CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3175	**Date: January 30, 2015**
	Change Request 8954

SUBJECT: Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)-Blinded Clinical Trial – Follow-Up CR to Implement a Second Claims Processing Procedure Code

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide direction as a follow-up to CR8757, Transmittal 2959, dated May 16, 2014. This CR provides additional direction specifically for a new PILD, procedure code when performed in a randomized, blinded clinical trial ONLY, for claims with dates of service on or after January 1, 2015.

EFFECTIVE DATE: January 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 2, 2015 - For Local System edits; July 6, 2015 - For Shared Shared Systems edits

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	32/330.1/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 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: 3175	Date: January 30, 2015	Change Request: 8954

SUBJECT: Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)-Blinded Clinical Trial – Follow-Up CR to Implement a Second Claims Processing Procedure Code

EFFECTIVE DATE: January 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 2, 2015 - For Local System edits; July 6, 2015 - For Shared Systems edits

I. GENERAL INFORMATION

A. Background:

Transmittal 2959, Change Request (CR) 8757, issued on May 16, 2014, provided coverage for percutaneous image-guided lumbar decompression (PILD) when provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) for beneficiaries with lumbar spinal stenosis (LSS) effective January 9, 2014. This coverage applies to beneficiaries who are enrolled in an approved clinical study that meets the following criteria: the clinical trial 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.

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

B. Policy: CR 8954 provides additional direction specifically for PILD, procedure code G0276, when performed in a randomized, blinded clinical trial ONLY, for claims with dates of service on or after January 1, 2015. HCPCS 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, is to be used ***only*** when the CED PILD trial is blinded, randomized, and controlled and contains a placebo procedure control arm. It appears in the January 2015 updates of the Medicare Physician Fee Schedule Database and the IOCE.

NOTE: Payment for HCPCS G0276 under the hospital OPPS can be found in the latest OPPS Addendum B, which can viewed from this CMS website: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html

NOTE: ALL PILD for LSS claims with dates of service December 31, 2014, and earlier, should be processed with procedure code 0275T ONLY and are not subject to reprocessing regardless of the type of

trial in which the services were rendered.

NOTE: Beginning with PILD for LSS claims with dates of service on and after January 1, 2015, there are 2 distinct procedure codes that are to be used: G0276 for clinical trials that are blinded, randomized, and controlled, and contain a placebo procedure control arm (use this CR 8954 for claims processing instructions), and 0275T for all other clinical trials (use CR 8757 for claims processing instructions).

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	
8954.1	Contractors shall recognize HCPCS procedure G0276 for PILD for LSS claims received with dates of service on and after January 1, 2015, when those services are provided in a blinded, randomized, controlled trial with a placebo procedure control arm under CED only.	X	X							IOCE
8954.2	Effective for PILD for LSS claims as specified in 8954.1, with dates of service on and after January 1, 2015, when billed in a place of service 22 (outpatient) or 24 (ambulatory surgical center), use HCPCS G0276, along with: • ICD-9 diagnosis range 724.01-724.03, or, • ICD-10 diagnosis range M48.05-M48.07 (when ICD-10 is implemented) Only when billed with: • Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) (once ICD-10 is implemented) either in the primary/secondary positions • Modifier -Q0 • An 8-digit clinical trial identifier number listed on the CMS CED Website.		X				X			
8954.2.1	Contractors shall return PILD for LSS claims, HCPCS G0276, as unprocessable when billed with a diagnosis code other than: 724.01-724.03 (ICD-9), or, M48.05-M48.07 (ICD-10) (when ICD-10 is implemented) With the following:		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Claim adjustment reason code (CARC) B22: “This payment is adjusted based on the diagnosis.” Remittance advice remark code (RARC) N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted." Group Code-Contractual Obligation (CO)									
8954.2.2	Contractors shall return PILD for LSS claims, HCPCS G0276, as unprocessable when billed in a place of service other than 22 (outpatient) or 24 (ambulatory surgical center). CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.” RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted." Group Code-Contractual Obligation (CO).		X							
8954.2.3	Contractors shall return PILD for LSS claims, HCPCS G0276, as unprocessable if they do not contain the required clinical trial diagnosis code V70.7 (ICD-9) or Z00.6 (ICD-10) (once ICD-10 is implemented) in either the primary/secondary positions with the following: CARC B22: “This payment is adjusted based on the diagnosis.” RARC M76: “Missing/incomplete/invalid diagnosis or condition” RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted." Group Code- CO		X				X			
8954.2.4	Contractors shall return PILD for LSS claims, HCPCS G0276, as unprocessable when billed without a -Q0 modifier with the following: CARC 4: “The procedure code is inconsistent with the		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	modifier used or a required modifier is missing." RARC N657: "This should be billed with the appropriate code for these services." RARC N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted." Group Code - CO									
8954.2.5	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							
8954.3	Effective for hospital outpatient procedures on type of bill (TOB)13X or 85X, on or after January 1, 2015, contractors shall allow payment for PILD for LSS, HCPCS G0276, along with: • ICD-9 diagnosis range 724.01-724.03; or, • ICD-10 diagnosis range M48.05-M48.07 (once ICD-10 is implemented) Only when billed with: • Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) (once ICD-10 is implemented) and condition code 30 either in the primary/secondary positions • Modifier -Q0 • An 8-digit clinical trial identifier number listed on the CMS CED Website	X				X				
8954.3.1	Effective for hospital outpatient procedures on TOB 13X or 85X, on or after January 1, 2015, contractors shall line-level deny claims for PILD for LSS, HCPCS G0276, along with:	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	ICD-9 diagnosis range 724.01-724.03; or, ICD-10 diagnosis range M48.05-M48.07 (once ICD-10 is implemented) When billed without: Diagnosis code ICD-9 V70.7 (ICD-10 Z00.6) (once ICD-10 is implemented) and condition code 30 either in the primary/secondary positions Modifier -Q0 An 8-digit clinical trial identifier number listed on the CMS CED Website, with the following: 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 –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.)									
8954.4	For PILD for LSS claims, HCPCS G0276, with dates of service on or after January 1, 2015, contractors shall not search their files. However, contractors shall adjust claims brought to their attention that may have processed in error.	X	X							
8954.5	Contractors shall be advised that this transmittal will not be updated after the implementation of ICD-10.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8954.6	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:
8954.2.5	Contractors shall follow the requirements outlined in CR8401, business requirement 5.1.

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

V. CONTACTS

Pre-Implementation Contact(s): Stuart Caplan, 410-786-8564 or stuart.caplan@cms.hhs.gov (Coverage) , JoAnna Baldwin, 410-786-7205 or joanna.baldwin@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) , 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)

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

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

(Rev.3175, Issued: 01-30-15, Effective: 01-01-15, Implementation: 03-02-15, For Local System edits; July 6, 2015- For Shared Systems edits)

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 (intralaminar 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".

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.3175, Issued: 01-30-15, Effective: 01-01-15, Implementation: 03-02-15, For Local System edits; July 6, 2015- For Shared Systems edits)

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.

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.)