## Contractor Information

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<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
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## LCD Information

### Document Information

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<td>L33646</td>
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<th>LCD Title</th>
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<td>Botulinum Toxins</td>
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**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).
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
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 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 >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 Botulism 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.


Brashear A, Gordon MF, Elovic E, et al, for the Botox Post-Stroke Spasticity Study Group. Intramuscular injection of


Graboski CL, Gray DS, Burnham RS. Botulinum toxin A versus bupivacaine trigger point injections for the treatment...


Mertz Pharmaceuticals. XEOMIN® (incobotulinumtoxinA) FDA approval Press Release 08/02/2010.

Mertz Pharmaceuticals. XEOMIN® (incobotulinumtoxinA) Product Label.


NGS and other Medicare local coverage determinations.


References reviewed for 10/01/2010 publication


References Reviewed for 11/01/2010 Reconsideration Request

BOTOX® Package Insert.


DYSPORT™ Package Insert.

MYOBLOC® Package Insert.


References Reviewed for Reconsideration 01/01/2011


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


**Bibliography**

N/A

## Revision History Information

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<tr>
<td>10/31/2019</td>
<td>R11</td>
<td>The LCD has been revised to add the following indications which were inadvertently removed with the last update:</td>
<td>• Typographical Error</td>
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<tr>
<td></td>
<td></td>
<td>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).</td>
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<td></td>
<td>AbobotulinumtoxinA is indicated for the treatment of lower limb spasticity in adults.</td>
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<td>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.</td>
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<tr>
<td>10/31/2019</td>
<td>R10</td>
<td>Consistent with Change Request 10901, all coding 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.</td>
<td>• Revisions Due To Code Removal</td>
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<tr>
<td>10/01/2018</td>
<td>R9</td>
<td>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.</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
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<td>06/16/2017</td>
<td>R8</td>
<td>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.</td>
<td>• Request for Coverage by a Practitioner (Part B)</td>
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<td>06/16/2017</td>
<td>R7</td>
<td>The following has been added to the “Indications” section of the LCD:</td>
<td>• Provider Education/Guidance</td>
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<td></td>
<td>Effective June 16, 2017, the FDA has approved abobotulinumtoxinA for the treatment of lower limb spasticity in adults.</td>
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<td>01/21/2016</td>
<td>R6</td>
<td>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.</td>
<td>• Typographical Error</td>
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<tr>
<td>01/21/2016</td>
<td>R5</td>
<td>FDA label update for onabotulinumtoxinA (effective 01/21/2016) has been added to the &quot;Indications&quot; section of the LCD under &quot;Spasticity&quot;. ICD-10-CM codes G83.31*, G83.32*, G83.33*, G83.34*, G83.81*, G83.82*, G83.89*,</td>
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<td>10/01/2015</td>
<td>R4</td>
<td>The following paragraph in the &quot;Indications&quot; section under &quot;Spasticity&quot; has been corrected to add &quot;upper extremity&quot;</td>
<td>Typographical Error</td>
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<td>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.</td>
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<tr>
<td>10/01/2015</td>
<td>R3</td>
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<td>Provider Education/Guidance</td>
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<td>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.</td>
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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:

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;

Out-dated information has been removed throughout the LCD.

The "Utilization" section has been revised to indicate:
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.

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<td>10/01/2015</td>
<td>R2</td>
<td>LCD updated to reflect administrative changes.</td>
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<td>10/01/2015</td>
<td>R1</td>
<td>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.</td>
<td>Revisions Due To ICD-10-CM Code Changes</td>
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## Associated Documents

### Attachments
N/A

### Related Local Coverage Documents

Article(s)
A52848 - Billing and Coding: Botulinum Toxins

### Related National Coverage Documents
N/A

### Public Version(s)

Updated on 11/22/2019 with effective dates 10/31/2019 - N/A
Updated on 10/25/2019 with effective dates 10/31/2019 - N/A
Updated on 09/21/2018 with effective dates 10/01/2018 - 10/30/2019
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

## Keywords

- Botox