

Medicare Advantage Medical Benefit Drug Policy



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Effective Date: 08/10/2023

Botulinum Toxin Type A
Botox[®] (onabotulinumtoxinA)
Dysport[®] (abobotulinumtoxinA)
Xeomin[®] (incobotulinumtoxinA)

HCPCS: Botox: J0585, Dysport: J0586, Xeomin: J0588

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
- a. Blepharospasm
 - b. Central demyelinating of corpus callosum
 - c. Cerebral Palsy
 - d. Cervical dystonia with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures
 - e. Demyelinating diseases of CNS
 - f. Facial nerve VII disorders
 - g. Facial nerve disorders, other
 - i. Facial myokymia, Melkersson's syndrome, facial/hemifacial spasms
 - h. Hereditary spastic paraplegia
 - i. Laryngeal spasm, laryngeal adductor spastic dysphonia, or stridulus
 - j. Leukodystrophy (CNS disease characterized by adrenal atrophy and diffuse cerebral demyelination)
 - k. Multiple sclerosis
 - l. Neuromyelitis optica
 - m. Organic writer's cramp
 - n. Orofacial dyskinesia (i.e., jaw closure dystonia), Meige syndrome
 - o. Schilder's disease
 - p. Spasmodic dysphonia
 - q. Spastic hemiplegia
 - r. Spasticity related to stroke
 - s. Spasticity related to spinal cord injury
 - t. Strabismus
 - u. Torsion dystonia, idiopathic and symptomatic (also known as **Oppenheim's** dystonia)
 - v. Upper limb spasticity in adult and pediatric patients 2 years of age and older to decrease the severity of

increased muscle tone in elbow flexors, wrist flexors, finger flexors, and thumb flexors

- w. Lower limb spasticity in adults and pediatric patients 2 years of age and older to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus and flexor digitorum longus)

B. Botulinum toxin type A may be considered for approval in patients with functional impairment resulting from one of the following conditions when generally accepted treatments are not effective or not tolerated:

- a. Anal fissures - patients will be assessed for trial and/or failure with other therapeutic alternatives, such as nitroglycerin ointment.
- b. Achalasia/Cardio spasm - in patients who have not responded to dilation therapy or who are considered poor surgical candidates.
- c. Primary axillary hyperhidrosis Botulinum toxin type A may be considered for approval when ALL of the following are met:
 - i. Treatable primary medical conditions and contributing factors (including drugs) causing secondary hyperhidrosis are identified and addressed where possible.
 - ii. Documented adequate trial of available agents (e.g., Topical antiperspirants, anticholinergic drugs)
 - iii. Medical treatment of persistent hyperhidrosis is not considered for approval in the absence of significant medical complications associated with the condition.
- d. Treatment of hyperhidrosis, including gustatory or palmar hyperhidrosis, may be considered for approval only when the hyperhidrosis is persistent and severe and has resulted in significant medical complications such as skin maceration with secondary infection.
- e. Chronic migraine headache - Botulinum toxin type A may be considered for approval when all ALL THREE (3) of the criteria in a, b, and c, below are met:
 - i. There is a persistent history of recurring debilitating headaches (15 or more days per month with migraine headache lasting for 4 hours per day or longer).
AND
 - ii. Adequate trials (at least 6 weeks) of prophylactic therapy from at least TWO different therapy classes listed in Appendix 3 were not effective, contraindicated, or not tolerated.
AND
 - iii. Other conditions or aggravating factors that are contributing to the development of chronic migraine headaches are being treated. Possible examples: dental or jaw problems, muscle tension, depression, fibromyalgia, sleep disorders and smoking.
- f. Incontinence, either idiopathic or due to neurogenic causes (e.g., spinal cord injury, multiple sclerosis) when therapy with two anticholinergic or other agents indicated for the treatment of idiopathic or neurogenic incontinence are not effective or not tolerated.
- g. Overactive bladder with symptoms of urge incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of two agents for the treatment of overactive bladder (e.g. anticholinergics or beta-3 receptor agonists).
- h. Chronic sialorrhea (drooling)
- i. Pelvic floor spasms - patients will be assessed on a case by case basis after trial and failure with at least 2 other therapeutic alternatives, such as muscle relaxants and benzodiazepines
- j. Trial and failure of the preferred products as specified in the **BCBSNE Part B drugs prior authorization list**

C. Quantity Limitations, Authorization Period and Renewal Criteria

- a. Quantity Limit: 6 months for initial therapy
- b. Initial Authorization Period: 1 year for continuation of therapy
- c. Renewal Criteria: Authorization will be reviewed for objective clinical response to confirm the medication is effective
 - i. For chronic migraine, the frequency or duration for chronic migraines will be reduced from the time of initial presentation with treatment by at least:

- a) 7 days/month (frequency)
- b) 100 hours/month (duration)
- d. Quantity Limits will be approved when used in accordance with FDA approved dosing. Any requests greater than this may require supporting documentation
- e. Continuation of therapy requires documented positive clinical response

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Botulinum toxin is a neurotoxin that is injected into a muscle to cause temporary paralysis of that muscle through the inhibition of acetylcholine release from peripheral cholinergic nerve endings. There are three commercial botulinum toxin type A products available: Botox (onabotulinumtoxinA), Dysport (abobotulinumtoxinA), and Xeomin (incobotulinumtoxinA). These agents differ in their manufacturing, isolation and purification processes and utilize different Clostridium batches.
- At comparable doses, the botulinum toxin A can be considered therapeutically equated. Data are limited and one botulinum toxin A product is not considered superior to the others. Botulinum toxin A products are not interchangeable and require medical expertise to convert patients from one formulation to another.

Appendix 1: International Headache Society Classification of Chronic Migraine Headache

- A. Headache (tension-type or migraine) on 15 or more days per month for at least 3 months.*
- B. Occurring in a patient who has had at least 5 attacks fulfilling criteria for a migraine without an aura
- C. On 8 or more days per month for at least 3 months headache has fulfilled criteria for pain and associated symptoms of migraine without aura in either or both of criteria 1 or 2 below:
 - 1. At least two of the following criteria a), b), c) and d) below are met:
 - a) Unilateral location
 - b) Pulsating quality
 - c) Moderate or severe pain intensity
 - d) Aggravation by or causing avoidance of routine physical activity
 - 2. Treated and relieved by triptan(s) or ergot before the expected development of the above symptoms.
- D. No medication overuse and not attributed to another causative disorder

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Appendix 2: Medications for Abortive Migraine Treatment

Class	Common Examples
Triptans	Imitrex [®] (sumatriptan), Maxalt [®] , Zomig [®] , Amerge [®] (naratriptan), Axert [®] , Frova [®] , Relpax [®]
Analgesics	Aspirin, acetaminophen
Non-steroidal Anti-inflammatory Drugs	Motrin [®] (ibuprofen), Naprosyn [®] (naproxen), Relafen [®] (nabumetone), Voltaren [®] (diclofenac), Orudis [®] (ketoprofen), Clinoril [®] (sulindac), Toradol [®] (ketorolac)

Appendix 3: Medications for Prophylaxis of Migraines

Class	Accepted Examples
Anticonvulsants	Depakote [®] (divalproex), Depakene [®] (sodium valproate), Topamax [®] (topiramate), Tegretol [®] (carbamazepine)
ACE inhibitor or Angiotensin Receptor Blocker	Zestril [®] (lisinopril), Atacand [®] (candesartan)
Beta Blockers	Inderal [®] (propranolol), Lopressor [®] (metoprolol), Tenormin [®] (atenolol), Corgard [®] (nadolol), Blocadren [®] (timolol), Bystolic [®] (nebivolol), Visken [®] (pindolol)
Calcium Channel Blockers	Procardia [®] (nifedipine), Cardizem [®] (diltiazem), Calan [®] (verapamil)
Antidepressants	Elavil [®] (amitriptyline), Effexor [®] (venlafaxine)
CGRP inhibitors	Nurtec ODT (rimegepant), Qulipta (atogepant), Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Vyepti (eptinezumab)

References:

1. J0585 Botulinum Toxin Type A, Medicare Part B Newsletter #178, December 1999, p. 6.
2. Botulinum-A Toxin, BlueCross BlueShield Association Medical Policy #5.01.05, 10/2008.
3. Botox[®] (onabotulinumtoxinA) [package insert]. Allergan, Inc., Irvine, CA. September 2019.
4. Simpson DM. "Clinical trials of botulinum toxin in the treatment of spasticity." *Muscle Nerve Suppl* 1997; 6: S169-75
5. Bhakta BB, et al. "Impact of botulinum toxin type A on disability and career burden due to arm spasticity after stroke: a randomized double-blind placebo-controlled trial." *J Neurol Neurosurg Psychiatry* 2000; Aug (2):217-21.
6. Lagalla G, et al. "Post-stroke spasticity management with repeated botulinum toxin injections in upper limb." *Am J Phys Med Rehabil* 2000; Jul-Aug; 79:377-84, 391-4.
7. Smith SJ, et al. "A double-blind placebo-controlled study of botulinum toxin in upper limb spasticity after stroke or head injury." *Clin Rehabil* 2000; Feb 14:5-13.
8. Bianchi L, et al. "Quantitative analysis of the pendulum test: application to multiple sclerosis patients treated with botulinum toxin." *Func Neurol* 1999; Apr-Jun; 14(2): 79-92.
9. Brisinda G, et al. "A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissures." *New Eng J Med* 1999; 341:65-69.
10. Giorgio M, et al. "Botulinum toxin injections in the internal anal fissure for treatment of chronic anal fissure long term results after two different dosage regimens." *Annals of Surgery* 1998; 228:1-10
11. Treatment of Hyperhidrosis, BlueCross BlueShield Association Policy #8.01.19, 8/2009.
12. Schulte-Mattler WJ, et al. "Treatment of tension type headache and botulinum toxin: a pilot study." *Eur J Med Res*

- 1999; May 26;4:183-6.
13. Davis D, et al. "Significant improvement of stiff-person syndrome after paraspinal injection of botulinum toxin A." *Mov Disord* 1993; July; 8:371-3.
 14. The cosmetic use of botulinum toxin, *The Medical Letter*. Vol 41(1057) July 16, 1999;63-4.
 15. USP DI® and Advice for Patient, Botulinum Toxin Type A, Revised 01/24/2001.
 16. Maria G, et al. "A comparison of botulinum toxin and saline for the treatment of chronic anal fissure." *N Eng J Med* 1998;338:217-20.
 17. Jost WH. "One hundred cases of anal fissure treated with botulinum toxin." *Dis Colon Rectum* 1997;40:1029-32.
 18. Brisinda G, et al. "A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure." *N Engl J Med* 1999;3:341:365-9.
 19. Vazzi MF, et al. "Botulinum toxin versus pneumatic dilatation in the treatment of achalasia: A randomized trial." *Gut* 1999;44:231-9.
 20. Laskawi R, et al. "Up-to-date report of botulinum A toxin for the treatment in patients with gustatory sweating." *Laryngoscope* 1998;108:381-4.
 21. Schneider P, et al. "Double blind trial of botulinum A toxin for the treatment of focal hyperhidrosis of the palms." *Br J Dermatol* 1997;136:548-52.
 22. Shelley WB, et al. "Botulinum toxin therapy for palmar hyperhidrosis." *J Am Acad Dermatol* 1998;38:227-9.
 23. Naumann M, et al. "Focal hyperhidrosis. Effective treatment with intracutaneous botulinum toxin." *Arch Dermatol* 1998;134:301-4.
 24. Levit F. "Treatment of hyperhidrosis by tap water ionophoresis." *Cutis* 1980; 26:192-4.
 25. Schachor D, et al. "Endoscopic transthoracic sympathectomy in the treatment of primary hyperhidrosis." *Arch Surg* 1994;129:241-4.
 26. 1996 BlueCross BlueShield Association, TEC Assessment; Tab 6.
 27. Rollnik JD, et al. "Treatment of tension type headache with botulinum toxin type A: a double-blind placebo controlled study." *Headache* 2000;40:300-5.
 28. Brin MF, et al. "Botox for migraine: double-blind, placebo-controlled region-specific evaluation." *Cephalalgia* 2000;20:421-22.
 29. Silberstein S, et al. "Botulinum toxin type A as a migraine preventive treatment." *Headache* 2000;40:445-50.
 30. Marras C, et al. "Botulinum toxin for simple motor tics. A randomized, double-blind, controlled clinical trial." *Neurology* 2001;56:605-10.
 31. Foster L, et al. "Botulinum toxin A and chronic low back pain." *Neurology* 2001;56:1290-3.
 32. Brin MF, et al. "A randomized double-masked, controlled trial of botulinum toxin type A in essential hand tremor." *Neurology* 2001;56:1523-8.
 33. Foster L, et al. "Botulinum toxin A and chronic low back pain. A randomized, double-blind study." *Neurology* 2001;56:1290-3.
 34. Yuen EC, et al " Entrapment and other focal neuropathies." *Neurol Clin* 1999;617-31.
 35. Brashear A, et al. "Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke." *N Engl J Med* 2002;347:395-400.
 36. BlueCross BlueShield Association Technology Evaluation Center Bulletin, Volume 19, Number 3, November 11, 2002, pp. 1-5.
 37. Giannantoni A, et al. "Intravesical resiniferatoxin versus botulinum-A toxin injections for neurogenic detrusor overactivity: a prospective randomized study." *J Urol* 2004;172:240-3
 38. Riccabona M, et al. "Botulinum-A toxin injection into the detrusor: a safe alternative in the treatment of children with myelomeningocele with detrusor hyperreflexia." *J Urol* 2004;171(2 pt 1):845-8.
 39. Smith CP, et al. "Botulinum toxin in urology: evaluation using an evidence-based medicine approach." *NCP Urol* 2004;1:31-7.
 40. Mancini F, et al. "Double-blind, placebo-controlled study to evaluate the efficacy and safety of botulinum toxin type A in the treatment of drooling in parkinsonism." *Mov Disord* 2003;18:685-8.
 41. Lipp A, et al. "A randomized trial of botulinum toxin A for treatment of drooling." *Neurology* 2003;61:1279-81.
 42. Schulte-Mattler WJ, et al. "Treatment of chronic tension-type headache with botulinum toxin A: a randomized, double-blind, placebo-controlled multicenter study." *Pain* 2004;109:110-4.

43. Ondo WG, et al. "Botulinum toxin A for chronic daily headache: a randomized, placebo-controlled, parallel design study." *Cephalalgia* 2004;24:60-5.
44. Padberg M, et al. "Treatment of chronic tension-type headache with botulinum toxin: a double-blind, placebo-controlled clinical trial." *Cephalalgia* 2004;24:675-80.
45. Unal M, et al. "Effect of botulinum toxin A on nasal symptoms in patients with allergic rhinitis: a double-blind, placebo-controlled clinical trial." *ACTA Otolaryngol* 2003;123:1060-3.
46. Adler C, et al. "Botulinum toxin type A for treating voice tremor." *Arch Neurol* 2004;61:1416-20.
47. Godevenos D, et al. "The treatment of chronic anal fissure with botulinum toxin." *Acta Chir Belg.* 2004;104:577-80.
48. Schurch B, et al. "Botulinum toxin type A is a safe and effective treatment for neurogenic urinary incontinence: results of a single treatment, randomized, placebo controlled 6-month study." *J Urol.* 2005;174(1):196-200.
49. Cannito MP, et al. "Perceptual analyses of spasmodic dysphonia before and after treatment." *Arch Otolaryngol Head Neck Surg.* 2004;130(12):1393-9.
50. Babcock MS, et al. "Treatment of pain attributed to plantar fasciitis with botulinum toxin A: a short-term, randomized, placebo-controlled, double-blind study." *Am J Phys Med Rehabil.* 2005;84(9):649-54.
51. Wong SM, et al. "Treatment of lateral epicondylitis with botulinum toxin: a randomized, double-blind, placebo-controlled trial." *Ann Intern Med.* 2005;143(11):793-7.
52. Lacy BE, et al. "The treatment of diabetic gastroparesis with botulinum toxin injection of the pylorus." *Diabetes Care.* 2004;27(10):2341-7.
53. Garcia-Compean D, et al. "Endoscopic injection of botulinum toxin in the gastric antrum for the treatment of obesity. Results of a pilot study." *Gastroenterol Clin Biol.* 2005;29(8-9):789-91.
54. Mathew NT, et al. "Botulinum toxin type A (BOTOX) for the prophylactic treatment of chronic daily headache: a randomized, double-blind, placebo-controlled trial." *Headache.* 2005;45(4):293-307.
55. Silberstein SD, et al. "Botulinum toxin type A for the prophylactic treatment of chronic daily headache: a randomized, double-blind, placebo-controlled trial." *Mayo Clin Proc.* 2005;80(9):1126-37.
56. Evers S, et al. "Botulinum toxin A in the prophylactic treatment of migraine--a randomized, double-blind, placebo-controlled study." *Cephalalgia.* 2004;24(10):838-43.
57. Lasgalla G, et al. Botulinum toxin type A for drooling in **Parkinson's** Disease: a double-blind, randomized placebo-controlled study. *Movement Disorders.* 2006;21(5):704-06.
58. Park DS, et al. Evaluation of short term clinical effects and presumptive mechanism of botulinum toxin type A as a treatment modality of benign prostatic hyperplasia. *Yonsei Med J.* 2006;47(5):706-14.
59. Qerama E, et al. A double-blind, controlled study of botulinum toxin A in chronic myofascial pain. *Neurology.* 2006;67:241-45.
60. Ferrante FM, et al. Evidence against trigger point injection technique for the treatment of cervicothoracic myofascial pain with botulinum toxin type A. *Anesthesiology.* 2005;103:377-83.
61. Cohen JL, et al. Botulinum toxin type A in the treatment of dermatochalasis: an open-label, randomized, dose-comparison study. *Journal of Drugs in Dermatology.* 2006;5:596-606.
62. Gui D, et al. Effect of botulinum toxin antral injection on gastric emptying and weight reduction in obese patients: a pilot study. *Aliment Pharmacol Ther.* 2006;23:675-80.
63. Abbott JA, et al. Botulinum toxin type A for chronic pain and pelvic floor spasm in women. *Obstet Gynecol* 2006;108:915-23.
64. Fruehauf H, et al. Efficacy and safety of botulinum toxin A injection compared with topical nitroglycerin ointment for the treatment of chronic anal fissure: a prospective randomized study. *Am J Gastroenterol* 2006;101:2107-12.
65. Elkind AH, et al. A series of three sequential, randomized, controlled studies of repeated treatments with botulinum toxin type A for migraine prophylaxis. *The Journal of Pain.* 2006;7:688-96.
66. Jabbari B, et al. Treatment of refractory, chronic low back pain with botulinum neurotoxin A: an open-label, pilot study. *Pain Medicine.* 2006;7:260-4.
67. Ney JP, et al. Treatment of chronic low back pain with successive injections of botulinum toxin A over 6 months. *Clin J Pain.* 2006;22:363-9.
68. Kajbafzadeh AM, et al. Intravesical injection of botulinum toxin type A: management of neuropathic bladder

- and bowel dysfunction in children with myelomeningocele. *Urology*. 2006;68:1091-7.
69. American Gastroenterological Association Technical Review on the Management of Hepatitis C. *Gastro* 2006;130:231-64.
 70. **Stedman's** medical dictionary. 27th ed. Baltimore: Lippincott Williams & Wilkins;2000. p 1662.
 71. National Institute of Neurological Disorders and Stroke [homepage on the internet]. Bethesda, MD. Updated October 4, 2011. Available from: <http://www.ninds.nih.gov/disorders/spasticity/spasticity.htm?css=print>. Accessed: February 7, 2012.
 72. Botulinum Toxin Types A and B. Medicare Medical Policy, B2002.20 RI, May 1, 2006.
 73. Liu HT et al. Intravesical botulinum toxin A injections plus hydrodistention can reduce nerve growth factor production and control bladder pain in interstitial cystitis. *Urology* 2007;70 (3): 463 – 468.
 74. Lowe NJ, et al. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. *J Am Acad Dermatol* 2007;56:604-11.
 75. Foschi D, et al. Treatment of morbid obesity by intraparietogastric administration of botulinum toxin: a randomized, double-blind, controlled study. *International Journal of Obesity* 2007;31:707-12.
 76. Relja M et al. A multicentre, double-blind, randomized, placebo-controlled, parallel group study of multiple treatments of botulinum toxin type A for the prophylaxis of episodic migraine headaches. *Cephalgia* 2007;27:492-503.
 77. Aurora SK, et al. Botulinum toxin type A prophylactic treatment of episodic migraine: a randomized, double-blind, placebo-controlled exploratory study. *Headache* 2007;47:486-99.
 78. Yoon SJ, et al. Low-dose botulinum toxin type A for the treatment of refractory piriformis syndrome. *Pharmacotherapy* 2007; 27(5):657-65).
 79. Jordan SE, et al. Selective botulinum chemodenervation of the scalene muscles for treatment of neurogenic thoracic outlet syndrome. *Ann Vasc Surg*. 2000 Jul;14(4):365-9.
 80. Hauser SL, Josephson SA, Harrison TR, Kasper DL, English JD, Braunwald E, Fauci AS, Engstrom JW, Longo DL, editors. *Harrison's Neurology in Clinical Medicine*. 16th ed. New York: McGraw-Hill Professional; 2006.
 81. Arts J, Holvoet L, Caenepeel P, Bisschops R, Sifrim D, et al. Clinical trial: a randomized-controlled crossover study of intrapyloric injection of botulinum toxin in gastroparesis. *Aliment Pharmacol Ther*. 2007;26(9):1251-8.
 82. FriedenberG FK, Palit A, Parkman HP, Hanlon A, Nelson DB. Botulinum toxin A for the treatment of delayed gastric emptying. *Am J Gastroenterol*. 2008;103(2):416-23.
 83. Silberstein SD, Göbel H, Jensen R, Elkind AH, Degryse R, et al. Botulinum toxin type A in the prophylactic treatment of chronic tension-type headache: a multicentre, double-blind, randomized, placebo-controlled, parallel-group study. *Cephalgia*. 2006;26(7):790-800.
 84. Straube A, Empl M, Ceballos-Baumann A, Tölle T, Stefenelli U, et al.; Dysport Tension-Type Headache Study Group. Pericranial injection of botulinum toxin type A (Dysport) for tension-type headache - a multicentre, double-blind, randomized, placebo controlled study. *Eur J Neurol*. 2008;15(3):205-13.
 85. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review). *Neurology*. 2008;70:1707-14. Available at www.neurology.org.
 86. Hayton MJ, Santini AJ, Hughes PJ, Frostick SP, Trail IA, et al. Botulinum toxin injection in the treatment of tennis elbow. A double-blind, randomized, controlled, pilot study. *J Bone Joint Surg Am*. 2005;87(3):503-7.
 87. Keizer SB, Rutten HP, Pilot P, Morré HH, v Os JJ, et al. Botulinum toxin injection versus surgical treatment for tennis elbow: a randomized pilot study. *Clin Orthop Relat Res*. 2002;(401):125-31.
 88. Karacalar A, Yilmaz N, Bilgici A, **Baş** B, Akan H. Botulinum toxin for the treatment of temporomandibular joint disk disfigurement: clinical experience. *J Craniofac Surg*. 2005 May;16(3):476-81.
 89. Ziegler CM, Haag C, Mühling J. Treatment of recurrent temporomandibular joint dislocation with intramuscular botulinum toxin injection. *Clin Oral Investig*. 2003;7(1):52-5.
 90. Freund BJ, Schwartz M. Relief of tension-type headache symptoms in subjects with temporomandibular disorders treated with botulinum toxin-A. *Headache*. 2002;42(10):1033-7.
 91. von Lindern JJ. Type A botulinum toxin in the treatment of chronic facial pain associated with temporomandibular

- dysfunction. *Acta Neurol Belg.* 2001;101(1):39-41.
92. Brashear A, Truong B, Charles D, et al. A randomized, double-blind, placebo-controlled study of intramuscular BOTOX® for the treatment of cervical dystonia [abstract]. *Mov Disord* 1998;13:276.
 93. Festen S, Gisbertz SS, van Schaagen F, Gerhards MF. Blinded randomized clinical trial of botulinum toxin versus isosorbide dinitrate ointment for treatment of anal fissure. *Br J Surg.* 2009;96(12):1393-9.
 94. Aurora SK, Dodick DW, Turkel CC, DeGryse RE, Silberstein SD, et al. OnabotulinumtoxinA for treatment of chronic migraine: Results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. *Cephalalgia.* 2010;30(7):793-803.95.
 95. Diener HC, Dodick DW, Aurora SK, Turkel CC, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: Results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia.* 2010;30(7):804-814.
 96. Silberstein SD. Practice parameter: Evidence-based guidelines for migraine headache (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology.* 2000;55:754.
 97. International Headache Society (IHS) [page on the internet]. IHS Classification ICHD-II (revised criteria). Available at: http://ihs-classification.org/en/02_klassifikation/05_anhang/01.05.01_anhang.html. Accessed on 2/7/2012.
 98. © 2013 RegenceRx - Botulinum toxin type A injection. May 2013.
 99. Jackson JL, Kuriyama A, Hayashino Y. Botulinum toxin A for prophylactic treatment of migraine and tension headaches in adults: a meta-analysis. *JAMA.* 2012;307:1736-45.
 100. Badgett R, Massey A. Review: Prophylactic botulinum toxin A reduces frequency of chronic migraine headaches in adults. *Ann Intern Med.* 2012;157:JC2-10.
 101. Albanese A. Terminology for preparations of botulinum neurotoxins: what a difference a name makes. *JAMA.* 2012;305:89-90.
 102. Wohlfarth K, Schwandt I, Wegner F, et al. Biological activity of two botulinum toxin type A complexes (Dysport and Botox) in volunteers: a double-blind, randomized, dose-ranging study. *J Neur.* 2008;255:1932-9.
 103. Dysport (abobotulinumtoxinA) [package insert] Wrexham, LL 13 9UF, UK; Ipsen Biopharmaceuticals. Inc; September 2017.
 104. Xeomin (incobotulinumtoxinA) [package insert] Dessau-Rosslau, Germany; Merz Group Services GmbH; December 2015.
 105. S.D.Silberstein, S. Holland, F. Freitage, *et al.* Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2012; 78:1337-1345.
 106. Press Release. Ipsen Announces FDA Approval of Dysport® (abobotulinumtoxinA) for Injection for the Treatment of Lower Limb Spasticity in Children Aged Two and Older. Available at: <http://www.ipсен.com/wp-content/uploads/2016/08/PR-Approval-Dysport-US-PLL.pdf>. Accessed on 10/10/2016.
 107. Press Release. Ipsen Announces FDA Approval of Dysport® (abobotulinumtoxinA) for Injection for the Treatment of Lower Limb Spasticity in Adults. Available at: <https://www.ipсен.com/media/press-relases/ipсен-announces-fda-approval-dysport-abobotulinumtoxina-treatment-lower-limb-spasticity-adults/>. Accessed on 10/6/2017.
 108. Purwar B, Khullar V. Use of Botulinum Toxin for Chronic Pelvic Pain. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5384509/>. Accessed on 10/6/2017
 109. Xeomin® (incobotulinumtoxinA) [prescribing information]. Merz Pharmaceuticals, LLC., Raleigh, NC. July 2018
 110. Lucas E. Medical Management of Neurogenic Bladder for Children and Adults: A Review. *Top Spinal Cord Inj Rehabil.* 2019;25(3):195-204. doi:10.1310/sci2503-195
 111. **Rawashdeh YF, et al. International Children's Continence Society's** Recommendations for Therapeutic Intervention in Congenital Neuropathic Bladder and Bowel Dysfunction in Children. *Neurourol Urodynam.*

31:615–620, 2012.

112. Gormley, E. Ann, Lightner, Deborah J. Burgio, Kathryn L., et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline. April 2019. Available at: [https://www.auanet.org/guidelines/overactive-bladder-\(oab\)-guideline](https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline).
113. Hsu FC, Weeks CE, Selph SS, et al. Updating the evidence on drugs to treat overactive bladder: a systematic review. *Int Urogynecol J.* 2019;30:1603-1617.
114. Melo-Carrillo A, Strassman AM, Nir RR, et al. Fremanezumab-A Humanized Monoclonal Anti-CGRP Antibody-Inhibits Thinly Myelinated (A δ) But Not Unmyelinated (C) Meningeal Nociceptors. *J Neurosci.* 2017;37(44):10587-10596. doi:10.1523/JNEUROSCI.2211-17.2017

Policy History		
#	Date	Change Description
1.4	Effective Date: 08/10/2023	Annual Review
1.3	Effective Date: 08/04/2022	Updated Appendix 3 to include CGRP inhibitors
1.2	Effective Date: 12/09/2021	Removed prescriber requirements and rebound headache criteria for migraine to align with CGRP inhibitor criteria.
1.1	Effective Date: 04/08/2021	Updated criteria sections for: <ul style="list-style-type: none">• Migraine headache: removed not to be used in combination with CGRP criteria• NDO: updated verbiage to state t/f two anticholinergics or other agents• OAB: Aligned criteria with Rx benefit by requiring t/f two agents for OAB Included expert opinion outreach regarding migraine combination therapy.
1.0	Effective Date: 4/16/2020	Medical policy established

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.