Local Coverage Determination (LCD):
Drugs and Biologicals: Botulinum Toxins (L34253)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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<td>10102 - MAC B</td>
<td>J - J</td>
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LCD Information

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CMS National Coverage Policy

- Title XVIII of the Social Security Act, Section 1833 (e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section(s) 1861(s) and (t). These sections outline coverage for drugs and biological and services and supplies.
- Title XVIII of the Social Security Act, Section 1862 (a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.
- Title XVIII of Social Security Act; Section 1862(a)(10). No payment may be made under part A or part B for any expenses incurred for items or services where such expenses are for cosmetic surgery, or are incurred in connection therewith; except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.
- Medicare Benefit Policy Manual (Pub.100-02), Chapter 15, Section 50.
- Medicare Claims Processing Manual (Pub. 100-04), Chapter 17, Section 20.
- Medicare Program Integrity Manual (Pub. 100-08), Chapter 13, Local Coverage Determinations.
- 42 CFR 411.15(h) Cosmetic surgery and related services, except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

Coverage Guidance

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

**Indications**

Because Botulinum Toxins (BT) are invasive, their use should be reserved for patients in whom a diagnosis has been established with reasonable certainty.

For most patients with these conditions BT promises significant but variable relief of symptoms that last for varying periods of time. Often times repeated injections are required for sustained relief of symptoms. Long-term effects of chronic BT therapy are unknown. Loss of response to repeated injections is seen and immuno-resistant is thought to be one mechanism.

1. OnabotulinumtoxinA (Botulinum Toxin A) (Botox ®) (J0585):
**FDA**: Treatment of:

A. Upper limb spasticity in adult patients;
B. Cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain;
C. Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients;
D. Blepharospasm associated with dystonia in patients ≥12 years of age;
E. Strabismus in patients ≥12 years of age;
F. Prophylaxis of headaches in adult patients with chronic migraine (>15 days per month with headache lasting 4 hours a day or longer);
G. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
H. 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.

**Off Label Use:**

A. Facial Spasm;
B. Hemifacial Spasm;
C. Spasmodic Dysphonia;
D. Focal hand dystonia (Writers' Cramp);
E. Chronic anal fissure refractory to conservative treatment;
F. Esophageal achalasia patients in whom surgical treatment is not indicated;
G. Frey's syndrome;
H. Spasticity resulting from brain, spinal cord and other neurological diseases (e.g. Cerebral Palsy, CVA, traumatic brain injury, anoxic brain injury, Multiple Sclerosis, etc.) that results in pain and/or impaired activities of daily living (ADLs);
I. Headache - Coverage for carefully-selected patients with intractable headache due to tension who have been refractory to standard and usual conventional therapy will be allowed. The medical literature now has more negative than positive studies for the use of botulinum toxin in the treatment of tension headache, however, research is ongoing. Reports in the literature, and from experienced clinicians, note response to therapy in some patients refractory to other standard therapy. For continuing botulinum toxin therapy, the patient must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin. Note: This indication is to be coded with ICD-10 code Z01.89.
J. Sialorrhea

2. AbobotulinumtoxinA (Botulinum Toxin A) (Dysport ®) (J0586):
FDA:
A. Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients;
B. Upper limb spasticity in adult patients.

Off Label Use:
A. Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients;
B. Blepharospasm associated with dystonia in patients ≥12 years of age;
C. Strabismus in patients ≥12 years of age.
D. Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).
E. Facial Spasm;
F. Hemifacial Spasm;
G. Spasmodic Dysphonia;
H. Focal hand dystonia (Writers’ Cramp);
I. Chronic anal fissure refractory to conservative treatment;
J. Esophageal achalasia patients in whom surgical treatment is not indicated;
K. Frey's syndrome;
L. Spasticity resulting from brain, spinal cord and other neurological diseases (e.g. Cerebral Palsy, CVA, traumatic brain injury, anoxic brain injury, Multiple Sclerosis, etc.) that results in pain and/or impaired activities of daily living (ADLs);
M. Headache - Coverage for carefully-selected patients with intractable headache due to tension who have been refractory to standard and usual conventional therapy will be allowed. The medical literature now has more negative than positive studies for the use of botulinum toxin in the treatment of tension headache, however, research is ongoing. Reports in the literature, and from experienced clinicians, note response to therapy in some patients refractory to other standard therapy. For continuing botulinum toxin therapy, the patient must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving botulinum toxin. Note: This indication is to be coded with ICD-10 code Z01.89.
N. Sialorrhea

3. IncobotulinumtoxinA (Botulinum Toxin A) (Xeomin ®) (J0588)

FDA: Treatment of
A. Adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients;
B. Blepharospasm in adults previously treated with onabotulinumtoxinA (Botox ®).

Off Label Use:
A. Upper limb spasticity in adult patients.
B. Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.
C. Spasticity resulting from brain, spinal cord and other neurological diseases (e.g. Cerebral Palsy, CVA, traumatic brain injury, anoxic brain injury, Multiple Sclerosis, etc.) that results in pain and/or impaired activities of daily living (ADLs);
D. Sialorrhea.

4. RimabotulinumtoxinB (Botulinum Toxin B) (Myobloc ®) (J0587):
FDA:

Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Off Label Use:

A. Sialorrhea
B. Myobloc ® will be covered for the same indications (other than cervical dystonia and sialorrhea) as Botox ®/Dysport ® when documentation supports the patient is unresponsive to Botox ®/Dysport ®.

Limitations

1. Treatment for cosmetic reasons such as craniofacial wrinkles will not be covered.
2. Medicare will allow payment for one injection per each functional muscle group/anatomical site regardless of the number of injections made into each group/site or the number of muscles that comprise the functional group.
3. Botulinum toxin treatment is not indicated for patients:
   A. receiving aminoglycosides, which may interfere with neuromuscular transmission; or
   B. with chronic paralytic strabismus, except to reduce antagonist contractor in conjunction with surgical repair.
4. Botulinum toxin is not recommended for patients with:
   A. strabismus, when angles are over 50 prism diopters;
   B. restrictive strabismus;
   C. Duane's syndrome with lateral rectus weakness; or
   D. secondary strabismus caused by prior surgical over-recession of the antagonist.
5. OnabotulinumtoxinA (Botulinum Toxin A) (Botox ®) and AbobotulinumtoxinA (Botulinum Toxin A) (Dysport ®) are not indicated for patients with new onset headache. Please refer to FDA Indications and Off Label Use for these products.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

ICD-10 Codes that Support Medical Necessity

The correct use of an ICD-10-CM code listed in the "ICD-10 Codes that Support Medical Necessity" section does not guarantee coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this LCD.

ICD-10 codes must be coded to the highest level of specificity. Consult the 'Official ICD-10-CM Guidelines for Coding and Reporting' in the current ICD-10-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

Group 1 Codes:

ICD-10 Codes                  Description
G04.1  Tropical spastic paraplegia
G11.4  Hereditary spastic paraplegia
G24.01 Drug induced subacute dyskinesia
G24.1 - G24.9 Genetic torsion dystonia - Dystonia, unspecified
G25.89 Other specified extrapyramidal and movement disorders
G35 - G36.0 Multiple sclerosis - Neuromyelitis optica [Devic]
G36.8 - G36.9 Other specified acute disseminated demyelination - Acute disseminated demyelination, unspecified
G37.1 - G37.9 Central demyelination of corpus callosum - Demyelinating disease of central nervous system, unspecified
G43.701 - G43.719 Chronic migraine without aura, not intractable, with status migrainosus - Chronic migraine without aura, intractable, without status migrainosus
G44.221 Chronic tension-type headache, intractable
G51.2 - G51.8 Melkerson's syndrome - Other disorders of facial nerve
G80.0 - G80.9 Spastic quadriplegic cerebral palsy - Cerebral palsy, unspecified
G81.10 - G81.14 Spastic hemiplegia affecting unspecified side - Spastic hemiplegia affecting left nondominant side
G82.20 - G83.34 Paraplegia, unspecified - Monoplegia, unspecified affecting left nondominant side
H49.00 - H49.23 Third [oculomotor] nerve palsy, unspecified eye - Sixth [abducent] nerve palsy, bilateral
H49.881 - H50.812 Other paralytic strabismus, right eye - Duane's syndrome, left eye
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<td>H50.9 -</td>
<td>Unspecified strabismus - Convergence excess</td>
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<td>H51.12</td>
<td>Other specified disorders of binocular movement - Unspecified disorder of binocular movement</td>
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<td>H51.8 -</td>
<td>Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side - Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting unspecified side</td>
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<td>H51.9</td>
<td>Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side - Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting unspecified side</td>
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<td>I69.031 -</td>
<td>Monoplegia of upper limb following nontraumatic intracranial hemorrhage affecting right dominant side - Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side</td>
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<td>I69.059</td>
<td>Monoplegia of upper limb following cerebral infarction affecting right dominant side - Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side</td>
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<td>I69.131 -</td>
<td>Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side - Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side</td>
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<td>I69.159</td>
<td>Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side - Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side</td>
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<td>I69.231 -</td>
<td>Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side - Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting unspecified side</td>
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<tr>
<td>I69.259</td>
<td>Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side - Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side</td>
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<td>I69.331 -</td>
<td>Monoplegia of upper limb following cerebral infarction affecting right dominant side - Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side</td>
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<td>Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side - Hemiplegia and hemiparesis following other cerebrovascular disease affecting unspecified side</td>
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<td>J38.5</td>
<td>Laryngeal spasm</td>
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<td>Disturbances of salivary secretion</td>
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<td>K59.4</td>
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<td>K60.0 -</td>
<td>Acute anal fissure - Anal fissure, unspecified</td>
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<td>K60.2</td>
<td>Lymphoedema of lower limb - Secondary focal hyperhidrosis</td>
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<td>L74.510 -</td>
<td>Primary focal hyperhidrosis, axilla - Secondary focal hyperhidrosis</td>
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<td>L74.52</td>
<td>Contracture of muscle, unspecified site - Contracture of muscle, multiple sites</td>
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<td>M62.40 -</td>
<td>Muscular disorders of urethra</td>
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<td>M62.49</td>
<td>Upper urinary tract obstruction, unspecified site - Urinary incontinence</td>
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<td>M62.838</td>
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<td>N31.0 -</td>
<td>Uninhibited neuropathic bladder, not elsewhere classified - Reflex neuropathic bladder, not elsewhere classified</td>
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<td>R61</td>
<td>Generalized hyperhidrosis</td>
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<td>Encounter for other specified special examinations</td>
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**Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation:** *Z01.89 is to be used to code for 'intractable headache due to tension'*

**ICD-10 Codes that DO NOT Support Medical Necessity**

**Group 1 Paragraph:** Any ICD-10-CM code that is not listed in the "ICD-10 Codes that Support Medical Necessity" section of this LCD.

**Group 1 Codes:**

**ICD-10 Codes**  **Description**

XX000  | Not Applicable
1. Documentation should include the following elements:
   
   A. support for the medical necessity of the Botulinum Toxin injections,
   B. a covered diagnosis,
   C. site, dosage by location, and frequency of the injections,
   D. support the clinical effectiveness for subsequent injections if needed.

2. If Myobloc® is given for a Botox®/Dysport® indication, documentation must support the patient was unresponsive to Botox®/Dysport®.

3. All coverage criteria must be clearly documented in the patient's medical record and made available to Medicare upon request.

4. Documentation must support CMS 'signature requirements' as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

**Utilization Guidelines**

1. Treatment with botulinum toxin products usually lasts at least 3 months (12 weeks).

2. For labeled indications, the dose and frequency of administration should be consistent with the FDA approved package insert.

**Sources of Information**

- Consultation with the Carrier Advisory Committee and other Medicare contractors
- Other Medicare Contractor’s Local Coverage Determinations
- Prescribing Information Dysport®
- Prescribing Information for Botox®
- Prescribing Information Myobloc®
- Prescribing Information Xeomin®
### Revision History Information

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<td>R9</td>
<td>Palmetto GBA Transition</td>
<td>• Change in Affiliated Contract Numbers</td>
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<td>11/01/2016</td>
<td>R8</td>
<td>12/29/16: All CPT/HCPCS codes have been combined into Group 1</td>
<td>• Reconsideration Request</td>
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<td>11/01/2016</td>
<td>R7</td>
<td>11/07/16-ICD-10 codes that support medical necessity have been expanded to be the same in all groups.</td>
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**What's New Posted Date: June 2016**  
**Effective Date: July 1, 2016**

The 'Indications' section for RimabotulinumtoxinB (Botulinum Toxin B) (Myobloc ®) (J0587) is being updated to allow the Off-Label Use for the treatment of Sialorrhea. Myobloc ® will continue to be covered for the same indications (other than cervical dystonia and sialorrhea) as Botox ®/Dysport ® when documentation supports the patient is unresponsive to Botox ®/Dysport ®.

In addition, ICD-10 diagnosis code K11.7 is being added to the list of 'ICD-10 Codes that Support Medical Necessity' for J0587.

Providers are encouraged to review this LCD to ensure compliance.

**What's New Posted Date: January 2016**  
**Effective Date: October 1, 2015**

The 'Indications' section for OnabotulinumtoxinA (Botulinum Toxin A) (Botox ®) (J0585) and AbobotulinumtoxinA (Botulinum Toxin A) (Dysport ®) (J0586) is being updated to allow the Off-Label Use for the treatment of 'intractable headache due to tension'.

In addition, ICD-10 diagnosis code Z01.89 is being added to the list of 'ICD-10 Codes that Support Medical Necessity' for J0585 and J0586.

**What's New Posted Date: September 2015**  
**Effective Date: October 15, 2015**

Corrected typographical error. Converted ICD-9 code (V72.85) to ICD-10 equivalent (Z01.89). No change in effective date or coverage.

Corrected Typographical Error.

**What's New Posted Date: September 2015**  
**Effective Date: October 15, 2015**

The 'Indications' section for AbobotulinumtoxinA (Botulinum Toxin A) (Dysport ®) (J0586) is being expanded to include the approved use for treatment of 'Upper limb spasticity in adult patients'.

• Other (Per CMD request.)

• Typographical Error

• Typographical Error
Providers are encouraged to review this LCD to ensure compliance.

What’s New Posted Date: January 2015
Effective Date: January 1, 2015

10/01/2015 R1

The 'Associated Information' section under 'Documentation Requirements' of this LCD is being updated to remove verbiage stating 'support for treatment when given outside of FDA frequency parameters'.

- Provider Education/Guidance

Associated Documents

Attachments N/A
Related Local Coverage Documents N/A
Related National Coverage Documents N/A

Public Version(s) Updated on 01/17/2018 with effective dates 01/29/2018 - N/A
Updated on 12/29/2016 with effective dates 11/01/2016 - 01/28/2018
Updated on 11/07/2016 with effective dates 11/01/2016 - N/A

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

Keywords

N/A Read the LCD Disclaimer

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