Local Coverage Determination (LCD): Category III Codes (L35490)

**Contractor Information**

Contractor Name
Wisconsin Physicians Service Insurance Corporation

**LCD Information**

**Document Information**

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>Original Effective Date</th>
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<tr>
<td>L35490</td>
<td>For services performed on or after 10/01/2015</td>
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<thead>
<tr>
<th>Original ICD-9 LCD ID</th>
<th>Revision Effective Date</th>
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<tr>
<td>N/A</td>
<td>For services performed on or after 10/01/2015</td>
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<table>
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<tr>
<th>Notice Period Start Date</th>
<th>Notice Period End Date</th>
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<tbody>
<tr>
<td>01/01/2015</td>
<td>02/15/2015</td>
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CMS National Coverage Policy
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) (1) (D) refers to limitations on items or devices that are investigational or experimental.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 14- Medical Devices, Section 10, Coverage of Medical Devices.

CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 23- Fee Schedule Administration and Coding Requirements, Section 30 Services paid under the Medicare Physicians Fee Schedule.

CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Sect.5.1 Reasonable and necessary provisions in LCDs & 7.1 Evidence supporting LCDs.

CMS Publication 100-03 Medicare National Coverage Determinations Manual Chapter 1, part 2, Section 150.13 Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS).


CMS Publication 100-04 Claims Processing Manual chapter 32, section 330 Billing
Requirements for Special Services, *Transmittal 2959, and CR8757.*

Coverage Guidance

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

The American Medical Association (AMA) develops temporary Current Procedural Terminology (CPT) Category III codes to track the utilization of emerging technologies, services, and procedures. The CATEGORY III CPT Code description does not establish a service or procedure as safe, effective or applicable to the clinical practice of medicine.

1. The creation of a CPT Category III code by the AMA "neither implies nor endorses clinical efficacy, safety or the applicability to clinical practice."
2. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The available published evidence must be considered and its quality shall be evaluated before a conclusion is reached.

**Indications and Limitations:**

Section 1862(a)(1)(A) of the Social Security Act (SSA) is the statutory basis for denying payment for types of care, items, services, and procedures, not excluded by any other statutory clause while meeting all technical requirements for coverage, that are determined to be any of the following:

1. Not generally accepted by the medical community as safe and effective in the setting and for the condition for which it is used;
2. Not proven safe and effective based on peer review or scientific literature;
3. Experimental;
4. Not medically necessary for a particular patient;
5. Furnished at a level, duration, or frequency that is not medically appropriate;
6. Not furnished in accordance with accepted standards of medical practice; or
7. Not furnished in a setting appropriate to the patient’s medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

1. Consistent with the symptoms of diagnosis of the illness or injury under treatment; **and**
2. Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental) **and**
3. Not furnished primarily for the convenience of the patient, the provider or supplier; **and**
4. Furnished at the most appropriate level of care that can be provided safely and effectively to the patient.
Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational and are not considered reasonable and necessary under SSA 1862(a)(1)(A). Medicare payment, therefore, may not be made for procedures performed using devices that have not been approved for marketing by the FDA unless performed within the context of a clinical trial qualifying under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) or in approved FDA Investigational Device Exemption (IDE) trial.

FDA designation/determination of a device as 510(k) mean(s) that the device has been approved for marketing by the FDA because it is similar to something already on the market that was "grandfathered in" by the FDA and therefore these devices are eligible for coverage.

In addition, items, services, or devices may also be not covered under SSA 1862 (a) (1) (D) (E) or (O).

If a provider believes that any Category III code not included in this LCD qualifies for coverage (is proven to be safe and effective as well as reasonable and necessary), that provider may request inclusion of the Category III code in this LCD through the LCD Reconsideration Process. Peer reviewed scientific evidence is required for consideration.

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**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.

N/A

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.
CPT/HCPCS Codes

**Group 1 Paragraph:** The following lists Category III services determined by WPS Medicare to be reasonable and medically necessary. Coverage will only be allowed when the service is delivered in clinical situations meeting medical necessity. For services addressed in a separate LCD all criteria addressed in that LCD must be met

**Group 1 Codes:**

- TRANSCATHETER PLACEMENT OF EXTRACRANIAL VERTEBRAL ARTERY STENT(S), INCLUDING RADIOLOGIC SUPERVISION AND INTERPRETATION, OPEN OR PERCUTANEOUS; INITIAL VESSEL
- TRANSCATHETER PLACEMENT OF EXTRACRANIAL VERTEBRAL ARTERY STENT(S), INCLUDING RADIOLOGIC SUPERVISION AND INTERPRETATION, OPEN OR PERCUTANEOUS; EACH ADDITIONAL VESSEL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
- IMPLANTATION OF INTRASTROMAL CORNEAL RING SEGMENTS
- HIGH DOSE RATE ELECTRONIC BRACHYTHERAPY, PER FRACTION
- EXCISION OF RECTAL TUMOR, TRANSANAL ENDOSCOPIC MICROSURGICAL
- APPROACH (IE, TEMS), INCLUDING MUSCULARIS PROPRIA (IE, FULL THICKNESS)
- INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE TRABECULAR MESHWORK; INITIAL INSERTION
- EXTERNAL ELECTROCARDIOGRAPHIC RECORDING FOR MORE THAN 48 HOURS UP TO 21 DAYS BY CONTINUOUS RHYTHM RECORDING AND STORAGE; INCLUDES RECORDING, SCANNING ANALYSIS WITH REPORT, REVIEW AND INTERPRETATION
- EXTERNAL ELECTROCARDIOGRAPHIC RECORDING FOR MORE THAN 48 HOURS UP TO 21 DAYS BY CONTINUOUS RHYTHM RECORDING AND STORAGE; RECORDING (INCLUDES CONNECTION AND INITIAL RECORDING)
- EXTERNAL ELECTROCARDIOGRAPHIC RECORDING FOR MORE THAN 48 HOURS UP TO 21 DAYS BY CONTINUOUS RHYTHM RECORDING AND STORAGE; SCANNING ANALYSIS WITH REPORT
- EXTERNAL ELECTROCARDIOGRAPHIC RECORDING FOR MORE THAN 48 HOURS UP TO 21 DAYS BY CONTINUOUS RHYTHM RECORDING AND STORAGE; REVIEW AND INTERPRETATION
- INSERTION OF OCULAR TELESCOPE PROSTHESIS INCLUDING REMOVAL OF CRYSTALLINE LENS
- INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE TRABECULAR MESHWORK; EACH ADDITIONAL DEVICE INSERTION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
**Group 2 Paragraph:** Coverage for this device will be allowed for FDA approved indications. Payment for 0171T and 0172T will be an inclusive payment. No additional code for approach or hardware placement should be billed or paid.

**Group 2 Codes:**

INSERTION OF POSTERIOR SPINOUS PROCESS DISTRACTION DEVICE
0171T (INCLUDING NECESSARY REMOVAL OF BONE OR LIGAMENT FOR INSERTION AND IMAGING GUIDANCE), LUMBAR; SINGLE LEVEL
INSERTION OF POSTERIOR SPINOUS PROCESS DISTRACTION DEVICE
0172T (INCLUDING NECESSARY REMOVAL OF BONE OR LIGAMENT FOR INSERTION AND IMAGING GUIDANCE), LUMBAR; EACH ADDITIONAL LEVEL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

**Group 3 Paragraph:** For claims with dates of service on or after January 9, 2014, PILD, procedure code 0275T, is a covered service only when billed as part of a clinical trial approved by CMS per NCD-167.

**Group 3 Codes:**

PERCUTANEOUS LAMINOTOMY/LAMINECTOMY (INTERLAMINAR APPROACH) FOR DECOMPRESSION OF NEURAL ELEMENTS, (WITH OR WITHOUT LIGAMENTOUS RESECTION, DISCECTOMY, FACETECTOMY 0275T AND/OR FORAMINOTOMY), ANY METHOD, UNDER INDIRECT IMAGE GUIDANCE (EG, FLUOROSCOPIC, CT), WITH OR WITHOUT THE USE OF AN ENDOSCOPE, SINGLE OR MULTIPLE LEVELS, UNILATERAL OR BILATERAL; LUMBAR

**ICD-10 Codes that Support Medical Necessity**

**Group 1 Paragraph:** The following ICD-10 Codes apply to CPT code 0191T and 0376T to support medical necessity.

**Group 1 Codes**

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>H40.1211</td>
<td>Low-tension glaucoma, right eye, mild stage</td>
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<tr>
<td>H40.1212</td>
<td>Low-tension glaucoma, right eye, moderate stage</td>
</tr>
<tr>
<td>H40.1221</td>
<td>Low-tension glaucoma, left eye, mild stage</td>
</tr>
<tr>
<td>H40.1222</td>
<td>Low-tension glaucoma, left eye, moderate stage</td>
</tr>
<tr>
<td>H40.1231</td>
<td>Low-tension glaucoma, bilateral, mild stage</td>
</tr>
</tbody>
</table>
H40.1232  Low-tension glaucoma, bilateral, moderate stage
H40.1311  Pigmentary glaucoma, right eye, mild stage
H40.1312  Pigmentary glaucoma, right eye, moderate stage
H40.1321  Pigmentary glaucoma, left eye, mild stage
H40.1322  Pigmentary glaucoma, left eye, moderate stage
H40.1331  Pigmentary glaucoma, bilateral, mild stage
H40.1332  Pigmentary glaucoma, bilateral, moderate stage
H40.1411  Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412  Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1421  Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422  Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1431  Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432  Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage

Showing 1 to 18 of 18 entries in Group 1

**Group 2 Paragraph:** The following ICD-10 Codes are used to support medical necessity with CPT code 0275T.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>M48.05</td>
<td>Spinal stenosis, thoracolumbar region</td>
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<tr>
<td>M48.06</td>
<td>Spinal stenosis, lumbar region</td>
</tr>
<tr>
<td>M48.07</td>
<td>Spinal stenosis, lumbosacral region</td>
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<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
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Showing 1 to 4 of 4 entries in Group 2

ICD-10 Codes that DO NOT Support Medical Necessity

**Group 1 Paragraph:** NA

**Group 1 Codes:** NA

Additional ICD-10 Information

N/A
General Information

1. The patient's medical record must contain documentation that fully supports the medical necessity for services or procedures described by Category III CPT Codes as they are covered by Medicare. (See section entitled Indications and Limitations of Coverage). This documentation includes, but is not limited to, relevant medical history, physical examination, results of pertinent diagnostic tests or procedures, and any other records that describe or support the evaluation and treatment of the patient.

2. All claims containing any Category III code referenced in this LCD may be subject to review and denial if documentation is incomplete and does not support reasonable and necessary indications.

3. All claims containing a Category III code not included in the list of CPT/HCPCS codes described in this LCD or another WPS Medicare document supporting coverage will be automatically denied as investigational.

Utilization Guidelines

Some of the category III codes discussed in this policy may be listed in a separate WPS Medicare LCD. In those situations, the name of the policy is provided in the table below and that LCD should be referenced for necessary coverage criteria.

0075T, 0076T Services described by CPT codes 0075T and 0076T are allowed when provided in accordance with NCD 20.7, Percutaneous Transluminal Angioplasty. Refer to CMS publication 100-03, Medicare National Determinations Manual, Chapter 1, Part 1, § 20.7. Billing instructions are listed in the CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 32, Sections 160-160.3. As directed in The CPT, use 0076T in conjunction with 0075T.

0099T Intrastromal corneal ring segments are considered medically necessary for reduction or elimination of myopia or astigmatism in persons with keratoconus or pellucid marginal degeneration who are no longer able to achieve adequate vision using contact lenses or spectacles and for whom corneal transplant is the only remaining option.

0171T, 0172T CMS determined that spinous process distraction device met criteria for
substantial clinical improvement and approved new technology add-on payment beginning fiscal year 2007. Coverage for this device will be allowed for FDA-approved indications. Payment for 0171T and 0172T will be an inclusive payment. No additional code for approach or hardware placement should be billed or paid.

0182T CPT code 0182T is the appropriate code for services provided for electronic brachytherapy. It is reimbursable with documentation of medical necessity.

0184T The National Comprehensive Cancer Network (NCCN) guideline on treatment of rectal cancer states that, when criteria for transanal resection are met, transanal endoscopic microsurgery (TEMS) can be used when the tumor can be adequately identified in the rectum. It further states that TEMS for more proximal lesions (greater than 8 cm from anal verge) may be technically feasible.

0191T An anterior segment aqueous drainage device, utilizing the internal approach, for use in combination with cataract surgery to reduce pressure inside the eye (intraocular pressure) in adult patients with mild or moderate open-angle glaucoma on medication. Medicare payment for glaucoma drainage device is included in the facility reimbursement for 0191T. On UB-04 claims, use revenue code 278 to report the glaucoma drainage device.

0275T This is a procedure proposed as a treatment for symptomatic Lumbar Spinal Stenosis (LSS) unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epiduragram. Effective for claims with dates of service on or after January 9, 2014, Percutaneous Image-Guided Lumbar Decompression (PILD) is covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study and meets the criteria listed in NCD-167.

0295T- 0298T An external electrocardiographic recording for more than 48 hours and up to 21 days. CPT/HCPCS codes 0295T, 0296T 0297T and 0298T are addressed in WPS Medicare LCD entitled Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring) CV-016.

0308T Effective July 1, 2012 CPT/HCPCS code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens) is payable. Further, claims submitted by Part A providers and ambulatory surgical centers for device pass-through category C1840 must be billed with HCPCS code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens) to receive pass-through payment.

Sources of Information and Basis for Decision
This bibliography presents those sources that were obtained during the development of this policy.

2. Other Medicare Contractors.

**Contractor Advisory Committee (CAC) Meeting**

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<th>Meeting Type</th>
<th>Meeting States</th>
<th>Meeting Information</th>
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<td>10/16/2014</td>
<td>CAC Meeting</td>
<td>Iowa, Kansas, Missouri, Nebraska</td>
<td>J5 MAC</td>
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<tr>
<td>09/15/2014</td>
<td>CAC Meeting</td>
<td>Indiana, Michigan</td>
<td>J8 MAC</td>
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**Comment Period Start Date**
10/16/2014

**End Date of Comment Period**
11/29/2014

**Released to Final LCD Date**
02/15/2015

**Revision History Information**
Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

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<th>Revision History Explanation</th>
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<td>10/01/2015</td>
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<td>02/01/2015: CPT Code 0376T added to the policy as an add-on code to be used in conjunction with CPT Code 0191T.</td>
<td>• Revisions Due To CPT/HCPCS Code Changes • Other</td>
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**Associated Documents**

Attachments
Final Comments, (PDF - 7 KB )
Related Local Coverage Documents
N/A
Related National Coverage Documents
N/A
Public Version(s)
Updated on 01/21/2015 with effective dates 10/01/2015 - N/A
Updated on 12/17/2014 with effective dates 10/01/2015 - N/A