

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2959	Date: May 16, 2014
	Change Request 8757

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

I. SUMMARY OF CHANGES: This Change Request (CR) purpose is effective for claims with dates of service on or after January 9, 2014, 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 the necessary criteria.

EFFECTIVE DATE: January 9, 2014

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 6, 2014

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
N	32/330/Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
N	32/330.1/Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims
N	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 obliged 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: 2959	Date: May 16, 2014	Change Request: 8757
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SUBJECT: Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)

EFFECTIVE DATE: January 9, 2014

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 6, 2014

I. GENERAL INFORMATION

A. Background: The Centers for Medicare and Medicaid Services (CMS) currently does not cover Percutaneous Image-guided Lumbar Decompression (PILD). 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

B. Policy:

After careful consideration CMS has determined that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

However, the CMS has determined that effective for claims with dates of service on or after January 9, 2014, 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 that meets the criteria below.

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.

Note: Contractors should refer to the business requirements below as well as the general clinical trial coverage information found in Pub. 100-03, Chapter 1, section 310, please also refer to CR 8401, Transmittal Code 2805, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims, Chapter 32, section 68, the specific requirements for PILD in Pub. 100-03, Chapter 1, section 150.13, and Pub. 100-04 Chapter, 32, section 330 in the Claims Processing Manual.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H		M A C	F I S S	M C S	V M S		C W F
8757 - 04.1	<p>Effective for claims with dates of service on and after January 09, 2014, when billed in a place of service 22 (outpatient) or 24(ambulatory surgical center), Medicare will only allow coverage with evidence development (CED) for percutaneous image-guided lumbar decompression (PILD) (procedure code 0275T) for lumbar spinal stenosis (LSS)</p> <ul style="list-style-type: none"> • ICD-9 diagnosis range 724.01-724.03 or • ICD-10 diagnosis range M48.05-M48.07) <p>Only when billed with:</p> <ul style="list-style-type: none"> • Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) either in the primary/secondary positions • Modifier Q0 • An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website 		X				X				
8757 - 04.2	<p>Contractors shall return the PILD claim as unprocessable when billed with a diagnosis code other than</p> <ul style="list-style-type: none"> • 724.01-724.03 (ICD-9) or • M48.05-M48.07 (ICD-10). <p>CARC B22: "This payment is adjusted based on the diagnosis."</p> <p>RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."</p> <p>Group Code-Contractual Obligation (CO).</p>		X				X				
8757 - 04.2.1	Contractors shall return a PILD claim as		X								

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	
	<p>unprocessable when billed in a place of service other than 22 (outpatient) or 24 (ambulatory surgical center).</p> <p>CARC 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."</p> <p>RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."</p> <p>Group Code-Contractual Obligation (CO).</p>									
8757 - 04.2.2	<p>Contractors shall return the PILD claim as unprocessable if it does not contain the required clinical trial diagnosis code V70.7 (ICD-9) or Z00.6 (ICD-10) in either the primary/secondary positions.</p> <p>CARC B22: "This payment is adjusted based on the diagnosis."</p> <p>RARC M76: "Missing/incomplete/invalid diagnosis or condition"</p> <p>RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."</p> <p>Group Code-Contractual Obligation (CO).</p>		X				X			
8757 - 04.2.3	<p>Contractors shall return the PILD claim as unprocessable when billed without a Q0</p> <p>CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing."</p> <p>RARC N657: "This should be billed with the appropriate code for these services."</p> <p>RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."</p> <p>Group Code-Contractual Obligation (CO).</p>		X				X			

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	
8757 - 04.3	Contractors shall accept the numeric, 8-digit clinical trial identifier number preceded by the two alpha characters of “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). NOTE: The “CT” prefix is required on a paper claim, but it is not required on an electronic claim.		X							
8757 - 04.3.1	For PILD claims submitted without a clinical trial identifier number, contractors shall follow the requirements outlined in CR8401, business requirement 5.1.		X							
8757 - 04.4	Effective for hospital outpatient procedures on type of bill (TOB) 13X or 85X, on or after January 9, 2014, Contractors shall allow payment for PILD, procedure code 0275T for lumbar spinal stenosis (LSS) <ul style="list-style-type: none"> • ICD-9 diagnosis range 724.01-724.03; or • ICD-10 diagnosis range M48.05-M48.07 Only when billed with: <ul style="list-style-type: none"> • Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) and condition code 30 either in the primary/secondary positions • Modifier Q0 • An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website 	X				X				
8757 - 04.5	Effective for hospital outpatient procedures on type of bill (TOB) 13X or 85X, on or after January 9, 2014, Contractors shall reject claims for PILD, procedure code 0275T for lumbar spinal stenosis (LSS) <ul style="list-style-type: none"> • ICD-9 diagnosis range 724.01-724.03; or 	X				X				

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	
	<ul style="list-style-type: none"> ICD-10 diagnosis range M48.05-M48.07 <p>When billed without:</p> <ul style="list-style-type: none"> Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) and condition code 30 either in the primary/secondary positions. Modifier Q0 An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website <p>CARC: 50 -These are non-covered services because this is not deemed a “medical necessity” by the payer.</p> <p>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.</p> <p>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.</p> <p>Group Code – Contractual Obligation (CO)</p> <p>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.)</p>									
8757 - 04.6	For PILD claims with dates of service on or after January 9, 2014, contractors shall not search their files. However, contractors shall adjust claims brought to their attention.	X	X							
8757 - 04.7	Contractors shall be advised that this transmittal will not be updated after the implementation of ICD-10.	X	X							

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	

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			
8757 - 04.8	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 one week of the availability of the provider education 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.	X	X				

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
8757-04.3.1	See CR8401, BR 8401.5.1

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

V. CONTACTS

Pre-Implementation Contact(s): Deirdre O'Connor, 410-786-3263 or Deirdre.oconnor@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage) , Brian Reitz, 410-786-5001 or

Brian.Reitz@cms.hhs.gov (Part B) , Shauntari Cheely, 410-786-1818 or Shauntari.Cheely@cms.hhs.gov (Part A) , Cynthia Thomas, 410-786-8169 or cynthia.thomas@cms.hhs.gov (Part A)

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.2959, Issued: 05-16-14)

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

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

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

(Rev. 2959, Issued: 05-16-14, Effective: 01- 09-14, Implementation: 10-06-14)

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. For complete Medical coverage guidelines, see National Coverage Determinations (NCD) Manual (Pub 100-03) § 150.13

330.1 – Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims **(Rev. 2959, Issued: 05-16-14, Effective: 01- 09-14, Implementation: 10-06-14)**

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, 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 claims with dates of service on or after January 9, 2014, 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 claims with dates of service on or after January 9, 2014, contractors shall pay for PILD 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 claims with dates of service on or after January 9, 2014, contractors shall pay for PILD 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 claims with dates of service on or after January 9, 2014, contractors shall pay for PILD 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 claims with dates of service on or after January 9, 2014, 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. 2959, Issued: 05-16-14, Effective: 01- 09-14, Implementation: 10-06-14)

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

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.)