

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE COULD HAVE SAVED  
UP TO \$20 MILLION OVER 5 YEARS  
IF CMS OVERSIGHT HAD BEEN  
ADEQUATE TO PREVENT PAYMENTS  
FOR MEDICALLY UNNECESSARY  
CHOLESTEROL BLOOD TESTS**

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# *Office of Inspector General*

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## Report in Brief

Date: May 2021

Report No. A-09-19-03027

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



### Why OIG Did This Audit

A prior OIG audit found that Medicare paid providers that had billed for medically unnecessary laboratory tests. Our preliminary review of Medicare claims identified providers that billed for direct-measurement, low-density lipoprotein (LDL) cholesterol tests (direct LDL tests) and lipid panels (a blood test that reports four measures of lipids, including LDL cholesterol) for the same beneficiary on the same date of service; some of these providers billed the direct LDL test every time they billed the lipid panel. These claims were at risk of noncompliance with Medicare requirements because, according to the Centers for Medicare & Medicaid Services (CMS), billing for a direct LDL test in addition to a lipid panel, while sometimes medically necessary, should happen with only limited frequency.

Our objective was to determine whether payments made to providers for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service complied with Medicare requirements.

### How OIG Did This Audit

Our audit covered Medicare Part B payments of about \$35 million for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service and that had dates of service from 2015 through 2019 (audit period).

## Medicare Could Have Saved up to \$20 Million Over 5 Years if CMS Oversight Had Been Adequate To Prevent Payments for Medically Unnecessary Cholesterol Blood Tests

### What OIG Found

Payments made to providers for direct LDL tests that were billed in addition to lipid panels did not comply with Medicare requirements. Under certain circumstances, it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractors explained that these circumstances should happen with only limited frequency. We determined that some providers billed LDL tests in addition to lipid panels for the same beneficiary on the same date of service more than 75 percent of the time. (We refer to such providers as “at-risk providers.”) In total, we identified \$20.4 million of Medicare payments made to at-risk providers for direct LDL tests.

Two Medicare contractors’ review of medical records associated with 20 judgmentally sampled claims found that all of the direct LDL tests billed in addition to lipid panels were medically unnecessary. Because the claim lines for the \$20.4 million in payments to at-risk providers for direct LDL tests had characteristics similar to the claim lines in the judgmental sample, we determined that up to \$20.4 million in payments were improper. If CMS had had oversight mechanisms to prevent such payments, Medicare could have saved up to \$20.4 million for our audit period.

### What OIG Recommends and CMS Comments

We recommend that CMS direct the Medicare contractors to: (1) develop oversight mechanisms to identify at-risk providers and prevent improper payments to these providers, which could have saved up to \$20.4 million for our audit period, and (2) educate providers on the billing of direct LDL tests in addition to lipid panels. Our detailed recommendations are in the report.

CMS did not concur with our first recommendation and stated that ordering direct LDL tests and lipid panels together is permissible under Medicare payment rules on the basis of the physician’s clinical judgment. Regarding our second recommendation, CMS stated that it has already issued education on correct coding requirements for the proper use of modifiers on claim lines.

We maintain that our finding and recommendations are valid. Although we acknowledge that Medicare permits ordering direct LDL tests and lipid panels together, the at-risk providers in our audit routinely billed these tests together, and CMS’s education does not specifically address such billing.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

A prior Office of Inspector General (OIG) audit found that Medicare paid providers that had billed for medically unnecessary laboratory tests.<sup>1,2</sup> The improper payments occurred because providers did not follow Medicare guidance, and the Centers for Medicare & Medicaid Services' (CMS's) system edits were not adequate to prevent these payments. Our preliminary review of Medicare claims identified providers that billed for direct-measurement, low-density lipoprotein (LDL) cholesterol tests (direct LDL tests) and lipid panels for the same beneficiary on the same date of service; some of these providers billed the direct LDL test every time they billed the lipid panel.<sup>3</sup> These claims were at risk of noncompliance with Medicare billing requirements because, according to CMS, billing for a direct LDL test in addition to a lipid panel, while sometimes medically necessary, should happen with only limited frequency.

### OBJECTIVE

Our objective was to determine whether payments made to providers for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service complied with Medicare requirements.

### BACKGROUND

#### The Medicare Program

The Medicare program provides health insurance to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Medicare Part B provides supplementary medical insurance for medical and other health services, including clinical laboratory tests performed in a laboratory or a physician's office. CMS administers the Medicare program.

CMS contracts with 7 Medicare administrative contractors (Medicare contractors) for 12 jurisdictions to, among other things, process and pay Medicare Part B claims, conduct

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<sup>1</sup> *Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests (A-09-16-02034)*, issued Feb. 14, 2018.

<sup>2</sup> In this report, the term "provider" refers to both clinical laboratories and physician offices.

<sup>3</sup> A lipid panel is a blood test that reports four different measures of lipids (fat or fatlike substances in the blood), including LDL cholesterol.

reviews and audits, safeguard against fraud and abuse, and educate providers on Medicare billing requirements.<sup>4</sup>

## Medicare Part B Coverage of Clinical Laboratory Tests

Medicare Part B covers clinical diagnostic laboratory tests that are ordered by a physician (or a qualified nonphysician practitioner) who is treating a beneficiary and who uses the results in the management of the beneficiary's specific medical problem (42 CFR § 410.32(a)). Laboratory tests include certain blood tests, urinalysis, tests on tissue specimens, and some screening tests.

Laboratory tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (42 CFR § 410.32(a)). The physician who ordered a test must maintain documentation of medical necessity in the beneficiary's medical record (42 CFR § 410.32(d)(2)(i)). Providers submitting a claim must maintain documentation received from the ordering physician (42 CFR § 410.32(d)(2)(ii)).<sup>5</sup> Providers receive payment for laboratory tests based on amounts listed on the Clinical Laboratory Fee Schedule, and beneficiaries generally pay nothing for Medicare-approved covered laboratory tests.

To receive Medicare payment for a laboratory test, the provider submits a claim (42 CFR § 424.5(a)(5)).<sup>6</sup> The Healthcare Common Procedure Coding System (HCPCS) is the approved system for reporting outpatient procedures, items, and services, and providers must use the appropriate HCPCS code on claim forms for most outpatient services (*Medicare Claims Processing Manual* (Claims Manual), Pub. No. 100-04, chapter 23, § 20 and § 20.3).<sup>7</sup> In addition to the HCPCS code reported on the claim line, providers may append a modifier to the claim

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<sup>4</sup> For each jurisdiction, CMS enters into a contract with one entity to serve as the Medicare contractor. Although there are 12 jurisdictions, there are only 7 Medicare contractors because 5 Medicare contractors were awarded contracts for 2 jurisdictions each. CMS Jurisdiction Map, as of June 2019, available online at <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-Jurisdiction-Map-Jun-2019.pdf>. Accessed on Nov. 20, 2020.

<sup>5</sup> For some laboratory tests, the provider submitting the claim and the ordering physician may be the same person.

<sup>6</sup> Each claim contains details regarding each provided service (called a claim line in this report).

<sup>7</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. HCPCS codes are divided into two groups: level I and level II. Level I HCPCS codes consist of Current Procedural Terminology (CPT) codes, a numeric coding system maintained by the American Medical Association (AMA), and are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II HCPCS codes are based on a standardized coding system and are used primarily to identify products, supplies, and services not included in the CPT codes. **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2015–2019 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.**

line, if applicable. A modifier is a two-digit code that provides additional information needed to process a claim (Claims Manual, chapter 23, § 20.3). Diagnosis codes on a claim may also be used in determining coverage and payment (Claims Manual, chapter 23, § 10).<sup>8</sup>

### **Medicare Part B Coverage of Blood Tests, Including Lipid Panels and Direct LDL Tests**

Medicare Part B covers cardiovascular-screening blood tests (e.g., blood tests for measuring cholesterol and triglyceride levels).<sup>9</sup> These tests help detect conditions that may lead to a heart attack or a stroke.

Lipid panels and direct LDL tests are specific types of blood tests used to assess the risk of developing cardiovascular disease:

- **The lipid panel** measures the levels of four specific lipids in the blood (total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and LDL cholesterol). Lipids are a group of fats and fatlike substances, which are important constituents of cells and sources of energy. The level of LDL cholesterol, sometimes called bad cholesterol, is calculated using the measured values of the other lipid components of the lipid panel: total cholesterol, HDL cholesterol, and triglycerides.<sup>10</sup>
- **The direct LDL test** measures the actual level of LDL cholesterol in the blood. When triglycerides are significantly elevated (above 400 milligrams per deciliter (mg/dl)), the equation to determine the level of LDL cholesterol using the lipid panel results is no longer valid. In these situations, the only way to accurately determine the level of LDL cholesterol is to measure it directly.

Because the level of LDL cholesterol can be calculated from the results of the other three tests in the lipid panel, testing for LDL cholesterol—in most cases—is not separately reimbursable when the lipid panel is performed for the same beneficiary on the same date of service.

### **CMS's Claims Processing System Edits**

To promote correct coding by providers and to prevent Medicare payments for improperly coded services, CMS developed the National Correct Coding Initiative (NCCI).<sup>11</sup> Medicare

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<sup>8</sup> Diagnosis codes are standardized codes used to describe diagnoses for medical conditions.

<sup>9</sup> Triglycerides are one type of lipid found in the blood.

<sup>10</sup> LDL cholesterol = total cholesterol – HDL cholesterol – (triglycerides/5).

<sup>11</sup> The NCCI coding policies are based on: (1) coding conventions defined in AMA's *Current Procedural Terminology (CPT) Manual*, (2) national and local policies and edits, (3) coding guidelines developed by national societies, (4) a review of current coding practices, and (5) an analysis of standard medical and surgical practices.



contractors implemented NCCI prepayment edits within their claim processing systems for dates of service on or after January 1, 1996.<sup>12</sup>

The NCCI edits include procedure-to-procedure edits that define pairs of HCPCS codes (i.e., code pairs) that generally should not be reported together for the same beneficiary on the same date of service. (These code pairs include CPT codes.) If a provider submits both HCPCS codes of the code pair for payment for the same beneficiary on the same date of service, one HCPCS code (the first HCPCS code of the code pair) is eligible for payment, but the edit will deny the other HCPCS code (the second HCPCS code of the code pair).<sup>13</sup> However, if both HCPCS codes are clinically appropriate and it is clinically appropriate to append an NCCI-associated modifier to the second HCPCS code of the code pair, both are eligible for payment.<sup>14</sup> A modifier must not be appended to a HCPCS code solely to bypass the NCCI edit if the clinical circumstances do not justify its use.

### **Lipid Panel and Direct LDL Test Code-Pair Edit**

On April 1, 2003, CMS added the lipid panel (CPT code 80061<sup>15</sup>) and the direct LDL test (CPT code 83721) code pair to the NCCI edits. According to the *NCCI Coding Policy Manual for Medicare Services* (NCCI Coding Policy Manual), there are limited circumstances in which the direct LDL test may be reported on the same date of service as the lipid panel for the same beneficiary (chapter I, section O.2, and chapter X, section G.1).<sup>16</sup>

The table on the following page shows the code pair for the lipid panel and direct LDL test and an example of how the total amount paid to the provider is higher when an NCCI-associated modifier (in this case, modifier 59) is appended to the second CPT code of the code pair (the direct LDL test).

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<sup>12</sup> The NCCI prepayment edits select certain claims; evaluate or compare information on the selected claims or other accessible sources; and, depending on the evaluation, take action on the claims, such as paying them in full, paying them in part, or denying payment for them.

<sup>13</sup> Often, the denied HCPCS code is a component of the other, more comprehensive HCPCS code.

<sup>14</sup> Effective July 1, 2019, Medicare allows certain NCCI-associated modifiers (e.g., modifier 59 (“distinct procedural service”)) to be appended to either HCPCS code of the code pair to bypass the NCCI edit, which is a change from the previous rule that required the modifier to be appended to the second HCPCS code of the code pair. According to CMS’s Medicare Learning Network Matters article MM8863, modifier 59 is the most widely used HCPCS modifier and is associated with considerable abuse and high levels of manual audit activity, leading to reviews, appeals, and even civil fraud and abuse cases.

<sup>15</sup> See footnote 7 for the AMA copyright notice.

<sup>16</sup> The chapter I, section O.2, language is in the 2015 through 2020 versions of the NCCI Coding Policy Manual. CMS removed this language from chapter I in the 2021 version. The chapter 10, section G.1, language is in the 2015 through 2018 versions of the NCCI Coding Policy Manual, which was revised in the 2019 and later versions.

**Table: The Provider Receives a Higher Total Payment When Modifier 59 Is Appended to the CPT Code for the Separately Billed Direct LDL Test**

First CPT Code of the Code Pair (Lipid Panel)	Payment	Second CPT Code of the Code Pair (Direct LDL Test)	Payment*	Modifier	Total Amount Paid
80061	\$18	83721	\$13	None	<b>\$18</b>
80061	\$18	83721	\$13	59	<b>\$31</b>

\* The Clinical Laboratory Fee Schedule payment for each direct LDL test was \$13 from calendar years (CYs) 2015 through 2017, \$12 for CY 2018, and \$11 for CY 2019.

**HOW WE CONDUCTED THIS AUDIT**

Medicare made Part B payments of \$35.8 million to 11,788 providers for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service and that had dates of service from calendar years (CYs) 2015 through 2019 (audit period). After we excluded payments to 9,000 providers with total payments of less than \$500 per provider during our audit period for the direct LDL tests that were billed in addition to lipid panels, our audit covered payments of approximately \$35 million.

We interviewed CMS and Medicare contractor officials to obtain an understanding of the billing requirements and system edits for direct LDL tests and lipid panels. Under certain circumstances (e.g., when triglycerides are significantly elevated (above 400 mg/dl)), it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractor officials explained that the circumstances when it would be medically necessary for a provider to do so should happen with only limited frequency.

Based on this information, we determined there were providers that routinely billed direct LDL tests and lipid panels for the same beneficiary on the same date of service. (We considered a provider to have billed routinely if, out of the total number of lipid panels that the provider performed, the provider billed the direct LDL tests in addition to lipid panels more than 75 percent of the time. We refer to such a provider as an “at-risk provider.”) We analyzed the claims data to remove those providers that did not routinely bill for these tests for the same beneficiary on the same date of service and identified approximately 1.7 million claims for direct LDL tests with Medicare payments of \$20.4 million that were made to 1,334 at-risk providers.

The 1.7 million claims we identified consisted of claim lines. We did not review entire claims; we reviewed only specific claim lines. (Each claim line we reviewed was a direct LDL test billed on the same claim as the lipid panel or on a separate claim.) We evaluated whether the specific

claim lines complied with Medicare requirements and selected within the jurisdictions of 2 Medicare contractors a judgmental sample of 20 claims that each contained a direct LDL test billed in addition to a lipid panel for the same beneficiary on the same date of service by an at-risk provider.<sup>17, 18</sup> The two Medicare contractors reviewed their respective jurisdictions' medical records for the selected claim lines on the sampled claims to determine the medical necessity of the direct LDL tests. The Medicare contractors did not perform medical reviews of all claim lines on the sampled claims to determine the medical necessity of all tests that were billed.

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 sufficient, 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.

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

## **FINDING**

Payments made to providers for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service did not comply with Medicare requirements. Specifically, the 2 Medicare contractors' review of the 20 judgmentally sampled claims found that all of the direct LDL tests billed in addition to lipid panels were medically unnecessary. Because the claim lines for the \$20.4 million in payments to 1,334 at-risk providers for direct LDL tests billed in addition to lipid panels had characteristics similar to the claim lines in the judgmental sample, for which all of the separately billed direct LDL tests were found to be medically unnecessary, we determined that up to \$20.4 million in payments were improper.<sup>19</sup>

CMS's oversight was not adequate to prevent improper payments for the direct LDL tests. If CMS had had oversight mechanisms to prevent such payments, Medicare could have saved up to \$20.4 million for our audit period.

## **FEDERAL REQUIREMENTS**

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (Social Security Act § 1862(a)(1)(A)). In addition, payments may not be made to any provider of services or other person without information necessary to

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<sup>17</sup> Each claim included all services performed or billed by a provider for a beneficiary on a single date of service.

<sup>18</sup> Although we selected claims for at-risk providers from only two Medicare contractors for this medical review, there were claims for at-risk providers submitted to all seven Medicare contractors.

<sup>19</sup> The unrounded amount is \$20,351,424.

determine the amount due such provider or other person (Social Security Act § 1833(e)). Medicare Part B covers clinical laboratory tests only if the treating physician uses the test results in the management of the beneficiary's specific medical problem (42 CFR § 410.32(a)).

According to the NCCI Coding Policy Manual, although the NCCI edits include procedure-to-procedure edits that define pairs of HCPCS codes that generally should not be reported together for the same beneficiary on the same date of service, there is a limited circumstance in which billing a direct LDL test in addition to a lipid panel may be separately reportable (i.e., may be separately billed):

. . . the NCCI has an edit with [the first CPT code of the code pair] 80061 (lipid [panel]) and [the second CPT code of the code pair] 83721 (LDL cholesterol by direct measurement). If the triglyceride level is less than 400 mg/dl, the LDL is a calculated value utilizing the results from the lipid [panel] for the calculation, and CPT code 83721 is not separately reportable. However, if the triglyceride level is greater than 400 mg/dl, the LDL may be measured directly and may be separately reportable with CPT code 83721 utilizing an NCCI-associated modifier to bypass the edit.<sup>20</sup>

The NCCI Coding Policy Manual also states: "CPT code 83721 (lipoprotein, direct measurement; direct measurement, LDL cholesterol) describes direct measurement of LDL cholesterol. It shall not be used to report a calculated LDL cholesterol."<sup>21</sup>

### **MEDICARE MADE UP TO \$20.4 MILLION IN IMPROPER PAYMENTS TO AT-RISK PROVIDERS FOR DIRECT LDL TESTS BILLED IN ADDITION TO LIPID PANELS FOR THE SAME BENEFICIARY ON THE SAME DATE OF SERVICE**

For our audit period, Medicare made \$20.4 million in payments to 1,334 at-risk providers for direct LDL tests billed in addition to lipid panels for the same beneficiary on the same date of service. Approximately 99 percent of these payments were for claim lines billed with an

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<sup>20</sup> NCCI Coding Policy Manual, chapter I, § O.2. This language is in the 2020 version of the NCCI Coding Policy Manual and all of the versions that were effective during our audit period (CYs 2015 through 2019). However, this language is no longer in the 2021 version.

<sup>21</sup> NCCI Coding Policy Manual, chapter X, § G.1. This language is in the 2019, 2020, and 2021 versions of the NCCI Coding Policy Manual. In the older versions of the manual, which were applicable during the first 4 years of our audit period (CYs 2015 through 2018), additional language in this section stated: "Direct measurement of LDL cholesterol in addition to . . . [the] lipid panel (CPT code 80061) may be reasonable and necessary if the triglyceride level is too high (greater than or equal to 400 mg/dl) to permit calculation of the LDL cholesterol. In such situations, CPT code 83721 should be reported with modifier 59." CMS stated that it removed this language because the NCCI Coding Policy Manual deals with only coding issues, not issues related to whether services are reasonable and necessary.

NCCI-associated modifier.<sup>22</sup> The modifier appended most often (i.e., for 97 percent of the claim lines) was modifier 59, which allowed the claim lines to bypass the NCCI edit that limits payment to just the lipid panel.

Under certain circumstances, it may be medically necessary for a provider to perform both the lipid panel and the direct LDL test on the same day for the same beneficiary—for example, if the beneficiary’s triglycerides are greater than 400 mg/dl. However, CMS and Medicare contractor officials explained to us that such testing should happen with only limited frequency.

The 2 Medicare contractors that reviewed the medical records for our judgmental sample of 20 claims from at-risk providers determined that, for each of the claim lines reviewed, either: (1) the medical records did not support the need for the separately billed direct LDL test or (2) performing the direct LDL test would have resulted in no change in the management of the beneficiary’s specific medical problem. None of the beneficiaries in our sample had a documented triglyceride level of greater than 400 mg/dl. Therefore, the Medicare contractors found that all of the direct LDL tests associated with the claim lines in the judgmental sample were medically unnecessary.

After analyzing the \$20.4 million in payments to 1,334 at-risk providers for direct LDL tests billed in addition to lipid panels for the same beneficiary on the same date of service, we determined that the claim lines for these payments had characteristics similar to the claim lines in the judgmental sample of 20 claims, for which all of the separately billed direct LDL tests were found to be medically unnecessary. Specifically, 99 percent of the claim lines were billed with NCCI-associated modifiers, such as modifier 59, and had similar diagnosis codes.<sup>23</sup> Therefore, we determined that up to \$20.4 million in payments were improper.

### **CMS OVERSIGHT WAS NOT ADEQUATE TO PREVENT IMPROPER PAYMENTS**

CMS’s oversight was not adequate to prevent improper payments for direct LDL tests billed in addition to lipid panels for the same beneficiary on the same date of service. CMS officials stated that there are no oversight mechanisms specific to identifying routine billing of direct LDL tests with lipid panels. CMS officials also stated that there are some educational materials for providers on blood tests that can be used for screening of lipids and on LDL tests in general but nothing specific to the issue of the billing of the code pair for the lipid panel and direct LDL test (i.e., CPT codes 80061 and 83721).

If CMS had had oversight mechanisms to identify at-risk providers (e.g., by reviewing claims for providers that routinely billed direct LDL tests in addition to lipid panels for the same

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<sup>22</sup> The other 1 percent of the payments consisted of claim lines billed with: (1) other modifiers, e.g., modifier 79 (“unrelated procedure or service by the same physician during the postoperative period”) or (2) no modifier.

<sup>23</sup> All of the claim lines in our judgmental sample were billed with modifier 59, and the top 4 diagnosis codes billed, which made up over 50 percent of the \$20.4 million in Medicare payments to the 1,334 at-risk providers, were included in our judgmental sample.

beneficiary on the same date of service and appended to those claim lines an NCCI-associated modifier) and prevent improper payments to these providers, Medicare could have saved up to \$20.4 million for our audit period.

## **RECOMMENDATIONS**

We recommend that the Centers for Medicare & Medicaid Services direct the Medicare contractors to:

- develop oversight mechanisms to identify at-risk providers (e.g., by reviewing claims for providers that routinely billed direct LDL tests in addition to lipid panels for the same beneficiary on the same date of service and appended to those claim lines an NCCI-associated modifier) and prevent improper payments to these providers, which could have saved up to \$20,351,424 for our audit period, and
- educate providers on the billing of direct LDL tests in addition to lipid panels (e.g., by providing guidance about the requirements for separately billing direct LDL tests).

## **CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, CMS did not concur with our first recommendation. CMS did not concur or nonconcur with our second recommendation but provided information on actions that it had taken or planned to take to address this recommendation. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix B.

After reviewing CMS's comments, we maintain that our finding and recommendations are valid.

### **CMS COMMENTS**

CMS did not concur with our first recommendation. CMS stated that ordering direct LDL tests and lipid panels together is permissible under Medicare payment rules on the basis of the physician's clinical judgment. CMS stated that it routinely conducts oversight to ensure that payments are made properly under Medicare coverage rules.

Regarding our second recommendation, CMS stated that it has already issued education on NCCI correct coding requirements for the proper use of modifiers. CMS also stated that this education is being updated and will continue to be reviewed and revised annually. CMS stated that determinations of whether direct LDL tests and lipid panels are reasonable and necessary depend on the practitioner's clinical judgment based on each patient's unique circumstances.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

We acknowledge that ordering direct LDL tests and lipid panels together is permissible under Medicare payment rules on the basis of the physician's clinical judgment; however, the at-risk providers in our audit routinely billed these tests together for the same beneficiary on the same date of service. As noted earlier in the report, CMS and Medicare contractor officials explained to us in interviews that the circumstances when it would be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service should happen with only limited frequency. In addition, we note that CMS did not indicate that its oversight involves targeting at-risk providers. Therefore, we continue to recommend that CMS develop oversight mechanisms to identify such providers and prevent improper payments to these providers for direct LDL tests billed in addition to lipid panels.

We acknowledge that CMS has already issued education on NCCI correct coding requirements for the proper use of modifiers. However, that education does not specifically address billing of direct LDL tests in addition to lipid panels.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Medicare made Part B payments of \$35,757,983 to 11,788 providers for direct LDL tests that were billed in addition to lipid panels for the same beneficiary on the same date of service and that had dates of service from CYs 2015 through 2019. After we excluded payments to 9,000 providers with total payments of less than \$500 per provider during our audit period for the direct LDL tests that were billed in addition to lipid panels, our audit covered payments of \$34,962,750.

We interviewed CMS and Medicare contractor officials to obtain an understanding of the billing requirements and system edits for direct LDL tests and lipid panels. Under certain circumstances (e.g., when triglycerides are significantly elevated (above 400 mg/dl)), it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractor officials explained that the circumstances when it would be medically necessary for a provider to do so should happen with only limited frequency.

Based on this information, we determined there were providers that routinely billed direct LDL tests and lipid panels for the same beneficiary on the same date of service. (We considered a provider to have billed routinely if, out of the total number of lipid panels that the provider performed, the provider billed the direct LDL tests in addition to lipid panels more than 75 percent of the time. We refer to such a provider as an “at-risk provider.”) We analyzed the claims data to remove those providers that did not routinely bill for these tests for the same beneficiary on the same date of service and identified 1,692,742 claims for direct LDL tests with Medicare payments of \$20,351,424 that were made to 1,334 at-risk providers.

The 1,692,742 claims we identified consisted of claim lines. We did not review entire claims; we reviewed only specific claim lines. (Each claim line we reviewed was a direct LDL test billed on the same claim as the lipid panel or on a separate claim.) We evaluated whether the specific claim lines complied with Medicare requirements and selected within the jurisdictions of 2 Medicare contractors a judgmental sample of 20 claims that each contained a direct LDL test billed in addition to a lipid panel for the same beneficiary on the same date of service by an at-risk provider.<sup>24, 25</sup> The two Medicare contractors reviewed their respective jurisdictions’ medical records for the selected claim lines on the sampled claims to determine the medical necessity of the direct LDL tests. The Medicare contractors did not perform medical reviews of all claim lines on the sampled claims to determine the medical necessity of all tests that were billed.

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<sup>24</sup> Each claim included all services performed or billed by a provider for a beneficiary on a single date of service.

<sup>25</sup> Although we selected claims for at-risk providers from only two Medicare contractors for this medical review, there were claims for at-risk providers submitted to all seven Medicare contractors.



We did not perform an overall assessment of the internal control structures of CMS or its Medicare contractors. Rather, we limited our review to those internal controls related to Medicare requirements for the billing of direct LDL tests in addition to lipid panels for the same beneficiary on the same date of service and the types of oversight that CMS had in place during our audit period. Specifically, we focused our assessment on three of the five internal control components that were most relevant to our audit objective: control environment, risk assessment, and control activities.<sup>26</sup> Because our audit was designed to provide only reasonable assurance that the internal controls we reviewed were effective, it would not necessarily have detected all internal control deficiencies.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the file.

We conducted our audit from February 2020 to February 2021.

## **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials to obtain an understanding of the requirements, system edits, and oversight specific to payment for the direct LDL tests and lipid panel CPT codes billed;
- interviewed officials at 3 Medicare contractors to obtain an understanding of the requirements and system edits specific to payment for the direct LDL tests and lipid panel CPT codes billed;<sup>27</sup>
- extracted from CMS's NCH file the paid claims data, including the modifiers and diagnosis codes billed, for Medicare Part B payments made to providers for direct LDL tests billed in addition to lipid panels for the same beneficiary on the same date of service with dates of service during our audit period;

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<sup>26</sup> The Government Accountability Office's (GAO's) *Standards for Internal Control in the Federal Government: September 2014* (GAO-14-704G), known as the Green Book, sets the internal control standards for Federal entities. The Green Book defines internal control as the plans, methods, policies, and procedures used by management to fulfill the mission, strategic plan, goals, and objectives of the entity. The Green Book approaches internal control through a hierarchal structure made up of five components: (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

<sup>27</sup> One Medicare contractor responded to our questions through email only.

- used computer matching, data mining, and data analysis techniques to identify claim lines, totaling \$35,757,983, paid to 11,788 providers for direct LDL tests billed in addition to lipid panels;
- removed 9,000 providers with total payments of less than \$500 per provider during our audit period for the direct LDL tests that were billed in addition to lipid panels to identify \$34,962,750 paid to 2,788 providers during our audit period;
- removed providers that did not routinely bill for direct LDL tests in addition to lipid panels to identify 1,692,742 claims billed by 1,334 at-risk providers that received Medicare payments of \$20,351,424;
- identified the modifiers and diagnosis codes that were included on the claim lines for the direct LDL tests that at-risk providers billed in addition to lipid panels;
- within the jurisdictions of 2 Medicare contractors, selected a judgmental sample of 20 claims that each had a direct LDL test billed in addition to a lipid panel by an at-risk provider;
- obtained and reviewed medical record documentation provided by the at-risk providers to support the 20 sampled claims;
- used the 2 Medicare contractors to determine whether the 20 sampled claims within their respective jurisdictions were medically necessary;
- used data analysis techniques to compare the 20 sampled claims with the claims for the \$20,351,424 in Medicare payments made to 1,334 at-risk providers to identify similar characteristics; and
- discussed the results of our audit with CMS officials.

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 sufficient, 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.

## APPENDIX B: CMS COMMENTS



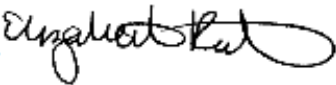
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator  
Washington, DC 20201

**DATE:** March 24, 2021

**TO:** Amy Frontz  
Deputy Inspector General for Audit Services

**FROM:** Elizabeth Richter   
Acting Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: Medicare Could Have Saved up to \$20 Million Over 5 Years if CMS Oversight Had Been Adequate to Prevent Payments for Medically Unnecessary Cholesterol Blood Tests (A-09-19-03027)

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 recognizes the importance of providing Medicare beneficiaries with access to medically necessary services, and, at the same time, working to prevent improper payments. 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 postpayment medical reviews. As part of this strategy, CMS recovers identified improper payments in accordance with relevant law and agency policies and procedures.

Medicare pays for both a lipid panel (which determines total serum cholesterol, high density cholesterol, and triglycerides, and calculates an estimated low density lipoprotein (LDL)) and a direct (measured) LDL test billed for the same beneficiary on the same date of service when reasonable and necessary. As such, and as the OIG notes, in 2003, CMS added the lipid panel and the direct LDL test code pair to the National Correct Coding Initiative (NCCI) edits with a Correct Coding Modifier Indicator of 1 to allow payment for both services for the same beneficiary on the same date of service when appropriate. The use of both tests together can be reasonable and necessary in certain circumstances, such as for beneficiaries with comorbidities or beneficiaries on certain medications. For example, if a patient has a history of hypertriglyceridemia, a direct measurement of LDL could be warranted at the time of the lipid panel. For that reason, practitioners and laboratories may use a modifier code to bill both of these tests in combination, if the clinical circumstances justify use of a modifier.

CMS reviews and updates the NCCI Policy Manual annually. The NCCI Policy Manual provides information on correct coding of medical services rather than reasonable and necessary criteria. Additionally, CMS has taken action to prevent improper Medicare payments by educating health care providers and suppliers on proper use of modifiers. CMS educates health care providers and suppliers (including practitioners and laboratories) on Medicare billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters. CMS will continue to review guidance and educate suppliers as necessary on an ongoing basis.

OIG's recommendations and CMS' responses are below.

**OIG Recommendation**

CMS should direct the Medicare contractors to develop oversight mechanisms to identify at-risk providers (e.g., by reviewing claims for providers that routinely billed direct LDL tests in addition to lipid panels for the same beneficiary on the same date of service and appended to those claim lines an NCCI-associated modifier) and prevent improper payments to these providers, which could have saved up to \$20,351,424 for our audit period.

**CMS Response**

CMS does not concur with this recommendation. Ordering these tests together is permissible under Medicare payment rules based on the physician's clinical judgement. As stated above, CMS routinely conducts oversight to ensure that payments are made properly under Medicare coverage rules.

**OIG Recommendation**

CMS should direct the Medicare contractors to educate providers on the billing of direct LDL tests in addition to lipid panels (e.g., by providing guidance about the requirements for separately billing direct LDL tests).

**CMS Response**

CMS has already issued education on NCCI correct coding requirements for the proper use of modifiers. This education is currently being updated (publication pending) and will continue to be reviewed and revised annually. Determinations of whether both tests are reasonable and necessary depend on the practitioner's clinical judgement based on each patient's unique circumstances.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.