

Myobloc® (rimabotulinumtoxinB) (Intramuscular/Intradermal)

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I. Length of Authorization

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

II. Dosing Limits

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

- Myobloc 2500 unit/0.5 mL Solution for Injection: 1 vial per 84 days
- Myobloc 5000 unit/mL Solution for Injection: 1 vial per 84 days
- Myobloc 10,000 unit/2 mL Solution for Injection: 1 vial per 84 days

B. Max Units (per dose and over time) [Medical Benefit]:

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)

Sialorrhea

- 50 billable units per 12 weeks (84 days)

Severe Primary Axillary Hyperhidrosis

- 100 billable units per 12 weeks (84 days)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient aged 18 years or greater; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing

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

Upper Limb Spasticity ‡

Prophylaxis for Chronic Migraines ‡

- Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab, etc.); **AND**
- Patient is utilizing prophylactic intervention modalities (i.e. pharmacotherapy, behavioral therapy, or physical therapy, etc); **AND**
- Patient has failed at least a 3 month trial of any two oral medications for the prevention of migraines (see list of prophylactic medications below for examples); **AND**
- Patient has 15 or more migraine-like headache days per month for at least 3 months; **AND**
 - Headaches have diagnostic migraine-features, on at least 8 days per month for at least 3 months (see list of diagnostic migraine features with and without aura below) §; **OR**
 - Patient suspected migraines are relieved by a triptan or ergot derivative medication

Sialorrhea associated with neurological disorders ‡

- Patient has Parkinson’s disease; **OR**
- Patient has severe developmental delays; **AND**
 - Patient has failed oral therapy ; **OR**
- Patient has cerebral palsy; **AND**
 - Patient has failed oral therapy

Severe Primary Axillary Hyperhidrosis ‡

- Patient has failed with topical agents; **AND**
- Patient has failed, or has contraindications to, oral pharmacotherapy; **AND**
 - Patient has a history of medical complications such as skin infections or significant functional impairments; **OR**
 - Patient has had a significant impact to activities of daily living due to condition

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

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, etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc)
Migraine Features

Migraine without aura

- At least five attacks have the following:
 - Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)
 - Headache has at least two of the following characteristics:
 - 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:
 - Nausea and/or vomiting
 - Photophobia and phonophobia

Migraine with aura

- At least two attacks have the following:
 - One or more of the following fully reversible aura symptoms:
 - Visual
 - Sensory
 - Speech and/or language
 - Motor
 - Brainstem
 - Retinal; **AND**
 - At least two of the following characteristics:
 - At least one aura symptom spreads gradually over ≥ 5 minutes, and/or two or more symptoms occur in succession
 - Each individual aura symptom lasts 5 to 60 minutes
 - At least one aura symptom is unilateral
 - The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include; symptoms of a toxin spread effect (e.g. asthenia, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties, 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 (e.g. Ashworth Scale, etc.)

Prophylaxis for chronic migraines

- 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.)

Sialorrhea associated with neurological disorders

- 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

V. Dosage/Administration

Myobloc

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
Sialorrhea	Up to 5,000 units divided among the affected muscles every 12 weeks
Severe Primary Axillary Hyperhidrosis	Up to 4,000 units per axilla every 12 weeks

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- Myobloc 2500 unit/0.5 mL Solution for Injection: 10454-0710-xx
- Myobloc 5000 unit/mL Solution for Injection: 10454-0711-xx
- Myobloc 10,000 unit/ 2mL Solution for Injection: 10454-0712-xx

VII. References

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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
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
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
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

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) and Local Coverage Determinations (LCDs) 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):

Jurisdiction(s): 15	NCD/LCD Document (s): L33949
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33949&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): N	NCD/LCD Document (s): L33274
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33274&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): J, M	NCD/LCD Document (s): L33458
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33458&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): 6; K	NCD/LCD Document (s): L33646
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33646&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): F	NCD/LCD Document (s): L35172
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35172&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): E	NCD/LCD Document (s): L35170
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35170&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34635
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34635&bc=gAAAAAAAAAAAAAA==	

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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