RimabotulinumtoxinB

NDC CODE(S)  10454-0710-XX Myobloc 2500 UNIT/0.5ML SOLN (SOLSTICE NEUROSCIENCES)
10454-0711-XX Myobloc 5000 UNIT/ML SOLN (SOLSTICE NEUROSCIENCES)
10454-0712-XX Myobloc 10000 UNIT/2ML SOLN (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 associated with neurological disorders
- 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

- RimabotulinumtoxinB is considered medically appropriate if ALL of the following criteria are met:
  - Individual is 18 years of age or older
  - Individual evaluated for any disorders which may contribute to respiratory or swallowing difficulty
  - Diagnosis of ANY ONE of the following:
    - Cervical dystonia with history of recurrent involuntary contraction of one or more muscles in the neck if ANY ONE of the following:
      - Sustained head tilt

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Abnormal posturing with limited range of motion in neck

- Hyperhidrosis, severe primary axillary if individual has ALL of the following:
  - Treatment is not adequately managed with topical agents (e.g., aluminum chloride, glycopyrronium, etc.) for ≥ 1 month trial
  - Condition causes ANY ONE of the following:
    - 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.)
    - Functional impairment/pain (e.g., inability perform critical activities of daily living due to condition)

- History of medical complications such as skin infections, significant functional impairments

- Sialorrhea associated with neurological disorders if individual has ANY ONE of the following:
  - Parkinson’s disease
  - Severe developmental delays with trial and failure, inability to tolerate or contraindication to an adequate trial of oral therapy (e.g., glycopyrrolate, benztropine, atropine, etc.)
  - Cerebral palsy with trial and failure, inability to tolerate or contraindication to an adequate trial of oral therapy (e.g., glycopyrrolate, benztropine, atropine, etc.)

- Spasticity Upper Limb
  - Chronic migraine prophylaxis if individual has ALL of the following:
    - Utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, or physical therapy, etc.)
    - Fifteen or more migraine-like headache days per month for at least 3 months
    - 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 Suspected migraines are relieved by a triptan or ergot derivative medication
    - Failed a minimum of 8 week trial of any two oral medications for the prevention of migraines (see list of prophylactic medications below for examples)
    - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab-aooe, 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)
- 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

- 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

RENEWAL CRITERIA

- RimabotulinumtoxinB is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria
  - Disease response is documented
  - Absence of unacceptable toxicity from the agent, e.g., symptoms of a toxin spread effect (e.g. asthenia, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties, etc)
  - Disease response as evidenced by **ANY ONE** of the following:
    - Cervical dystonia with improvement in the severity and frequency of pain AND improvement of abnormal head positioning
    - Chronic migraine prophylaxis, significant decrease in number and frequency of headaches and improvement in function AND continues to utilize prophylactic intervention modalities (i.e. pharmacotherapy, behavioral therapy, physical therapy, etc.)
    - Hyperhidrosis, severe primary axillary with significant reduction in spontaneous axillary sweat production AND significant improvement in activities of daily living
    - Sialorrhea associated with neurological disorders with significant decrease in saliva production
    - Spasticity in upper Limb with significant decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g. Ashworth Scale, etc.)

### INDICATION(S) | DOSAGE & ADMINISTRATION
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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

**LENGTH OF AUTHORIZATION**

Coverage will be provided six months and may be renewed

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Refer to DOSAGE LIMITS below

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).

SOURCES


Lexi-Comp Online. (2019, February). AHFS DI. RimabotulinumtoxinB. Retrieved April 12, 2019 from Lexi-Comp Online with AHFS.


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EFFECTIVE DATE  7/31/2019

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