 Approved Revision: Do Not Implement until 8/31/21

RimabotulinumtoxinB (Myobloc®)

NDC CODE(S) 10454-0710-XX MYOBLOC 2500UNIT/0.5ML Solution (SOLSTICE NEUROSCIENCES)
10454-0711-XX MYOBLOC 5000UNIT/ML Solution (SOLSTICE NEUROSCIENCES)
10454-0712-XX MYOBLOC 10000UNIT/2ML Solution (SOLSTICE NEUROSCIENCES)

DESCRIPTION

Botulinum toxin, produced by the bacterium Clostridium botulinum, is one of the most potent naturally occurring neurotoxins known. It induces chemodenervation by first binding to acceptors on motor nerve terminals. It then enters the terminals and blocks the release of acetylcholine and other neurotransmitters at the neuromuscular junction. This renders smooth and striated muscles incapable of contraction. Acetylcholine also mediates the sympathetic innervation of the sweat glands, explaining how botulinum toxin disrupts the cholinergic outflow to the skin and halts glandular secretion.

The minute amount of toxin used clinically produces only partial, localized chemical denervation with transient results. Over time, axons generate temporary sprouts which release acetylcholine and the original nerve terminal is eventually re-established, ending the toxin's therapeutic activity.

Seven antigenic-specific serotypes of botulinum toxin have been identified, types A, B, C-1, D, E, F and G, but only botulinum toxin types A and B are commercially available. These commercial preparations of the two serotypes (three of serotype A and one of serotype B) vary widely in potency and dosage. They have been given different names to reinforce these differences and to prevent medication errors. It is emphasized that the use and dosage of different formulations of botulinum toxin is not interchangeable.

This policy addresses only the type B formulation rimabotulinumtoxinB marketed as Myobloc®.

POLICY

- RimabotulinumtoxinB for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Cervical dystonia
  - Severe primary hyperhidrosis, axillary
  - Upper Limb Spasticity
  - Sialorrhea
- RimabotulinumtoxinB for the prevention of chronic migraine headaches is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- RimabotulinumtoxinB for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- 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

- 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

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

Upper Limb Spasticity

Prophylaxis for Chronic Migraines

- Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., 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

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

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 §

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 ~~, 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
  ▪ 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

RENEWAL CRITERIA

- Patient continues to meet universal and indication specific criteria as identified in the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of a toxin spread effect (e.g., 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

- 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, Physician Global Assessment, Clinical Global Impression (CGI), 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.)

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

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: 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

LENGTH OF AUTHORIZATION

Coverage will be provided six months and may be renewed

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

- 350 billable units per 12 weeks (84 days)

Severe Primary Axillary Hyperhidrosis

- 100 billable units per 12 weeks (84 days)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE 8/31/2021

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