

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE IMPROPERLY PAID
PHYSICIANS FOR EPIDURAL
STEROID INJECTION SESSIONS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



**Amy J. Frontz
Deputy Inspector General
for Audit Services**

**March 2023
A-07-21-00618**

Office of Inspector General

<https://oig.hhs.gov/>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: March 2023

Report No. A-07-21-00618

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

To address inappropriate billing for and overuse of epidural steroid injections, 10 of the 12 Medicare Administrative Contractors' (MACs') jurisdictions developed coverage limitations, through Local Coverage Determinations (LCDs), for epidural steroid injection sessions. These coverage limitations allow for physicians to be reimbursed for a maximum number of epidural steroid injection sessions in a 6-month or a 12-month period.

Prior OIG audits found that Medicare did not always pay physicians for spinal facet-joint denervation and injection sessions in accordance with Federal requirements.

Our objective was to determine whether Medicare paid physicians for epidural steroid injection sessions in accordance with Medicare requirements.

How OIG Did This Audit

During our audit period (January 1, 2019, to December 31, 2020), the MACs paid physicians \$52.8 million for 303,408 epidural steroid injection sessions. We analyzed the 303,408 sessions and identified 80,419 sessions totaling \$13.8 million that exceeded the coverage limitation for the respective MAC jurisdiction.

Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions

What OIG Found

Medicare did not always pay physicians for epidural steroid injection sessions in accordance with Medicare requirements. For our audit period, Medicare improperly paid physicians \$3.6 million on behalf of beneficiaries who received more epidural steroid injection sessions than were permitted by the coverage limitations in the applicable LCDs. These improper payments occurred because neither the Centers for Medicare & Medicaid Services's (CMS's) oversight nor the MACs' oversight was adequate to prevent or detect improper payments for epidural steroid injection sessions.

After our audit period, all 12 MAC jurisdictions updated their LCDs with revised coverage limitations that were specific to epidural steroid injections.

What OIG Recommends and CMS Comments

We recommend that CMS: (1) direct the MACs to recover the \$3.6 million in improper payments made to physicians for epidural steroid injection sessions; (2) instruct the MACs to, based on the results of this audit, notify appropriate physicians (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the physicians can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; (3) assess the effectiveness of oversight mechanisms, put in place after our audit period, that are specific to preventing or detecting improper payments to physicians for more than the allowed number of epidural steroid injection sessions, and modify the oversight mechanisms, if necessary, based on that assessment; and (4) direct the MACs (or other designated entities) to review a sample of claims for injection sessions administered after our audit period but before the revised coverage limitations became effective to identify and recover any improper payments.

CMS concurred with all of our recommendations and described actions that it had taken or planned to take to address our recommendations, to include directing the MACs to recover overpayments, instructing the MACs to notify physicians of potential overpayments, determining whether any modifications to oversight mechanisms are necessary, and sharing this report with medical review contractors to consider whether additional reviews should be performed, and any identified overpayments recovered, as part of the contractors' overall improper payment reduction strategies.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	2
Medicare Part B.....	2
Epidural Space and Medicare Coverage of Epidural Steroid Injection Sessions.....	2
Physician Submission of Claims for Epidural Steroid Injection Sessions.....	4
Medicare Requirements for Physicians To Identify and Return Overpayments....	5
How We Conducted This Audit.....	5
FINDINGS.....	6
Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions.....	7
Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions Administered During a 6-Month Period.....	7
Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions Administered During a 12-Month Period.....	7
CMS and Medicare Administrative Contractor Oversight Was Inadequate To Prevent or Detect Improper Payments to Physicians.....	9
The Medicare Administrative Contractors Revised Their Coverage Limitations for Epidural Steroid Injection Sessions After Our Audit Period.....	9
RECOMMENDATIONS.....	10
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	10
APPENDICES	
A: Audit Scope and Methodology.....	12
B: Medicare Administrative Contractor and Geographic Composition for Each Jurisdiction.....	14
C: Overpayments of Epidural Steroid Injection Sessions by Jurisdiction.....	15
D: CMS Comments.....	16

INTRODUCTION

WHY WE DID THIS AUDIT

An epidural steroid injection is a procedure that physicians use to treat pain arising from irritations in and inflammations of spinal nerve roots.¹ To address inappropriate billing for and overuse of epidural steroid injections, 10 of the 12 Medicare Administrative Contractors' (MACs') jurisdictions developed coverage limitations for epidural steroid injection sessions.² These coverage limitations allow for physicians to be reimbursed for a maximum number of epidural steroid injection sessions in a 6-month or a 12-month period.³

In addition, prior Office of Inspector (OIG) audits found that Medicare did not always pay physicians for spinal facet-joint denervation sessions and selected facet-joint injection sessions in accordance with Federal requirements. Specifically, MACs with coverage limitations for selected spinal facet-joint denervation and selected facet-joint injection sessions reimbursed physicians for more than the allowed number of facet-joint injection sessions. These audits found that MACs improperly paid physicians \$9.5 million and \$748,555, respectively.⁴

Therefore, we conducted this audit to determine whether Medicare made improper payments from January 1, 2019, to December 31, 2020 (audit period), for epidural steroid injection sessions in the MAC jurisdictions that had defined coverage limitations.

OBJECTIVE

Our objective was to determine whether Medicare paid physicians for epidural steroid injection sessions in accordance with Medicare requirements.

¹ Throughout this report, we use the terms "epidural steroid injection(s)" and "epidural injection(s)" interchangeably as appropriate, depending on their context.

² A session is a single date of service on which a beneficiary received epidural steroid injection(s) to treat pain within the spinal areas (cervical/thoracic or lumbar/sacral). The cervical and thoracic regions of the spine are located in the upper back, which includes the neck; the lumbar region of the spine is located in the lower back.

³ A 6-month period, sometimes referred to as a "rolling 6-month period," involves a date range that starts with the date of an individual service and ends 182 days later. A 12-month period, sometimes referred to as a "rolling 12-month period or rolling year," involves a date range that starts with the date of an individual service and ends 365 days later.

⁴ *Medicare Improperly Paid Physicians for Spinal Facet-Joint Denervation Sessions* ([A-09-21-03002](#)), issued Dec. 3, 2021, and *Medicare Improperly Paid Physicians for More Than Five Spinal Facet-Joint Injection Sessions During a Rolling 12-Month Period* ([A-09-20-03003](#)), issued Oct. 9, 2020. Facet-joint denervation is a procedure used to treat neck or back pain caused by arthritis in or injury to the facet joints in the spine. Facet-joint injections of an anesthetic, with or without a steroid, are used to diagnose or treat chronic neck and back pain. Those reports refer to the sessions in which either coverage limitation was exceeded as "selected facet-joint denervation sessions" and "selected facet-joint injection sessions."

BACKGROUND

Medicare Part B

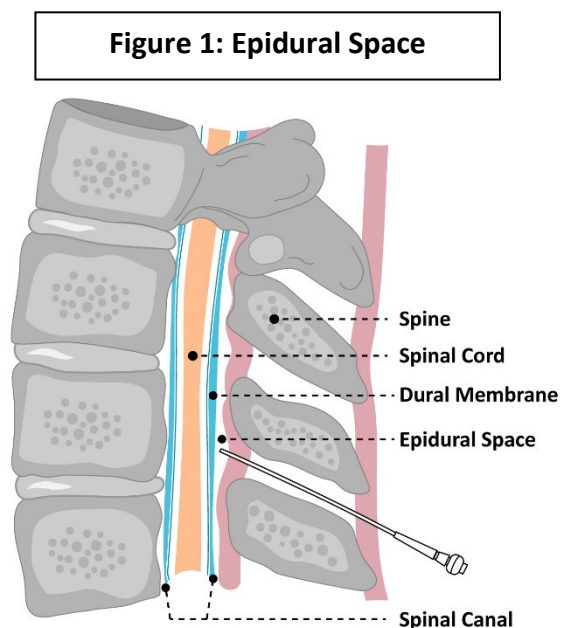
Medicare Part B provides supplementary medical insurance, including coverage for the cost of epidural steroid injection sessions when they are medically reasonable and necessary. The Centers for Medicare & Medicaid Services (CMS) administers Part B and contracts with MACs to, among other things, determine reimbursement amounts and pay claims, conduct audits, and safeguard against fraud and abuse. Each MAC is responsible for processing claims submitted by physicians within 1 or more of 12 designated regions, or jurisdictions, of the United States and its Territories. Appendix B shows the MAC and geographic composition for each jurisdiction, along with the corresponding LCDs that were in effect during our audit period.

Epidural Space and Medicare Coverage of Epidural Steroid Injection Sessions

The epidural space lies outside the dural membrane but inside the spinal canal. (See Figure 1 to the right.) It runs the length of the spine and contains, in addition to traversing nerves, fatty tissue and blood vessels.⁵ The spinal nerve roots, which stimulate movement and feeling throughout the spinal canal, can be affected by a number of irritations and inflammations. As a result of mechanical irritation, inflammation, or other processes, the spinal nerve roots can become a significant and disabling source of pain, and injury to a spinal nerve root can result in pain, weakness, and sensory loss.

Physicians generally perform epidural steroid injections to treat pain arising from irritations in and inflammations of the spinal nerve roots.

Physicians administer these injections in the cervical, thoracic, lumbar, or sacral regions of the spine, using one of three distinct techniques, each of which involves introducing a needle into the epidural space (by a different route of entry for each technique). These are termed the interlaminar, caudal, and transforaminal approaches.⁶ The procedures typically involve the injection of a solution containing corticosteroids and anesthetic into the epidural space of the

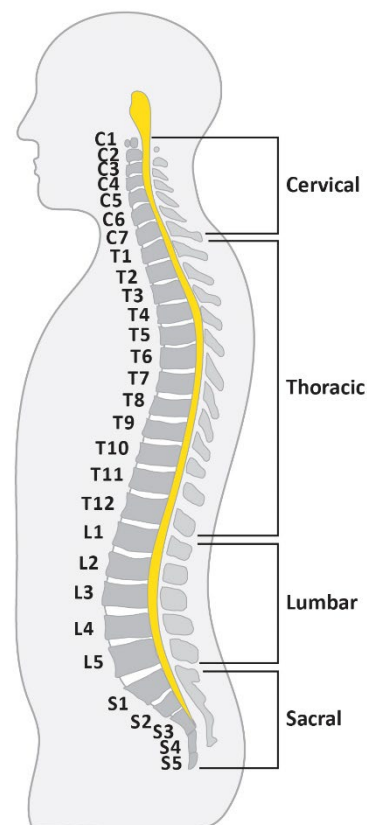


⁵ A traversing nerve is a nerve root that crosses the disc and exits the spine at the next level below. For example, the L5 nerve root is the traversing nerve root at the L4-L5 level and is the exiting nerve root at the L5-S1 level.

⁶ The interlaminar epidural steroid injection is made posterior between two adjacent vertebrae in the midline area. The caudal injections are administered in the lowest epidural space (sacral area). The transforaminal epidural steroid injection targets specific nerve roots.

spine, although saline may be included at times. Figure 2 to the right depicts the spinal regions, differentiated (beginning at the base of the skull) between the cervical, thoracic, lumbar, and sacral regions.

Figure 2: Spinal Regions



Epidural steroid injections have been shown to reduce pain, and their use may have the effect of lowering surgical rates for specific spinal disorders.⁷ The effect of the injections on pain is palliative rather than curative, and repeat injections may be beneficial in the management of pain in patients who have a favorable response to an initial injection.

For 10 of the 12 MAC jurisdictions, Medicare Part B covers a limited number of epidural steroid injection sessions for a beneficiary during a 6- or a 12-month period. The MACs' Local Coverage Determinations (LCDs) for epidural steroid injections in those 10 jurisdictions specify that:^{8, 9}

- during a 6-month period, Medicare will cover a maximum of three epidural steroid injection sessions for beneficiaries in eight jurisdictions (LCDs L36521 for Jurisdictions 5 and 8, L34982 for Jurisdiction E, L34980 for Jurisdiction F, L36920 for Jurisdictions H and L, and L35148 for Jurisdictions J and M) or a maximum of five epidural steroid injection sessions for beneficiaries in two jurisdictions (LCDs L34807 for Jurisdiction 15 and L33906 for Jurisdiction N);¹⁰
- during a 12-month period, Medicare will cover a maximum of six epidural steroid injection sessions for beneficiaries in nine jurisdictions (LCDs L36521 for Jurisdictions 5

⁷ As stated in the *Analysis for Evidence* in the LCDs, issued December 2021.

⁸ An LCD is a decision by a MAC whether to cover a particular item or service on a contractor-wide basis in accordance with 1862(a)(1)(A) of the Social Security Act (the Act).

⁹ National Government Services, Inc. (NGS), did not limit the number of epidural steroid injection sessions to be reimbursed during a 6-month or 12-month period for the other two jurisdictions (LCD L35937 for Jurisdictions 6 and K).

¹⁰ Because the MACs' LCDs did not define specific timeframes for any particular 6-month period, for our calculations we designated a 182-day timeframe (see also footnote 3) by taking half of a 365-day timeframe. One of the 10 MAC jurisdictions (covered by LCD L33906) specified that the coverage limitations applied 6-month intervals (i.e., March 3, 2019, through September 1, 2019). For this MAC, we reviewed the epidural injection sessions within each 6-month period during our audit period (i.e., March 3, 2019, through September 1, 2019; then September 29, 2019, through March 29, 2020; and so on). Two of the 10 MAC jurisdictions (LCD L36521) referred to this same timeframe as a "rolling year."

and 8, L34982 for Jurisdiction E, L34980 for Jurisdiction F, L36920¹¹ for Jurisdictions H and L, L35148 for Jurisdictions J and M, and L34807 for Jurisdiction 15).

This report uses the term “epidural steroid injection session(s)” in the context of both the 6-month and 12-month coverage limitations.

According to the LCDs, the evidence of the clinical effectiveness of epidural steroid injections has not been well established in the medical literature. The MACs have thus established coverage limitations through LCDs. As indicated in the most recent epidural steroid injection LCDs (L39054, L36920, L39015, L39036, L33906, L38994, L39240, and L39242), studies now support that a single injection can relieve pain in appropriately selected patients.^{12, 13} These LCDs add that the use of single injections is consistent with the natural history of the disease course, which will result in spontaneous improvement of symptoms over time. As of the publication of this audit report, relevant medical literature reported that repeat injections were necessary for a minority of patients (about 20 percent), with less than 5 percent of patients requiring and receiving more than three injections. National data also confirm that more than four injections are administered in less than 5 percent of cases in the Medicare beneficiary population. Literature and observational studies have not, however, reached consensus as to the timing and intervals of the injections after the initial injection.

Although more research and consensus are needed, the existing evidence generally agrees on the appropriateness of a maximum of four injections over a 12-month period for most patients. Additionally, the natural history of the diseases when treated with epidural steroid injections would rarely involve more than one spinal region. The review of national data found that less than 0.05 percent (i.e., less than one-twentieth of 1 percent) of epidural steroid injection sessions involved more than one region in the same session.

Physician Submission of Claims for Epidural Steroid Injection Sessions

Federal law prohibits Medicare payment unless the physician has furnished information necessary to determine the amounts due (Social Security Act (the Act) § 1833(e)). Each submitted Medicare Part B claim contains detail regarding each provided service.

Medicare requires a uniform procedure coding system for all physicians’ services (the Act § 1848(c)(5)). To receive a Medicare payment for an epidural steroid injection, a physician submits a claim and indicates whether the injection was administered to the cervical/thoracic spine or the lumbar/sacral spine. The physician’s claim uses one of seven primary CPT codes,

¹¹ Novitas Solutions, Inc. (Novitas), defined a rolling 12-month period as 350 days. Therefore, we used 350 days in our analysis when reviewing the claims from Jurisdiction L (for which Novitas was the MAC).

¹² These LCDs do not specify a timeframe (i.e., 6 months or 12 months) in relation to the results of these studies.

¹³ An “appropriately selected patient” refers to a patient who meets the requirements to receive an epidural steroid injection.

depending on the spinal region: 62320, 62321, and 62325 for the cervical/thoracic spine and 62322, 62323, 62326, and 62327 for the lumbar/sacral spine.¹⁴

Medicare Requirements for Physicians To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, physicians must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Physicians must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.¹⁵

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, physicians can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.¹⁶

HOW WE CONDUCTED THIS AUDIT

During our audit period, the MACs paid physicians \$52.8 million for 303,408 epidural steroid injection sessions. We analyzed the 303,408 sessions and identified 80,419 sessions totaling \$13.8 million that exceeded the coverage limitation for the respective MAC jurisdiction.

For each epidural steroid injection session, we evaluated compliance with Medicare billing requirements, and we relied on claim information to make our determination. We did not use medical review to determine whether services were medically necessary. Additionally, we did not contact any of the physicians who administered the epidural steroid injection sessions.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain enough, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹⁴ **The five-character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2018–2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

¹⁵ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

¹⁶ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Medicare did not always pay physicians for epidural steroid injection sessions in accordance with Medicare requirements. Specifically, for our audit period, we identified the following deficiencies:

- The MACs for the 10 jurisdictions with a coverage limitation for the number of epidural steroid injection sessions in a 6-month period made improper payments of \$2.4 million;¹⁷ and
- The MACs for the 9 jurisdictions with a coverage limitation for the number of epidural steroid injection sessions in a 12-month period made improper payments of \$1.2 million.¹⁸

Table 1 breaks out these findings by timeframe (6-month or 12-month period) and conveys the numbers of beneficiaries and unallowable epidural steroid injection sessions as well as the amounts of the overpayments associated with each timeframe.

Table 1: Total Overpayments of Epidural Steroid Injection Sessions¹⁹

Period of Time	Number of Beneficiaries	Unallowable Sessions	Overpayments
6-Month	11,724	14,119	\$2,388,564
12-Month	3,638	6,719	\$1,196,858
Totals	15,362	20,838	\$3,585,422

In total, Medicare improperly paid physicians \$3.6 million.²⁰ These improper payments occurred because neither CMS's oversight nor the MACs' oversight was adequate to prevent or detect improper payments to physicians for epidural steroid injection sessions.

¹⁷ The total improper payment amount for the 6-month periods was \$2,388,564.

¹⁸ The total improper payment amount for the 12-month periods was \$1,196,858.

¹⁹ This table summarizes the improper payments made to those 10 MAC jurisdictions that specified coverage limitations in their LCDs during our audit period. See Appendix C for additional details.

²⁰ The unrounded amount was \$3,585,422.

MEDICARE IMPROPERLY PAID PHYSICIANS FOR EPIDURAL STEROID INJECTION SESSIONS

Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions Administered During a 6-Month Period

During our audit period, for 10 of the 12 MAC jurisdictions, the applicable LCDs limited reimbursement to no more than the allowable number of epidural steroid injection sessions per beneficiary in a 6-month period (LCDs L34807 for Jurisdiction 15, L34982 for Jurisdiction E, L34980 for Jurisdiction F, L33906 for Jurisdiction N, L36521 for Jurisdictions 5 and 8, L35148 for Jurisdictions J and M, and L36920 for Jurisdictions H and L).²¹

In the 10 MAC jurisdictions with coverage limitations for the number of epidural steroid injection sessions per beneficiary in a 6-month period, the MACs improperly paid some physicians for more than the allowable number of injection sessions, as discussed in the paragraph below. In these cases, Medicare improperly paid physicians for at least one epidural injection session above the maximum number of sessions per beneficiary in a 6-month period. The number of improperly paid injection sessions for these beneficiaries ranged from 1 to 10 sessions.

Thus, the MACs for the 10 jurisdictions with coverage limitations made improper payments totaling \$2.4 million for 14,119 epidural injection sessions. We identified 11,724 beneficiaries who between them received 14,119 unallowable epidural injection sessions, beyond the allowable number of epidural steroid injection sessions in a 6-month period.

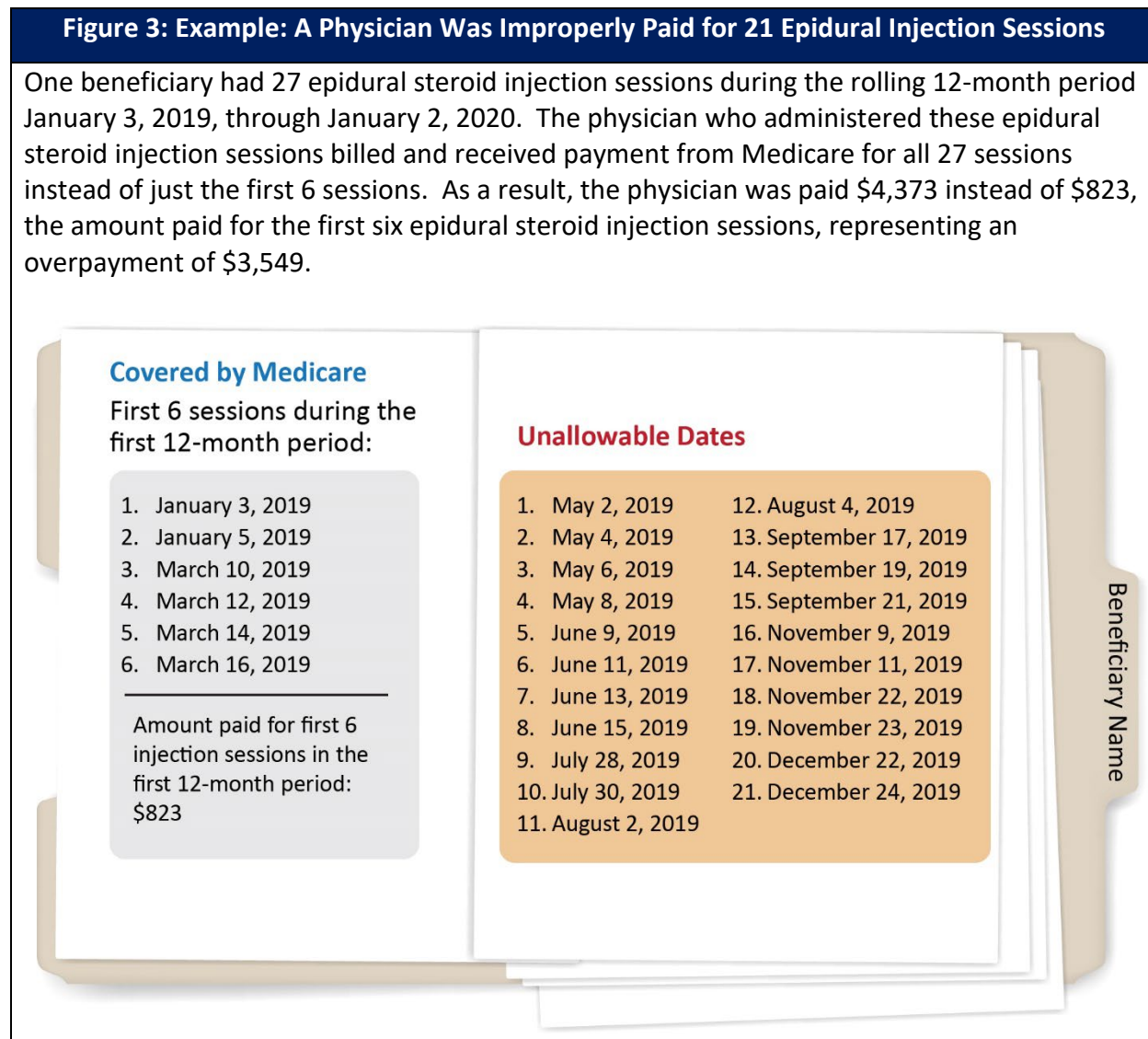
Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions Administered During a 12-Month Period

During our audit period, for 9 of the 12 MAC jurisdictions, the applicable LCDs limited reimbursement to no more than 6 epidural steroid injection sessions per beneficiary in a 12-month period (LCDs L34982 for Jurisdiction E, L34980 for Jurisdiction F, L36521 for Jurisdictions 5 and 8, L35148 for Jurisdictions J and M, L36920 for Jurisdictions H and L, and L34807 for Jurisdiction 15).

In the nine MAC jurisdictions with a coverage limitation for the number of epidural steroid injection sessions per beneficiary in a 12-month period, the MACs improperly paid some physicians for more than six injection sessions, as discussed below. In these cases, Medicare improperly paid physicians for at least one epidural injection session above the six-session maximum per beneficiary in a 12-month period. The number of improperly paid injection sessions for these beneficiaries ranged from 1 to 21 sessions.

²¹ During a 6-month period, applicable LCDs limited coverage to a maximum of three epidural steroid injection sessions for beneficiaries in eight jurisdictions (Jurisdictions 5, 8, E, F, H, L, J, and M) or a maximum of five epidural steroid injection sessions for beneficiaries in two jurisdictions (Jurisdictions 15 and N).

The example in Figure 3 shows an instance in which a physician was improperly paid during a 12-month period for epidural steroid injection sessions that exceeded the coverage limitation.



Thus, the MACs for the 9 jurisdictions with a coverage limitation made improper payments totaling \$1.2 million for 6,719 epidural steroid injection sessions.^{22, 23} We identified 3,638 beneficiaries who between them received 6,719 unallowable epidural steroid injection sessions, beyond the allowable number of epidural steroid injection sessions in a 12-month period.

²² This finding does not include improper payments that we already identified in the previous finding (i.e., more than three epidural steroid injection sessions in a 6-month period).

²³ First Coast Service Options, Inc.'s (First Coast's) and NGS's LCDs did not identify a coverage limitation for the number of epidural steroid injection sessions in a 12-month period.

CMS AND MEDICARE ADMINISTRATIVE CONTRACTOR OVERSIGHT WAS INADEQUATE TO PREVENT OR DETECT IMPROPER PAYMENTS TO PHYSICIANS

During our audit period, CMS oversight of the MACs was not always adequate to prevent or detect improper payments to physicians during the 6-month and 12-month periods in which beneficiaries received more than the allowable number of epidural steroid injection sessions. Specifically, CMS said that it could not implement proper oversight mechanisms to ensure that the MACs did not improperly pay physicians for epidural injections because of the differences between the MACs' LCD limitations. If CMS had had oversight mechanisms in place that could be tailored to the coverage limitations applicable to each MAC jurisdiction, CMS could have reduced the number of improperly paid epidural steroid injection sessions that we identified during our audit (totaling \$3.6 million for 20,838 sessions).

Furthermore, the MACs' oversight of the claims submitted by physicians was also not always adequate to prevent or detect improper payments to physicians during the 6-month and 12-month periods in which beneficiaries received more than the allowable number of epidural steroid injection sessions. During our audit period, only one MAC (covering two jurisdictions) had implemented claims processing system edits to prevent overpayments. However, the results of our audit suggest that those edits were not always effective. If the MACs had had oversight mechanisms in place, they could have reduced the number of improperly paid epidural steroid injection sessions that we identified during our audit.²⁴

THE MEDICARE ADMINISTRATIVE CONTRACTORS REVISED THEIR COVERAGE LIMITATIONS FOR EPIDURAL STEROID INJECTION SESSIONS AFTER OUR AUDIT PERIOD

After our audit period, all 12 MAC jurisdictions updated their LCDs specific to epidural steroid injections to limit the number of allowable injection sessions per beneficiary, per spinal region (cervical/thoracic spine or lumbar/sacral), to 4 sessions in a 12-month period. These revised coverage limitations became effective for epidural steroid injections administered on or after December 5, 2021 (LCDs L33906 for Jurisdiction N, L36920 for Jurisdictions H and L, L39036 for Jurisdictions 6 and K, L38994 for Jurisdictions J and M, L39015 for Jurisdiction 15, and L39054 for Jurisdictions 5 and 8). For the other two MAC jurisdictions, the updated LCDs became effective for epidural steroid injections administered on or after June 19, 2022 (LCDs L39242 and L39240 for Jurisdictions E and F). CMS officials stated that CMS developed and implemented oversight mechanisms that could prevent future improper payments for more than four epidural steroid injection sessions per spinal region for a beneficiary in a 12-month period. Because CMS implemented these oversight mechanisms after our audit period, we did not assess them or verify their effectiveness.

²⁴ CMS, working with MACs, is responsible for developing oversight mechanisms for MACs to implement to prevent increased Medicare program costs caused by improper payments. For example, CMS develops edits that the MACs implement in their claims processing systems to perform the following functions: select certain claims for review; evaluate or compare information on the selected claims or from other accessible sources; and, depending on the evaluation, take action on the claims, such as paying them in full, paying them in part, denying payment for them, or suspending payment while the claims undergo manual review.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- direct the MACs to recover the \$3,585,422 in improper payments made to physicians for epidural steroid injection sessions;
- instruct the MACs to, based on the results of this audit, notify appropriate physicians (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the physicians can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation;
- assess the effectiveness of oversight mechanisms, put in place after our audit period, that are specific to preventing or detecting improper payments to physicians for more than 4 epidural steroid injection sessions in a 12-month period and modify the oversight mechanisms, if necessary, based on that assessment; and
- direct the MACs (or other CMS-designated entities) to review a sample of claims for epidural steroid injection sessions administered during the period beginning on January 1, 2021, and ending on the date that the revised coverage limitations (i.e., up to four sessions per 12-month period) became effective in the relevant MAC's jurisdiction (i.e., December 5, 2021, or June 19, 2022), to identify instances in which Medicare paid physicians for injection sessions that exceeded the number of allowable sessions (in accordance with the applicable LCDs) and recover any improper payments identified.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with all of our recommendations and described actions that it had taken or planned to take to address our recommendations. These actions included directing the MACs to recover overpayments “consistent with relevant law and the agency’s policies and procedures,” instructing the MACs to notify physicians of potential overpayments, determining whether any modifications to oversight mechanisms are necessary, and sharing this report with medical review contractors to consider whether additional reviews should be performed, and any identified overpayments recovered, as part of the contractors’ “overall improper payment reduction strategies.”

For our first recommendation, CMS referred to the possibility that multiple physicians could have fulfilled the billing requirements for the epidural steroid injection sessions for the same beneficiary, without knowledge of the specific billing of another physician, and stated that those physicians may not be liable because they could be found to be without fault under section 1870(b) of the Act. CMS added, however, that multiple physicians who are members of the same medical practice and submit epidural steroid injections that exceed the limit for the

same beneficiary would not be without fault. CMS also said that since our audit period, it had “implemented claims processing controls, including system edits, to prevent and detect these types of overpayments.”

CMS’s comments appear in their entirety as Appendix D.

With respect to CMS’s reference to the “without fault” provision of section 1870(b) of the Act, CMS (acting through a MAC or other contractor), not OIG, makes the decision regarding whether a physician’s liability can be waived under the “without fault” provision. Moreover, because OIG audit recommendations do not represent final determinations by CMS, the decision to waive liability under the “without fault” provision can only be made after CMS determines that an overpayment exists.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period, the MACs paid physicians \$52,808,887 for 303,408 epidural steroid injection sessions. We analyzed the 303,408 sessions and identified 80,419 sessions totaling \$13.8 million that exceeded the coverage limitation for the respective MAC jurisdiction.

For each epidural steroid injection session, we evaluated compliance with Medicare billing requirements, and we relied on claim information to make our determination. We did not use medical review to determine whether services were medically necessary. We did not contact any of the physicians who administered the epidural steroid injection sessions.

We assessed CMS's internal controls and compliance with laws and regulations necessary to satisfy the audit objective. We assessed principles related to risk assessment and control activities. However, because our audit was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's Integrated Data Repository file, but we did not assess the completeness of the file.

We conducted our audit, which included contacting CMS in Baltimore, Maryland, from October 2021 to December 2022.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations, as well as the MACs' LCDs;
- interviewed staff at the MACs to verify whether they had coverage limitations for the number of epidural steroid injection sessions for the 6-month and 12-month periods;
- interviewed staff at CMS regarding the types of oversight mechanisms specific to reimbursing physicians in the MAC jurisdictions whose LCDs had coverage limitations for epidural steroid injection sessions;
- used CMS's Integrated Data Repository file to identify claims that physicians billed for epidural steroid injections in the cervical or thoracic region (billed using CPT codes 62320, 62321, and 62325, 64479, 64480) and the lumbar or sacral region (billed using

CPT codes 62322, 62323, 62326, 62327, 64483, and 64484),²⁵ with dates of service during our audit period;

- performed data analysis to identify during our audit period: (1) beneficiaries who received more than the allowable number of epidural steroid injection sessions in a 6-month period (footnote 21), and (2) beneficiaries who received more than 6 epidural steroid injection sessions in a 12-month period, depending on the MAC jurisdiction's specific coverage limitation;
- calculated improper payments in which: (1) the MACs for 10 jurisdictions with specified coverage limitations paid physicians for epidural steroid injection sessions that exceeded the number of allowable sessions for a 6-month period (in accordance with the applicable LCDs), and (2) the MACs for 9 MAC jurisdictions paid physicians for epidural steroid injection sessions that exceeded the number of allowable sessions for a 12-month period (in accordance with the applicable LCDs); and
- discussed the results of our audit with CMS officials on May 26, 2022.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain enough, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

²⁵ See footnote 14 for the CPT copyright information.

APPENDIX B: MEDICARE ADMINISTRATIVE CONTRACTOR AND GEOGRAPHIC COMPOSITION FOR EACH JURISDICTION^{26, 27}

Jurisdiction	MAC	States and Territories	LCD
5	Wisconsin Physicians Service Government Health Administrators (WPS)	Iowa, Kansas, Missouri, Nebraska	L36521
6	NGS	Illinois, Minnesota, Wisconsin	L35937
8	WPS	Indiana, Michigan	L36521
15	CGS Administrators, LLC (CGS)	Kentucky, Ohio	L34807
E	Noridian Healthcare Solutions, LLC (Noridian)	American Samoa, California, Guam, Hawaii, Nevada, Northern Mariana Islands	L34982
F	Noridian	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	L34980
H	Novitas	Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas	L36920
J	Palmetto GBA, LLC (Palmetto)	Alabama, Georgia, Tennessee	L35148
K	NGS	Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont	L35937
L	Novitas	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania	L36920
M	Palmetto	North Carolina, South Carolina, Virginia, West Virginia	L35148
N	First Coast	Florida, Puerto Rico, U.S. Virgin Islands	L33906

²⁶ The jurisdiction designation, MAC, and geographic composition for each jurisdiction are accurate as of June 2021.

²⁷ The LCDs identified in this table were effective during our audit period. The LCDs for these jurisdictions were later updated and became effective on December 5, 2021, or June 19, 2022.

APPENDIX C: OVERPAYMENTS OF EPIDURAL STEROID INJECTION SESSIONS BY JURISDICTION

Jurisdiction	Medicare Administrative Contractor	6-Month Period			12-Month Period			Total Improper Payment Amount
		Allowable Number of Epidural Steroid Injection Sessions	Number of Sessions Above Allowable Number of Sessions	Payment Amount for Sessions Above Allowable Number of Sessions	Allowable Number of Epidural Steroid Injection Sessions	Number of Sessions Above Allowable Number of Sessions	Payment Amount for Sessions Above Allowable Number of Sessions	
5	WPS	3	760	\$107,015	6	562	\$106,818	\$213,833
8	WPS	3	813	126,707	6	583	99,417	226,124
15	CGS	5	53	9,361	6	470	85,871	95,232
E	Noridian	3	1,309	240,281	6	1,092	221,207	461,488
F	Noridian	3	1,566	277,632	6	520	95,870	373,502
H	Novitas	3	3,176	496,911	6	996	143,289	640,200
J	Palmetto	3	1,334	189,296	6	707	106,882	296,178
L	Novitas	3	2,154	371,685	6	827	143,532	515,217
M	Palmetto	3	2,278	429,874	6	962	193,972	623,846
N	First Coast	5	676	139,802				139,802
Total			14,119	\$2,388,564		6,719	\$1,196,858	\$3,585,422



DATE: February 02, 2023

TO: Amy K. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Chiquita Brooks-LaSure *Chiquita LaSure*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions (A-07-21-00618)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. CMS takes the health and safety of individuals with Medicare seriously, and is committed to providing them with access to medically necessary services and, at the same time, working to protect the Medicare Trust Funds from improper payments.

CMS contracts with Medicare Administrative Contractors (MACs), which serve as the primary operational contact between the Medicare Fee-For-Service (FFS) program and the health care providers and suppliers enrolled in the program. The MACs perform many activities including processing Medicare FFS claims, educating providers and suppliers about Medicare FFS billing requirements, and reducing the number of improper payments for claims that do not comply with Medicare's coverage, coding, payment, and billing policies. Additionally, MACs have the statutory authority to determine which healthcare items and services are medically reasonable and necessary and to develop local coverage determinations (LCDs) for their individual jurisdictions, taking into account local variations in the practice of medicine.

Lumbar epidural steroid injections are performed to treat pain arising from spinal nerve roots. During the OIG's audit period of January 2019 to December 2020, 10 of the 12 MAC jurisdictions had instituted LCDs to limit Medicare coverage of epidural steroid injections to a maximum of six sessions in the spine per rolling 12-month period. In addition, eight of these jurisdictions had coverage limitations of three sessions in the spine during a six-month period, while two jurisdictions had a coverage limitation of five sessions during a 6-month period. As OIG noted, after the OIG's audit period, all 12 MAC jurisdictions updated their LCDs specific to epidural steroid injections to limit the number of allowable epidural steroid injection sessions per beneficiary, per spinal region, to four sessions in a rolling 12-month period. These revised coverage limitations became effective for seven MAC jurisdictions beginning on December 5, 2021, three

MAC jurisdictions beginning on December 12, 2021, and beginning on June 19, 2022 for the two remaining MAC jurisdictions.

In addition to the MACs' efforts to administer Medicare FFS claims, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system and prepayment and post payment medical reviews. For example, CMS uses the Fraud Prevention System (FPS) to analyze Medicare FFS claims. This system uses sophisticated algorithms to target investigative resources, generate alerts for suspect claims or providers and suppliers, and provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity. CMS uses the FPS information as well as additional approaches and strategies, to prevent and address improper payments using a variety of administrative tools and actions, including claims denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals. CMS leverages the FPS to reflect the coverage limitations set forth by MACs. As part of the program integrity strategy, CMS recovers identified overpayments in accordance with relevant law and agency policies and procedures.

While CMS appreciates the OIG's work in this area, CMS notes that OIG relied solely on claim information for this study. OIG did not conduct medical reviews to determine whether services were medically necessary. OIG also did not contact any of the physicians who administered the epidural steroid injection sessions. Without conducting medical record reviews, it is unclear whether the potential overpayments that the OIG identified were the result of medically necessary procedures. Through the administrative appeals process, a medical necessity review may be conducted and the denied services may be subsequently deemed medically necessary.

The OIG's recommendations and CMS's responses are below.

OIG Recommendation 1

The OIG recommends that the Centers for Medicare & Medicaid Services direct the MACs to recover the \$3,585,422 in improper payments made to physicians for epidural steroid injection sessions.

CMS Response

CMS concurs with this recommendation. CMS will direct the MACs to recover the identified overpayments consistent with relevant law and the agency's policies and procedures.

However, CMS recognizes the possibility that multiple physicians could have fulfilled the billing requirements for the epidural steroid injection sessions for the same beneficiary without knowledge of the specific billing of another physician. These physicians may not be liable because they could be found without fault under section 1870(b) of the Social Security Act. However, multiple physicians who are members of the same medical practice and submit epidural steroid injections that exceed the limit for the same beneficiary will not be without fault. Since the OIG's audit period, CMS has implemented claims processing controls, including system edits, to prevent and detect these types of overpayments.

OIG Recommendation 2

The OIG recommends that the Centers for Medicare & Medicaid Services instruct the MACs to, based on the results of this audit, notify appropriate physicians (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the physicians can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

CMS Response

CMS concurs with this recommendation. CMS will analyze the OIG's data to identify appropriate physicians to notify of potential overpayments. CMS will then instruct its MACs to notify the identified physicians of OIG's audit and potential overpayments. CMS will track any returned overpayments made in accordance with this recommendation and the 60-day rule.

OIG Recommendation 3

The OIG recommends that the Centers for Medicare & Medicaid Services assess the effectiveness of oversight mechanisms, put in place after our audit period, that are specific to preventing or detecting improper payments to physicians for more than 4 epidural steroid injection sessions in a 12-month period and modify the oversight mechanisms, if necessary, based on that assessment.

CMS Response

CMS concurs with the recommendation. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments and are constantly looking for ways to improve the effectiveness of the various oversight mechanisms. CMS will take the OIG's recommendation into consideration as we determine whether any modifications to the existing oversight mechanisms may be necessary.

OIG Recommendation 4

The OIG recommends that the Centers for Medicare & Medicaid Services direct the MACs (or other CMS-designated entities) to review a sample of claims for epidural steroid injection sessions administered during the period beginning on January 1, 2021, and ending on the date that the revised coverage limitations (i.e., up to four sessions per 12-month period) became effective in the relevant MAC's jurisdiction (i.e., December 5, 2021, or June 19, 2022), to identify instances in which Medicare paid physicians for injection sessions that exceeded the number of allowable sessions (in accordance with the applicable LCDs) and recover any improper payments identified.

CMS Response

CMS concurs with this recommendation. CMS will share the OIG's report with the medical review contractors to consider whether additional reviews of epidural steroid injections should be performed as part of their overall improper payment reduction strategies. Any identified overpayments associated with these reviews will be recovered in accordance with agency policies and procedures. Additionally, it should be noted that the Recovery Audit Contractors have had a complex medical necessity and documentation requirements review of transforaminal epidural steroid injections approved since October 2018.¹

¹ Additional information about the Recovery Audit Contractor review is available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0119-Transforaminal-Epidural-Steroid-Injection-to-the-Lumbar-or-Sacral-Level>