

## Myobloc® (rimabotulinumtoxinB) (Intramuscular/Intradermal)

Document Number: IC-0240

Last Review Date: 05/03/2020

Date of Origin: 06/21/2011

Dates Reviewed: 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 02/2013, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018, 04/2019, 09/2019, 01/2020, 05/2020, 05/2021

### I. Length of Authorization

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

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- 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

#### B. 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

- 35 billable units per 12 weeks (84 days)

##### Severe Primary Axillary Hyperhidrosis

- 100 billable units per 12 weeks (84 days)

### III. Initial Approval Criteria <sup>1-26</sup>

Coverage is provided in the following conditions:

- 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, etc.); **AND**

#### **Cervical Dystonia † Φ<sup>1,2</sup>**

- 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

#### **Chronic Sialorrhea †<sup>1,13-18,33</sup>**

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

#### **Upper Limb Spasticity ‡<sup>2-6</sup>**

#### **Prophylaxis for Chronic Migraines ‡<sup>7-10,19-22,24,31</sup>**

- Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (i.e., eptinezumab, erenumab, galcanezumab, fremanezumab, etc.) [*NOTE: This does not include CGRP inhibitors used for acute treatment (i.e., ubrogepant)*]; **AND**
- 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)

#### **Severe Primary Axillary Hyperhidrosis ‡<sup>11,12,25,26,32</sup>**

- 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.)

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

### Migraine-Prophylaxis Oral Medications (*list not all-inclusive*)

- 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 § 31

#### 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 <sup>1</sup>

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 reaction, etc.; **AND**
- Disease response as evidenced by the following:

### Cervical dystonia <sup>1,2</sup>

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

### Upper Limb Spasticity <sup>2-6,30</sup>

- 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 <sup>20</sup>

- 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 <sup>1,13-18,33</sup>

- Significant decrease in saliva production

#### Severe primary axillary hyperhidrosis <sup>11,12,25,26,32</sup>

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

### V. Dosage/Administration <sup>1,3-11,13-18,30</sup>

| Indication                            | Dose  |
|---------------------------------------|---|
| Cervical Dystonia                     | Initial dose: 2,500 – 5,000 units divided among the affected muscles.<br>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.<br>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   |

### VI. 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

## 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 |
|-------|-------------|

**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):**

|   |   |
|---|---|
| <b>Jurisdiction(s):</b> 6 & K   | <b>NCD/LCD/LCA Document (s):</b> A52848 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52848&amp;bc=gAAAAAAAAAAAA</a>                         |   |
| <b>Jurisdiction(s):</b> 5 & 8   | <b>NCD/LCD/LCA Document (s):</b> A57474 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57474&amp;bc=gAAAAAAAAAAAA</a>                         |   |
| <b>Jurisdiction(s):</b> 9; N  | <b>NCD/LCD/LCA Document (s):</b> A57715 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57715&amp;bc=gAAAAAAAAAAAA&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57715&amp;bc=gAAAAAAAAAAAA&amp;</a> |   |
| <b>Jurisdiction(s):</b> 15  | <b>NCD/LCD/LCA Document (s):</b> A56472 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56472&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56472&amp;bc=gAAAAAAAAAAAAAA==</a>                         |   |
| <b>Jurisdiction(s):</b> F   | <b>NCD/LCD/LCA Document (s):</b> A57186 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57186&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57186&amp;bc=gAAAAAAAAAAAAAA==</a>                         |   |
| <b>Jurisdiction(s):</b> E   | <b>NCD/LCD/LCA Document (s):</b> A57185 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57185&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A57185&amp;bc=gAAAAAAAAAAAAAA==</a>                         |   |
| <b>Jurisdiction(s):</b> J & M   | <b>NCD/LCD/LCA Document (s):</b> A56646 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56646&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56646&amp;bc=gAAAAAAAAAAAAAA==</a>                         |   |

|   |   |
|---|---|
| <b>Jurisdiction(s):</b> H & L   | <b>NCD/LCD/LCA Document (s):</b> A58423 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A58423&amp;bc=gAAAAAAAAAAAA&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A58423&amp;bc=gAAAAAAAAAAAA&amp;</a> |   |

| <b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b> |   |   |
|--|---|---|
| <b>Jurisdiction</b>  | <b>Applicable State/US Territory</b>  | <b>Contractor</b>                                 |
| 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                           |