Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INAPPROPRIATE MEDICARE PAYMENTS FOR TRANSFORAMINAL EPIDURAL INJECTION SERVICES

Daniel R. Levinson
Inspector General

August 2010
OEI-05-09-00030

EXECUTIVE SUMMARY

OBJECTIVE

1. To determine the extent to which Medicare Part B payments for transforaminal epidural injections met Medicare requirements.
2. To determine what safeguards existed to ensure Medicare Part B payments for transforaminal epidural injections met Medicare requirements.

BACKGROUND

Medicare Part B physician payments for transforaminal epidural injections increased from $57 million in 2003 to $141 million to 2007. This represents an increase of almost 150 percent.

Transforaminal epidural injections are a type of interventional pain management technique used to diagnose or treat pain. Transforaminal epidural injections may be used to treat pain that starts in the back and radiates down the leg, such as that from a herniated disc pressing on a nerve. Two primary codes, 64479 and 64483, are used to bill a single injection in the cervical/thoracic or lumbar/sacral areas of the spine, respectively. Each primary code has an associated add-on code for use when injections are provided at multiple spinal levels.

Medicare Part B contractors are responsible for implementing program safeguards to reduce payment error. To safeguard payments, contractors may create local coverage determinations (LCD), implement electronic edits (hereinafter referred to as edits), or conduct medical review.

We conducted a medical record review of a stratified random sample of 433 transforaminal epidural injection services performed in 2007. In addition, we reviewed documents and conducted structured interviews with contractor staff about program safeguards for transforaminal epidural injections.

FINDINGS

Thirty-four percent of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements, resulting in approximately $45 million in improper payments.

Medicare allowed an additional $23 million in improper facility payments associated with physician services in error. Nineteen percent of transforaminal epidural injection services had a documentation error.

Documentation errors were more likely to occur in office settings. Thirteen percent of transforaminal epidural injection services had a medical necessity error. Eight percent had a coding error. Seven percent had an overlapping error.

In 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards. Nine of the fourteen contractors had an LCD for transforaminal epidural injections. However, only one contractor enforced all LCD requirements through edits.

No contractor staff reported performing a medical review.

RECOMMENDATIONS

Based on the results of our review, the Centers for Medicare & Medicaid Services (CMS) should:

Conduct provider education, directly and through contractors, about proper documentation.

Strengthen program safeguards to prevent improper payment for transforaminal epidural injection services. To improve program safeguards, CMS could encourage contractors to examine transforaminal epidural injection services provided in offices. CMS could also encourage contractors to develop LCDs for transforaminal epidural injections and develop additional edits enforcing LCD requirements. Finally, CMS could encourage contractors to use medical review to identify improper payments for transforaminal epidural injection services.

Take appropriate action regarding the undocumented, medically unnecessary, and miscoded services identified in our sample. We will forward information on these services to CMS under separate cover.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations and outlined steps to improve its oversight of payments for transforaminal epidural injection services. We did not make any changes to the report based on CMS's comments.

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INTRODUCTION

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2. To determine what safeguards existed to ensure Medicare Part B payments for transforaminal epidural injections met Medicare requirements.

BACKGROUND

Chronic pain affects more adults in the United States than diabetes, heart disease, and cancer combined.[1] Several organizations, including the Department of Veterans Affairs and the Joint Commission, have recommended that physicians routinely assess pain in their patients. Treatment varies depending on the type of pain and can range from noninvasive to invasive, or interventional, techniques.[2]

Medicare paid over $2 billion in 2007 for interventional pain management services.[3] Examples of interventional pain management services include injections, nerve blocks, and spinal cord stimulation.

From 2003 to 2007, Medicare physician payments for transforaminal epidural injections, a type of interventional pain management service, increased by almost 150 percent.[4] Physician payments for transforaminal epidural injections increased from $57 million in 2003 to $141 million in 2007.[5] These payments represent approximately 11 percent of all Medicare physician payments for interventional pain management services.[6]

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[1] American Pain Foundation, *Pain Facts & Figures,* July 8, 2009. Accessed at http://www.painfoundation.org/ on February 1, 2010.

[2] Noninvasive pain management techniques may include physical therapy; invasive, or interventional, techniques may include injections near the source of pain.

[3] Estimate based on Office of Inspector General (OIG) analysis of physician claims for interventional pain management procedure codes in a 1-percent sample of the 2007 National Claims History (NCH) outpatient and physician/supplier file.

[4] Estimate based on OIG analysis of physician claims for transforaminal epidural injection procedure codes in the following Medicare claims files: (1) 2003 1-percent sample of NCH physician/supplier file and (2) 2007 100-percent NCH physician/supplier file.

[5] Ibid.

[6] Estimate based on OIG analysis of physician claims in the following Medicare claims files: (1) 2007 100-percent NCH physician/supplier file and (2) 1-percent sample of the 2007 NCH physician/supplier file.

The number of Medicare physician claims for transforaminal epidural injection services increased by 130 percent from 2003 to 2007.[7] Over 295,000 Medicare beneficiaries received transforaminal epidural injection services in 2007.[8]

In addition, a number of investigations by OIG and the Federal Bureau of Investigation (FBI) have found fraudulent activity related to transforaminal epidural injections. In one joint OIG-FBI case, an Ohio physician was convicted of multiple counts of health care fraud for fraudulent interventional pain management procedures, including transforaminal epidural injections.[9] In a separate case in 2008, a Maryland physician pled guilty to health care fraud after submitting $1.75 million in false claims to Medicare and other insurers. The false claims were for transforaminal epidural injections and other interventional pain management services.[10]

Transforaminal Epidural Injections

Transforaminal epidural injections may be used to treat back and leg pain, including pain that starts from the back and radiates down the leg, such as that from a herniated disc pressing on a nerve. For some patients with chronic pain, transforaminal epidural injections of medication into the back help to reduce inflammation and relieve pain.

A transforaminal epidural injection is given through the foramen (plural "foramina") of the spinal column. The foramen is an opening in a vertebra where the spinal cord nerve roots exit the spine. The spinal column includes 24 levels of movable vertebrae that are divided, from top to bottom, into cervical, thoracic, and lumbar regions.[11] Each level of vertebrae has a pair of foramina, one on the left side and one on the right side.[12]

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[7] Estimate based on OIG analysis of physician claims for transforaminal epidural injection procedure codes in the following Medicare claims files: (1) 2003 1-percent sample of NCH physician/supplier file and (2) 2007 100-percent NCH physician/supplier file.

[8] Based on OIG analysis of physician claims for transforaminal epidural injection procedure codes in the 2007 100-percent NCH Medicare Part B physician/supplier file.

[9] U.S. Department of Justice, U.S. Attorney's Office, Northern District of Ohio, *Press Release,* June 9, 2006. Accessed at http://www.usdoj.gov/ on November 24, 2009.

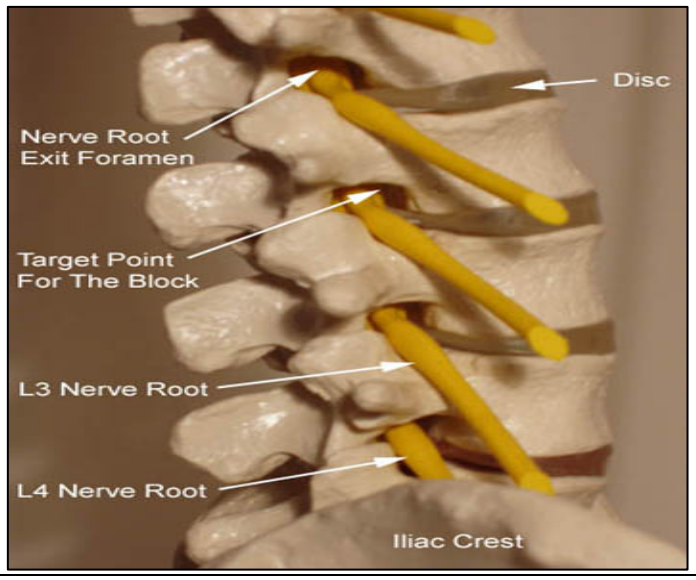
[10] Sara Taylor, *Doctor with Waldorf office guilty of fraud,* Southern Maryland Newspapers Online, February 27, 2008. Accessed at http://www.somdnews.com/ on June 12, 2009.

[11] Henry Gray, *Anatomy of the Human Body*, II.,3. Accessed at http://www.bartleby.com on July 28, 2010.

[12] Ibid.

During a transforaminal epidural injection, the physician injects medication through the foramen close to the affected nerve root in the patient's back. This technique may enable the physician to inject the medication as close to the source of pain as possible, reducing inflammation and relieving the patient's pain. See Figure 1 for an example of the target point, through the foramen, for a transforaminal epidural injection.

Figure 1: Trans-foraminal Epidural Injections



Source: The Pain Clinic. "Selective Transforaminal Nerve Root Blocks." Accessed at http://www.painclinic.org/ on September 2, 2009.

Radiographic guidance. To reduce patient risk, many physicians use radiographic guidance (such as live x-ray) to establish the placement of the needle and avoid puncturing the spinal cord and vertebral arteries that are located near the injection point. Some physicians perform the procedure without radiographic guidance, which is referred to as a "blind" injection. One study concluded that physicians "blindly" performing epidural injections failed to correctly perform the injections for 25 percent of cases.[13] Even in cases where transforaminal epidural injections have been administered with radiographic guidance,

[13] G. El-Khoury, et al. *Epidural Steroid Injection: A Procedure Ideally Performed with Fluoroscopic Control.* Radiology, vol. 168 (2), pp. 554–557.

complications resulting in stroke, paralysis, and death have been documented.[14]

Frequency of injections. The appropriate frequency of transforaminal epidural injections varies by patient. Typically, a patient receives an initial injection, referred to as a diagnostic injection, which helps confirm the suspected source of pain and determine whether the transforaminal injection is successful at relieving the pain. If a patient responds well and demonstrates pain relief, the patient receives a second injection, referred to as a therapeutic injection, at a subsequent visit. Therapeutic injections could continue at subsequent visits if a patient continues to demonstrate sustained pain relief.

Setting and specialty. Transforaminal epidural injections may be performed in a variety of settings. Approximately 43 percent of the injections were performed in office settings, 29 percent in ambulatory surgical centers (ASC), and 27 percent in hospital outpatient departments.[15] Less than 1 percent of transforaminal epidural injections were performed in other settings.

A physician in any specialty can perform a transforaminal epidural injection. However, in 2007, three types of specialists performed 86 percent of the transforaminal epidural injections.[16] They are anesthesiologists, pain management specialists, and rehabilitation physicians. A variety of other physician specialists performed the remaining 14 percent, including orthopedic surgeons, neurologists, radiologists, and family practice physicians.

Medicare Requirements for Transforaminal Epidural Injections

General provisions of the Social Security Act (the Act) govern Medicare reimbursement for all services, including transforaminal epidural injections. Section 1862(a)(1)(A) of the Act states that Medicare will cover only services that are considered to be reasonable and necessary. Reasonable and necessary services are those used in the diagnosis or treatment of illness or to improve the functioning of a malformed body part.

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[14] Graham C. Scanlon, et al. *Cervical transforaminal epidural steroid injections: more dangerous than we think?* Spine, vol. 32 (11), p. 1249.

[15] OIG analysis of physician claims for transforaminal epidural injection procedure codes in the 2007 100-percent NCH Medicare Part B physician/supplier file.

[16] Ibid.

Providers must properly document medical care to support that it is medically necessary. Section 1833(e) of the Act prohibits payment for a claim that is missing necessary information. Further, Medicare requires that providers keep documentation in the medical record to support the claim submitted, including, but not limited to, provider notes and test reports.[17] Providers must submit this information to Medicare upon request to support medical necessity.[18]

Providers must use uniform procedure codes to report all services, including transforaminal injection services.[19] The CPT codes and descriptions for transforaminal epidural injections are listed in Table 1.[20] Two primary codes, 64479 and 64483, are used for a single injection in the cervical/thoracic or lumbar/sacral regions of the spine, respectively. Each primary code has an associated add-on code for use when more than one level is injected. The add-on codes are 64480 (cervical/thoracic) and 64484 (lumbar/sacral).

Table 1: Transforaminal Epidural Injection CPT Codes and Descriptions

CPT Code	Description
64479	Injection; anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, single level
64480 (add on)	Injection; anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level
64483	Injection; anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, single level
64484 (add on)	Injection; anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, each additional level

Source: American Medical Association CPT descriptions, 2007.

[17] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch.3, § 11.1. The Manual does not provide examples of the types of test reports required. Test reports for transforaminal epidural injection services would likely include reports from diagnostic tests that may identify whether the patient has a condition that is appropriately treated with transforaminal epidural injections.

[18] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch.3, § 11.1.

[19] Section 1848(c)(5) of the Act requires the Secretary of Health & Human Services to develop a uniform coding system for all physician services. The American Medical Association's Current Procedural Terminology (CPT) codes are a numeric coding system consisting of descriptive terms that are used primarily to describe medical services and procedures performed by physicians and other health care practitioners.

[20] Although physicians may refer to transforaminal epidural injections as diagnostic or therapeutic, both types of injections are reported using the same procedure code. Procedure codes do not distinguish between diagnostic and therapeutic.

Medicare Part B Payments for Transforaminal Epidural Injections

Medicare reimburses physicians for transforaminal epidural injections according to the Medicare Physician Fee Schedule.[21] Medicare reimburses ASCs and hospital outpatient departments for their facility expenses separately from the payments made to physicians.

Physician Payments. The Medicare Physician Fee Schedule includes two types of rates, based on setting: those paid to physicians for services rendered in nonfacilities, such as their offices; and those paid to physicians for services rendered in facilities, such as ASCs or hospitals. Physician Fee Schedule rates for office services are generally higher than those for facility services because they include payment for practice expenses, such as building costs, administrative salaries, and equipment. Medicare Physician Fee Schedule rates are adjusted to account for geographic location. The base rates for physician payments for transforaminal epidural injections in 2007 are listed in Table 2.[22]

Table 2: Medicare Physician Fee Schedule Base Rates, 2007

CPT code	Office	Facility
64479	$327.81	$112.56
64480	$151.21	$73.52
64483	$328.95	$99.67
64484	$156.90	$62.15

Source: Medicare Physician Fee Schedule, 2007.

Reimbursements for primary codes 64479 and 64483 are higher because they include presurgical and postsurgical expenses related to the procedure that the add-on codes, 64480 and 64484, do not.

Physician payments also vary based on the modifiers[23] billed with the CPT. For example, bilateral transforaminal epidural injections, which are performed on both the right side and the left side of a vertebral level, should be billed using modifier 50, which increases reimbursement to 150 percent of the base rate.

[21] Section 1848(a)(1) of the Act established the Medicare Physician Fee Schedule as the basis for Medicare reimbursement for all physician services beginning in January 1992.

[22] Base rates are national Medicare Physician Fee Schedule amounts with no adjustment for geographic variation by locality.

[23] Modifiers are two-digit codes billed in conjunction with the appropriate CPT code.

Facility Payments. Medicare reimburses ASCs and hospital outpatient departments based on ASC payment groups and the hospital outpatient prospective payment system, respectively. The base rates for facility payments for transforaminal epidural injections in 2007 were $333 in an ASC and $390.95 in a hospital outpatient department.[24]

Claims Processing and Program Safeguards

CMS is in the process of transitioning its contracts with the private organizations that process and pay Medicare claims, formerly known as carriers. CMS is replacing carriers with Medicare Administrative Contractors (MAC). MACs will process all Part A and Part B claims within new jurisdictions covering all States. By 2011, MACs should be operational in every State and the District of Columbia.

Carriers and MACs (hereinafter referred to as contractors) are responsible for implementing program safeguards to reduce payment errors. To safeguard payments, they may create local coverage determinations (LCD)[25], implement electronic edits (hereinafter referred to as edits), or conduct medical review.

LCDs. Contractors may develop their own coverage guidelines called LCDs when no National Coverage Determination (NCD) exists.[26] LCDs vary by contractor and may result in different coverage in different parts of the country.

LCDs help to safeguard Medicare services by defining whether services are reasonable and necessary and therefore covered by Medicare. Among other reasons, contractors may develop LCDs to address problems presenting a significant risk to the Medicare Trust Fund or a patient's access to care.[27]

LCDs typically cover the following topics: (1) indications and limitations of coverage and/or medical necessity, (2) covered diagnosis codes supporting medical necessity, (3) documentation requirements, and (4) utilization requirements.

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[24] Ambulatory Surgical Center Approved Healthcare Common Procedure Coding System (HCPCS) Codes and Payment Rates, 2007, and Hospital Outpatient Prospective Payment Rates, 2007.

[25] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch.13, § 1.3.

[26] NCDs, issued by CMS, govern how Medicare will cover specific services, procedures, or technologies at a national level.

[27] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-8, ch. 13, § 4.

Edits. Contractors may implement edits to prevent improper payments. These edits are part of the claims-processing system that automatically pays all or part of a claim, denies all or part of a claim, or suspends all or part of the claim for manual review.

CMS encourages contractors to develop edits to enforce criteria in an LCD.[28] Once a contractor develops an edit, it must annually evaluate the edit for effectiveness. CMS considers an edit effective when it has a reasonable rate of denials, a reasonable dollar return on the cost of operation, or potential to avoid significant risk to beneficiaries.[29]

Medical review. Contractor staff may request and review medical records to address program vulnerabilities related to coverage and coding. CMS requires contractors to analyze data in order to target medical review activities at identified problem areas and prioritize medical review resources.

Related Report

A recent OIG study found problems with another type of interventional pain management service, facet joint injections. OIG found that 63 percent of facet joint injection services allowed by Medicare in 2006 did not meet Medicare requirements, resulting in approximately $96 million in improper payments. [30]

METHODOLOGY

To determine the extent to which payments for transforaminal epidural injections met Medicare requirements and what safeguards existed, we (1) conducted a medical record review of a sample of Medicare claims from 2007, (2) reviewed CMS and contractor policies related to safeguarding transforaminal epidural injection services, and (3) conducted structured telephone interviews with contractor staff.

Scope

We focused our review on Medicare physician claims for transforaminal epidural injections. Unless otherwise stated, all estimates refer to physician payments.

[28] CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 13, §§ 5.3 and 10.

[29] CMS, *Medicare Program Integrity Manual,* Pub. No. 100-08, ch.3, § 5.1.1.

[30] OIG, *Medicare Payments for Facet Joint Injection Services*, OEI 05-07-00200, September 2008.

Sample Selection

The population from which we sampled consisted of all 2007 allowed physician services in the NCH physician/supplier file for transforaminal epidural injection CPT codes 64479, 64480, 64483, and 64484. We restricted our population to Medicare physician services billed in offices, ASCs, or hospital outpatient departments as 99 percent of transforaminal injection services were billed in these settings.[31] We excluded claims that were less than $15 to avoid performing medical record review on low dollar claims.[32] The population consisted of approximately 800,000 claims and $141 million in allowed physician payments. From this population, we selected a stratified random sample of 440 Medicare physician line item claims,[33] stratifying by place of service reported on the claim (office or facility) and the Medicare-allowed amount. See Appendix A for further details on the sample selection, data collection, and data analysis.

Data Collection

After excluding 2 services from the 440 in our sample because of ongoing OIG investigations, we requested, by mail, complete medical records from physicians for 438 sampled services. We classified providers for five services as nonresponders.[34] Thus, we based our analysis on the remaining 433 line items. This represents a 99-percent response rate.

In June and July 2009, we conducted structured telephone interviews with staff at the 11 contractors that were processing Medicare Part B claims at that time. Between 2007 and 2009, the number of contractors processing Medicare Part B claims was reduced from 14 to 11. These 11 contractors that we interviewed covered the entire country at the time of the interviews.

During each interview, we asked contractor staff for information about program safeguards in place in 2007, the timeframe associated with our analysis. Specifically, we clarified our understanding of the LCDs and

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[31] Based on OIG analysis of physician claims for transforaminal epidural injection procedure codes in the 2007 100-percent NCH Medicare Part B physician/supplier file.

[32] These claims represented less than 1 percent of the population.

[33] Multiple line items may be billed within a single claim. Hereinafter, line items will be referred to as services.

[34] A nonresponder is defined as a provider with whom no successful contact was made after at least three written contacts and two phone calls. Providers with whom successful contact was made who did not return the requested medical records were not counted as nonresponders, but rather as having a documentation error.

inquired about what edits they had in place associated with the LCDs. Because CMS requires the outgoing contractors to inform the incoming contractors of edits on LCDs, we were able to obtain written confirmation from the 11 contractors that we interviewed about the program safeguards used by all 14 contractors operating in 2007. Thus, we report on information from all 14 contractors operating in 2007.

We collected and reviewed all 30 LCDs for transforaminal injections in place in 2007. LCDs are published on the CMS Web site. We requested and received from contractor staff written confirmation of the correct LCDs in all States for 2007.

To understand how program safeguards may have changed since 2007, we also consulted with all contractors about 2009 safeguards, including LCDs and edits.

Medical Record Review. We used a medical record review contractor to conduct the medical record review. The reviewers included three board-certified physicians with interventional pain management and transforaminal epidural injection experience and one certified professional coder. One physician and the coder reviewed each of the medical records.

The reviewers determined whether the service was adequately documented and medically necessary and whether the appropriate CPT code and modifier(s) were used. Reviewers based their determination on a review of the medical record and their professional judgment.

Data Analysis

To determine the extent to which payments for transforaminal epidural injections met Medicare requirements, we analyzed the results of the medical review. We determined the percentage of physician services that did not meet Medicare requirements. We also calculated the projected physician dollars associated with these services. We then compared physician office error rates to facility (ASC and hospital outpatient department) error rates. Finally, we used the NCH files, containing ASC and hospital outpatient department facility payments, to match to the associated physician service found to be in error and then projected the identified facility dollars paid in error.

To determine what safeguards existed for transforaminal epidural injections, we analyzed all documentation of program safeguards and reviewed information collected during the contractor interviews. We analyzed the number and type of LCD requirements that the contractor

had in 2007. In addition, we analyzed the number and type of edits each contractor had in 2007. We considered a contractor to have an LCD or edit if it covered at least one State within the contractor's jurisdiction at any time in 2007. To determine whether any safeguards changed, we analyzed the LCDs and edits in 2009 and compared those to the ones in place in 2007. Finally, we reviewed information collected during the interviews to assess what other program safeguards contractors had in place.

Comprehensive Error Rate Testing

CMS established the Comprehensive Error Rate Testing (CERT) to calculate the Medicare fee-for-service paid claims error rate. As of 2009, the CERT has not reported any specific information about transforaminal epidural injections. This review was not designed to reproduce or to review CERT findings.

Limitations

We were not able to calculate medical review error rates by contractor to assess whether the contractor safeguards had an impact on error rates. We were unable to do this because we did not stratify our sample by contractor, so our sample size per contractor was too small to project or compare error rates across contractors.

Standards

This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

Thirty-four percent of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements, resulting in approximately $45 million in improper payments

Medicare allowed approximately $45 million in improper payments to physicians for transforaminal epidural injections in 2007. These improper payments represent 32 percent of the $141 million in physician payments for transforaminal epidural injections in 2007.

Thirty-four percent of transforaminal epidural injection services did not meet Medicare requirements. Table 3 shows the error rates and associated payments for physician claims by error type. Confidence intervals for projected error rates and payments are in Appendix B.

Table 3: Improperly Paid Medicare Transforaminal Epidural Injection Services—Physician Claims, 2007

	Sample		Projected	
Type of Error	Services	Allowed Amount	Services	Allowed Amount
Documentation	87	$19,504	19%	$29 million
Medical Necessity	56	$12,109	13%	$19 million
Coding	35	$3,626	8%	$6 million
(Overlapping Errors)	(30)	($6,161)	(7%)	($9 million)
Total	**148**	**$29,078**	**34%***	**$45 million**

Source: OIG analysis of medical review results, 2009.

*Numbers do not always sum to total because of rounding.

Medicare allowed an additional $23 million in associated facility claims for transforaminal epidural injections in error in ASCs and hospital outpatient departments. See Appendix A for further discussion of estimates for associated facility claims. Although the focus of this review is on physician claims, we also analyzed facility claims that were submitted for the physician claims paid in error to provide additional context. The remaining analyses focus on physician claims only.

Nineteen percent of transforaminal epidural injection services had a documentation error

Medicare allowed approximately $29 million for physician services that were undocumented or insufficiently documented. Although some

documentation errors may be the result of recordkeeping problems, others may represent services not rendered. Records lacking documentation to show that care was provided do not meet Medicare requirements.

Ten percent of transforaminal epidural injection services were undocumented. Medicare allowed approximately $14 million for undocumented transforaminal epidural injection services. For the majority of these services, a record was submitted but contained no documentation of the sampled service. In all other cases, the requested record was never submitted.

Nine percent of transforaminal epidural injection services were insufficiently documented. Medicare allowed approximately $15 million for insufficiently documented transforaminal epidural injection services. Most records were missing a description of the procedure as billed. Some other records had a procedure note, but were missing details of the procedure, such as the location and frequency of the injection. In each case, the reviewer concluded that there was insufficient documentation to support the service.

Documentation errors were more likely to occur in office settings. Twenty-seven percent of transforaminal epidural injection services provided in offices had a documentation error, compared to 13 percent of transforaminal epidural injection services provided in facilities. See Table 4 for error rates by setting and error type.

Table 4: Error Rates by Setting and Error Type for Medicare Transforaminal Epidural Injection Services—Physician Claims, 2007

Type of Error	Office	Facility
Documentation*	27%	13%
Medical Necessity	18%	9%
Coding	8%	9%
Any Error	41%**	28%

Source: OIG analysis of medical review results, 2009.
*Statistically significant difference at the 95-percent confidence level.
**Numbers do not sum to total because of overlapping errors.

Thirteen percent of transforaminal epidural injection services had a medical necessity error

Medicare allowed approximately $19 million to physicians for transforaminal epidural injection services that medical reviewers determined were medically unnecessary. In most instances, the record contained no evidence of a condition that required a transforaminal epidural injection. In some instances, the procedure was repeated at close intervals with no evidence that it was relieving the patient's pain.

Eight percent of transforaminal epidural injection services had a coding error

Medicare allowed $6 million to physicians in overpayments, net of underpayments, for transforaminal epidural injection services that were miscoded. The reviewer found primarily that physicians improperly used add-on codes and bilateral modifiers. In some instances, the physicians performed less intensive procedures, but billed for transforaminal epidural injections.

All but one of the miscoded services resulted in overpayment. The one underpayment was a bilateral transforaminal epidural injection service for which the provider billed only a unilateral service.

In 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards

Contractors used LCDs primarily to safeguard Medicare payments for transforaminal epidural injections. However, only one contractor enforced all LCD requirements through edits. No contractors performed medical reviews to safeguard services in 2007.

Nine contractors had an LCD for transforaminal epidural injections

Nine of the fourteen contractors had an LCD for transforaminal epidural injection services in 2007. These LCDs covered 30 States.

Most commonly, these contractors had the following requirements in their LCDs: (1) requiring that the procedure be performed only on patients with acceptable diagnoses codes, (2) requiring that providers use radiographic guidance for the procedure, (3) prohibiting multiple pain management services on the same day, and (4) limiting the frequency of the procedure. Less common requirements included requiring more conservative treatments (such as physical therapy) prior to transforaminal epidural injections and allowing only experienced providers to perform the procedure.

Among the four most common LCD requirements, contractors most frequently required that providers perform the procedure only on patients with acceptable diagnoses codes. All nine contractors with LCDs listed this requirement in their LCD. In addition, eight of the nine contractors required radiographic guidance in their LCD. Overall, six of the nine contractors listed all four of the most common requirements in their LCD.

Subsequent to our analysis period, the number of contractors with LCDs decreased. In 2009, 7 contractors had LCDs covering 23 States.

Eight contractors did not enforce all of their LCD requirements with edits

Although, in general, contractor staff reported that edits were the best way to enforce the requirements in their LCDs, only one contractor enforced all LCD requirements with edits. Two contractors did not have any edits. See Table 5 for a list of the most common LCD requirements and corresponding edits by contractor.

Table 5: 2007 Common LCD Requirements and Edits by Contractor

Contractor	Diagnoses		Radiographic Guidance		Prohibits Other Pain Management Services Same Day		Frequency	
	LCD	Edit	LCD	Edit	LCD	Edit	LCD	Edit
1	●	✔	●		●		●	
2	●	✔	●		●		●	
3	●	✔	●	✔				
4	●	✔	●					
5	●	✔	●		●	✔	●	
6	●	✔			●			
7	●		●		●		●	✔
8	●		●		●		●	
9	●		●		●		●	
10								
11								
12								
13								
14								

Source: OIG interviews and document review, 2009.

The most commonly used edits ensured that claims were paid only for procedures performed on patients with acceptable diagnoses codes. Six of the nine contractors listing acceptable diagnoses codes in the LCD had corresponding edits. These edits were intended to automatically check that physicians billed only acceptable diagnoses and deny claims billed without acceptable diagnoses codes.

Contractors seldom used other edits to enforce requirements in their LCDs. Only one of the eight contractors requiring radiographic guidance in the LCD created a corresponding edit. Only one of the seven contractors prohibiting multiple pain management services on the same day had a corresponding edit. Only one of the six contractors with frequency limits in the LCD developed a corresponding edit.

Contractors did not use edits to enforce less common requirements from LCDs.

In some instances, contractors could not create edits because claims lacked the required information to implement the edits. For example, several contractors had LCDs that limited the frequency of injections per spinal level, but claims did not capture which of the spinal levels in the back were injected. Similarly, several contractors had LCDs with different frequency limits for diagnostic and therapeutic injections, but claims did not capture whether an injection was diagnostic or therapeutic.

In other instances, claims captured the required information, but contractors did not create edits to enforce LCD requirements. Most contractors had an LCD requiring that providers use radiographic guidance. Providers separately bill radiographic guidance on the claims. However, only one contractor developed an edit related to radiographic guidance.

Subsequent to our analysis period, the number of contractors with edits decreased. In 2007, 7 of the 14 contractors had at least 1 edit covering 20 States. In 2009, only four contractors had edits enforcing their LCD requirements. These edits covered seven States.

No contractors reported performing medical reviews

No contractor staff reported performing medical reviews for transforaminal epidural injections in 2007.

Most contractor staff reported that they analyzed data for transforaminal epidural injections, but did not find any outliers warranting medical review. CMS requires that contractors analyze data to prioritize the use of limited medical review resources. Contractors might do a medical review if they notice outliers in the data, such as one provider that bills substantially more than his peers.

Despite limited use of medical review, contractor staff reported that it is a useful safeguard because it reveals problems not identifiable through data analysis or edits. Staff from five contractors stated that medical review is more comprehensive than either edits or data analysis. For example, in 2009, one contractor performing a medical review for transforaminal epidural injections found that providers were administering too much steroid medication, a potentially dangerous practice. The contractor staff reported that this problem was revealed only through a detailed medical review.

RECOMMENDATIONS

This report identifies problems with Medicare payments for transforaminal epidural injections. Thirty-four percent of transforaminal epidural injection services in 2007 did not meet Medicare requirements, resulting in improper payments of approximately $45 million. Further, Medicare allowed an additional $23 million in associated facility claims for transforaminal epidural injections in error. Transforaminal epidural injection services delivered in office settings were more likely to have a documentation error compared to services delivered in facilities. Nine of fourteen contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards. No contractors performed medical reviews for transforaminal epidural injection services in 2007.

This report is the second in a series on Medicare pain management services. A 2008 OIG report found that 63 percent of facet joint injections in 2006 did not meet Medicare requirements, resulting in improper payments of $96 million. The previous report found that facet joint injections delivered in office settings were more likely to have an error.

Based on the results of this body of work, CMS should:

Conduct provider education, directly and through contractors, about proper documentation

Nineteen percent of transforaminal epidural injection services had a documentation error. CMS should conduct provider education regarding proper documentation to reduce future documentation errors. CMS should also direct contractors to conduct provider education about proper documentation for transforaminal epidural injection services.

Strengthen program safeguards to prevent improper payment for transforaminal epidural injection services

To strengthen program safeguards, CMS could encourage contractors to:

Examine transforaminal epidural injection services provided in offices. Both our current study and our 2008 facet joint injection study found higher error rates for services performed in offices. Contractors could examine services provided in offices to safeguard Medicare payments.

Develop LCDs for transforaminal epidural injections. Between 2007 and 2009, the number of States covered by an LCD for transforaminal epidural injection services decreased from 30 to 23. Contractors that do not have an LCD to define requirements for transforaminal epidural

injections may consider developing one. As noted in the limitations section of this report, we were not able to assess whether contractor safeguards, such as LCDs, had an impact on error rates. However, LCDs may be helpful to control improper payments for other reasons, such as establishing criteria for law enforcement action.

Develop additional edits enforcing LCD requirements for transforaminal epidural injection services. Both our current study and our 2008 facet joint injection study found that not all LCD requirements were enforced by edits. In addition, between 2007 and 2009, the number of States covered by at least 1 edit for transforaminal epidural injection services decreased from 20 to 7. Contractors could strengthen current safeguards for both transforaminal epidural injection services and facet joint injection services by developing edits to enforce the requirements.

Use medical review to identify improper payments for transforaminal epidural injection services. Thirty-four percent of transforaminal epidural injection services were paid in error. Thirteen percent were medically unnecessary. Additional medical reviews may limit future improper payments and protect beneficiaries from unnecessary services.

Take appropriate action regarding the undocumented, medically unnecessary, and miscoded services identified in our sample

We will forward information on these services to CMS under separate cover.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations and outlined steps to improve its oversight of payments for transforaminal epidural injection services. We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix C.

APPENDIX ~ A

Detailed Methodology

Sample Selection

The population from which we sampled consisted of all the allowed physician services in the Centers for Medicare & Medicaid Services National Claims History (NCH) file for Current Procedural Terminology (CPT) codes 64479, 64480, 64483, and 64484 performed in 2007. We stratified the sample by place of service and dollar amount. We stratified by place of service to compare rates by setting (office and facility). Previous work found significantly different error rates between these two settings. We further stratified by the dollar amount of the claims to improve our ability to provide an overall estimate of the dollars in error with an acceptable confidence interval. We randomly selected 110 claims from each stratum for review, for a total of 440 claims. Table A-1 shows the sampling stratification and population of claims for CPT codes 64479, 64480, 64483, and 64484.

Table A-1: Sampling Stratification for Transforaminal Epidural Injection Claims

Stratum	Description	Population	Sampled Claims
1 - Office	> $325	103,987	110
2 - Office	≥ $15 to ≤ $325	242,074	110
3 – Facility (Ambulatory Surgical Center (ASC) and Hospital Outpatient)	> $100	149,362	110
4 – Facility ASC and Hospital Outpatient)	≥ $15 to ≤ $100	311,278	110
Total		**806,701**	**440**

Source: Office of Inspector General (OIG) analysis of 2007 NCH physician/supplier file.

Data Collection

Medical Record Review. We used a medical record review contractor to conduct the medical record review. We requested, by mail, complete medical records and documentation from physicians for the services in our sample. We specified that providers send the following materials, if available: initial patient evaluation and exam, test results, radiographic evidence of needle placement, and procedure notes. For additional context, we also requested that providers furnish all

documentation for all services provided to the beneficiary 4 months before and 1 month after the sampled date of service.

We requested the beneficiary's medical record from the provider associated with the sampled claim. We used the Unique Physician Identification Number validation file and the National Provider Identifier to obtain contact information for the provider when mailing the request.

We allowed at least 7 weeks from the date of the initial request for the sampled provider to fax or mail the records to the medical review contractor. We made at least two additional written attempts followed by two telephone calls to obtain the records. The last written request was mailed by signature-required certified mail.

Our response rate for this study was 99 percent. Of the 440 services that we originally sampled, 2 services were removed because of ongoing OIG investigations. Then we requested records for the remaining 438 sampled services. We classified five of these as nonresponders. We classified two services as nonresponders because we were unable to locate the sampled provider, and we classified three services as nonresponders because the provider returned the record too late to be reviewed. Our analysis was based on the 433 remaining services in the sample for which we received a response.

Test Review. To test our review instrument and ensure uniformity among the reviewers, we conducted a preliminary medical review of 20 services. These services were randomly sampled from the same population where we drew our final sample. However, the preliminary sample was chosen separately from the sample used for the final review. We analyzed the results of the test review and discussed them with the reviewers. The reviewers resolved inconsistencies in the results and suggested changes to the review instrument. Some of the changes were incorporated into the final review instrument as appropriate.

Data Analysis

Calculation of improper physician payments. We calculated the total actual and projected dollars paid in error for these services. For services that were not medically necessary, insufficiently documented, or not documented, we counted the entire Medicare-allowed amount as improper and projected the amount paid in error. For services with a coding error, we determined whether Medicare overpaid or underpaid. We then calculated the total net difference for all services with a coding error and projected it to the population.

We projected dollars in error and percentage of services in error to the population of all transforaminal epidural injection services in 2007. We removed any overlap in sampled services that had multiple errors.

Calculation of improper facility payments. In addition, we calculated and projected the facility payments associated with physician services that were performed in facilities and did not meet documentation or medical necessity requirements. For services performed in ASCs and hospital outpatient departments, we used the NCH Part B file and the hospital outpatient file, respectively, and matched facility claims to physician claims using the dates of service, CPT, and beneficiary identification. After matching the claims, we projected the facility dollars paid in error.

Our estimate of facility dollars associated with physician services in error is conservative. First, we excluded physician services in error because of incorrect coding. It would have required a coding review of the facility claim to determine the amount in error on the facility claim, which was beyond the scope of our study. Second, among the errors that we did attempt to match, we were not able to find all matching facility claims. We were able to match only 69 percent of sampled physician services performed in facilities and having a documentation or medical necessity error to their associated facility payment.

APPENDIX ~ B

Confidence Intervals for Selected Estimates

Table B-1: Estimates of All Errors

Estimate Description	Point Estimate	95-Percent Confidence Interval
Percentage of services with any error	33.9%	29.1%–38.7%
Percentage of services with any documentation error	19.2%	15.4%–23.0%
Percentage of services with no documentation	9.8%	6.8%–12.7%
Percentage of services with insufficient documentation	9.4%	6.6%–12.4%
Percentage of services that were not medically necessary	12.9%	9.6%–16.3%
Percentage of services coded incorrectly	8.3%	5.5%–11.2%
Percentage of services with overlapping errors	6.6%	4.1%–9.0%
Percentage of amount allowed in error among all allowed amounts for transforaminal epidural injection services	31.7%	27.0%–36.4%

Source: Office of Inspector General (OIG) analysis of medical review results, 2009.

Table B-2: Estimates of Improper Physician Payments Associated With All Errors

Estimate Description	Point Estimate	95-Percent Confidence Interval
Amount allowed for services with any error	$44,833,417	$38,188,484–$51,478,349
Amount allowed for services with any documentation error	$28,895,365	$22,934,192–$34,856,538
Amount allowed for services with no documentation	$14,005,827	$9,505,141–$18,506,513
Amount allowed for services with insufficient documentation	$14,889,538	$10,360,675–$19,418,401
Amount allowed for services that were not medically necessary	$18,831,045	$13,779,543–$23,882,548
Amount allowed for services coded incorrectly	$6,248,458	$3,829,614–$8,667,303
Amount allowed for services with overlapping errors	$9,141,452	$5,352,508–$12,930,395

Source: OIG analysis of medical review results, 2009.

Table B-3: Estimate of Improper Facility Payments Associated With Any Error

Estimate Description	Point Estimate	95-Percent Confidence Interval
Amount allowed for services with any error	$22,859,369	$15,118,460–$30,600,278

Source: OIG analysis of medical review results, 2009.

Table B-4: Estimates of Errors by Setting and Type

Error Type	Setting	Point Estimate	95-Percent Confidence Interval
Documentation	Office	27.0%	20.5%–33.5%
	Facility	13.3%	8.6%–18.0%
Medical Necessity	Office	17.7%	12.1%–23.3%
	Facility	9.3%	5.1%–13.4%
Coded Incorrectly	Office	8.0%	4.0%–12.0%
	Facility	8.6%	4.6%–12.6%
Any Error	Office	41.3%	34.1%–48.4%
	Facility	28.3%	22.0%–34.7%

Source: OIG analysis of medical review results, 2009.

APPENDIX ~ C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: MAY 10 2010

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator and Chief Operating Officer

SUBJECT: Office of Inspector General (OIG) Draft Report: "Inappropriate Medicare Payments for Transforaminal Epidural Injection Services" (OEI-05-09-00030)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report, "Inappropriate Medicare Payments for Transforaminal Epidural Injection Services." The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources the OIG has invested to determine the extent to which Medicare Part B payments for transforaminal epidural injections met Medicare requirements.

Transforaminal epidural injections are a pain management technique used to diagnose or treat pain. The OIG conducted a medical record review of a stratified random sample of 433 transforaminal epidural injections performed in 2007. The OIG determined that thirty-four percent of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements. In addition, OIG reported that nine out of fourteen CMS contractors had a Local Coverage Determination (LCD) for transforaminal epidural injection services but only one contractor enforced all LCD requirements with edits.

The CMS appreciates the work of OIG on this issue and will work to improve our oversight of these payments in the future. As a result of its findings, the OIG made the following recommendations:

OIG Recommendation
Conduct provider education, directly and through contractors, about proper documentation.

CMS Response
The CMS concurs with this recommendation. CMS will direct contractors to conduct provider education about proper documentation for transforaminal epidural injections especially provided in offices. CMS will issue a Medicare Learning Network Matters Article on this topic related to documentation requirements and expectations.

OIG Recommendation
Strengthen program safeguards to prevent improper payment for transforaminal epidural injection services.

CMS Response
Examine transforaminal epidural injection services provided in offices.
The CMS concurs. To strengthen program safeguards, CMS will instruct the appropriate Medicare contractors to review their claims data for transforaminal epidural injection services particularly in the office, due to higher error rates in that setting.

Develop LCDs for transforaminal epidural injection services.
The responsibility to determine whether or not to develop an LCD lies with the Medicare Administrative Contractors (MACs). CMS will share the results of the OIG report with the Medicare contractors, who may develop policies under their own authority and based on CMS manual instructions.

Develop additional edits enforcing LCS requirements for transforaminal epidural injection services.
The CMS concurs. CMS will instruct contractors to examine whether sufficient edits are in place to enforce LCDs.

Use medical review to identify improper payments for transforaminal epidural injection services.
The CMS concurs. CMS will instruct the MACs to take appropriate action consistent with their individual prioritized medical review strategy. MACs use their medical review strategies to best focus their resources relative to other vulnerabilities.

OIG Recommendation
Take appropriate action regarding the undocumented, medically unnecessary, and miscoded services identified in our sample.

CMS Response
The CMS concurs. CMS will share the OIG report and any additional claim information received with the appropriate Medicare contractors. CMS will instruct them to consider the issues identified in this report and the additional claim information when prioritizing their Medicare review strategies.

The CMS requests that OIG furnish the necessary data, including Medicare contractor numbers, provider numbers, claims information including the paid date, HIC numbers, etc. to accomplish our review. In addition, CMS requests that Medicare contractor-specific data be written to separate CD-ROMs or separate hardcopy worksheets to better facilitate the transfer of information to the appropriate contractors.

The CMS appreciates the OIG's efforts and insight on this report. CMS looks forward to continually working with OIG on issues related to waste, fraud and abuse in the Medicare program.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

Laura Kordish served as the team leader for this study and Beth McDowell served as the lead analyst. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed to the report include Lisa Minich and Lauren Rosapep; central office staff who contributed include Sandy Khoury and Megan Ruhnke.

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