

**LCD - Botulinum Toxins (L33949)**

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**Contractor Information**

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

**LCD Information****Document Information****LCD ID**

L33949

**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 12/07/2023

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**Notice Period Start Date**

N/A

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**Notice Period End Date**

N/A

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**Issue****Issue Description**

No changes were made.

**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:

## 40.10 Drugs and Biologicals [Coverage of Comprehensive Outpatient Rehabilitation Facility services]

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

### 50.1–50.5 Drugs and Biologicals 120 Ambulatory Surgical Center Services

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

### 260 Non-coverage for Cosmetic Procedures

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 CGS' 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.

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 and dystonia. 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 hand.

### **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.

## **Headache/Migraine**

Coverage will only be allowed for those patients 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; or all muscles of one limb and their associated girdle muscles.

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.

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

When the Botulinum Toxins drug is denied, the related injection code(s) will also be subject to denial.

## **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. CGS is not responsible for the continuing viability of Web site addresses listed below.

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**Bibliography**

N/A

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
12/07/2023	R18	R18  Revision Effective: 12/07/2023  Revision Explanation: Updated typographical error.  <i>03-06-2024: 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</i>	<ul style="list-style-type: none"><li>• Typographical Error</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p><i>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>	
12/07/2023	R17	<p>R17</p> <p>Revision Effective: 12/07/2023</p> <p>Revision Explanation: Annual review, no changes were made.</p> <p><i>11/29/2023: 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>• Other (Annual Review)</li> </ul>
12/01/2022	R16	<p>R16</p> <p>Revision Effective: 12/01/2022</p> <p>Revision Explanation: Annual review, no changes were made.</p> <p><i>12/29/2022: 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>• Other (Annual Review)</li> </ul>
11/25/2021	R15	<p>R15</p> <p>Revision Effective: 11/25/2021</p> <p>Revision Explanation: Annual review, no changes were made.</p> <p><i>11/19/2021: 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</i></p>	<ul style="list-style-type: none"> <li>• Other (Annual Review)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p><i>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>	
11/28/2019	R14	<p>R14</p> <p>Revision Effective: N/A</p> <p>Revision Explanation: Annual review, no changes made.</p> <p><i>11/16/2020: 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>• Other (Annual Review)</li> </ul>
11/28/2019	R13	<p>R13</p> <p>Revision Effective: 11/28/2019</p> <p>Revision Explanation: Annual review, no changes made.</p> <p><i>11/19/2019: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 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>• Other (Annual Review, no changes made)</li> </ul>
11/28/2019	R12	<p>R12</p> <p>Revision Effective: 11/28/2019</p> <p>Revision Explanation: Removed other comments section from policy text and associated documentation information and placed into the related billing and coding article.</p> <p><i>11/19/2019: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 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>• Provider Education/Guidance</li> </ul>
09/19/2019	R11	<p>R11</p>	<ul style="list-style-type: none"> <li>• Revisions Due To Code Removal</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>Revision Effective: 09/19/2019 Revision Explanation: Converted policy into new policy template that no longer includes coding section based on CR 10901. For Approval, no changes.</p> <p>09/13/2019: <i>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>	
09/19/2019	R10	<p>R10</p> <p>Revision Effective: 09/19/2019</p> <p>Revision Explanation: Converted policy into new policy template that no longer includes coding section based on CR 10901.</p> <p>09/12/2019: <i>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 Code Removal</li> </ul>
04/04/2019	R9	<p>R9</p> <p>Revision Effective date: 04/04/2019</p> <p>Revision Explanation: All coding was removed from policy based on CR10901. New Billing and Coding article was related to policy and replaced supplemental article that was retired.</p> <p>03/29/2019- <i>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>• Other (Code Migration)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2018	R8	<p>R8</p> <p>Revision Effective date: N/A</p> <p>Revision Explanation: Annual review no changes</p> <p><i>11/26/2018-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>Other (Annual review)</li> </ul>
10/01/2018	R7	<p>Revision#:R7</p> <p>Revision Effective date: 10/01/2018</p> <p>Revision Explanation: During the annual ICD-10 update G51.31, G51.32, G51.33 were added to group 5 and code H02.151, H02.152, H02.153, H02.154, H02.155, H02.156 were added to group 9.</p> <p><i>09/18/2017-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>Revisions Due To ICD-10-CM Code Changes</li> </ul>
10/01/2015	R6	<p>Revision#:R6</p> <p>Revision Effective date: N/A</p> <p>Revision Explanation: annual review no changes</p> <p><i>11/28/2017-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>Other (annual review)</li> </ul>
10/01/2015	R5	<p>Revision#:R5</p> <p>Revision Effective date: N/A</p> <p>Revision Explanation: annual review no changes</p>	<ul style="list-style-type: none"> <li>Other (Annual Review)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2015	R4	Revision#:R4 Revision Effective date:10/01/2015 Revision Explanation: Added the following ICD-10 codes to group seven for coverage: G82.20-G82.22, G83.81-g83.82, G83.89, I69.041-I69.044, and I69.049.	<ul style="list-style-type: none"> <li>Reconsideration Request</li> </ul>
10/01/2015	R3	Revision#:R3 Revision Effective date: N/A Revision Explanation: annual review no changes	<ul style="list-style-type: none"> <li>Other (Annual review)</li> </ul>
10/01/2015	R2	Revision#:R2 Revision Effective date: 10/01/2015 Revision Explanation: Accepted 2015 HCPCS description change for 43201 and 43236.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2015	R1	Revision #: R1 Revision Effective:N/A REvision Explanation: Third quarter HCPCS changes had code description for CPT codes 64644, 64645, and 64647.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

### Articles

[A56472 - Billing and Coding: Botulinum Toxins](#)

### Related National Coverage Documents

N/A

### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
03/06/2024	12/07/2023 - N/A	Currently in Effect (This Version)
11/29/2023	12/07/2023 - N/A	Superseded
12/29/2022	12/01/2022 - 12/06/2023	Superseded

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## Keywords

N/A