Myobloc® (rimabotulinumtoxinB)
(Intramuscular/Intradermal)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

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)

Overactive Bladder
- 150 billable units per 12 weeks (84 days)

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

Universal Criteria [1]

- 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, etc.); **AND**

Cervical Dystonia † Φ [1,2]

- 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 † [1,13-18,33]

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

Upper Limb Spasticity ‡ [2-6]

Prophylaxis for Chronic Migraines ‡ [7-10,19-22,24,31,34,35,39]

- Patient is utilizing prophylactic intervention modalities (i.e. avoiding migraine triggers, pharmacotherapy, behavioral therapy, or physical therapy, etc.); **AND**
- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 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 > 3 months:
    - Headaches have characteristics and symptoms consistent with migraine**§**; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- One of the following apply:
  - 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 **±**); **OR**
  - Patient had previous treatment with a CGRP antagonist used for prevention of migraines

Severe Primary Axillary Hyperhidrosis ‡ [11,12,25,26,32,36]

- Patient has tried and failed ≥ 1 month trial of a topical agent (e.g., 20% aluminum chloride, glycopyrronium, aluminum zirconium trichlorohydrate, 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 (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings, etc.)

Overactive Bladder (OAB) ‡ [37.38]

- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**

- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (e.g., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium, etc.) or beta-adrenergic (e.g., mirabegron, vibegron, etc.) classes

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

± Migraine-Prophylaxis Oral Medications *(list not all-inclusive)*[19,21,24,39]
• Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol, etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc.)
§ Migraine Features [24,31,34]
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 three of the following characteristics: – 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) – The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the 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, swallowing/breathing difficulties, etc.), serious hypersensitivity reactions (i.e., angioedema, urticaria, rash, anaphylaxis, serum sickness, soft tissue edema, and dyspnea), etc.; **AND**

- Disease response as evidenced by the following:

Cervical Dystonia [1,2]

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

Upper Limb Spasticity [2-6,30]

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

Prophylaxis for Chronic Migraines [20,24,31]

- 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 [1,13-18,33]

- Significant decrease in saliva production

Severe Primary Axillary Hyperhidrosis [11,12,25,26,32]

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

Overactive Bladder (OAB) [37,38]

- Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
- Patient's post-void residual (PVR) periodically assessed as medically appropriate

V. Dosage/Administration [1-12,30,31,37]

Indication	Dose
Cervical Dystonia	Initial dose: 2,500 to 5,000 units divided among the affected muscles. Re-treatment: 2,500 to 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 to 3,500 units (500 to 1,500 units per parotid gland and 250 units per submandibular gland) every 12 weeks. Maximum dose: 3,500 units divided among the affected muscles every 12 weeks.

Severe Primary Axillary Hyperhidrosis	Up to 4,000 units per axilla every 12 weeks
Overactive Bladder	Up to 15,000 units divided among the affected muscles every 12 weeks
Note: *Units of Myobloc are specific to the preparation and assay method utilized and are not interchangeable with other preparations of botulinum toxin products and cannot be compared to or converted into units of any other botulinum toxin products*	

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Myobloc 2,500 unit/0.5 mL single-dose vial solution for Injection: 10454-0710-xx
- Myobloc 5,000 unit/mL single-dose vial solution for Injection: 10454-0711-xx
- Myobloc 10,000 unit/2mL single-dose vial 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
N32.81	Overactive bladder

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6 & K	A52848	National Government Services, Inc. (NGS)
5 & 8	A57474	Wisconsin Physicians Insurance Corp (WPS)
N	A57715	First Coast Service Options, Inc.
15	A56472	CGS Administrators, LLC
F	A57186	Noridian Healthcare Solutions, LLC
E	A57185	Noridian Healthcare Solutions, LLC
J & M	A56646	Palmetto GBA
H & L	A58423	Novitas Solutions, Inc.

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
15	KY, OH	CGS Administrators, LLC