RimabotulinumtoxinB

ACG: A-0519 (AC)
Link to Codes

MCG Health
Ambulatory Care
27th Edition

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[A](22)(23)(24)(25)(26):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) due to neurologic disease, as indicated by **1 or more** of the following[B](35)(37)(38)(39)(40)(41):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, and incobotulinumtoxinA) 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) **(EG 2)** 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)(9)(10)(11) **(EG 2)**

Criteria

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.(27)(28)(29)(30)(31)(32) **(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.(33) **(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.(34) **(EG 1)**

For sialorrhea due to neurologic disease, 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.(35) **(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.(41) **(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.(42) **(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.(37)(38)(40)(43)(44)(45) **(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.(12) **(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.(13)(14)(15) **(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.(16) **(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.(17)(18) **(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.(19) **(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.(20) **(EG 2)**

For upper esophageal sphincter 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 to assess the efficacy and safety of botulinum toxin for improving upper esophageal sphincter dysfunction in patients with dysphagia did not identify any relevant randomized controlled trials and stated there was insufficient evidence to inform clinical practice.(21) **(EG 1)**

References

1. Myobloc (rimabotulinumtoxinB) injection. Physician Prescribing Information [Internet] Solstice Neurosciences, Inc. 2021 Mar Accessed at: https://myobloc.com/. [created 2000; accessed 2022 Nov 11] [Context Link 1, 2, 3, 4]
2. Pirazzini M, Rossetto O, Eleopra R, Montecucco C. Botulinum neurotoxins: biology, pharmacology, and toxicology. Pharmacological Reviews 2017;69(2):200-235. DOI: 10.1124/pr.116.012658. [Context Link 1, 2, 3] View abstract...
3. Safarpour Y, Jabbari B. Botulinum toxin treatment of movement disorders. Current Treatment Options in Neurology 2018;20(2):4. DOI: 10.1007/s11940-018-0488-3. [Context Link 1] View abstract...
4. Orsini M, et al. Botulinum neurotoxin type A in neurology: update. Neurology International 2015;7(2):5886. DOI: 10.4081/ni.2015.5886. [Context Link 1] View abstract...
5. Zakin E, Simpson D. Evidence on botulinum toxin in selected disorders. Toxicon 2018;147:134-140. DOI: 10.1016/j.toxicon.2018.01.019. [Context Link 1] View abstract...
6. Ferrari A, Manca M, Tugnoli V, Alberto L. Pharmacological differences and clinical implications of various botulinum toxin preparations: a critical appraisal. Functional Neurology 2018;33(1):7-18. [Context Link 1] View abstract...
7. Jankovic J. Botulinum toxin: State of the art. Movement Disorders 2017;32(8):1131-1138. DOI: 10.1002/mds.27072. [Context Link 1] View abstract...
8. Brin MF, James C, Maltman J. Botulinum toxin type A products are not interchangeable: a review of the evidence. Biologics 2014;8:227-241. DOI: 10.2147/BTT.S65603. [Context Link 1] View abstract...
9. Fraint A, Vittal P, Comella C. Considerations on patient-related outcomes with the use of botulinum toxins: is switching products safe? Therapeutics and Clinical Risk Management 2016;12:147-154. DOI: 10.2147/TCRM.S99239. [Context Link 1] View abstract...
10. Steward L, Brin MF, Brideau-Andersen A. Novel native and engineered botulinum neurotoxins. Handbook of Experimental Pharmacology 2021;263:63-89. DOI: 10.1007/164_2020_351. [Context Link 1] View abstract...
11. Hasan F. Manufacturing and clinical formulations of botulinum neurotoxins. Handbook of Experimental Pharmacology 2021;263:49-62. DOI: 10.1007/164_2019_311. [Context Link 1] View abstract...

12. Duthie JB, Vincent M, Herbison GP, Wilson DI, Wilson D. Botulinum toxin injections for adults with overactive bladder syndrome. Cochrane Database of Systematic Reviews 2011, Issue 12. Art. No.: CD005493. DOI: 10.1002/14651858.CD005493.pub3. [Context Link 1] View abstract...

13. Wade R, et al. Interventional management of hyperhidrosis in secondary care: a systematic review. British Journal of Dermatology 2018;179(3):599-608. DOI: 10.1111/bjd.16558. [Context Link 1] View abstract...

14. de Almeida AR, Montagner S. Botulinum toxin for axillary hyperhidrosis. Dermatologic Clinics 2014;32(4):495-504. DOI: 10.1016/j.det.2014.06.013. [Context Link 1] View abstract...

15. Lakraj AA, Moghimi N, Jabbari B. Hyperhidrosis: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxins. Toxins (Basel) 2013;5(4):821-840. DOI: 10.3390/toxins5040821. [Context Link 1] View abstract...

16. An JS, Hyun Won C, Si Han J, Park HS, Seo KK. Comparison of onabotulinumtoxinA and rimabotulinumtoxinB for the treatment of axillary hyperhidrosis. Dermatologic Surgery 2015;41(8):960-967. DOI: 10.1097/DSS.0000000000000429. [Context Link 1] View abstract...

17. Andringa A, van de Port I, van Wegen E, Ket J, Meskers C, Kwakkel G. Effectiveness of botulinum toxin treatment for upper limb spasticity after stroke over different ICF domains: a systematic review and meta-analysis. Archives of Physical Medicine and Rehabilitation 2019;100(9):1703-1725. DOI: 10.1016/j.apmr.2019.01.016. [Context Link 1] View abstract...

18. Kaku M, Simpson DM. Spotlight on botulinum toxin and its potential in the treatment of stroke-related spasticity. Drug Design, Development and Therapy 2016;10:1085-99. DOI: 10.2147/DDDT.S80804. [Context Link 1] View abstract...

19. Gracies JM, Bayle N, Goldberg S, Simpson DM. Botulinum toxin type B in the spastic arm: a randomized, double-blind, placebo-controlled, preliminary study. Archives of Physical Medicine and Rehabilitation 2014;95(7):1303-1311. DOI: 10.1016/j.apmr.2014.03.016. [Context Link 1] View abstract...

20. Practice parameter: pharmacologic treatment of spasticity in children and adolescents with cerebral palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology 2010 (AAN reaffirmed 2019);74(4):336-343. DOI: 10.1212/WNL.0b013e3181cbcd2f. (Reaffirmed 2022 May) [Context Link 1] View abstract...

21. Regan J, Murphy A, Chiang M, McMahon BP, Coughlan T, Walshe M. Botulinum toxin for upper oesophageal sphincter dysfunction in neurological swallowing disorders. Cochrane Database of Systematic Reviews 2014, Issue 5. Art. No.: CD009968. DOI: 10.1002/14651858.CD009968.pub2. [Context Link 1] View abstract...

22. Thenganatt MA, Jankovic J. Treatment of dystonia. Neurotherapeutics 2014;11(1):139-152. DOI: 10.1007/s13311-013-0231-4. [Context Link 1] View abstract...

23. Mills RR, Pagan FL. Patient considerations in the treatment of cervical dystonia: focus on botulinum toxin type A. Patient Preference and Adherence 2015;9:725-731. DOI: 10.2147/PPA.S75459. [Context Link 1] View abstract...

24. Bledsoe IO, Comella CL. Botulinum toxin treatment of cervical dystonia. Seminars in Neurology 2016;36(1):47-53. DOI: 10.1055/s-0035-1571210. [Context Link 1] View abstract...

25. Jabbari B. History of botulinum toxin treatment in movement disorders. Tremor and Other Hyperkinetic Movements 2016;6:394. DOI: 10.7916/D81836S1. [Context Link 1] View abstract...

26. Marsili L, Bologna M, Jankovic J, Colosimo C. Long-term efficacy and safety of botulinum toxin treatment for cervical dystonia: a critical reappraisal. Expert Opinion on Drug Safety 2021;20(6):695-705. DOI: 10.1080/14740338.2021.1915282. [Context Link 1] View abstract...

27. Simpson DM, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2016;86(19):1818-1826. DOI: 10.1212/WNL.0000000000002560. [Context Link 1] View abstract...

28. Albanese A, et al. Practical guidance for CD management involving treatment of botulinum toxin: a consensus statement. Journal of Neurology 2015;262(10):2201-13. DOI: 10.1007/s00415-015-7703-x. [Context Link 1] View abstract...

29. Albanese A, et al. EFNS guidelines on diagnosis and treatment of primary dystonias. European Journal of Neurology 2011;18(1):5-18. DOI: 10.1111/j.1468-1331.2010.03042.x. (Reaffirmed 2022 May) [Context Link 1] View abstract...

30. Patel S, Martino D. Cervical dystonia: from pathophysiology to pharmacotherapy. Behavioural Neurology 2013;26(4):275-282. DOI: 10.3233/BEN-2012-120270. [Context Link 1] View abstract...

31. Contarino MF, et al. Clinical practice: evidence-based recommendations for the treatment of cervical dystonia with botulinum toxin. Frontiers in Neurology 2017;8:35. DOI: 10.3389/fneur.2017.00035. [Context Link 1] View abstract...

32. Han Y, Stevens AL, Dashtipour K, Hauser RA, Mari Z. A mixed treatment comparison to compare the efficacy and safety of botulinum toxin treatments for cervical dystonia. Journal of Neurology 2016;263(4):772-780. DOI: 10.1007/s00415-016-8050-2. [Context Link 1] View abstract...

33. Marques RE, et al. Botulinum toxin type B for cervical dystonia. Cochrane Database of Systematic Reviews 2016, Issue 5. Art. No.: CD004315. DOI: 10.1002/14651858.CD004315.pub3. [Context Link 1] View abstract...

34. Duarte GS, et al. Botulinum toxin type A versus botulinum toxin type B for cervical dystonia. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD004314. DOI: 10.1002/14651858.CD004314.pub3. [Context Link 1] View abstract...

35. Dashtipour K, Bhidayasiri R, Chen JJ, Jabbari B, Lew M, Torres-Russotto D. RimabotulinumtoxinB in sialorrhea: systematic review of clinical trials. Journal of Clinical Movement Disorders 2017;4:9. DOI: 10.1186/s40734-017-0055-1. [Context Link 1, 2, 3] View abstract...

36. Daniel SJ. Botulinum toxin injection techniques for pediatric sialorrhea. Operative Techniques In Otolaryngology--Head and Neck Surgery 2015;26:42-49. DOI: 10.1016/j.otot.2015.01.004. [Context Link 1]

37. Sridharan K, Sivaramakrishnan G. Pharmacological interventions for treating sialorrhea associated with neurological disorders: A mixed treatment network meta-analysis of randomized controlled trials. Journal of Clinical Neuroscience 2018;51:12-17. DOI: 10.1016/j.jocn.2018.02.011. [Context Link 1, 2] View abstract...

38. Seppi K, et al. Update on treatments for nonmotor symptoms of Parkinson's disease-an evidence-based medicine review. Movement Disorders 2019;34(2):180-198. DOI: 10.1002/mds.27602. (Reaffirmed 2022 Jul) [Context Link 1, 2] View abstract...

39. Moller E, et al. Repeated treatments of drooling with botulinum toxin B in neurology. Acta Neurologica Scandinavica 2015;131(1):51-57. DOI: 10.1111/ane.12309. [Context Link 1] View abstract...

40. Hosp C, Naumann MK, Hamm H. Botulinum toxin treatment of autonomic disorders: Focal hyperhidrosis and sialorrhea. Seminars in Neurology 2016;36(1):20-28. DOI: 10.1055/s-0035-1571214. [Context Link 1, 2] View abstract...

41. Isaacson SH, et al. Safety and efficacy of rimabotulinumtoxinB for treatment of sialorrhea in adults: a randomized clinical trial. JAMA Neurology 2020;77(4):461-469. DOI: 10.1001/jamaneurol.2019.4565. [Context Link 1, 2] View abstract...

42. Shehee L, O'Rourke A, Garand KL. The role of radiation therapy and botulinum toxin injections in the management of sialorrhea in patients with amyotrophic lateral sclerosis: a systematic review. Journal of Clinical Neuromuscular Disease 2020;21(4):205-221. DOI: 10.1097/CND.0000000000000273. [Context Link 1] View abstract...

43. Squires N, Humberstone M, Wills A, Arthur A. The use of botulinum toxin injections to manage drooling in amyotrophic lateral sclerosis/motor neurone disease: a systematic review. Dysphagia 2014;29(4):500-8. DOI: 10.1007/s00455-014-9535-8. [Context Link 1] View abstract...

44. Miller RG, et al. Practice parameter update: The care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009 (AAN reaffirmed 2014);73(15):1227-1233. DOI: 10.1212/WNL.0b013e3181bc01a4. (Reaffirmed 2022 May) [Context Link 1] View abstract...

45. Isaacson J, Patel S, Torres-Yaghi Y, Pagan F. Sialorrhea in Parkinson's disease. Toxins (Basel) 2020;12(11):691. DOI: 10.3390/toxins12110691. [Context Link 1] View abstract...

Footnotes

[A] For cervical dystonia, rimabotulinumtoxinB is injected into affected muscles, with or without electromyographic guidance, with dosing tailored to head and neck position, location of pain, muscle hypertrophy, and history of prior response (including to previous botulinum toxin injection) and adverse events. Most patients return to pretreatment status after about 3 to 4 months. Subsequent administration may then take place as necessary.(1) [A in Context Link 1]

[B] For sialorrhea, rimabotulinumtoxinB is injected directly into the parotid and submandibular glands.(35)(36) [B in Context Link 1]

Codes

CPT®: 64616, 64617, 64642, 64643, 64644, 64645, 64646, 64647

HCPCS: J0587

MCG Health
Ambulatory Care 27th Edition

Last Update: 9/21/2023 5:45:25 AM
Build Number: 27.2.2023092114759.013030