

LCD - Botulinum Toxin Types A and B Policy (L35170)

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
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID
L35170

AMA CPT / ADA CDT / AHA NUBC Copyright
Statement

LCD Title

Botulinum Toxin Types A and B Policy

Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL35170](#)

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 10/01/2019

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

12/29/2016

Notice Period End Date

02/12/2017

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 16, §120. General Exclusions from Coverage (Cosmetic Surgery).

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

Botulinum toxin injections are used to treat various focal muscle spastic disorders and excessive muscle contractions such as dystonia, spasms, twitches, etc. These drugs produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. Botulinum toxins have the advantage of being potent neuromuscular blocking agents with good selectivity and duration of action.

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.

Botulinum Toxin Type A (Botox-onabotulinumtoxinA, Xeomin -incobotulinumtoxinA and Dysport-abotulinumtoxinA) are derived from a culture of Hall strain Clostridium Botulinum. Botulinum toxin type B (Myobloc – rimabotulinumtoxinB) is derived from the Bean strain of Clostridium Botulinum. Type B has the same action on neuromuscular conduction (blockade) as Type A.

Botulinum toxin type A and botulinum toxin type B have many similarities and as experience has been gained, medical consensus has gradually developed that the two toxins have similar, but not identical, properties. Each botulinum toxin product is pharmacologically and clinically distinct, and therefore, not interchangeable with any other botulinum toxin product. As a result, approved indications for the two toxins differ. This A/B MAC has determined that the separate accepted indications for the four toxins will be combined into a single list of covered indications in this Local Coverage Determination (LCD) policy. However, it is the responsibility of providers to use each drug in accordance with the FDA approved indications unless there are valid and documented reasons stating why the unapproved/off label form is used, *"Providers should consult the package insert of each neurotoxin to identify the FDA approved indications for each product."*

Please note that the unit dose of one form must not be equated with the unit dose of any of the others, i.e., one unit of Botox does not equal one unit of Dysport, Xeomin or Myobloc.

1. Before consideration of coverage may be made, it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions. An exception to this general rule is that for certain treatments including focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, or dysphonia, botulinum toxin can be an initial mode of therapy, and in these circumstances, it is not necessary to show that other methods of treatment have been tried and proven unsuccessful.

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 Covered ICD-10-CM section of the billing and coding article (A57185). This group of codes shall be used only when accompanied by spasticity of central nervous system origin. Recently, there has been approval by the FDA for use in upper limb spasticity. All other uses in the treatment of other types of spasm, including smooth muscle types, will be considered as investigational (not proven effective) and, therefore, noncovered by Medicare. Claims submitted for tension headaches, myofascial pain, irritable colon, biliary dyskinesia, other forms of smooth muscle spasm not specifically addressed in the policy, and any other spastic conditions not listed in the ICD-10 CM Codes That Support Medical Necessity section of the Billing and Coding article (A57185) will be considered investigational, not safe and effective, or not accepted as the standard of practice within the medical community and, therefore, not medically reasonable and necessary.

3. Botulinum toxin can be used to reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and walking, to allow better range of motion, to permit better physical therapy, and to reduce severe spasm in order to provide adequate perineal and palmar hygiene.

4. Botulinum toxin has indications for overactive bladder and severe primary axillary hyperhidrosis,

5. Due to the rarity of severe organic writer's cramp, Medicare would not expect to see the treatment of this condition billed frequently.

6. There may be patients who require Electromyography (EMG) in order to determine the proper injection site(s). The electromyography procedure codes specified in the HCPCS section of this policy may be covered if the physician has difficulty in determining the proper injection site(s).

It should be noted that needle electromyographic procedures include the interpretation of electrical waveforms measured by equipment that produces both visible and audible components of electrical signals recorded from the muscle(s) studied by the needle electrode. Electromyography equipment must be capable of showing both visual and

auditory components of the electrical activity produced by and recorded from within muscle tissue by the needle electrode for myopathy or neuropathy diagnosis. For purposes of botulinum injection guidance, the EMG tools that have audible output alone are sufficient.

7. For the appropriate initial and total doses of botulinum toxins please consult the FDA manufacturers' recommendations or the AHFS.

8. Coverage of treatments provided may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of a botulinum toxin, fail to produce a satisfactory clinical response. In such situations it may be appropriate to use an alternative botulinum toxin **once** in order to determine if a more satisfactory response can be obtained. Providers must also document the results of and response to these injections.

9. Requests may be considered for redetermination (formerly appeal) for continued treatment during a treatment period or for resumption at a later date if satisfactory results have not been obtained and compelling clinical evidence of medical necessity for continued treatment is presented.

10. Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as a single limb, single eyelid, side of the face, side of the neck, both vocal cords, etc.

11. For treatment of achalasia and cardio spasm, botulinum toxin should be used only after one or more of these conditions have been met and documented:

- The patient has failed conventional therapy.
- The patient is at high risk of complications from pneumatic dilation or surgical myotomy.
- The patient who refuses surgical myotomy or balloon dilation, in preference to a less invasive risky procedure.
- A prior myotomy or dilatation has failed.
- A prior dilatation caused an esophageal perforation.
- The patient has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilatation-induced perforation.

12. Botulinum Toxin is covered for prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer). It is also covered for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

13. **Treatment of skin wrinkles** using botulinum toxin is cosmetic and **is not covered by Medicare.**

14. Acceptance of botulinum toxin **has not been established** for the following conditions (USP DI 2006):

- Deviations over 50 prism diopters
- Restrictive strabismus
- Chronic paralytic strabismus except to reduce antagonist contracture in conjunction with surgical repair
- Duane's syndrome with lateral rectus muscle weakness
- Recurrent temporomandibular joint (TMJ) disorder

15. Anal spasm, irritable colon, biliary dyskinesia, or any treatment of spastic conditions not listed as covered in this policy are considered to be cosmetic, investigational, or not safe and effective.

16. The use of botulinum toxin to treat muscle tension is considered not proven effective.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation must support the medical necessity of this service as outlined in the Indication and Limitations of Coverage and/or Medical Necessity section of this policy

Additional Documentation Requirement

The patient's medical record should include the following elements to support the medical necessity of the Botulinum Toxin injection:

- Type of botulinum toxin used: Botox (onabotulinumtoxinA), Dysport (abotulinumtoxinA), Xeomin (incobotulinumtoxinA) or Myobloc (rimabotulinumtoxinB)
- Strength of toxin used
- A covered diagnosis (However, when a form of botulinum toxin is used for an indication that is not a listed indication in the AHFS, a physician statement in the medical record stating the reason(s) why the unapproved form was used is also required).
- A statement that traditional methods of treatments have been tried and proven unsuccessful (except for focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, or dysphonia).
- Dosage used in the injections.
- Support for the medical necessity of electromyography procedures if performed.
- Support of the clinical effectiveness of the injections.
- A complete description of the site(s) injected.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

Sources of Information

1. Schnider I, Thumfart WF, Pototschnig C, Eckel HE. Treatment of dysfunction of the cricopharyngeal muscle with botulinum A toxin: Introduction of a new, noninvasive method. *Ann Otol Rhinol Laryngol.* Jan 1994;103(1):31-5.
2. Tsui JK, Bhatt M, Calne S, Calne DB. Botulinum toxin in the treatment of writer's cramp: a double-blind study. *Neurology.* Jan 1993;43(1):183-5.
3. Pasricha PJ, Ravich WJ, Hendrix TR, Sostre S, Jones BJ, Kalloo AN. Intrasphincteric Botulinum Toxin for the Treatment of Achalasia. *NEJM.* Mar 1995;332(12):774-816.
4. Drug Information for the Health Professional. *USP DI.* Vol 1. 27th ed. Greenwood Village, CO: Thomason Micromedex; 2006:590-6.
5. *AHFS Drug Information.* 2006

6. Goetz CG. ed. *Textbook of Clinical Neurology*. 2nd ed. Philadelphia, PA: Saunders; 2003.
7. Walsh PC, Retik AB, Vaughan ED, et al. *Campbell's Urology*. 8th ed. Elsevier Health Sciences; 2002.
8. Frontera WR, Silver JK. *Essentials of Physical Medicine and Rehabilitation*. 1st edition. Philadelphia, PA: WB Saunders; 2002.
9. Yanoff M, Duker JM. *Ophthalmology*. 2nd edition. St Louis, MO: Mosby Inc. 2004.
10. Panicker JN, De Seze M, Fowler CJ. Rehabilitation in practice of Neurogenic Lower Urinary Tract Dysfunction and its Management. *Clin Rehabil*. Jul 2010;24(7):579-89.
11. Bauer RM, Gratzke C, Roosen A, Hocaoglu Y, Mayer ME, Bucher A, et al. Patient-Reported Side Effects of Intradetrusor Botulinum Toxin Type A for Idiopathic Overactive Bladder Syndrome. *Uro Int*. Jul 2010; [Epub ahead of print].
12. Mehnert U, Birzele J, Reuter K, Schurch B. The Effect of Botulinum Toxin Type A on Overactive Bladder Symptoms in Patients with Multiple Sclerosis: A Pilot Study. *J Urol*. Sep 2010;184(3):11011-6 [Epub ahead of print].
13. Anger JT, Weinberg A, Suttorp MJ, Litwin MS, Shekelle PG. Outcomes of intravesical Botulinum toxin for idiopathic overactive bladder symptoms: a systematic review of the literature. *J Urol*. Jun 2010;183(6):2258-64. [Epub Apr 2010].
14. Pinto R, Lopes T, Frias B, Silva A, Silva JA, Silva CM, et al. Trigonal Injection of Botulinum Toxin A in Patients with Refractory Bladder Pain Syndrome/Interstitial Cystitis. *Eur Urol*. Sep 2010; 58(3):360-5.
15. Safari S, Jamali S, Habibollahi P, Arshadi H, Nejat F, Kajbafzaded AM. Intravesical injections of Botulinum toxin type A for management of neuropathic bladder: a comparison of two methods. *Urology*. Jul 2010;76(1):225-30. [Epub Jan 2010].
16. Medical consultants

Note: Full disclosure of sources of information is found in the original contractor's LCD.

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REA
10/01/2019	R14	Under Coverage Indications, Limitations and/or Medical Necessity: Deleted 17. Due to the short life of Botulinum toxin, Medicare will reimburse the unused portion of these drugs only when vials are not split between patients. Use modifier JW to code for	

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REA
		<p><i>drug wastage on a separate line of the claim form. The documentation must show in the patient's medical record the exact dosage of the drug given, exact amount and reason for unavoidable wastage, and the exact amount of the discarded portion of the drug. 18. Scheduling of more than one patient is encouraged to prevent wastage of Botulinum toxins. If a vial is split between two patients, the billing in these instances must be for the exact amount of Botulinum toxin used on each individual patient. Medicare would not expect to see billing for the full fee amount for Botulinum toxin on each beneficiary when the vial is split between two or more patients. Corrected grammatical and typographical.</i></p>	
10/01/2019	R13	<p>10/01/2019: 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.</p> <p>LCD was converted to the "no-codes" format.</p>	•
10/01/2018	R12	<p>10/01/2019: 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.</p> <p>The following codes were added for 2019 ICD10 Coding Update:</p> <p>Group I Additions: H02.042;H02.045;H02.141;H02.142;H02.144;H02.145;G44.221;G44.229</p> <p>Group II Additions: G51.31*;G51.32*;G51.33*;G82.51*;G36.1*;G80.3*;G82.52*;G82.53*;G83.82*;G83.89*</p> <p>Group III Additions: I63.343*; I69.932*;I69.942*;I69.943*;I69.944*;I69.961*;I69.963*;I69.964*;I69.965*</p>	•
10/01/2018	R11	<p>10/08/2018: 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.</p> <p>Typographical Error corrected - Asterisk Explanation in Group I coding to include N31.0; N31.1 and N31.9</p>	•
10/01/2018	R10	<p>08/30/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that</p>	•

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REA
		<p>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.</p> <p>Effective 10/1/2018, LCD is revised per the annual ICD-10-CM code update to:</p> <p>Add ICD-10-CM codes: I63.81; I63.89; G51.31; G51.32; G51.33</p>	
10/01/2017	R9	<p>08/24/2017: 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.</p> <p>Effective 10/1/2017, LCD is revised per the annual ICD-10-CM code update to:</p> <p>Add ICD-10-CM codes: I63.211*; I63.212*; I63.323*; I63.333*; I63.513*; I63.523*; I63.533* to Group 3.</p>	
02/13/2017	R8	<p>Revision to correct 49499 to 43499 and to clarify K22.0 may be billed with other appropriate CPT codes in Group I asterisk in Medical Necessity ICD-10 Codes Asterisk Explanation and to indicate the G93.4 in the R5 Revision History Table was to be G83.4</p>	
02/13/2017	R7	<p>Effective for dates of service 6/1/2016 - code 92265 is removed from the LCD. Please see the Nerve Conduction Studies and Electromyography LCD for coverage criteria.</p> <p>Typographical errors in Group 1 Paragraph - corrected CPT codes in the ICD-10 Section: 95875 was changed to 95873 and 92265 removed.</p>	
02/13/2017	R6	<p>This LCD version was created as a result of DL35170 being released to a Final LCD and Coding Guidelines have been removed due to information included in LCD.</p>	
10/01/2016	R5	<p>N31.0, N31.1 had addition of * and N31.9* added to Group One codes. G93.4* and G95.89* added to secondary diagnosis.</p>	
10/01/2016	R4	<p>2016-2017 ICD 10 Update: To Add I63.013*, I63.033*, I63.113*, I63.133*, I63.213, I63.233, I63.313, I60.2* to Group III Codes</p>	
10/01/2015	R3	<p>The LCD revised to add the ICD-10-CM subsequent (D) and sequela (S) codes for S14.0XX - S24.154.</p>	

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REA
10/01/2015	R2	The LCD is revised to add the sentence "Recently, abotulinumtoxinA (Dysport) has been approved by the FDA for upper limb spasticity" in the Coverage Indications, Limitations and/or Medical Necessity section. Also added ICD10 codes G82.53, G83.21, G83.22, G83.23, G83.24, I69.931, I69.932, I69.33, I69.934, I69.951, I69.952, I69.953, and I69.954.	
10/01/2015	R1	The LCD is revised to add ICD-10-CM G43.109 to the Group 1 list codes with an asterisk explanation that the chart must document the patient has chronic migraine.	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57185 - Billing and Coding: Botulinum Toxin Types A and B Policy](#)

[A55383 - Response to Comments: Botulinum Toxin Types A and B](#)

LCDs

[DL35170 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
04/12/2022	10/01/2019 - N/A	Currently in Effect (This Version)
09/19/2019	10/01/2019 - N/A	Superseded

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

Keywords

N/A