CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 199	**Date: July 11, 2017**
	Change Request 10089

Transmittals 196 and 3787, dated May 26, 2017, is being rescinded and replaced by Transmittals 199 and 3805 dated, July 11, 2017 to update references in the CPM and NCD manuals and to add clarifying language. In the NCD manual, the reference to Pub 100-04, Chapter 32, and Section 68 needs to be changed to Section 69. In the CPM manual, the reference in Pub. 100-04, Chapter 32, Section 68 needs to be changed to Section 69 and clarifying language needs to be added to indicate that CMS will cover procedure code 0275T for PILD only when the procedure is performed within any other CED approved randomized and non-blinded clinical trial. All other information remains the same.

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to notify contractors that effective for dates of service on or after December 7, 2016, Medicare will cover PILD under CED for beneficiaries with LSS who are enrolled in a CMS-approved prospective longitudinal study.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: December 7, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 11, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/150.13/Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)(Various Effective Dates Below) (Rev.)

III. FUNDING:
For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 199	Date: July 11, 2017	Change Request: 10089

Transmittals 196 and 3787, dated May 26, 2017, is being rescinded and replaced by Transmittals 199 and 3805 dated, July 11, 2017 to update references in the CPM and NCD manuals and to add clarifying language. In the NCD manual, the reference to Pub 100-04, Chapter 32, and Section 68 needs to be changed to Section 69. In the CPM manual, the reference in Pub. 100-04, Chapter 32, Section 68 needs to be changed to Section 69 and clarifying language needs to be added to indicate that CMS will cover procedure code 0275T for PILD only when the procedure is performed within any other CED approved randomized and non-blinded clinical trial. All other information remains the same.

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

EFFECTIVE DATE: December 7, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 11, 2017

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) currently covers Percutaneous Image-guided Lumbar Decompression (PILD) under the Coverage with Evidence Development (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 (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

The Social Security Act, section 1862(a)(1)(E) 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 prospective, randomized, controlled clinical trial (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 which 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 Social Security Act, CMS will expand the January 2014 NCD to cover PILD for LSS under CED through a prospective longitudinal study that meet certain criteria listed in Section 150.13 of the NCD manual.

B. Policy: Effective for dates of service on or after December 7, 2016, Medicare will cover PILD under CED for beneficiaries with LSS who are enrolled in a CMS-approved prospective longitudinal study PILD procedures using an FDA-approved/cleared device that completed a CMS-approved RCT that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal # 2959, dated May 16, 2014). This is an expansion of coverage for PILD under CED, therefore the current coding and editing instructions remain unchanged.

Note: Contractors should refer to the following sources of the Medicare Claims Processing Manual as well as published transmittals for complete PILD guidance for both blinded and non-blinded clinical trials:

- Pub. 100-03, Chapter 1, section 150.13
- Pub. 100-03, Chapter 1, Section 310
- Pub. 100-04, Chapter, 32, Section 68
- Pub. 100-04, Chapter, 32, Section 330
- Transmittal 2805, CR 8401
- Transmittal 2959, CR 8757
- Transmittal 3175, CR 8954

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10089 - 03.1	Effective for claims with dates of service on and after December 07, 2016, Medicare will continue to allow coverage with evidence development (CED) for percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) for beneficiaries enrolled in an approved clinical trial that meets the criteria listed in Section 150.13 of the NCD manual. Refer to Pub 100-04, Chapter 32, section 330 in claims processing manual for detailed Business Requirements.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10089 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Tara Hall, 410-786-1000 or Tara.Hall@cms.hhs.gov (Coverage) , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims) , Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , Shauntari Cheely, 410-786-1818 or Shauntari.Cheely@cms.hhs.gov (Institutional Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1, Part 2 (Sections 90 – 160.25)
Coverage Determinations

150.13 – Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) (Various Effective Dates Below)

(Rev.199, Issued: 07- 11- 17, Effective: 12- 07-16, Implementation: 08-11-17)

A. General

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 (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

B. Nationally Covered Indications

Effective for dates of service specified below, the Centers for Medicare & Medicaid Services (CMS) has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) *of the Social Security Act (the Act)* through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study that meets the criteria *in section I or II below:*

I. *Effective for services performed on or after January 9, 2014, PILD will be covered by Medicare through CED for beneficiaries with LSS who are enrolled in an approved clinical study that meets the following criteria.* CMS has a particular interest in improved beneficiary function and quality of life, specific characteristics that identify patients who may benefit from the procedure, and the duration of benefit. A clinical study seeking Medicare payment for PILD for LSS must address one or more aspects of the following questions in a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments, including appropriate medical or surgical interventions or a sham controlled arm, for patients randomized to the non-PILD group.

The study protocol must specify a statistical analysis and a minimum length of patient follow up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of benefit.

i. Does PILD provide a clinically meaningful improvement of function and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?

ii. Does PILD provide clinically meaningful reduction in pain in Medicare beneficiaries with LSS compared to other treatments?

iii. Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services, compared to other treatments?

These studies must be designed so that the contribution of treatments in addition to the procedure under study are either controlled for or analyzed in such a way as to determine their impact.

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 Code of Federal Regulations (CFR) Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR§312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org).
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

II. Effective for services performed on or after December 7, 2016, CMS will cover through a prospective, longitudinal study PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT) that met the criteria listed in section I above.

The CMS-approved prospective, longitudinal study must answer at least one of the following questions:

i. Does PILD provide a clinically meaningful improvement of function (e.g., reduced acute and

post-acute hospitalizations, nursing home care or inpatient rehabilitation services) and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?

ii. *Does PILD provide a clinically meaningful reduction in pain (e.g., as measured by class, dose, duration of prescription pain medication use) in Medicare beneficiaries with LSS compared to other treatments?*

iii. *Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services (e.g., repeat PILD procedures, other interventions and surgical treatments), compared to other treatments?*

The prospective, longitudinal study must also meet the following criteria:

1. *The protocol must specify a statistical analysis and a minimum length of patient follow-up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of the benefit.*

2. *The eligibility requirements, both inclusion and exclusion criteria that were specified in the CMS-approved RCT protocol, must be maintained in the new prospective, longitudinal study.*

3. *All study sites and study results must be listed in the ClinicalTrials.gov database.*

All CMS-approved clinical research studies must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. *The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.*
b. *The rationale for the study is well supported by available scientific and medical evidence.*
c. *The study results are not anticipated to unjustifiably duplicate existing knowledge.*
d. *The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.*
e. *The study is sponsored by an organization or individual capable of completing it successfully.*
f. *The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the CFR at 45 CFR Part 46. If a study is regulated by the FDA, it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.*
g. *All aspects of the study are conducted according to appropriate standards of scientific integrity.*
h. *The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.*
i. *The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.*
j. *The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).*
k. *The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).*
l. *The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies,*

how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. *The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.*

Consistent with section 1142 of the Act, tAHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

All clinical research study protocols must be reviewed and approved by CMS. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below:

Director, Coverage and Analysis Group
Re: PILD CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore MD 21244-1850

Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov
Email subject line: "CED [NCD topic (i.e. PILD)] [name of sponsor/primary investigator]"

The information will be reviewed, and approved studies will be identified on the CMS website - https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html.

C. Nationally Non-Covered Indications

Effective for services performed on or after January 9, 2014, *PILD for LSS may only be covered under the context of a clinical trial as described in section B above according to section 1862(a)(1)(E) of the Social Security Act.* CMS has determined that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Act.

D. Other

Endoscopically assisted laminotomy/laminectomy, which requires open and direct visualization, as well as other open lumbar decompression procedures for LSS are not within the scope of this NCD *and coverage is at contractor discretion.*

(This NCD last reviewed December 2016.)