012 Mar; 39(2 Suppl 2):S1-S9.
23. Glaser DA, Hebert AA, Nast A, et al. Topical glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials. J Am Acad Dermatol. 2019;80(1):128. Epub 2018 Jul 10
24. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18. doi: 10.1111/head.13456. Epub 2018 Dec 10.
25. Haider A, Solish N. Focal hyperhidrosis: diagnosis and management. CMAJ. 2005;172(1):69-75.
26. Nawrocki S, Cha J. The Etiology, Diagnosis and Management of Hyperhidrosis: A Comprehensive Review. Part II. Therapeutic Options. J Am Acad Dermatol. 2019 Jan 30. pii: S0190-9622(19)30167-7.
27. Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. Neurology. 2004; 62:37-40.
28. Racette BA, Good L, Sagitto S, Perlmutter JS. Botulinum toxin B reduces sialorrhea in Parkinsonism. Mov Disord. 2003; 18:1059-1061.
29. Jackson CE, Gronseth G, Rosenfeld J, et al. Randomized double-blind study of botulinum toxin type B for sialorrhea in ALS patients. Muscle Nerve. 2009;39(2):137
30. National Government Services, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848). Centers for Medicare & Medicaid Services, Inc. Updated on 10/25/2019 with effective date 10/31/2019. Accessed April 2020.
31. Noridian Administrative Services, LLC Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186). Centers for Medicare & Medicaid Services, Inc. Updated on 09/19/2019 with effective date 10/1/2019. Accessed April 2020.
32. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article: Billing and Coding: Botulinum Toxin Type A & Type B (A57474). Centers for Medicare & Medicaid Services, Inc. Updated on 12/17/2019 with effective date 12/26/2019. Accessed April 2020
33. CGS, Administrators, LLC. Local Coverage Article: Billing and Coding: Billing and Coding for Botulinum Toxins (A56472). Centers for Medicare & Medicaid Services, Inc. Updated on 11/19/2019 with effective date 11/28/2019. Accessed April 2020.
34. Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B Policy (A57185). Centers for Medicare & Medicaid Services, Inc. Updated on 09/19/2019 with effective date 10/01/2019. Accessed April 2020.

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35. Palmetto GBA. Local Coverage Article: Billing and Coding: Chemodenervation (A56646). Centers for Medicare & Medicaid Services, Inc. Updated on 10/02/2019 with effective date 10/10/2019. Accessed April 2020.
36. Palmetto GBA. Local Coverage Article: Billing and Coding: Upper Gastrointestinal Endoscopy and Visualization (A56389). Centers for Medicare & Medicaid Services, Inc. Updated on 10/10/2019 with effective date 10/17/2019. Accessed April 2020.
37. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Botulinum Toxins (A57715). Centers for Medicare & Medicaid Services, Inc. Updated on 11/21/2019 with effective date 10/03/2019. Accessed April 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G24.3	Spasmodic torticollis
G25.89	Other specified extrapyramidal and movement disorders
G35	Multiple sclerosis
G37.0	Diffuse sclerosis of central nervous system
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G81.13	Spastic hemiplegia affecting right nondominant side
G81.14	Spastic hemiplegia affecting left nondominant side
G82.53	Quadriplegia, C5-C7, complete
G82.54	Quadriplegia, C5-C7, incomplete
G83.0	Diplegia of upper limbs, Diplegia (Upper), Paralysis of both upper limbs
G83.20	Monoplegia of upper limb affecting unspecified side

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G83.21	Monoplegia of upper limb affecting right dominant side
G83.22	Monoplegia of upper limb affecting left dominant side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.039	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.059	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.139	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting unspecified site
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.159	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side

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I69.239	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting unspecified site
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.259	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified site
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.839	Monoplegia of upper limb following other cerebrovascular disease affecting unspecified site
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side
I69.859	Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side
I69.931	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right dominant side
I69.932	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left dominant side
I69.933	Monoplegia of upper limb following unspecified cerebrovascular disease affecting right non-dominant side
I69.934	Monoplegia of upper limb following unspecified cerebrovascular disease affecting left non-dominant side
I69.939	Monoplegia of upper limb following unspecified cerebrovascular disease affecting unspecified side

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I69.951	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right dominant side
I69.952	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left dominant side
I69.953	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting right non-dominant side
I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting left non-dominant side
I69.959	Hemiplegia and hemiparesis following unspecified cerebrovascular disease affecting unspecified side
K11.7	Disturbances of salivary secretions
L74.510	Primary focal hyperhidrosis, axilla
M43.6	Torticollis

Dual coding requirements:

- Primary G and M codes require a secondary G or I code in order to be payable

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): 6; K	NCD/LCD/LCA Document (s): A52848
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&bc=gAAAAAAAAAAAA	

Jurisdiction(s): 5, 8	NCD/LCD/LCA Document (s): A57474
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&bc=gAAAAAAAAAAAA	

Jurisdiction(s): 9; N	NCD/LCD/LCA Document (s): A57715
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57715&bc=gAAAAAAAAAAAA&	

Jurisdiction(s): 15	NCD/LCD/LCA Document (s): A56472
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56472&bc=gAAAAAAAAAAAA ==	

Jurisdiction(s): F	NCD/LCD/LCA Document (s): A57186
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<https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57186&bc=gAAAAAAAAAAAAAAAAA>==

Jurisdiction(s): E	NCD/LCD/LCA Document (s): A57185
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57185&bc=gAAAAAAAAAAAAAAAAA ==	

Jurisdiction(s): J & M	NCD/LCD/LCA Document (s): A56646
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56646&bc=gAAAAAAAAAAAAAAAAA ==	

Jurisdiction(s): J & M	NCD/LCD/LCA Document (s): A56389
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56389&bc=gAAAAAAAAAAAAAAAAA ==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Myobloc was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Myobloc

Effective Date: 01/01/2022
Reviewed: 10/2021, 1/2022, 3/2023, 12/2023, 01/2024
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according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.