Local Coverage Determination (LCD):
Chemodenervation (L33458)

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

Contractor Information

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LCD Information

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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 reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862 (a)(1)(D) states no payment can be made for services that are for research or experimentation.

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 Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §50.4.1, Approved use of drug

CMS Internet-Only Manual, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §160.1, Induced lesions of nerve tracts

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Chemodenervation refers to the use of chemical agents to produce neuromuscular blockade for the purpose of
selective weakening of specific muscles, or muscle groups. This policy applies to the use of neurotoxins as well as other chemical agents used for this purpose.

Botulinum toxin, a neurotoxin produced by clostridium botulinum, produces a clinical effect by blocking the release of neurotransmitters, principally acetylcholine, from nerve endings. There are currently four botulinum neurotoxins available in the US with different FDA-approved indication(s): three distinct serotype A botulinum toxin therapeutic products, onabotulinumtoxinA (BOTOX®), abobotulinumtoxinA (DYSPORT®) and incobotulinumtoxinA (XEOMIN®), and the serotype B botulinum toxin product, rimabotulinumtoxinB (MYOBLOC®).

The FDA-approved labeling for each product states that the potency units of the botulinum toxin products are not interchangeable. Labeling differs from product to product; dosing units are not comparable. It is the physician’s responsibility to select the appropriate product and dose in accordance with FDA-approval indications for use, compendia-supported uses, and supported by peer reviewed specific scientific literature.

Chemodenervation techniques are indicated/covered for:

1. Chemodenervation of muscle innervated by the facial nerve in the management of blepharospasm or hemifacial spasm.

2. Chemodenervation of cervical spinal muscles in the management of spasmodic torticollis.

3. Chemodenervation of extremity muscles in the management of dystonias, cerebral palsy, upper and lower limb spasticity (see Note: ) and multiple sclerosis

4. Chemodenervation of extraocular muscles in the management of strabismus.

5. Chemodenervation of the lower esophageal sphincter in the management of achalasia.


7. Chemodenervation of bilateral frontalis, trapezius, temporalis, sternocleidomastoid, and splenius capitis muscles for treatment of chronic tension headache and intractable daily headache.

8. Chemodenervation of procerus and bilateral frontalis, corrugator, occipitalis, temporalis, trapezius, and cervical paraspinal muscle group for the prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

   **Note:** Onabotulinumtoxin A (BOTOX®), is the only botulinum toxin product that is FDA-approved for the prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

9. Chemodenervation of sweat glands for the treatment of severe primary hyperhidrosis that is inadequately managed with topical agents. Severe is defined for this purpose as level 3 (sweating barely tolerable/frequently interferes with daily activity) or level 4 (sweating intolerable/always interferes with daily activities) on the Hyperhidrosis Disease Severity Scale (HDSS).

10. Chemodenervation of the internal anal sphincter for the treatment of chronic anal fissure.

11. Chemodenervation of the detrusor urinae muscle for the treatment of over activity associated with a neurologic condition in adults with an inadequate response to anticholinergic treatment and 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.
12. Chemodenervation of the parotid and submandibular salivary glands, bilaterally.

**Limitations**

Chemodenervation for the treatment of headaches is limited to patients who experience headaches that may result in permanent cerebral dysfunction, or are intractable because the patient cannot tolerate or does not benefit from standard therapies. Candidates for this treatment are patients with:

1. Intractable migraines (with or without aura).
2. Intractable chronic tension-type headache with moderate to severe pain.
3. Chronic daily headaches defined as patients experiencing more than 15 days of headache per month (either migraine or tension-type features).
4. Chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer) (for the prophylaxis of headaches - in adult patients only).

**Note:** Intractable headache is defined as a patient meeting one of the following criteria for treatment (applies only to disease states 1-3, listed above):

1. Failed trials of at least three preventive pharmacologic migraine therapies (e.g. beta-blockers, anticonvulsants, antidepressants) with or without concomitant behavioral and physical therapies, after titration to maximal tolerated doses or have medical contraindications to common therapies or who cannot tolerate common preventative therapies; or
2. Experience chronic daily headaches or recurrent headaches at least twice per month causing disability lasting three or more days per month; or
3. Standard abortive medication is required more than twice per week, or is contraindicated, ineffective or not tolerated.

**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.

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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.

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CPT/HCPCS Codes

Group 1 Paragraph:

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ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

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Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation:

XX000
ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

Group 1 Codes: N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

Legible documentation to support medical necessity must be present for each date of service billed on the claim. Documentation should include the following elements:

- Specific botulinum toxin used
- Dosage of toxin used (including dosage in units per site)
- A complete description of the site(s) injected
- A covered diagnosis (however, when a form of botulinum toxin is used for an indication that is not supported by FDA-approval and/or compendia support, a physician statement in the medical record stating the reason(s) why the unsupported form was used is also required)
- Support of the clinical effectiveness of the injections, noting date of last injection (if applicable)
- Support for the medical necessity of electromyography or stimulation guidance procedures if performed.

Utilization Guidelines

Chemodenervation treatment has a variable lasting beneficial effect from twelve to sixteen weeks, following which the procedure may need to be repeated. It is appropriate to inject the lowest clinically effective dose at the greatest feasible interval that results in the desired clinical result.

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

Sources of Information

N/A

Bibliography


Pasricha PJ, Ravich WJ, Hendix TR, Sostre S, Jones B, Kalloo AN. Intrasphisincteric Botulinum Toxin for the Treatment...


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**Revision History Information**

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<th>REVISION HISTORY DATE</th>
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<td>07/04/2019</td>
<td>R21</td>
<td>All coding located in the Coding Information section has been moved into the related Billing and Coding: Chemodenervation A56646 article and removed from the LCD.</td>
<td>• Provider Education/Guidance</td>
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<td><em>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.</em></td>
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<tr>
<td>10/01/2018</td>
<td>R20</td>
<td>Under ICD-10 Codes that Support Medical Necessity Group: 3 Paragraph added HCPCS code J0588. This revision is due to a reconsideration request. Under ICD-10 Codes that Support Medical Necessity Group: 4 Codes added ICD-10 codes G51.31, G51.32 and G51.33. Under ICD-10 Codes that Support Medical Necessity Group: 4 Codes deleted ICD-10 code G51.3. This revision is due to the 2018 Annual ICD-10 Code Update and is effective on October 1, 2018.</td>
<td>• Revisions Due To ICD-10-CM Code Changes • Reconsideration Request</td>
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<td>07/09/2018</td>
<td>R19</td>
<td>Under <strong>Coverage Indications, Limitations and/or Medical Necessity</strong> deleted the verbiage “Onabotulinumtoxin A (Botox®) is the only botulinum toxin that is FDA approved for lower limb spasticity in adults”. 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.</td>
<td>• Reconsideration Request</td>
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<td>03/15/2018</td>
<td>R18</td>
<td>Under <strong>CMS National Coverage Policy</strong> deleted the “s” from the cited Internet-Only Manual references X2. Throughout the LCD punctuation was corrected. Under <strong>Coverage Indications, Limitations and/or Medical Necessity #7</strong> corrected the spelling of splenius. Throughout the LCD punctuation was corrected. Under <strong>Bibliography</strong> author initials were added to the author name WJ Binder and the spelling of the author name Heckmann was corrected. 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.</td>
<td>• Provider Education/Guidance • Typographical Error • Other</td>
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<td>02/26/2018</td>
<td>R17</td>
<td>The Jurisdiction &quot;J&quot; Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.</td>
<td>• Change in Affiliated Contract Numbers</td>
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<td>10/01/2017</td>
<td>R16</td>
<td>Under <strong>ICD-10 Codes that Support Medical Necessity Group 2: Codes</strong> added ICD-10 codes G12.23, G12.24 and G12.25. These revisions are due to the 2017 Annual ICD-10 Updates.</td>
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<td>07/07/2017</td>
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<td>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.</td>
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<td>03/07/2017</td>
<td>R13</td>
<td>Under <strong>Coverage Indications, Limitations and/or Medical Necessity-Indication 9</strong> revised the verbiage to read “Chemodenervation of sweat glands for the treatment of severe primary hyperhidrosis that is inadequately managed with topical agents. Severe is defined for this purpose as level 3 (sweating barely tolerable/frequently interferes with daily activity) or level 4 (sweating intolerable/always interferes with daily activities) on the Hyperhidrosis Disease Severity Scale (HDSS)”. Under <strong>CPT/HCPCS Codes Group 1: Paragraph</strong> added primary procedure CPT codes 64653 and 64999 to the verbiage “Use CPT codes 95873 and 95874 in addition to the code for the primary procedure CPT codes 64612, 64615, 64616, 64642, 64643, 64644, 64645, 64646, 64647”. Under <strong>Group 1: Codes</strong> added CPT codes 64653 and 64999. Under <strong>Group 8: Paragraph</strong> added CPT codes 64653 and 64999 and added the verbiage “<em>64999 to billed only with L74.512 and L74.513 with chemodenervation</em>”.</td>
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| 03/07/2017            | R12                     | Under **Coverage Indications, Limitations and/or Medical Necessity Note bullet 8, Note and Limitations bullet 4** revised the verbiage “(= 15 days per month with headache lasting 4 hours a day or longer)” to now read “(15 days per month with headache lasting 4 hours a day or longer)”. Under **Note**: revised the verbiage “Intractable headache is defined as a patient meeting one of the following criteria for treatment” to read “Intractable headache is defined as a patient meeting one of the following criteria for treatment (applies only to disease states 1-3, listed above)”. Under **ICD-10 Codes that Support Medical Necessity Group 7: Codes** removed G83.81 and G83.82 and added these codes to **Group 6: Codes (for 64642-64647)**. | • Provider Education/Guidance  
• Revisions Due To ICD-10-CM Code Changes |
| 12/10/2016            | R11                     | Under **CMS National Coverage Policy** revised “Manuals” to now read "Manual". Under **CPT/HCPCS Codes Group 6: Codes** added G83.81 and G83.82 effective for claims for dates of service beginning 09/29/2016. Under **CPT/HCPCS Codes Group 7: Codes** deleted G83.81 and G83.82 as these codes were moved to Group 6 for chemodenervation of the extremity or trunk. | • Provider Education/Guidance  
• Other |
| 09/29/2016            | R10                     | Under **Coverage Indications, Limitations and/or Medical Necessity** bullet 3 revised the verbiage to read “Chemodenervation of extremity muscles in the management of dystonias, cerebral palsy, upper and lower limb spasticity (see **Note:** ) and multiple sclerosis”. Under **Note**: added the verbiage “Onabotulinumtoxin A (Botox®) is the only botulinum toxin that is FDA approved for lower limb spasticity in adults” to the end of the sentence. Under **ICD-10 Codes that Support Medical Necessity Group 7: Codes** added ICD-10 Codes G83.81 and G83.82. | • Provider Education/Guidance  
• Reconsideration Request  
• Revisions Due To ICD-10-CM Code Changes |
| 09/01/2016            | R9                      | Under **CPT/HCPCS Codes Group 1: Paragraph** in the second sentence deleted CPT codes 64611 and 64617. The verbiage was corrected to now read "Use CPT codes 95873 and 95874 in addition to the code for the primary procedure CPT codes 64612, 64615, 64616, 64642, 64643, 64644, 64645, 64646, and 64647”effective on or after October 01, 2015. | • Provider Education/Guidance  
• Revisions Due To CPT/HCPCS Code Changes |
| 07/05/2016            | R8                      | Under **CPT/HCPCS Codes Group 1: Paragraph** added verbiage related to achalasia. Under **CPT/HCPCS Codes Group 1: Codes** deleted CPT code 43201. Under **ICD-10 Codes that Support Medical Necessity** deleted Group 1: **Paragraph** stating CPT code 43201; HCPCS codes J0585, | • Provider Education/Guidance  
• Revisions Due To CPT/HCPCS Code Changes |
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| 01/22/2016            | R7                      | Under **Coverage Indications, Limitations and/or Medical Necessity** under #3 added “upper limb spasticity”; under #8 added “*NOTE: Onabotulinamtoxin A (BOTOX®), is the only botulinum toxin product that is FDA-approved for the prophylaxis of headaches in adult patients with chronic migraines (= 15 days per month with headache lasting 4 hours a day or longer)” which was moved from the **Utilization Section** of this policy. Under **Limitations** made a few grammatical changes; changes the word “they” in the first paragraph to read the patient and added “*NOTE:” in front of Intractable headache is defined..... Under **Associated Information** in the **Utilization Guidelines** removed the “Onabotulinamtoxin A (BOTOX®), is the only botulinum toxin product that is FDA-approved for the prophylaxis of headaches in adult patients with chronic migraines (15 days per month with headache lasting 4 hours a day or longer)” as stated above. | Changes  
- Revisions Due To ICD-10-CM Code Changes  
- Provider Education/Guidance  
- Public Education/Guidance  
- Typographical/Guidance  
- Other (Annual Validation) |
| 12/16/2015            | R6                      | Under **ICD-10 Codes that Support Medical Necessity** added ICD-10 codes I69.051, I69.052, I69.053, I69.054, I69.151, I69.152, I69.153, I69.154, I69.251, I69.252, I69.253, I69.254, I69.351, I69.352, I69.353, I69.354, I69.851, I69.852, I69.853, I69.854, I69.951, I69.952, I69.953, and I69.954 to Group 7 as the drug Dysport (abobotulinumtoxinA) HCPCS code J0585 was also approved for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors by the FDA. | Provider Education/Guidance  
- Automated Edits to Enforce Reasonable & Necessary Requirements  
- Reconsideration Request  
- Revisions Due To ICD-10-CM Code Changes |
| 10/01/2015             | R5                      | Under **CMS National Coverage Policy** revised Section of Pub 100-2 of CMS Internet-Only Manuals to now read 50.4.1. | Provider Education/Guidance  
- Other (Maintenance Annual Validation) |
| 10/01/2015             | R4                      | Under CPT/HCPCS Codes the following codes have had descriptor changes for CPT codes 64644, 64645, 64647. The change was due to the Annual HCPCS Update, CR 8975, dated 10/24/2014. | Provider Education/Guidance  
- Automated Edits to Enforce Reasonable & Necessary Requirements  
- Provider Education/Guidance  
- Other (Maintenance Annual Validation) |
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| 10/01/2015            | R3                      | Under CPT/HCPCS Codes section descriptor changes were made to CPT Codes 64644, 64645 and 64647, effective 7/1/2014. | Necessary Requirements  
  • Revisions Due To CPT/HCPCS Code Changes |
| 10/01/2015            | R2                      | Under ICD-10 Codes that Support Medical Necessity added the following ICD-10 codes to Group 8: G43.011, G43.019, G43.111, G43.119, G43.411, G43.419, G43.511, G43.519, G43.611, G43.619, G43.811, G43.819, G43.831, G43.839, G43.911, G43.919, G43.A1, and G43.B1. | Provider Education/Guidance  
  • Automated Edits to Enforce Reasonable & Necessary Requirements  
  • Reconsideration Request  
  • Revisions Due To ICD-10-CM Code Changes |
| 10/01/2015            | R1                      | Under CPT/HCPCS Codes, Group 2, paragraph section, added CPT codes 63611 and 64615 for clarification in LCD. Under Sources of Information and Basis for Decision removed the statement, "The development and coverage guidelines in this policy were based on a review of pertinent medical literature, policies from other Medicare contractors, and discussions with appropriate specialists," as this statement was deemed no longer necessary within the text of the LCD. | Other ( Provider questioning 64611 and 64615 usage in LCD.) |

**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)
A56646 - Billing and Coding: Chemodenervation
A55428
- (MCD Archive Site)LCD(s)
DL33458

Created on 08/12/2019. Page 13 of 14
Keywords

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