

LCD - Botulinum Toxin Type A & Type B (L34635)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	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

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				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	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	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

[DL34635](#)

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 10/01/2023

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

09/30/2021

Notice Period End Date

11/13/2021

Issue

Issue Description

Biannual review was completed with no change in coverage. Minor grammatical changes made throughout.

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.

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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. Botulinum toxins are used in the treatment of overactive skeletal muscles (e.g., Hemifacial spasm, dystonia and 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 4 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 specific to the preparation of neurotoxin and varies 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. 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 to use each drug in accordance with approved indications. While this policy contains **a single** list of covered indications, this is not meant to imply that botulinum toxin products are interchangeable.

1. 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, non-covered by Medicare.
2. Since organic writer's cramp is uncommon, Medicare would not expect to see the treatment of this condition to be billed frequently.
3. 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 3 months at which time the patient may require repeat injections to control the spastic or excessive muscular condition.

4. It is usually considered not medically necessary to give botulinum toxin injections for spastic conditions more frequently than every 12 weeks.
5. Coverage of treatments provided may be continued unless any 2 treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin failed to produce satisfactory clinical response.
6. Botulinum toxin may be covered in the treatment of achalasia. According to the 2018 ISDE achalasia guidelines, botulinum injections should mainly be used in patient's age 50 or greater and for patients that are unfit for surgery or as a bridge to more definitive therapies such as surgery or balloon dilatation.¹
7. Chronic migraine is defined as a "headache occurring on 15 or more days a month for more than three months, which, on at least eight days/month has the features of migraine headache."² Treatment of chronic migraines will be covered when they meet the following diagnostic criteria: for migraine with aura and /or criteria for migraine without aura. Treatment with botulinum toxin may be given every 12 weeks as multiple injections around the head and neck.

A. Migraine with aura²:

1. At least two attacks fulfilling the following criteria a and b

a. One or more of the following fully reversible aura symptoms

- Visual (aura, changes in vision)
- sensory (e.g., tingling in hands or face, pins and needles, numbness)
- speech and/or language difficulties)
- motor (e.g., weakness)
- brainstem (e.g., vertigo, tinnitus, loss of hearing, diplopia, ataxia not attributable to sensory deficit, and decreased level of consciousness)
- retinal (visual disturbance, flash of light, blind spot)

b. At least three of the following six characteristics:

- at least 1 aura symptom spreads gradually over > 5 minutes
- 2 or more aura symptoms occur in succession
- each individual aura symptoms last 5-60 minutes
- at least 1 aura symptom is unilateral
- at least 1 aura symptom is positive
- the aura is accompanied, or followed within 60 minutes, by headache

B. Migraine without aura²:

1. At least 5 attacks fulfilling the following criteria

- **Headache attacks lasting 4-72 hours (when untreated or unsuccessfully treated)**

- **Headache has at least two of the following:**

- unilateral location
- pulsating quality
- moderate or severe pain intensity
- aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)

- **During headache at least one of the following:**

- nausea and/or vomiting
- photophobia and phonophobia

8. Botulinum toxin for chronic anal fissure may be considered for the patient who has not responded satisfactorily to conservative treatment. Conservative treatment may include the use of bulking agents, sitz baths or topical agents.
9. Botulinum toxin is covered for hyperhidrosis that significantly affects one's quality of life and cannot be managed adequately with topical agents.

Summary of Evidence

Migraine

The Health technology assessment for the acute and preventive treatment of migraine: A position statement of the International Headache Society indicates that the frequency of headaches is an important factor of classifying chronic migraines. Chronic migraine is defined as at least 3 months with 15 or more monthly headache days (MHDs), at least eight of which satisfy criteria for migraine.

"It is recommended that HTAs assess migraine frequency by counting days with migraine per month or days with headache per month, and the respective units of measure should be monthly migraine days (MMDs) and monthly headache days (MHDs). A migraine day is defined as any calendar day on which the patient had onset, continuation, or recurrence of a migraine headache."³

FDA labels indicate that the safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month).

Achalasia

ACG Clinical Guidelines: Diagnosis and Management of Achalasia recommends "botulinum toxin injection as first-line therapy for patients with achalasia that are unfit for definitive therapies compared with other less-effective pharmacological therapies." "Botulinum toxin is the best studied pharmacotherapy in achalasia, and it is the most effective pharmacological treatment that can be offered; however, its benefits are short lived, and the medication should not be offered as first-line treatment to patients who are fit for myotomy."⁴

Anal Fissures

"Lateral internal sphincterotomy is still regarded as the gold standard treatment for chronic fissures, despite known potential for serious morbidity, namely fecal incontinence. Therefore, a search for less invasive procedures has been ongoing, including topical nitrates and botulinum toxin injections. However, nitrates are poorly tolerated due to their association with headaches. This chemical denervation is not permanent, and the clinical efficacy generally lasts for 2-3 months, which is enough time for sphincter resting pressure reduction to allow for healing."⁵

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2023	R13	Posted 09/28/2023: Biannual review completed 08/14/2023 with no change in coverage. Minor grammatical changes made throughout.	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/14/2021	R12	<p>09/30/2021- Updated the definition of Chronic migraines to Chronic migraine is defined as a "headache occurring on 15 or more days a month for more than three months, which, on at least eight days/month has the features of migraine headache."². Treatment of chronic migraines will be covered when they meet the following diagnostic criteria: for migraine with aura and /or criteria for migraine without aura. Treatment with botulinum toxin may be given every 12 weeks as multiple injections around the head and neck. Added #9: Botulinum toxin is covered for hyperhidrosis that significantly affects one's quality of life and cannot be managed adequately with topical agents. Added information on migraine with and without aura to #7. Removed "Before consideration of coverage may be made: 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." Updated and moved the citations from "Sources of information" to the "Bibliography" section. Moved "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" to the Billing and Coding Article</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
11/26/2020	R11	<p>11/26/2020 Documentation Requirement Number 8. "Botulinum toxin type A incobotulinumtoxinA for blepharospasm ONLY if there is a history of the beneficiary having previous history of receiving onabotulinumtoxinA." removed because current literature does not support the statement. Documentation Requirements relocated to A57474 Billing and Coding: Botulinum Toxin Type A & B. Format revision completed</p>	<ul style="list-style-type: none"> • Other
01/30/2020	R10	<p>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.</p>	<ul style="list-style-type: none"> • Other
10/31/2019	R9	<p>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</p>	<ul style="list-style-type: none"> • Other (Changes in response to CMS Change Request 10901. Review

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		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.	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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Other
10/01/2015	R2	02/01/2015 corrected description of codes 64644, 64645 and 64647 added "s" to the word muscle.	<ul style="list-style-type: none"> • Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2015	R1	12/01/2014 Annual review, removed outdated change request information and updated references, corrected grammatical error, no change to coverage.	<ul style="list-style-type: none"> Other (Maintenance annual review)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[DA57474 - \(MCD Archive Site\)](#)

[A57474 - Billing and Coding: Botulinum Toxin Type A & Type B](#)

[A58907 - Response to Comments: Botulinum Toxin Type A & Type B \(DL34635\)](#)

LCDs

[DL34635 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/19/2023	10/01/2023 - N/A	Currently in Effect (This Version)
09/22/2021	11/14/2021 - 09/30/2023	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A