

# LCD - Botulinum Toxins (L33646)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">National Government Services, Inc.</a>	MAC - Part A	06101 - MAC A	J - 06	Illinois
<a href="#">National Government Services, Inc.</a>	MAC - Part B	06102 - MAC B	J - 06	Illinois
<a href="#">National Government Services, Inc.</a>	MAC - Part A	06201 - MAC A	J - 06	Minnesota
<a href="#">National Government Services, Inc.</a>	MAC - Part B	06202 - MAC B	J - 06	Minnesota
<a href="#">National Government Services, Inc.</a>	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
<a href="#">National Government Services, Inc.</a>	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14111 - MAC A	J - K	Maine
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14112 - MAC B	J - K	Maine
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
<a href="#">National Government Services, Inc.</a>	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

## LCD Information

### Document Information

**LCD ID**

L33646

**LCD Title**

Botulinum Toxins

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

N/A

**Original Effective Date**

For services performed on or after 10/01/2015

**Revision Effective Date**

For services performed on or after 05/01/2021

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

CPT codes, descriptions and other data only are copyright 2021 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Current Dental Terminology © 2021 American Dental Association. All rights reserved.

Copyright © 2013 - 2021, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the American Hospital Association (AHA) copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816. You may also contact us at ub04@aha.org.

**Notice Period Start Date**

N/A

**Notice Period End Date**

N/A

**CMS National Coverage Policy**

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1862(a)(10) excludes coverage for cosmetic surgery.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Code of Federal Regulations:

42 CFR, Section 410.32, indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see Sec. 411.15(k)(1) of this chapter).

CMS Publications:

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 8:

50.5 Drugs and Biologicals [Coverage of SNF services]

70 Medical and Other Health Services Furnished to SNF Patients.

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 12:

40.9 Drugs and Biologicals [Comprehensive Outpatient Rehabilitation Facility (CORF) Coverage]

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15:

50.1–50.5 Drugs and Biologicals

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 16:

120 Cosmetic Surgery

CMS Publication 100-04; *Medicare Claims Processing Manual*, Chapter 17:

40 Discarded Drugs and Biologicals

CMS Publication 100-04; *Medicare Claims Processing Manual*, Chapter 30:

20.2.1 Categorical Denials

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

#### **Abstract:**

Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonias, spasms, and twitches. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated. The clinical indications for Botulinum toxins have increased exponentially since first used two decades ago. They are used in the treatment of overactive skeletal muscles (e.g. hemifacial spasm, dystonia, spasticity), smooth muscles (e.g. detrusor overactivity and achalasia), glands (e.g. sialorrhoea and hyperhidrosis) and additional conditions that are being investigated.

There are currently four Botulinum toxin products commercially available in the United States: Botox® (onabotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), Dysport™ (abobotulinumtoxinA), and Xeomin® (incobotulinumtoxinA). Each preparation has distinct pharmacological and clinical profiles specified on the product insert. Dosing patterns are also specific to the preparation of neurotoxin and are very different between different serotypes. Failure to recognize the unique characteristics of each formulation of Botulinum toxin can lead to undesired patient outcomes. It is expected that physicians will be familiar with and experienced in the use of these agents, and utilize evidence-based medicine to select the appropriate drug and dose regimen for each patient condition. Physicians may decide which agent to use in beneficiary care except as noted below. Although Botulinum toxins have only been FDA-approved for limited uses, they are frequently used off-label as well. A patient who is not responsive or who ceases to respond to one serotype may respond to the other.

This local coverage determination provides National Government Services' indications and limitations of coverage for these pharmaceutical products.

#### **Indications:**

##### **Spasticity**

Botulinum toxin can be used to reduce spasticity or excessive muscular contractions, to relieve pain, to assist with posture and walking, to improve range of motion, to enhance the effectiveness of physical therapy, and to reduce

severe spasm to allow better perineal hygiene in patients with spasticity secondary to spastic hemiplegia and hemiparesis.

Organic writer's cramp is uncommon, and so Botulinum toxin for the treatment of organic writer's cramp should be infrequent.

Botulinum toxin is indicated for disorders associated with spastic conditions as above and dystonia. Please note: covered spastic conditions are listed in Article A52848 under "ICD-10-CM Codes that Support Medical Necessity." The wide range of Botulinum toxin dosages used in a treatment session is determined by patient age, degree of spasticity, number of injections made into each muscle and number of muscles treated.

Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck and upper extremity.

OnabotulinumtoxinA is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

AbobotulinumtoxinA is indicated for the treatment of lower limb spasticity in adults.

### **Blepharospasm**

Botulinum toxin injection therapy is accepted first line treatment for patients with blepharospasm and/or hemifacial spasm. If the upper and lower lid of the same eye and/or adjacent facial muscles, or brow are injected at the same surgery, the procedure is considered to be unilateral. Bilateral procedures will only be considered when both eyes or both sides of the face are injected.

### **Achalasia**

Botulinum toxin for achalasia may be considered for the patient who has not responded satisfactorily to conventional therapy; is at high risk of complication from pneumatic dilation or surgical myotomy; has had treatment failure with pneumatic dilation or surgical myotomy; had perforation from pneumatic dilation; has an epiphrenic diverticulum or hiatal hernia; or has esophageal varices.

### **Anal Fissure**

Botulinum toxin for chronic anal fissure may be considered for the patient who has not responded satisfactorily to conventional therapy.

### **Hyperhidrosis**

OnabotulinumtoxinA has been approved by the Federal Drug Administration (FDA) for treatment of severe primary axillary hyperhidrosis (primary focal hyperhidrosis) that is inadequately managed with topical therapy. Compendia list onabotulinumtoxinA and rimabotulinumtoxinB as acceptable off-label agents for this condition. The definition of primary focal hyperhidrosis is severe sweating, beyond physiological needs; focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least two (2) of the following characteristics: bilateral and relatively symmetric, significant impairment in daily activities, age of onset less than 25 years, positive family history, and cessation of focal sweating during sleep.

### **Sialorrhea**

The treatment of sialorrhea due to conditions such as motor neuron disease or Parkinson's disease in those patients who have failed to respond to a reasonable trial of traditional therapies (eg., anticholinergics and speech therapy) or who have a contraindication to or cannot tolerate anticholinergic therapy, will be allowed for coverage.

### **Urinary Incontinence**

Urinary incontinence due to neurogenic detrusor overactivity (NDO) commonly occurs in patients with spinal cord injuries (SCI) or neurological diseases such as multiple sclerosis (MS). Patients with NDO usually use clean intermittent self-catheterization (CIC) to empty the bladder. When incontinence episodes occur between catheterizations, oral anticholinergic agents are used to decrease bladder contractility and improve incontinence.

OnabotulinumtoxinA is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults and patients five years of age and older who have an inadequate response to or are intolerant of an anticholinergic medication.

### **Headache/Migraine**

Coverage will only be allowed for those patients with chronic daily headaches (headache disorders occurring greater than 15 days a month - in many cases daily with a duration of four or more hours - for a period of at least 3 months) who have significant disability due to the headaches, and have been refractory to standard and usual conventional therapy. The etiology of the chronic daily headache may be chronic tension-type headache or chronic migraine (CM). CM is characterized by headache on  $\geq 15$  days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment. For continuing Botulinum toxin therapy the patients must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin.

### **Limitations:**

Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as one eye (including all muscles surrounding the eye including both upper and lower lids); one side of the face; the neck; or extremity and/or trunk muscle(s).

Failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype.

Treatment of wrinkles using Botulinum toxins is considered to be cosmetic, and is not covered under Medicare.

Payment will not be made for any spastic condition of smooth muscle, such as spastic colon and biliary dyskinesia, or of any spastic condition not listed under "ICD-10-CM Codes That Support Medical Necessity" in Article A52848.

The cost of special syringes is not separately payable. They are considered part of the surgical procedure.

### **Summary of Evidence**

N/A

### **Analysis of Evidence (Rationale for Determination)**

N/A

# General Information

## Associated Information

N/A

## Sources of Information

This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

Allergan Pharmaceuticals Package Insert. Botox® (Botulinum Toxin Type A) Purified Neurotoxin Complex.

American Hospital Formulary System 2007. Botulinum Toxin.

American Society for Gastrointestinal Endoscopy. Guideline esophageal dilation. *Gastrointestinal Endoscopy*. 2006;63(6):755-760.

Aurora S. Botulinum toxin type A for the treatment of migraine. *Expert Opin Pharmacother*. 2006;7(8):1085-1095.

Balikian RV, Zimble MS. Primary and adjunctive uses of botulinum toxin type A in the periorbital region. *Otolaryngol Clin N Am*. 2007;40:291-303.

Brashear A, Gordon MF, Dykstra DD, et al. (1999). Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A responsive cervical dystonia. *Neurology*. 1999;53(7):1439-1446.

Brashear A, Gordon MF, Elovic E, et al, for the Botox Post-Stroke Spasticity Study Group. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *N Engl J Med*. 2002;347(6):395-400.

Brashear A, McAfee AL, Kuhn ER, Ambrosius WT. Treatment with botulinum toxin type B in upper- limb spasticity. *Archives of Physical Medicine and Rehabilitation*. 2003;84(1):103-107.

Brin MF, Lew MF, Adler CH, et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. *Neurology*. 1999;53(7):1431-1438.

Centers for Disease Control and Prevention. Injection safety. Information for providers. FAQs regarding safe practices for medical injections. Page last updated: February 9, 2011. <http://www.cdc.gov/injectionsafety/providers.html>. Accessed 06/30/2011.

Chen YH, Kuo HC. Botulinum A toxin treatment of urethral sphincter pseudodyssynergia in patients with cerebrovascular accidents or intracranial lesions. *Urol Int*. 2004;73(2):156-162.

Contrarino MF, Pompili M, Tittoto P, et al. Botulinum toxin B ultrasound-guided injections for sialorrhea in amyotrophic lateral sclerosis and Parkinson's disease. *Parkinsonism and Related Disorders*. 2007;13:299-303.

de Seze M, Petit H, Gallien P, et al. Botulinum A toxin and detrusor sphincter dyssynergia: a double-blind lidocaine-controlled study in 13 patients with spinal cord disease. *Eur Urol*. 2002;42(1):56-62.

Dodick DW, Mauskop A, Elkind AH, DeGryse R, Brin MF, Silberstein SD. Botulinum toxin type A for the prophylaxis of chronic daily headache: subgroup analysis of patients not receiving other prophylactic medications: a randomized double-blind, placebo-controlled study. *Headache*. 2005;45(4):315-324.

- Duthis J, Wilson DI, Herbison GP, Wilson D. Botulinum toxin injections for adults with overactive bladder syndrome. *Cochrane Database of Systematic Reviews* 1007, Issue 3. Art. No.: CD005493. DOI: 10.1002/14651858.CD005493.pub2.
- Esenyel M, Aldemir T, Gursoy E, Esenyel CZ, Demir S, Durmosoglu. Myofascial pain syndrome: Efficacy of different therapies. *J Back Musculoskeletal Rehabil.* 2007;20(1):43-47.
- Evers S, Vollmer-Haase J, Schwaag S, et al. Botulinum toxin A in the prophylactic treatment of migraine – a randomized, double-blind, placebo controlled study. *Cephalagia.* 2004;24(10):838-843.
- Farinelli I, Coloprisko G, De Filippis S, Martelletti P. Long-term benefits of botulinum toxin type A (BOTOX) in chronic daily headache: a five-year long experience. *J Headache Pain.* 206;(7)6:407-412.
- Giannantoni A, Di Stasi SM, Stephen RL, Bini V, Contantini E, Porena M. Intravesical resiniferatoxin versus botulinum\_A toxin injections for neurogenic detrusor overactivity: a prospective randomized study. *J Urol.* 2004;172(1):240-243.
- Giess R, Nauman M, Werner E, et al. Injections of botulinum toxin A into the salivary glands improve sialorrhea in amyotrophic lateral sclerosis. *Neurol Neurosurg Psychiatry.* 2000;69:121-123.
- Göbel H, Heinze A, Heinze-Kuhn K, Austermann K. Botulinum toxin A in the treatment of headache syndromes and pericranial pain syndromes. *Pain.* 2001;91(3):195-199.
- Göbel H, Heinze A, Heinze-Kuhn K, Jost WH. Evidence-based medicine: botulinum toxin A in migraine and tension-type headache. *J Neurol.* 2001;248(Suppl 1):34-38.
- Graboski CL, Gray DS, Burnham RS. Botulinum toxin A versus bupivacaine trigger point injections for the treatment of myofascial pain syndrome: A randomized double blind crossover study. *Pain.* 2005;118(1-2):170-175.
- Ho KY, Tan KH. Botulinum toxin A for myofascial trigger point injection: A qualitative systematic review. *Eur J Pain.* 2007;11(5):519-527.
- Institute for Clinical Systems Improvement. Health care guideline: diagnosis and treatment of headache. Tenth Edition; January 2011.
- Jongerijs PH, van den Hoogen FJA, van Limbeek J, Gabreels FJ, van Julst K, Rotteveel JJ. Effect of botulinum toxin in the treatment of drooling: A controlled clinical trial. *Pediatrics.* 2004;114:620-627.
- Lagalla G, Millevolte M, Capecchi M, Provinciali L, Ceravolo MG. Botulinum toxin type A for drooling in Parkinson's disease: a double-blind, randomized, placebo controlled study. *Mov Disord.* 2006;21(5):704-707.
- Lipp A, Trottenberg T, Schink T, Kupsch A, Arnold G. A randomized trial of botulinum toxin A for treatment of drooling. *Neurology.* 2003;61:1279-1281.
- Mathew NT, Frishberg BM, Gawel M, Dimitrova R, Gibson J, Turkel C. 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.
- Mertz Pharmaceuticals. XEOMIN® (incobotulinumtoxinA) FDA approval Press Release 08/02/2010.
- Mertz Pharmaceuticals. XEOMIN® (incobotulinumtoxinA) Product Label.



Nauman MK, Hamm H, on behalf of the Botox Hyperhidrosis Clinical Study Group. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomized, parallel group, double blind, placebo controlled trial. *BMJ*. 2001;323(15):596-599

Nauman MK, Hamm H, Lowe NJ, on behalf of the Botox Hyperhidrosis Clinical Study Group. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomized controlled trial. *British Journal of Dermatology*. 2002;147:1218-1226.

Naik MN, Sparkar CNS, Murthy R, Honavar SG. Botulinum toxin in ophthalmic plastic surgery. *Indian Journal of Ophthalmology*. 2005;53:279-288.

NGS and other Medicare local coverage determinations.

Ojala T, Arokoski JPA, Partanend J. The effect of small doses of botulinum toxin A on neck-shoulder myofascial pain syndrome: A double-blind, randomized, and controlled crossover trial. *Clin J Pain*. 2006;22(1):90-96.

Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. *Neurology*. 2004;62:37-40.

Ondo WG, Vuong KD, Derman HS. Botulinum toxin A for chronic daily headache: a randomized, placebo-controlled, parallel design study. *Cephalagia*. 2004;24(1):60-65.

Patel AK, Patterson JM, Chapple CR. Botulinum toxin injections for neurogenic and idiopathic detrusor overactivity: a critical analysis of results. *Eur Urol*. 2006;50(4):684-710.

Porta M. A comparative trial of Botulinum toxin type A and methylprednisolone for the treatment of myofascial pain syndrome and pain from chronic muscle spasm. *Pain*. 2000;84(1-2):101-105.

Reitz A, Stohrer M, Kramer G, et al. European experience of 200 cases treated with botulinum-A toxin injections into the detrusor muscle for urinary incontinence due to neurogenic detrusor overactivity. *Eur Urol*. 2004;45(4):510-515.

Relja M, Poole AC, Schoenen J, Pascual J, Lei X, Thompson C. A multicentre, double-blind, randomized, placebo-controlled, parallel group study of multiple treatments of botulinum toxin type A (BoNTA) for the prophylaxis of episodic migraine headaches. *Cephalagia*. 2007;27(6):492-503.

Rollnik JD, Tanneberger O, Schubert M, Schneider U, Dengler R. Treatment of tension-type headache with botulinum toxin type A: a double-blind placebo-controlled study. *Headache*. 2000;40(4):300-305.

Rowland L. Perspective: stroke, spasticity, and botulinum toxin. *N Engl J Med*. 2002;347(6):382-383.

Schmitt WJ, Slowey E, Fravi N, Weber S, Burgunder JM. Effect of botulinum toxin A injections in the treatment of chronic tension-type headache: a double-blind, placebo-controlled trial. *Headache*. 2001;41(7):658-664.

Schulte-Baukloh H, Schobert J, Stolze T, Sturzebecher B, Weiss C, Knispel HH. Efficacy of botulinum-A toxin bladder injections for the treatment of neurogenic detrusor overactivity in multiple sclerosis patients: an objective and subjective analysis. *NeuroUrol Urodyn*. 2006;25(2):110-115.

Schulte-Mattler WJ, Krack P. Treatment of chronic tension-type headache with botulinum toxin A: a randomized, double-blind, placebo-controlled multicenter study. *Pain*. 2004;109(1-2):110-114.

Schurch B, de Seze M, Denys P, et al. Botulinum toxin type A is a safe and effective treatment of neurogenic urinary incontinence: results of a single treatment randomized, placebo controlled 6-month study. *J Urol*. 2005;174(1):196-

200.

Silberstein S, Mathew N, Saper J, Jenkins S. Botulinum toxin type A as a migraine preventive treatment. *Headache*. 2000;40(6):445-450.

Silberstein SD, Stark SR, Lucas SM, Christie SN, DeGryse RE, Turkel CC. 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):1126-1137.

Sloop RR, Cole BA, Rodolfo O. Human response to botulinum toxin injection: type B compared with type A. *Neurology*. 1997;49(11):189-194.

Smuts JA, Baker MK, Smuts HM, lassen JMR, Rossouw E, Barnard PWA. Prophylactic treatment of chronic tension-type headache using botulinum toxin type A. *Eur J Neurol*. 1999;6(suppl 4):S99-S102.

Turk-Gonzales M, Odderson IBR. Quantitative reduction of saliva production with botulinum toxin type B injection into salivary glands. *Neurorehabilitation and Neural Repair*. 2005;19(1):58-61.

U.S Food and Drug Administration. FDA News Release 10/15/2010. FDA approves Botox to treat chronic migraine.

U.S. Food and Drug Administration (FDA) Web site. <https://www.accessdata.fda.gov/scripts/cder/daf/> Accessed 04/16/2021.

Wheeler AH, Goolkasian P, Gretz SS. A randomized, double-blind, prospective pilot study of botulinum toxin injection for refractory, unilateral, cervicothoracic, paraspinal myofascial pain syndrome. *Spine*. 1998;23(15):1662-1667.

Zesiewicz TA, Elble R, Louis ED, et al. American Academy of Neurology. Practice parameter: therapies for essential tremor. Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2005;64(2-2):2008-2020.

#### References reviewed for 10/01/2010 publication

Naumann M, So Y, Argoff CE, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1707-1714.

Simpson DM, Gracies JM, Graham HK, et al. Assessment: Botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1691-1698.

Simpson DM, Blitzer A, Brashear A, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70:1699-1706.

#### References Reviewed for 11/01/2010 Reconsideration Request

BOTOX® Package Insert.

Brashear A, Gordon MF, Elovic E, et al. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *N Engl J Med*. 2002;347(6):395-400.

Childers MK, Brashear A, Jozefczyk P, et al. Dose-dependent response to intramuscular botulinum toxin type A for

upper-limb spasticity in patients after a stroke. *Arch Phys Med Rehabil.* 2004;85(7):1063-1069.

DYSPORT™ Package Insert.

MYOBLOC® Package Insert.

Simpson DM, Gracies JM, Yablon SA, et al. Botulinum neurotoxin versus tizanidine in upper limb spasticity: a placebo-controlled study. *J Neurol Neurosurg Psychiatry.* 2009;80:380-385 originally published online October 31, 2008.

U.S. Food and Drug Administration. FDA approves Botox to treat spasticity in flexor muscles of the elbow, wrist, and fingers. (March 9, 2010). <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm203776.htm>.

#### References Reviewed for Reconsideration 01/01/2011

Dodick DW, Turkel CC, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. *Headache.* 2010;50:921-936.

#### References added based on a reconsideration request received 04/20/2012:

Farid M, El Monem HA, Omar W, et al. Comparative study between biofeedback retraining and botulinum neurotoxin in the treatment of anismus patients. *Int J Colorectal Dis.* 2009;24:115–120.

Irani K, Rodriguez L, Doody DP, Goldstein AM. Botulinum toxin for the treatment of chronic constipation in children with internal anal sphincter dysfunction. *Pediatr Surg Int.* 2008;24:779–783.

Maria G, Cadeddu F, Brandara F, Marniga G, Brisinda G. Experience with type A botulinum toxin for treatment of outlet-type constipation. *Am J Gastroenterol.* 2006;101:2570–2575.

Messineo A, Codrich D, Monai M, Martelloski S, Ventura A. The treatment of internal anal sphincter achalasia with botulinum toxin. *Pediatr Surg Int.* 2001;17:521-523.

#### **Bibliography**

N/A

---

## **Revision History Information**

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
05/01/2021	R13	Based on an FDA label update, the indication for “Urinary Incontinence” has been updated to add “and patients five years of age and older” to the following paragraph:  OnabotulinumtoxinA is indicated for the treatment of overactive bladder (OAB) with symptoms of urge	<ul style="list-style-type: none"><li>• Provider Education/Guidance</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>urinary incontinence, urgency, and frequency, in adults and patients five years of age and older who have an inadequate response to or are intolerant of an anticholinergic medication.</p>	
10/31/2019	R12	<p>The following IOM sections have been corrected:</p> <p>CMS Publication 100-02, <i>Medicare Benefit Policy Manual</i>, Chapter 12:</p> <p>40.9 Drugs and Biologicals [Comprehensive Outpatient Rehabilitation Facility (CORF) Coverage]</p> <p>CMS Publication 100-02, <i>Medicare Benefit Policy Manual</i>, Chapter 15:</p> <p>260 Ambulatory Surgical Center Services</p> <p>CMS Publication 100-02, <i>Medicare Benefit Policy Manual</i>, Chapter 16:</p> <p>120 Cosmetic Surgery</p>	<ul style="list-style-type: none"> <li>• Typographical Error</li> </ul>
10/31/2019	R11	<p>The LCD has been revised to add the following indications which were inadvertently removed with the last update:</p> <p>OnabotulinumtoxinA is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).</p> <p>AbobotulinumtoxinA is indicated for the treatment of lower limb spasticity in adults.</p> <p>OnabotulinumtoxinA is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.</p>	<ul style="list-style-type: none"> <li>• Typographical Error</li> </ul>
10/31/2019	R10	<p>Consistent with Change Request 10901, all coding</p>	<ul style="list-style-type: none"> <li>• Revisions Due To</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A52848. There has been no change in coverage with this LCD revision.</p>	Code Removal
10/01/2018	R9	<p>LCD revised for annual ICD-10-CM code updates. ICD-10-CM code G51.3 has been deleted and replaced by ICD-10-CM codes G51.31, G51.32 and G51.33 in Group 5 in the "ICD-10 Codes that Support Medical Necessity" section of the LCD.</p> <p><i>DATE (10/01/2018): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Revisions Due To ICD-10-CM Code Changes</li> </ul>
06/16/2017	R8	<p>Based on a practitioner request, ICD-10-CM code G43.011 has been added to Group 11 in the "ICD-10-CM Codes that Support Medical Necessity" section effective for dates of service on or after 10/01/2015.</p> <p><i>DATE (10/01/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Request for Coverage by a Practitioner (Part B)</li> </ul>
06/16/2017	R7	<p>The following has been added to the "Indications" section of the LCD:</p> <p>Effective June 16, 2017, the FDA has approved abobotulinumtoxinA for the treatment of lower limb spasticity in adults.</p> <p><i>DATE (09/01/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<i>fields included on the LCD are applicable as noted in this policy.</i>	
01/21/2016	R6	ICD-10 CM codes G83.31*, G83.32*, G83.33* and G83.34* were inadvertently included in the Revision History Explanation. These ICD-10-CM codes were not added to the Group 8 list of payable codes.	<ul style="list-style-type: none"> <li>• Typographical Error</li> </ul>
01/21/2016	R5	<p>FDA label update for onabotulinumtoxinA (effective 01/21/2016) has been added to the "Indications" section of the LCD under "Spasticity". ICD-10-CM codes G83.31*, G83.32*, G83.33*, G83.34*, G83.81*, G83.82*, G83.89*, I69.041*, I69.042*, I69.043*, I69.044*, I69.141*, I69.142*, I69.143*, I69.144*, I69.241*, I69.242*, I69.243*, I69.244*, I69.341*, I69.342*, I69.343*, I69.344*, I69.841*, I69.842*, I69.843*, I69.844*, I69.941*, I69.942*, I69.943* and I69.944* have been added to the Group 8: list of payable codes effective for dates of service on or after 01/21/2016. In the "Documentation Requirements" section of the LCD, "or lower limb" has been added to the following bulleted item:</p> <p style="padding-left: 40px;">documentation of the medical necessity for this treatment. For spastic conditions other than upper or lower limb spasticity, blepharospasm, hemifacial spasm, cervical dystonia or other focal dystonias, documentation should include a statement that the spastic condition has been unresponsive to conventional treatment;</p> <p>Out-dated information has been removed throughout the LCD.</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>
10/01/2015	R4	<p>The following paragraph in the "Indications" section under "Spasticity" has been corrected to add "upper extremity"</p> <p style="padding-left: 40px;">Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck, and upper</p>	<ul style="list-style-type: none"> <li>• Typographical Error</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		extremity.	
10/01/2015	R3	<p>The following paragraph in the "Indications" section under "Spasticity" has been revised to add "shoulder:"</p> <p>Electromyography or muscle stimulation, rather than site pain or tenderness, to determine injection site(s) for Botulinum toxin may be necessary, especially for spastic conditions of the face, neck, hand and shoulder.</p> <p>The "Utilization" section has been revised to indicate:</p> <p>Dose and frequency should be in accordance with the FDA label. When services are performed in excess of established parameters, they may be subject to review for medical necessity.</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>
10/01/2015	R2	LCD updated to reflect administrative changes.	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>
10/01/2015	R1	The following ICD-10-CM codes have been added to Group 8 ICD-10 Codes that Support Medical Necessity: G24.9, G81.10*, G82.50*, G83.10* and G83.20* and ICD-10-CM code G04.1* has been removed. The following ICD-10-CM codes have been added to Group 10 ICD-10 Codes that Support Medical Necessity: H50.00, H50.10, H50.30, H50.40, H50.50 and H50.60.	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

### Articles

[A52848 - Billing and Coding: Botulinum Toxins](#)

### Related National Coverage Documents

N/A

## Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
04/23/2021	05/01/2021 - N/A	Currently in Effect (This Version)
10/21/2020	10/31/2019 - 04/30/2021	Superseded
11/22/2019	10/31/2019 - N/A	Superseded
10/25/2019	10/31/2019 - N/A	Superseded

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

## Keywords

- Botox