



Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)

MLN Matters Number: MM10089 **Revised**

Related Change Request (CR) Number: 10089

Related CR Release Date: July 25, 2017

Effective Date: December 7, 2016

Related CR Transmittal Number: R3811CP
and R200NCD

Implementation Date: June 27, 2017

Note: This article was revised on July 26, 2017, to reflect the revised CR10089 issued on July 25. In the article, the transmittal numbers, CR release date, implementation date, and the Web addresses for accessing the transmittals are revised. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for providers and other physicians billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10089 announces that effective for dates of service on or after December 7, 2016, Medicare will cover Percutaneous Image-guided Lumbar Decompression (PILD) under Coverage with Evidence Development (CED) for beneficiaries with Lumbar Spinal Stenosis (LSS) who are enrolled in a Centers for Medicare & Medicaid Services (CMS)-approved prospective longitudinal study. PILD procedures using an FDA-approved/cleared device that completed a CMS-approved prospective, randomized, controlled clinical trial (RCT) that met the criteria are listed in the January 2014 NCD ([CR8757](#)).

BACKGROUND

CMS currently covers PILD under the CED paradigm. PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic 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 (for example, fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram.

Section 1862(a)(1)(E) of the Social Security Act (the Act) authorizes coverage for PILD for beneficiaries with LSS under CED. On January 9, 2014, CMS posted its first NCD (150.13) covering PILD for beneficiaries with LSS when provided in a RCT meeting certain conditions under CED. Clinical studies must be designed using current validated and reliable measurement instruments and clinically appropriate comparator treatments for patients randomized to the non-PILD group.

On April 13, 2016, CMS accepted a complete formal request for a reconsideration of the NCD that limited coverage of PILD for LSS to a CMS-approved prospective RCT. After considering the related published literature and public comments as required by Section 1862(l) of the Act, CMS will expand the January 2014 NCD to cover PILD for LSS under CED through a prospective longitudinal study that meets certain criteria listed in Chapter 1, Section 150.13 of the NCD manual (Pub. 100-03). You should refer to Chapter 1, Section 310 of the NCD Manual, as well as Chapter 32, Sections 69 and 330, of the “Medicare Claims Processing Manual” (Pub. 100-04) for more information.

NOTE: As mentioned in [CR 8954](#), there are 2 distinct procedure codes that are to be used: G0276 only for clinical trials that are blinded, randomized, and controlled, and contain a placebo procedure control arm (use CR 8954 for claims processing instructions), and 0275T for **all** other approved clinical trials (use CR 8757 for claims processing instructions).

CR 10089 does not replace but rather is in addition to CR 8757 and CR 8954.

ADDITIONAL INFORMATION

You can review the list of approved clinical studies related to PILD for LSS at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD.html> on the CMS website.

The official instruction, CR10089, issued to your MAC regarding this change consists of two transmittals. The first modifies the “Medicare Claims Processing Manual” and it is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3811CP.pdf>. The second updates the NCD manual and it is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R200NCD.pdf>. The revised sections of both manuals are attached to their respective transmittals.

You may also want to review [CR 8401](#) and [CR 8954](#).

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
March 22, 2021	We replaced an article link with a related CR link.
July 26, 2017	The article was revised on July 26, 2017, to reflect the revised CR10089 issued on July 25. In the article, the transmittal numbers, CR release date, implementation date, and the Web addresses for accessing the transmittals are revised. All other information remains the same.
June 5, 2017	Initial article released.

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