

LCD - Chemodenervation (L33458)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information

Document Information

LCD ID

L33458

LCD Title

Chemodenervation

Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL33458](#)

Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 05/27/2021

Revision Ending Date

N/A

Retirement Date

N/A

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Notice Period Start Date

01/19/2017

Notice Period End Date

03/06/2017

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.

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 4 botulinum neurotoxins available in the United States (US) with different Federal Drug Administration (FDA)-approved indication(s): 3 distinct serotype A botulinum toxin therapeutic products, [onabotulinumtoxinA \(BOTOX®\)](#), [abobotulinumtoxinA \(DYSPOUR®\)](#) 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
6. Chemodenervation of laryngeal muscles in the treatment of adductor spasmodic dysphonia
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 1 of the following criteria for treatment (applies only to disease states 1-3, listed above):

1. Failed trials of at least 3 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 3 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

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 12 to 16 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

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
05/27/2021	R24	Under Bibliography changes were made to citations to reflect AMA citation guidelines.	<ul style="list-style-type: none">• Provider Education/Guidance
09/10/2020	R23	Under Coverage Indications, Limitations and/or Medical Necessity added hyperlinks for FDA indications. Under Bibliography added citations and hyperlinks for FDA indications and changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the LCD. Acronyms were inserted where appropriate throughout the LCD. The registered mark was inserted where applicable throughout the LCD. <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</i>	<ul style="list-style-type: none">• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p><i>the LCD are applicable as noted in this policy.</i></p>	
10/10/2019	R22	<p>This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs. There has been no change in coverage with this LCD revision. Title XVIII of the Social Security Act, §1833(e) was removed from the CMS National Coverage Policy section of this LCD and placed in the related Billing and Coding: Chemodenervation A56646 article.</p> <p><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"> • Provider Education/Guidance
07/04/2019	R21	<p>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.</p> <p><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"> • Provider Education/Guidance
10/01/2018	R20	<p>Under ICD-10 Codes that Support Medical Necessity Group: 3 Paragraph added HCPCS code J0588. This revision is due to a reconsideration request.</p> <p>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.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>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.</p>	
07/09/2018	R19	<p>Under Coverage Indications, Limitations and/or Medical Necessity deleted the verbiage " Onabotulinumtoxin A (Botox®) is the only botulinum toxin that is FDA approved for lower limb spasticity in adults".</p> <p>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.</p>	<ul style="list-style-type: none"> • Reconsideration Request
03/15/2018	R18	<p>Under CMS National Coverage Policy deleted the "s" from the cited Internet-Only Manual references X2. Throughout the LCD punctuation was corrected. Under Coverage Indications, Limitations and/or Medical Necessity #7 corrected the spelling of splenius. Throughout the LCD punctuation was corrected. Under Bibliography author initials were added to the author name WJ Binder and the spelling of the author name Heckmann was corrected.</p> <p><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"> • Provider Education/Guidance • Typographical Error • Other
02/26/2018	R17	<p>The Jurisdiction "J" 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.</p>	<ul style="list-style-type: none"> • Change in Affiliated Contract Numbers

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2017	R16	<p>Under ICD-10 Codes that Support Medical Necessity Group 2: Codes added ICD-10 codes G12.23, G12.24 and G12.25. These revisions are due to the 2017 Annual ICD-10 Updates.</p> <p>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.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
07/07/2017	R15	<p>Under ICD-10 Codes That Support Medical Necessity Group 8: Paragraph added the * Note related to CPT code 64653. Under ICD-10 Codes That Support Medical Necessity Group 8: Codes added ICD 10 codes H04.211, H04.212, H04.213 and L74.52. Under Sources of Information and Basis for Decision added Keegan DJ, Geerling G, Lee JP, Blake G, Collin JR, Plant GT. Botulinum toxin treatment for hyperlacrimation secondary to aberrant regenerated seventh nerve palsy or salivary gland transplantation. <i>Br J Ophthalmol.</i> 2002;86(1):43-46.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Reconsideration Request
06/26/2017	R14	<p>Under Coverage Indications, Limitations and/or Medical Necessity-Indication 9 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 CPT/HCPCS Codes Group 1: Paragraph 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 Group 1: Codes added CPT codes 64653 and 64999. Under Group 8: Paragraph added CPT codes 64653 and 64999 and added the verbiage "*64999 to billed only with L74.512 and L74.513 with chemodenervation".</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Reconsideration Request
03/07/2017	R13	<p>Under Coverage Indications, Limitations and/or Medical Necessity bullet 8, Note and Limitations bullet 4</p>	<ul style="list-style-type: none"> • Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		corrected 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)".	
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) .	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
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, J0586, J0587, J0588 and Group 1: Codes including ICD-10 code K22.0.	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes • Revisions Due To ICD-10-CM Code Changes
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.	<ul style="list-style-type: none"> • Provider Education/Guidance • Public Education/Guidance • Typographical Error • 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, 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Provider Education/Guidance • Other (Maintenance Annual Validation)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
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.	<ul style="list-style-type: none"> • Provider Education/Guidance • Automated Edits to Enforce Reasonable & Necessary Requirements • Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R3	Under CPT/HCPCS Codes section descriptor changes were made to CPT Codes 64644, 64645 and 64647, effective 7/1/2014.	<ul style="list-style-type: none"> • Provider Education/Guidance • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Other (Provider questioning 64611 and 64615 usage in LCD.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A55428 - \(MCD Archive Site\)](#)

[A56646 - Billing and Coding: Chemodenervation](#)

LCDs

[DL33458 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
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Keywords

- Chemodenervation