RimabotulinumtoxinB

ACG: A-0519 (AC)
Link to Codes

MCG Health
Ambulatory Care
30th Edition

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Clinical Indications

- RimabotulinumtoxinB may be indicated for **1 or more** of the following(1)(2)(3)(4)(5):
  - Cervical dystonia (spasmodic torticollis), as indicated by **1 or more** of the following(26)(27)(28)(29)(30):N
    - Initial course, as indicated by **ALL** of the following:
      - Age 16 years or older
      - Neck pain or abnormal head position causing adverse effect on daily functioning
      - No fixed contractures causing decreased neck range of motion
      - No infection at proposed injection site
      - No neuromuscular disease (eg, myasthenia gravis)
    - Subsequent course, as indicated by **ALL** of the following:
      - Age 16 years or older
      - Favorable response to prior administration of rimabotulinumtoxinB
  - Sialorrhea (excessive salivation), as indicated by **1 or more** of the following(38)(39)(40)(41)(42)(43)(44):N
    - Initial course
    - Subsequent course, with favorable response to prior administration of rimabotulinumtoxinB

Evidence Summary

Background

RimabotulinumtoxinB is a neurotoxin purified from cultures of the type B strain of *Clostridium botulinum*.(1) **(EG 2)** Botulinum toxin injection into striated muscles results in paralysis within 2 to 5 days, lasting for 2 to 3 months. Botulinum toxin has inhibiting effects on dystonia and spasticity, and it blocks autonomic activity to smooth muscle and exocrine glands. There are 7 different serotypes (A to G), each with varying potencies and characteristics of action.(6) **(EG 2)** Type A (commercially available as onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA, daxibotulinumtoxinA, prabotulinumtoxinA, and letibotulinumtoxinA) has been by far the most-studied serotype, but type B, the subject of far fewer studies, is also commercially available as rimabotulinumtoxinB.(1)(2)(7)(8)(9)(10)(11)(12) **(EG 1)** The commercially available agents differ in synthesis and purification processes, potency, duration of action, and tendency toward clinically relevant systemic spread due to migration from the injection site.(2)(8)(13)(14)(15)(16) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 40 published peer reviewed articles, 4 specialty society or other evidence-based guidelines, and 3 Cochrane systematic reviews.

For cervical dystonia (spasmodic torticollis), evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Expert evidence-based guidelines and a network meta-analysis have concluded that all 4 commercially available botulinum toxins are effective as first-line treatment for this condition.(31)(32)(33)(34)(35) **(EG 1)** A systematic review and meta-analysis of 4 randomized studies of 441 patients found significant evidence that rimabotulinumtoxinB is effective in reducing intensity of impairment from cervical dystonia, including intensity, disability, and pain.(36) **(EG 1)** A systematic review of 3 randomized studies with 270 patients found that there is low-quality evidence that botulinum toxin A and botulinum toxin B have comparable efficacy for cervical dystonia.(37) **(EG 1)**

For sialorrhea, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review of 6 randomized controlled trials and comparative clinical studies (162 total patients) treating sialorrhea due to Parkinson disease, amyotrophic lateral sclerosis, or neuroleptic medication concluded that botulinum toxin type B significantly reduced sialorrhea.(38) **(EG 1)** A randomized controlled trial compared 2 doses of rimabotulinumtoxinB (2500 units and 3500 units) with placebo in 187 adult patients with sialorrhea secondary to any disorder, most frequently Parkinson disease. At 4 weeks following injection, both treatment dose groups demonstrated improvements in unstimulated salivary flow rate compared with placebo.(44) **(EG 1)** A systematic review evaluating botulinum toxins for sialorrhea in patients with amyotrophic lateral sclerosis identified 3 studies of botulinum toxin type B, including one randomized controlled trial and 2 single-arm studies (43 total patients). Botulinum toxin type B therapy was associated with subjective symptom improvement as compared with baseline and placebo, but studies were limited by the use of nonvalidated outcome measures and lack of blinding.(45) **(EG 1)** Expert consensus guidelines and review articles recommend that botulinum toxin type B may be considered as a treatment option for sialorrhea in patients with neurologic disease, including amyotrophic lateral sclerosis.(40)(41)(43)(46)(47)(48) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For bladder dysfunction, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of randomized trials reported a relatively short duration of efficacy of only 10 weeks for botulinum toxin type B compared with 3 to 12 months for botulinum toxin type A.(17) **(EG 1)**

For hyperhidrosis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Expert evidence-based reviews found evidence of effectiveness for botulinum type A preparations; however, evidence specifically related to rimabotulinumtoxinB for this condition was lacking.(18)(19)(20) **(EG 2)** A randomized controlled trial of 24 patients with axillary hyperhidrosis who were assigned to either onabotulinumtoxinA or rimabotulinumtoxinB found comparable efficacy, safety, and patient satisfaction after 20 weeks, although the authors could not rule out bias due to small sample size and stated that larger confirmatory studies are necessary.(21) **(EG 1)**

For poststroke spasticity, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Expert evidence-based reviews have not found any conclusive studies of the efficacy of rimabotulinumtoxinB because most studies have focused on botulinum toxin type A.(22)(23) **(EG 2)** A randomized controlled study of 24 adults with disabling elbow flexor overactivity after either stroke or traumatic brain injury found that rimabotulinumtoxinB administration was associated with significant short-term improvement for up to 3 months, but the authors indicated that larger studies with longer-term follow-up of functional improvement are needed.(24) **(EG 1)**

For spasticity in children with cerebral palsy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** An expert evidence-based review found only limited studies suggesting efficacy of rimabotulinumtoxinB for spasticity, with some studies suggesting less potency and duration for rimabotulinumtoxinB as compared with botulinum toxin type A.(25) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(49); 42 CFR 422.101(50)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(51); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(52); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(53)

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HCPCS: J0587

Last Update: 1/25/2026 2:42:43 AM
Build Number: 30.0.2026012500524.025256