Local Coverage Determination (LCD): Botulinum Toxin Type A & Type B (L34635)

Alert: Codes are moving from LCDs to Articles! Learn more (../staticpages/notice-board-info.aspx)

Select the **Print Complete Record**, **Add to Basket** or **Email Record** Buttons to print the record, to add it to your basket or to email the record.
Printing Note:
To print an entire document, use the **Need a PDF** Button or the **Print Complete Record** Button.
Note: Documents with coding fields will include all codes in each group.

To print only the current visible page contents, use the **Print** Button in the page header.

Section Navigation Select Section ▼ **Go**

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=143&ver=1)	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=147&ver=1)	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=144&ver=1)	MAC - Part A	05201 - MAC A	J - 05	Kansas

Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=148&ver=1)	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=145&ver=1)	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=149&ver=1)	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=146&ver=1)	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=151&ver=1)	MAC - Part B	05402 - MAC B	J - 05	Nebraska

Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=268&ver=1)	MAC - Part A	05901 - MAC A	J - 05	Alabama Alaska Arizona Arkansas California - Entire State Colorado Connecticut Delaware Florida Georgia Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Maine Maryland Massachusetts Michigan Mississippi Missouri - Entire State Montana Nebraska Nevada New Hampshire New Jersey New Mexico North Carolina North Dakota Ohio Oklahoma Oregon Pennsylvania Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Washington West Virginia Wisconsin Wyoming

Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=264&ver=1)	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=265&ver=1)	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=266&ver=1)	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=267&ver=1)	MAC - Part B	08202 - MAC B	J - 08	Michigan

LCD Information

Document Information

LCD ID
L34635

LCD Title
Botulinum Toxin Type A & Type B

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/30/2020

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services.

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Change Request 10901, Local Coverage Determinations (LCDs)

CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.4 - Reasonable and Necessary Provisions in an LCD.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonia, 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 and spasticity), smooth muscles (e.g. Detrusor over activity 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: onabotulinumtoxinA, rimabotulinumtoxinB, abobotulinumtoxinA, and 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. 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.

Limitations
Voluntary muscular contraction depends upon the release of acetylcholine from vesicles within a nerve ending following stimulation of the nerve. The acetylcholine is released into the neuromuscular junction, binding to specific proteins called receptors in the membrane of the muscle fiber. The effect of the acetylcholine at these receptors is to cause the muscle to contract. When a sufficient amount of acetylcholine has been released with subsequent binding to the muscle fiber proteins, muscle contraction occurs. Botulinum toxin type A and botulinum toxin type B create a chemical blockade by inhibiting the release of acetylcholine from the nerve ending vesicles thereby preventing the acetylcholine from binding to the proteins in the receptor site on the muscle. Localized weakness or paralysis occurs in the muscle injected with botulinum toxin.

Approved indications for botulinum toxin type A and toxin type B differ. WPS GHA has determined that the separate accepted indications for the botulinum toxin products will be combined into a single list of covered indications in this Local Coverage Determination (LCD). It is the responsibility of providers, however, to use each drug in accordance with approved indications unless there are valid and documented reasons stating why the unapproved or unaccepted form is used. While this policy contains **a single** list of covered indications, this is not meant to imply that botulinum toxin products are interchangeable.

Before consideration of coverage may be made:

1. In most cases it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other methods used to control and/or treat spastic condition.
2. Coverage of botulinum toxin for certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries, and multiple sclerosis) will be limited to those conditions listed in the Billing and Coding: Botulinum Toxin Type A & B (A57474). All other uses in the treatment of other types of spasm will be considered as investigational and therefore, noncovered by Medicare.
3. Since organic writer's cramp is uncommon, Medicare would not expect to see the treatment of this condition to be billed frequently.

4. The patient who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin. Other spastic or muscular contraction conditions, such as eye muscle disorders, (e.g., blepharospasm) may require lesser amounts of botulinum toxin. For larger muscle groups, it is generally agreed that once a maximum dose per site has been reached and there is no response, the treatment is discontinued. The treatments may be resumed at a later date. With response, the effect of the injections generally lasts for three months at which time the patient may require repeat injections to control the spastic or excessive muscular condition.
5. It is usually considered not medically necessary to give botulinum toxin injections for spastic conditions more frequently than every 90 days. There may be slight variation based on FDA indications for a particular product.
6. Coverage of treatments provided may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin failed to produce satisfactory clinical response.
7. Medicare will allow payment for one injection per site regardless of the number of injections made into the site. The site description is included in the CPT code description. Payment will be based on the Medicare Physician Fee Schedule and National Correct Coding Initiative.
8. Botulinum toxin may be covered in the treatment of achalasia. This use appears to be safe and effective. Two-thirds of patients respond within six months of treatment and effectiveness lasts an average of more than one year for the initial treatment, although shorter and longer durations have been reported.
   The use of botulinum toxin should not be endorsed for all patients, but it can be considered individually if:
   A. The patient has failed conventional therapy;
   B. The patient is at high risk of complications of pneumatic dilation or surgical myotomy;
   C. The patient has failed a prior myotomy or dilation;
   D. The patient has had a previous dilation-induced perforation;
   E. The patient has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilation-induced perforation.

   Some patients may fail a first injection and respond to a second. Further therapy should be questioned if two treatments in a row fail. Therapy can be repeated later in those who fail after an initial response.
9. Migraine headaches are described as an intense pulsing or throbbing pain in one area of the head. The headaches are often accompanied by nausea, vomiting, and sensitivity to light and sound. Migraine usually begins with intermittent headache attacks 14 days or fewer each month (episodic migraine), but some patients go on to develop the more disabling chronic migraine. To treat chronic migraines, botulinum toxin is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future headache symptoms. Botulinum toxin has not been shown to work for the treatment of migraine headaches that occur 14 days or less per month, or for other forms of headache.
10. Botulinum toxin for chronic anal fissure may be considered for the patient who has not responded satisfactorily to conventional therapy.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

General Information

Associated Information
Documentation Requirements
Documentation should include the following elements:

1. Support for the medical necessity of the botulinum toxin (type A or type B) injection
2. A covered diagnosis
3. Dosage and frequency of the injections
4. Support for the medical necessity of electromyography procedures performed in conjunction with botulinum toxin type A injections to determine the proper injection site(s)
5. Support of the clinical effectiveness of the injections
6. Specific site(s) injected
7. Medical Record must support the treatment of chronic migraine with a history of migraine and experiencing headaches on most days of the month.
8. Botulinum toxin type A incobotulinumtoxinA for blepharospasm, ONLY if there is a history of the beneficiary having previous history of receiving onabotulinumtoxinA.

Utilization Guidelines
NA

Sources of Information
Brashear A, McAfee AL, Kuhn ER, Fyffe J. (2004) Botulinum toxin type B in upper-limb poststroke spasticity: a double-blind, placebo-controlled trial. *Arch Phys Med Rehabil*.85:705-9.

Delgado M R, Hirtz D., Aisen M., et al. (2010) 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*. 74;336.

Kyrmizakis, D.E., Pangalos, A., Papadakis, C.E. et al. (2004, July) The use of botulinum toxin type A in the treatment of Frey and crocodile tears syndromes. *J Oral Maxillofac Surg*. 62(7):840-4.

Naumann, M., So, Y., Argoff, C.E. et al. (2008, May 6) Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review). Report from the American Academy of Neurology Therapeutics and Technology Assessment subcommittee. *Neurology*. 70(19):1707-14.

Pasricha, Pankaj et al. (1996). Botulinum toxin for achalasia; long-term outcome and predictors of response, *Gastroenterology*. 1410-1415.

Restivo, D.A., Lanza, S., Patti, F. et al. (2002, December 24) Improvement of diabetic autonomic gustatory sweating by botulinum toxin type A. *Neurology*. 59(12):1971-3.

Saadia, D., Voustianiouk, A., Wang, A.K. et al. (2001, December 11) Botulinum toxin type A in primary palmar hyperhidrosis: randomized, single-blind, two-dose study. *Neurology*. 11; 57(11):2095-9.

Simpson DM, Gracies JM Graham HK, et al. (2008) 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*. 70:1691-1698.

Bibliography
N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/30/2020	R10	01/30/2020 Format change to Sentence 2 under Limitations: Added “Billing and Coding: Botulinum Toxin Type A & B (A57474)” and removed “Codes that Support Medical Necessity section of this policy” because it is no longer relevant. No changes in coverage.	• Other
10/31/2019	R9	10/31/2019 Change Request 10901 Local Coverage Determinations (LCDs): it will no longer be appropriate to include Current Procedure Terminology (CPT)/Health Care Procedure Coding System (HCPCS) codes or International Classification of Diseases Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All CPT/HCPCS and ICD-10 codes have been removed from this LCD and placed in Billing and Coding: Botulinum Toxin Type A & Type B. Consistent with Change Request 10901 language from IOMs and/or regulations has been removed and the applicable manual/regulation has been referenced. Review completed 10/08/2019.	• Other (Changes in response to CMS Change Request 10901. Review completed.)

10/01/2018	R8	10/01/2018 ICD-10-CM code update deleted G51.3 and added G51.31, G51.32, and G51.33 to Group 7.	• Revisions Due To ICD-10-CM Code Changes
09/01/2018	R7	09/01/2018 Annual review completed 08/07/2018 with no changes in coverage. Punctuation errors corrected.	• Other (Annual Review)
09/01/2017	R6	09/01/2017 Annual review completed 08/09/2017 with no changes in coverage. 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.	• Other (Annual Review)
10/01/2016	R5	10/01/2016 ICD-10-CM code update Group 10 deleted codes I69.01, I69.11, I69.21, I69.31, I69.81, I69.91 annual review no other changes.	• Other (annual review) • Revisions Due To ICD-10-CM Code Changes
12/01/2015	R4	12/01/2015 Annual review, added clarification under limitations number five: There may be slight variation based on FDA indications for a particular product.	• Other (Maintenance annual review)

10/01/2015	R3	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R2	02/01/2015 corrected description of codes 64644, 64645 and 64647 added “s” to the word muscle.	• Other
10/01/2015	R1	12/01/2014 Annual review, removed outdated change request information and updated references, corrected grammatical error, no change to coverage.	• Other (Maintenance annual review)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57474 - Billing and Coding: Botulinum Toxin Type A & Type B (/medicare-coverage-database/details/article-details.aspx?articleId=57474&ver=5&LCDId=34635&DocID=L34635&bc=AAAAAAAAgAAA&)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/24/2020 with effective dates 01/30/2020 - N/A
Updated on 10/23/2019 with effective dates 10/31/2019 - 01/29/2020 (/medicare-coverage-database/details/lcd-details.aspx?LCDId=34635&ver=25&DocID=L34635&bc=AAAAAAAAgAAA&)
Updated on 09/18/2018 with effective dates 10/01/2018 - 10/30/2019 (/medicare-coverage-database/details/lcd-details.aspx?LCDId=34635&ver=22&DocID=L34635&bc=AAAAAAAAgAAA&)
Some older versions have been archived. Please visit the MCD Archive Site (http://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=34635:20) to retrieve them.

Keywords

N/A

Read the **LCD Disclaimer (../staticpages/lcd-disclaimer.aspx)**

CMS.gov

A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore, MD 21244

Go to HHS Home Page (https://www.hhs.gov/)

CMS & HHS Websites

Medicare.gov Link to the medicare.gov website - Opens in a new window (https://www.medicare.gov)

MyMedicare.govLink to the MyMedicare.gov website - Opens in a new window (https://www.MyMedicare.gov)

Medicaid.gov - Opens in a new window (https://www.Medicaid.gov)

InsureKidsNow.gov - Opens in a new window (https://www.insurekidsnow.gov)

HealthCare.gov - Opens in a new window (https://www.HealthCare.gov)

HHS.gov/Open - Opens in a new window (https://www.hhs.gov/open/)

Tools

AcronymsCenters for Medicare & Medicaid Services Acronym Lookup tool - Opens in a new window (https://www.cms.gov/apps/acronyms)

Contacts - Opens in a new window (https://www.cms.gov/apps/contacts)

Glossary - Opens in a new window (https://www.cms.gov/apps/glossary/)

Archive - Opens in a new window (https://www.archive-it.org/collections/2744)

Helpful Links

Web Policies & Important Links (https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/index.html)

For Developers (https://developer.cms.gov/)

Privacy Policy (https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/Privacy-Policy.html)

Privacy settings

Plain Language (https://www.medicare.gov/about-us/plain-writing/plain-writing.html)

Freedom of Information Act (https://www.cms.gov/center/freedom-of-information-act-center.html)

No Fear Act (https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/NoFearAct.html)

Nondiscrimination/Accessibility (https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/CMSNondiscriminationNotice.html)

HHS.gov - Opens in a new window (https://www.hhs.gov)

Inspector General - Opens in a new window (https://www.oig.hhs.gov)

USA.gov - Opens in a new window (https://www.usa.gov)

Help with file formats & plug-ins (https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/Help.html)

Receive Email Updates

Submit