

Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (NCD 150.13)

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Related Medicare Advantage Policy Guidelines

- [Category III CPT Codes](#)
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Policy Summary

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Overview

Percutaneous image-guided lumbar decompression (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 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 epidurogram. The procedure that most closely falls under this description is known as the Minimally Invasive Lumbar Decompression (mild®) procedure.

Guidelines

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.

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

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

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- 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.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 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.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- 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.
- 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.
- 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>).
- 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.
- 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 Social Security 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:

- 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?

- 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?
- 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:

- 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.
- 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.
- 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:

- 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.
- The rationale for the study is well supported by available scientific and medical evidence.
- The study results are not anticipated to unjustifiably duplicate existing knowledge.
- 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.
- The study is sponsored by an organization or individual capable of completing it successfully.
- 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.
- All aspects of the study are conducted according to appropriate standards of scientific integrity.
- The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- 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.
- 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).
- 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 accessible 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).
- 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.
- 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, AHRQ 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, as well as the investigator's contact information.

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>.

Nationally Non-Covered Indications

Effective for services performed on or after January 09, 2014, PILD for LSS may only be covered under the context of a clinical trial as described 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 Social Security Act](#).

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 policy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

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HCPCS Code	Description
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Modifier	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Place of Service Code	Description
19	Off Campus-Outpatient Hospital
22	On Campus-Outpatient Hospital
24	Ambulatory surgical center

Diagnosis Code	Description
M48.05	Spinal stenosis, thoracolumbar region

Diagnosis Code	Description
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
Z00.6	Encounter for examination for normal comparison and control in clinical research program

References

CMS National Coverage Determinations (NCDs)

[NCD 150.13 Percutaneous image-guided lumbar decompression for lumbar spinal stenosis](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L35490 Category III Codes	A56902 Billing and Coding: Category III Codes	WPS	AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
L35094 Services That Are Not Reasonable and Necessary Retired 07/01/2020	A56967 Billing and Coding: Services That Are Not Reasonable and Necessary Retired 07/01/2020	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
N/A	A52375 Category III CPT® Code Coverage Retired 09/26/2019	CGS	KY, OH	KY, OH

CMS Claims Processing Manual

[Chapter 32; § 330 Percutaneous Image-guided Lumbar Decompression \(PILD\) for Lumbar Spinal Stenosis \(LSS\)](#)

CMS Transmittal(s)

[Transmittal 2955, Change Request 8401, Dated 05/14/2014 \(Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims\)](#)

[Transmittal 3805, Change Request 10089, Dated 07/11/2017 \(Percutaneous Image-guided Lumbar Decompression \(PILD\) for Lumbar Spinal Stenosis \(LSS\)\)](#)

MLN Matters

[Article MM8401, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

[Article MM10089, Percutaneous Image-guided Lumbar Decompression \(PILD\) for Lumbar Spinal Stenosis \(LSS\)](#)

UnitedHealthcare Commercial Policy

[Surgical Treatment for Spine Pain](#)

Other(s)

[Medicare Managed Care Manual Chapter 4: § 10.7 Clinical Trials, CMS Website](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
08/12/2020	Applicable Codes <ul style="list-style-type: none">Removed Bill Type codes 13X and 85X Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG237.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).