

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3805	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Transmittals 196 and 3787, dated May 26, 2017, is being rescinded and replaced by Transmittals 199 and 3805 dated, July 11, 2017 to update references in the CPM and NCD manuals and to add clarifying language.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.

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	32/Table of Contents
R	32/330.1/Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims
R	32/330.2/Claims Processing Requirements for PILD for Outpatient Facilities

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. 100-04	Transmittal: 3805	Date: July 11, 2017	Change Request: 10089
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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 epidurogram.

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			D M E M A C	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
10089 - 04.1	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 330.1 and 300.2 for updated information.	X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			D M E M A C	C E D I		
		A	B	H H H				
10089 - 04.2	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 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	X	X					

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
	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): Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage) , Tara Hall, 410-786-4347 or Tara.Hall@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage) , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims) , 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 Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev.3805, Issued: 07- 11-17)

330.1 – Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims

330.2 - Claims Processing Requirements for PILD for Outpatient Facilities

30.1 – Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims (Rev. 3805, Issued: 07- 11-17, Effective: 12- 07-16, Implementation: 08-11-17)

For claims with dates of service on or after January 9, 2014, PILD (procedure code 0275T) is a covered service when billed as part of a clinical trial approved by CMS. The description for CPT 0275T is “Percutaneous laminotomy/laminectomy (intradiscal 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”.

For claims with dates of service on or after January 1, 2015, PILD (procedure code G0276) is a covered service when billed as part of a clinical trial approved by CMS. HCPCS G0276 is “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”.

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 procedure using an FDA-approved/cleared device that completed a CMS-approved randomized, controlled clinical trial (RCT) that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal # 2959, dated May 16, 2014).

The claim may only contain one of these procedure codes, not both. To use G0276, the procedure must be performed in an approved CED clinical trial that is randomized, blinded, and contains a placebo control arm of the trial. CMS will cover procedure code 0275T for PILD only when the procedure is performed within a CED approved randomized and non-blinded clinical trial. Regardless of the type of CED approved clinical trial (e.g. G0276 vs 0275T), PILD is only covered when billed for the ICD-9 diagnosis of 724.01-724.03 or the ICD-10 diagnosis of M48.05-M48.07, when billed in places of service 22 (Outpatient) or 24 (Ambulatory Surgical Center), when billed along with V70.7 (ICD-9) or Z00.6 (ICD-10) in either the primary/secondary positions, and when billed with modifier Q0.

Additionally, per Transmittal 2805 (Change Request 8401), issued October 30, 2013, all claims for clinical trials must contain the 8 digit clinical trial identifier number.

The following message(s) shall be used to notify providers of return situations that may occur:

Professional Claims 8-digit Clinical Trial Number

For PILD claims with procedure code 0275T with dates of service on or after January 9, 2014, or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD only when billed with the numeric, 8-digit clinical trial identifier number preceded by the two alpha characters "CT" when placed in Field 19 of paper Form CMS-1500, or when entered without the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4). Claims for PILD which are billed without an 8-digit clinical trial identifier number shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return PILD claims billed without an 8-digit clinical trial identifier number as unprocessable:

Claims Adjustment Reason Code 16: "Claim/service lacks information or has submission/billing error(s) which is needed for adjudication".

Remittance Advice Remark Code N721: "This service is only covered when performed as part of a clinical trial."

Remittance Advice Remark Code MA50: "Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Professional Claims Place of Service – 22 or 24

For PILD claims with procedure code 0275T with dates of service on or after January 9, 2014, or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed in place of service 22 or 24. Claims for PILD which are billed in any other place of service shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return PILD claims not billed in place of service 22 or 24:

Claims Adjustment Reason Code 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Professional Claims Modifier – Q0

For PILD claims with procedure code 0275T with dates of service on or after January 9, 2014, or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed with modifier Q0. Claims for PILD which are billed without modifier Q0 shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return PILD claims billed without modifier Q0 as unprocessable:

Claims Adjustment Reason Code 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing."

Remittance Advice Remark Code N657: "This should be billed with the appropriate code for these services."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Non-covered Diagnosis

For PILD claims with procedure code 0275T with dates of service on or after January 9, 2014, or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed with the ICD-9 diagnosis of 724.01-724.03 or the ICD-10 diagnosis of M48.05-M48.07.

The following messages shall be used when Medicare contractors return PILD claims, billed without the covered diagnosis, as unprocessable:

Claims Adjustment Reason Code B22: "This payment is adjusted based on the diagnosis."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Clinical Trial Diagnosis

For PILD claims with procedure code 0275T with dates of service on or after January 9, 2014, or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD only when billed with the ICD-9 diagnosis of V70.7 (ICD-9) or Z00.6 (ICD-10) in either the primary or secondary positions. The following messages shall be used when Medicare contractors return PILD claims, billed without the clinical trial diagnosis, as unprocessable:

Claims Adjustment Reason Code B22: "This payment is adjusted based on the diagnosis."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

330.2 - Claims Processing Requirements for PILD for Outpatient Facilities (Rev. 3805, Issued: 07- 11-17, Effective: 12- 07-16, Implementation: 08-11-17)

Hospital Outpatient facilities shall bill for percutaneous image-guided lumbar decompression (PILD) procedure code 0275T effective on or after January 9, 2014, or procedure code G0276 effective on or after January 1, 2015, for lumbar spinal stenosis (LSS) on a 13X or 85X TOB. Refer to Section 69 of this chapter for further guidance on billing under CED.

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 procedure using an FDA-approved/cleared device that completed a CMS-approved randomized, controlled clinical trial (RCT) that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal # 2959, dated May 16, 2014).

Hospital outpatient procedures for PILD shall be covered when billed with:

- ICD-9 V70.7 (ICD-10 Z00.6) and Condition Code 30.
- Modifier Q0
- An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website

Hospital outpatient procedures for PILD shall be rejected when billed without:

- ICD-9 V70.7 (ICD-10 Z00.6) and Condition Code 30.
- Modifier Q0
- An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website

Claims billed by hospitals not participating in the trial /registry, shall be rejected with the following message:

CARC: 50 -These are non-covered services because this is not deemed a “medical necessity” by the payer.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code –Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)