IMPORTANT REMINDER
This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description
Botulinum toxin is a neurotoxin that is injected into a muscle to cause temporary paralysis or relaxation of that muscle. This policy covers the one commercial botulinum toxin type B product, rimabotulinumtoxinB (Myobloc). Botulinum toxin type A products (Botox, Dysport, and Xeomin) are covered in a separate policy.
Policy/Criteria

I. Most contracts require prior authorization approval of rimabotulinumtoxinB prior to coverage. RimabotulinumtoxinB may be considered medically necessary in patients with one of the following conditions:

A. **Cervical dystonia** or **spasmodic torticollis**, when criteria 1 and 2 below are met:
   1. Documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures.
   2. Documented pain or functional impairment originating from the dystonia.

B. **Sialorrhea** (drooling), excessive.

C. **Urinary incontinence** due to detrusor overactivity, either idiopathic or due to neurogenic causes (e.g., spinal cord injury, multiple sclerosis), or incontinence due to overactive bladder (OAB), when therapy with anticholinergic agents is ineffective or not tolerated.

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx does not consider rimabotulinumtoxinB to be a self-administered medication.

B. When prior authorization is approved, rimabotulinumtoxinB may be authorized in quantities up to four injection treatments within a 48-week period.

C. Authorization may be reviewed at least every 12 months to confirm that current medical necessity criteria are met and that the medication is effective.

III. RimabotulinumtoxinB is considered investigational for all other conditions, including, but not limited to:

A. Carpal tunnel syndrome

B. Hyperhidrosis (such as axillary or palmar)

C. Spasticity not otherwise specified (other than spasmodic torticollis), such as:
   1. Cerebral palsy (CP)-related spasticity
   2. Hemifacial spasm
   3. Spasmodic dysphonia
   4. Spasmodic dystonia
   5. Spastic movement disorders in children
   6. Spastic trismus, including TMJ
   7. Upper limb spasticity following stroke
**Position Statement**

**Summary**

- RimabotulinumtoxinB is a form of botulinum toxin (type B) and is approved for the treatment of cervical dystonia or spasmodic torticollis to reduce the severity and pain associated with abnormal neck position.

- RimabotulinumtoxinB is also used for reduction of sialorrhea in patients with a variety of neurological disorders. The goal of therapy is to reduce sialorrhea-associated complications, such as aspiration pneumonia or skin breakdown. For urinary incontinence due to detrusor overactivity, rimabotulinumtoxinB may be a treatment option for patients with symptoms not responding to other treatment options.

- Botulinum toxins (BTX-A and BTX-B) have also been studied in many different conditions where muscle tension is thought to play a role. The quality of evidence from the majority of these studies is poor.

- FDA labeling indicates that units of rimabotulinumtoxinB cannot be compared to or converted into units of any other botulinum toxin. Therefore, the efficacy, dosing and safety of rimabotulinumtoxinB cannot be based on extrapolation from other studies using other botulinum toxin serotypes.

- Use of botulinum toxin (all serotypes) for treatment of wrinkles or other cosmetic conditions is considered not medically necessary and frequently excluded by contract.

**Clinical Efficacy**

**Cervical Dystonia or Spasmodic Torticollis**

- Cervical dystonia (or spasmodic torticollis) is characterized by involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures.

- Results from three clinical studies support the efficacy of rimabotulinumtoxinB in reducing neck pain and the severity of the abnormal head position associated with cervical dystonia or spasmodic torticollis in patients previously responsive to BTX-A \[^1,2\] or those patients who no longer respond to BTX-A. \[^3\]

**Sialorrhea**

- Anatomically guided injections of rimabotulinumtoxinB into the parotid and submandibular glands appear to effectively improve sialorrhea in patients with Parkinson's disease. \[^4-6\] and amyotrophic lateral sclerosis (ALS). \[^7\]

- A randomized controlled trial demonstrated a decrease in frequency and severity of sialorrhea in children with cerebral palsy who received rimabotulinumtoxinB injected into the salivary glands. \[^8\]

**Urinary Incontinence due to overactive bladder (OAB)**

- Injection of rimabotulinumtoxinB into the bladder appears to improve urinary urgency, frequency and nocturia in patients with refractory detrusor overactivity.

- A Cochrane review concluded both botulinum type A and B formulations are effective treatment options for urinary incontinence due to refractory detrusor overactivity due to neurogenic or idiopathic OAB. \[^9\]
**Use of botulinum toxic type B in other conditions**

- The evidence for the use of rimabotulinumtoxinB in a variety of conditions is limited to pilot trials and case reports, including hyperhidrosis (axillary and palmar), \(^{10-13}\) carpal tunnel syndrome, \(^{14}\) and myofascial pain due to nerve entrapment (e.g. piriformis syndrome or shoulder impingement). \(^{15,16}\) The evidence from these trials is of poor quality and the response to therapy was variable. Larger, well-designed trials are necessary to confirm the results, as well as establish benefit relative to standard of care treatments.

- Similarly, small pilot studies, case reports and observational studies have suggested potential benefit of rimabotulinumtoxinB in the treatment of various spastic disorders (other than spasmodic torticollis), including spasmodic dystonia, \(^{17}\) upper limb spasticity following stroke, \(^{18,19}\) spastic movement disorders in children, \(^{20}\) arm dystonia in children with cerebral palsy, \(^{21}\) spastic trismus a muscle spasm of the jaw, which may include the temporomandibular joint (TMJ), \(^{22}\) and hemifacial spasm. \(^{23}\) The evidence from these trials is of poor quality. Larger, well-designed clinical trials are needed to assess safety and efficacy of rimabotulinumtoxinB in these conditions.

**Safety** \(^{24}\)

- The most commonly reported adverse events observed in clinical trials of rimabotulinumtoxinB include dry mouth, dysphagia, dyspepsia, and injection site pain.

- All botulinum toxin products have a boxed warning and Risk Evaluation and Mitigation Strategy (REMS) program for the potential for toxin to spread from the site of injection and produce symptoms consistent with botulinum toxin effects. Symptoms may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties and may occur hours to weeks after injection. Swallowing and breathing difficulties can be life threatening. Deaths have been reported.

- The safety, efficacy and dosage of botulinum toxins have not been established for any condition in children less than 12 years of age.

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**Cross References**

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<tr>
<th>Cross References</th>
<th>Details</th>
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<td>Botulinum Toxin, BlueCross BlueShield Association Medical Policy, 5.01.05; Reviewed Date: 12/2016.</td>
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<tr>
<td>Treatment of Hyperhidrosis, BlueCross BlueShield Association Medical Policy, 8.01.19; Reviewed Date: 5/2016.</td>
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<td>Surgical Treatments for Hyperhidrosis, Medical Policy; Med 165.</td>
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<td>Botox®, Dysport®, Xeomin®, Botulinum toxin type A injection, Medication Policy Manual, Policy dru006</td>
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<td>Cosmetic and Reconstructive Surgery, Surgery Section; Medical Policy No. 12.</td>
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References


23. Trosch, RM, Adler, CH, Pappert, EJ. Botulinum toxin type B (Myobloc) in subjects with hemifacial spasm: results from an open-label, dose-escalation safety study. Mov Disord. 2007 Jul 15;22(9):1258-64. PMID: 17588242

Revision History

<table>
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<tr>
<th>Revision Date</th>
<th>Revision Summary</th>
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<tr>
<td>2/17/2017</td>
<td>Clarify quantity limits to 4 doses per 48-weeks (versus use of 12 months). Clarify authorization “may” be reviewed every 12 months.</td>
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<tr>
<td>2/12/2016</td>
<td>No criteria changes</td>
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