Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments

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

June 2023
A-09-22-03010

Office of Inspector General

https://oig.hhs.gov

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

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. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

Office of Counsel to the Inspector General. OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and civil monetary penalties, monitors Corporate Integrity Agreements, and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, 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: June 2023
Report No. A-09-22-03010

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

CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments

Why OIG Did This Audit

Prior OIG work identified increased spending on Medicare Part B genetic testing, as well as fraudulent billing of genetic tests. Although there may be legitimate reasons for the increased spending, the increases indicate the potential for improper payments. Our prior analysis showed that, for 2016 through 2019, Current Procedural Terminology (CPT) code 81408 was the genetic-testing procedure code with the second highest total Part B payments and was the molecular pathology procedure (a type of genetic test) with the highest Medicare payment amount ($2,000). This CPT code may be billed when testing for multiple genes associated with rare diseases. Because these diseases generally manifest in childhood, the genes associated with them would not generally be tested for in the Medicare population, which is predominantly 65 years of age and older. Therefore, there is a risk of Medicare improper payments for this CPT code.

Our objective was to determine whether the Centers for Medicare & Medicaid Services' (CMS's) oversight of Medicare payments for CPT code 81408 was adequate to reduce the risk of improper payments.

How OIG Did This Audit

To determine whether there was a risk of improper payments, we analyzed the Medicare Part B claims associated with payments of $888.2 million for more than 450,000 genetic tests billed under CPT code 81408 that had dates of service from 2018 through 2021 (audit period). We also interviewed CMS and Medicare contractor officials.

What OIG Found

CMS and the Medicare Administrative Contractors' (MACs') oversight of Medicare payments for CPT code 81408 did not: (1) ensure that all Medicare enrollees had established relationships with ordering providers; (2) ensure that Medicare payments for CPT code 81408 were related to diseases associated with genes that would generally be tested and billed under that CPT code; and (3) include adequate monitoring of the number of tests billed under CPT code 81408, a Tier 2 molecular pathology procedure (MPP) code, to determine whether that number exceeded the number of tests billed under Tier 1 MPP codes. (Tier 2 MPPs are generally performed in lower volumes than Tier 1 MPPs because the diseases being tested for are rare.) In addition, not all MACs could identify the specific gene tested by laboratories billing CPT code 81408. Finally, although five of the seven MACs had Local Coverage Article guidance that prohibited or limited use of CPT code 81408, two MACs' Local Coverage Articles did not limit its use.

Although CMS officials stated that CMS conducts data analysis (e.g., to identify high-risk providers), CMS did not ensure that the MACs provided sufficient oversight over billing of and payments for CPT code 81408. Two of the MACs' payments made up 97 percent of the total payments for CPT code 81408 for our audit period. Because there were no longer payments for this CPT code by the end of our audit period (December 31, 2021), we consider the issues identified by this audit corrected. However, based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment.

What OIG Recommends and CMS Comments

We recommend that CMS direct the appropriate Medicare contractors to: (1) review claims billed under CPT code 81408 for our audit period to determine whether they complied with Medicare requirements and (2) determine the amount of improper payments for the claims that did not comply with Medicare requirements and recover up to $888.2 million for claims that were at risk of improper payment during our audit period. The report contains the detailed recommendations and one other recommendation.

CMS concurred with our first and third recommendations. CMS did not concur or nonconcur with our second recommendation but provided information on actions that it planned to take to address this recommendation.

The full report can be found at https://oig.hhs.gov/oas/reports/region9/92203010.asp.

TABLE OF CONTENTS

APPENDICES

INTRODUCTION

WHY WE DID THIS AUDIT

Prior Office of Inspector General (OIG) work identified increased spending on Medicare Part B genetic testing, as well as fraudulent billing of genetic tests.[1] Although there may be legitimate reasons for the increased spending on genetic testing, the increases indicate areas of concern, such as the potential for improper payments. Our prior analysis showed that, for calendar years (CYs) 2016 through 2019, Current Procedural Terminology (CPT)[2] code 81408 was the genetic-testing procedure code with the second highest total Medicare Part B payments and was the molecular pathology procedure (a type of genetic test) with the highest Medicare payment amount ($2,000). CPT code 81408 may be billed when testing for multiple genes associated with rare diseases, such as Duchenne and Becker muscular dystrophy.[3] Because these diseases generally manifest in childhood, the genes associated with them would not generally be tested for in the Medicare population, which is predominantly 65 years of age and older. Therefore, there is a risk of Medicare improper payments for this CPT code.

OBJECTIVE

Our objective was to determine whether the Centers for Medicare & Medicaid Services' (CMS's) oversight of Medicare payments for CPT code 81408 was adequate to reduce the risk of improper payments.

BACKGROUND

The Medicare Program and the Role of the Medicare Administrative Contractors

The Medicare program provides health insurance to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Medicare Part A covers inpatient hospital services and other health services provided to eligible enrollees. Medicare Part B provides

---

[1] Prior OIG reports include *Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern* (A-09-20-03027), issued December 16, 2021; *Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests* (OEI-09-20-00450), issued December 18, 2020; and *Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions* (OEI-09-19-00100), issued August 6, 2020.

[2] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2018–2021 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.**

[3] Muscular dystrophies are a group of genetic conditions characterized by progressive muscle weakness and wasting (atrophy). The Duchenne and Becker types of muscular dystrophy are two related conditions that primarily affect skeletal muscles, which are used for movement, and heart (cardiac) muscle.

supplementary medical insurance for medical and other health services, including clinical laboratory tests (such as genetic tests) performed in a laboratory or a physician's office.

CMS administers the Medicare program. CMS contracts with 7 Medicare Administrative Contractors (MACs) for 12 defined geographic areas (i.e., jurisdictions) to, among other things, process and pay Medicare Part B claims, conduct reviews and audits, safeguard against fraud and abuse, and educate providers on Medicare billing requirements.[4] A provider generally submits claims to the MAC that serves the jurisdiction in which the provider is physically located. CMS also contracts with other Medicare contractors to provide a wide range of services, such as medical reviews focused on vulnerabilities identified through data analysis.

Genetic Testing

Genetic testing is the use of laboratory procedures to analyze genes, chromosomes, or gene products. These procedures provide specific information about inherited variations in and identify changes in an individual's genes or chromosomes. Genetic tests use a sample collected from a person's blood, hair, skin, amniotic fluid, or tissue from the inside of the cheek (i.e., a cheek swab). Samples may be collected in a physician's office, at a laboratory, or by a person at home. To be tested, the sample is then sent to a laboratory that specializes in genetic testing.

Genetic tests are used for many reasons. Some genetic tests are used for predictive purposes, such as determining whether a person has a risk of developing a genetic condition that runs in the person's family before showing symptoms (e.g., testing for genes associated with a higher risk of developing breast cancer). Other genetic tests are used to diagnose a genetic condition when symptoms are present (e.g., testing for genes associated with Duchenne and Becker muscular dystrophy). Physicians may use the results of a genetic test to confirm or rule out a suspected genetic condition or to help determine a person's chance of developing or passing on a genetic disorder.

The Use of CPT Code 81408 To Bill for Genetic Tests

Laboratories use CPT code 81408 on claims to bill for a type of genetic test called a level 9 molecular pathology procedure (MPP). MPPs have broad clinical and research applications and fall into two tiers:

- The CPT codes for Tier 1 MPPs generally describe testing for a specific gene. For example, CPT code 81162 is used to bill for the testing of genes associated with a higher risk of developing a specific type of breast cancer. In CY 2021, there were 169 Tier 1 MPP CPT codes covered under the Clinical Laboratory Fee Schedule (CLFS).

[4] For each jurisdiction, CMS enters into a contract with one entity to serve as the MAC. Although there are 12 jurisdictions, there are only 7 MACs because 5 MACs were awarded contracts for 2 jurisdictions each. The CMS Jurisdiction Map, up to date as of June 2021, is available online at https://www.cms.gov/files/document/ab-jurisdiction-map-jun-2021.pdf. Accessed on July 22, 2021.

- The CPT codes for Tier 2 MPPs, such as CPT code 81408, generally include a list of genes that may be tested for under the specific code. For example, CPT code 81408 may be used to bill for the testing of 24 different genes. (Generally, a laboratory may bill CPT code 81408 multiple times if it is testing for multiple genes included under this code.) According to the American Medical Association's (AMA's) *CPT,* Tier 2 MPPs are generally performed in lower volumes than Tier 1 MPPs because the diseases being tested for are rare. In CY 2021, there were nine Tier 2 MPP CPT codes covered under the CLFS.[5]

CPT code 81408 may be billed when testing for multiple genes associated with rare diseases. The majority of the examples of diseases associated with the 24 genes listed for CPT code 81408 in AMA's *CPT* are rare diseases that manifest in childhood—such as Duchenne and Becker muscular dystrophy, Joubert syndrome, and Marfan syndrome—and therefore the genes associated with these diseases would not generally be tested for in the Medicare population, which is predominantly 65 years old and older.[6, 7] However, there are some genes that could be appropriately tested for in the Medicare population under CPT code 81408—for example, the gene associated with a rare disease listed in AMA's *CPT* as "malignant hypothermia," which causes a severe reaction to anesthesia. Accordingly, use of CPT code 81408 should be relatively infrequent.

Medicare Part B Coverage of Genetic Tests

Medicare does not pay for expenses incurred 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 (the Act) § 1862(a)(1)(A)). Consistent with the Act, Medicare does not pay for preventive screening tests except for those specifically authorized by statute (e.g., colorectal cancer screening tests). When genetic tests are used for predictive purposes, CMS considers them to be screening tests and therefore they are not covered by Medicare. However, genetic tests used to diagnose genetic conditions or determine treatment in the presence of signs and symptoms of disease may be covered by Medicare.

To be covered under Medicare Part B, a clinical laboratory test, such as a genetic test, must be ordered by a physician or a qualified nonphysician practitioner (both called ordering providers

[5] The nine Tier 2 MPPs consist of CPT codes 81400 (level 1 MPP) through 81408 (level 9 MPP). These CPT codes are arranged in order of increasing complexity of the tests; 81400 is the least complex, and 81408 is the most complex.

[6] Joubert syndrome is a genetic disorder that affects many parts of the body, which can be caused by mutations in more than 30 genes. The signs and symptoms of this condition vary among affected individuals, even among members of the same family. Marfan syndrome is a genetic disorder that affects connective tissue in many parts of the body. Connective tissue provides strength and flexibility to structures such as bones, ligaments, muscles, blood vessels, and heart valves.

[7] Medical professionals at the MACs stated that although an enrollee might be diagnosed with one of these diseases in adulthood, the diagnosis could be made through an alternative method, such as a lower-cost blood test or ultrasound. One medical professional stated that the MAC would almost never see tests for diseases related to the genes generally tested and billed under CPT code 81408 performed in the Medicare population.

in this report) who is treating an enrollee for a specific medical problem and who uses the results in the management of that problem. Tests must be related to the treatment of a specific medical problem and must be ordered by the physician who is treating the enrollee or the tests are not considered reasonable and necessary (42 CFR § 410.32(a)). Enrollees pay no coinsurance or deductible for Medicare-covered laboratory tests.

Medicare pays laboratories for genetic tests based on amounts listed on the CLFS. To receive Medicare payment for a genetic test, a provider, such as a laboratory, submits a claim (42 CFR § 424.5(a)(5)).[8] Providers must use the appropriate procedure codes on claim forms for most outpatient services, including genetic tests (*Medicare Claims Processing Manual*, Pub. No. 100-04 (Claims Manual), chapter 23, §§ 20 and 20.3). For outpatient service claims, providers report the full diagnosis code for the diagnosis shown to be chiefly responsible for the outpatient services.[9] Diagnosis codes on a claim may also be used in determining coverage and payment (Claims Manual, chapter 23, § 10). In general, the diagnosis code used on the claim should be related to the service provided, such as a genetic test billed under CPT code 81408.

In 2021, the Medicare payment amount for CPT code 81408 on the CLFS was $2,000, which was the highest payment amount of all of the Tier 1 and Tier 2 MPPs. The next highest payment amount was $1,160, for CPT codes 81229 and 81277, which are Tier 1 MPPs.

CMS and MAC Oversight of Medicare Part B Payments for Genetic Testing

CMS and the MACs have various oversight mechanisms for preventing and detecting overpayments for genetic testing, including genetic tests billed under CPT code 81408.

CMS's National Coverage Determinations and Postpayment Reviews To Identify High-Risk Providers

CMS develops National Coverage Determinations (NCDs) for specific services that are applied on a national basis for all Medicare enrollees.[10] CMS has issued two NCDs related to genetic testing: one for next generation sequencing and one for pharmacogenomic testing for warfarin response.[11] Neither NCD specifically covers use of CPT code 81408. CMS told us that there are

[8] Each claim contains details regarding each provided service.

[9] Diagnosis codes are standardized codes used to describe diagnoses for medical conditions. For services provided on October 1, 2015, or later, the Department of Health and Human Services has adopted the International Classification of Diseases, 10th Revision, Clinical Modification, as the standard medical data code set for multiple conditions, including diseases (45 CFR § 162.1002(c)(2)(i)).

[10] An NCD is a determination regarding whether a particular item or service is covered nationally under Medicare (the Act § 1869(f)(1)(B)) and is considered by CMS as a Medicare requirement.

[11] Next generation sequencing is a genetic testing technique that identifies one or more genetic variations in an individual. Pharmacogenomic testing for warfarin response is used to determine how an individual's genetic makeup affects the body's response to warfarin (e.g., Coumadin), a blood-thinning drug.

no plans to issue any NCDs specific to level 9 MPPs, including genetic tests billed under CPT code 81408. In addition, CMS conducts postpayment reviews that analyze claims data to identify high-risk providers.

MACs' Local Coverage Determinations and Local Coverage Articles

In addition to implementing NCDs developed by CMS, the MACs develop and implement Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) specific to services within their jurisdictions. An LCD is a decision by a MAC whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act (the Act § 1869(f)(2)(B)), and CMS considers LCDs Medicare requirements. MACs may also develop and issue LCAs, which generally contain billing, coding, or other guidance that relate to LCDs. CMS considers LCAs guidance rather than Medicare requirements.

LCDs and LCAs may vary by MAC and result in different coverage in different jurisdictions. The MACs' LCDs cover MPPs but do not have specific requirements related to billing CPT code 81408. However, all of the MACs have issued LCA guidance on billing CPT code 81408. (See Appendix B for LCDs and LCAs related to genetic testing, including CPT code 81408.)

MACs' Identification of Genes Tested Under CPT Code 81408

It is important for a MAC to be able to identify the gene being tested by a laboratory because if the gene being tested is not identified, there is a risk that the gene tested and billed under CPT code 81408 is not one of the genes generally tested and billed under this CPT code, which could result in overpayments. The seven MACs' ability to identify the specific gene tested by laboratories billing CPT code 81408 varied by MAC. Specifically, at the time of our audit, four of the seven MACs used a process to identify the specific gene tested and billed under CPT code 81408. The three other MACs either required the gene being tested to be listed in the narrative of the Medicare claim or did not have any requirements or guidance related to identifying the gene tested and billed under CPT code 81408.

Medicare Requirements for Providers To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers 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.[12]

[12] The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 FR 7654 (Feb. 12, 2016).

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, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.[13]

HOW WE CONDUCTED THIS AUDIT

Medicare Part B paid $888.2 million for more than 450,000 genetic tests billed under CPT code 81408 that had dates of service from CYs 2018 through 2021 (audit period). These tests were provided to approximately 240,000 enrollees. Of the $888.2 million, $865.7 million (97 percent) was paid by two of the seven MACs. In addition, of the $888.2 million, $413.2 million (47 percent) was paid to the 10 laboratories (of 237 laboratories in total) that received the most Medicare payments for CPT code 81408 during our audit period.

To determine whether there was a risk of improper payments, we analyzed Medicare Part A and Part B claims associated with the approximately 240,000 enrollees. Specifically, we analyzed the Medicare Part B claims associated with the $888.2 million in payments for CPT code 81408 to determine whether there were any services or diagnoses that were related to diseases associated with genes that are generally tested and billed under CPT code 81408. We also analyzed the Medicare Part A and Part B claims associated with the 240,000 enrollees to determine whether the enrollees had established relationships with the ordering providers on the claims billed under CPT code 81408. (For the purpose of this report, we defined "established relationship" as an enrollee having had at least two visits with the ordering provider in the 6 months before the date of service on the claim.[14]) Finally, we analyzed Medicare Part B summary data for Tier 1 CPT codes to identify the total number of genetic tests billed under each Tier 1 CPT code by year during our audit period and the total payments for those tests, and we compared the total genetic tests billed under each Tier 1 CPT code with the total genetic tests billed under CPT code 81408. We did not review supporting documentation associated with the Medicare Part A and Part B data or use medical review to determine the accuracy of coding or medical necessity of the genetic tests.

We interviewed CMS and MAC officials to obtain an understanding of oversight mechanisms in place for CPT code 81408 and reviewed CMS and MAC requirements and guidance related to coverage of and billing for genetic tests under CPT code 81408.

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.

[13] 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 FR at 7670.

[14] One MAC also used this definition, which was shown in one of its LCAs.

Appendix A describes our audit scope and methodology.

FINDINGS

CMS's oversight of Medicare payments for CPT code 81408 was not adequate to reduce the risk of improper payments. Specifically:

- CMS and the MACs' oversight did not ensure that all enrollees had established relationships with ordering providers.

- CMS and the MACs' oversight did not ensure that Medicare payments for CPT code 81408 were related to diseases associated with genes that would generally be tested and billed under that CPT code.

- CMS and the MACs' oversight did not include adequate monitoring of the number of tests billed under CPT code 81408 to determine whether that number exceeded the number of tests billed under Tier 1 MPP codes.

- Not all MACs could identify the specific gene tested by laboratories that billed CPT code 81408.

- Although five of the seven MACs had LCA guidance that prohibited or limited use of CPT code 81408, two MACs' LCAs did not limit its use.

Based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment.[15] As of the publication of this report, this amount includes claims outside the 4-year claim-reopening period.[16] Notwithstanding, providers can request that their MAC reopen the initial determinations for those claims for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period.[17]

CMS AND THE MACs' OVERSIGHT DID NOT ENSURE THAT ALL ENROLLEES HAD ESTABLISHED RELATIONSHIPS WITH ORDERING PROVIDERS

For a clinical laboratory test to be covered under Medicare Part B, the ordering provider must be treating the enrollee for a specific medical problem and use the results of the test in the management of that problem (42 CFR § 410.32(a)). Thus, an enrollee must have a relationship with the provider ordering a laboratory test, such as a genetic test billed under CPT code 81408.

[15] The unrounded amount is $888,169,038.

[16] 42 CFR § 405.980(b)(2) (permitting a contractor to reopen within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a party to request that a contractor reopen within 4 years for good cause).

[17] 42 CFR § 405.980(c)(4).

During our audit period, of the 239,944 total enrollees associated with the genetic tests billed under CPT code 81408, 193,085 (80 percent) did not have an established relationship with the ordering provider shown on the claim. In addition, of these 193,085 enrollees, 166,779 had not visited the ordering provider in the year before the date of service.

We analyzed the top 10 ordering providers' relationships with the enrollees on the claims billed under CPT code 81408, which showed that 7 providers in CY 2018 and 8 providers in CY 2019 did not have established relationships with any of the enrollees for whom they ordered genetic tests billed under CPT code 81408.[18] Two of the top 10 ordering providers were part of a fraud scheme involving genetic testing.[19]

In addition, in CY 2018, the ordering provider who was associated with the most Medicare payments for CPT code 81408 did not have an established relationship with any of the enrollees for whom the provider ordered genetic tests for that CPT code. This provider ordered 4,942 tests for CPT code 81408 (8 percent of all genetic tests billed under CPT code 81408 for CY 2018) for 3,034 enrollees. The 28 laboratories associated with the tests ordered by this provider received $9.7 million in Medicare Part B payments for CPT code 81408.

CMS AND THE MACs' OVERSIGHT DID NOT ENSURE THAT MEDICARE PAYMENTS FOR CPT CODE 81408 WERE RELATED TO DISEASES ASSOCIATED WITH GENES THAT WOULD GENERALLY BE TESTED AND BILLED UNDER THAT CPT CODE

In general, the diagnosis code used on a claim should be primarily related to the outpatient service provided, such as a genetic test billed under CPT code 81408 (Claims Manual, chapter 23, § 10.3). We would expect the diagnosis code used on a CPT code 81408 claim to be related to the diseases associated with the genes that are generally tested and billed under CPT code 81408. Our analysis of claims data identified I10, Essential (primary) hypertension (i.e., high blood pressure), as the principal diagnosis code that was included on the most claims billed under CPT code 81408.[20] These claims made up 24.3 percent of the total Medicare payments for this CPT code. MAC officials told us that the use of CPT code 81408 is not reasonable and necessary in connection with hypertension. The diseases associated with the 10 principal diagnosis codes included on the claims with the highest total Medicare payments

[18] The top 10 ordering providers were the 10 ordering providers associated with the most Medicare payments for CPT code 81408 in each year from CYs 2018 through 2021.

[19] In September 2019, OIG issued a fraud alert about fraud schemes involving genetic testing, which resulted in 35 individuals being charged for their alleged participation in these schemes, involving $2.1 billion in losses to Medicare. One of these fraud schemes included recruiters (also known as marketers) who offered Medicare enrollees "free" screenings or cheek swabs for genetic testing to obtain their Medicare information for identity theft or fraudulent billing purposes.

[20] The principal diagnosis code is the code for the condition determined to be chiefly responsible for the outpatient service.

were not listed as examples of diseases commonly associated with any of the genes that would generally be tested and billed under CPT code 81408.[21]

See the table for a list of the 10 principal diagnosis codes and their percentages of the total payments for CPT code 81408.

Table: The 10 Principal Diagnosis Codes Associated With Claims With the Highest Total Medicare Payments and Their Percentages of Total Payments for CPT Code 81408 (CYs 2018 Through 2021)

Diagnosis Code	Diagnosis Code Description	Total Payment	Percentage of Total Payments for CPT Code 81408
I10	Essential (primary) hypertension	$215,850,538	24.3
Z803	Family history of malignant neoplasm of breast	37,514,823	4.2
Z853	Personal history of malignant neoplasm of breast	36,738,551	4.1
Z800	Family history of malignant neoplasm of digestive	34,180,027	3.9
E7800	Pure hypercholesterolemia, unspecified	22,833,880	2.6
Z1509	Genetic susceptibility to other malignant neoplasm	22,800,120	2.6
Z8546	Personal history of malignant neoplasm of prostate	18,752,402	2.1
E785	Hyperlipidemia, unspecified	16,380,682	1.8
I429	Cardiomyopathy, unspecified	15,334,401	1.7
I2510	Atherosclerotic heart disease of native coronary artery without angina pectoris	11,886,786	1.3

For 10 judgmentally selected enrollees, we reviewed the Medicare Part B claims history for CYs 2017 through 2021 to identify any services or diagnoses that were related to diseases associated with genes that would generally be tested and billed under CPT code 81408 (e.g., diagnosis code Q8740, Marfan's syndrome, unspecified). For all 10 enrollees, we did not identify any such services or diagnoses.

[21] Of the total payments for CPT code 81408 with dates of service during our audit period, $432 million (49 percent) was associated with claims that included 1 of the 10 principal diagnosis codes. The remaining 2,669 diagnosis codes (of 2,679 diagnosis codes in total) made up 51 percent of the total payments for CPT code 81408.

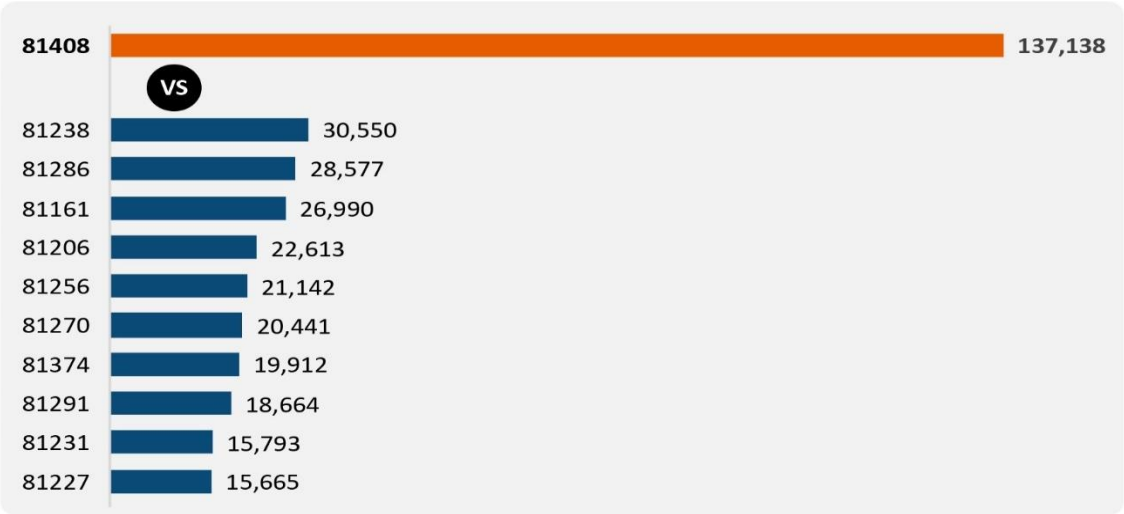
In addition to reviewing the claims history for the 10 selected enrollees, we reviewed the 4-year Medicare Part B claims history (CYs 2017 through 2021) for 1 judgmentally selected enrollee who did not have an established relationship with the ordering provider on the claims. The claims history showed diagnoses such as hyperthyroidism, hypertension, and osteoarthritis. In those 4 years, the enrollee did not have any services or diagnoses that were related to diseases associated with genes that are generally tested and billed under CPT code 81408.

CMS AND THE MACs' OVERSIGHT DID NOT INCLUDE ADEQUATE MONITORING OF THE NUMBER OF TESTS BILLED UNDER CPT CODE 81408 TO DETERMINE WHETHER THAT NUMBER EXCEEDED THE NUMBER OF TESTS BILLED UNDER TIER 1 MOLECULAR PATHOLOGY CODES

According to AMA's *CPT,* Tier 2 MPPs, such as those billed under CPT code 81408, are generally performed in lower volumes than Tier 1 MPPs because the incidence of the disease being tested is rare for Tier 2 MPPs. CMS and the MACs' oversight did not include adequate monitoring of the number of tests billed under CPT code 81408 to determine whether that number exceeded the number of tests billed under CPT codes for Tier 1 MPPs. CMS officials stated that they conduct data analysis on billing volume. However, in CY 2021, laboratories billed 137,138 genetic tests under CPT code 81408, which was a greater number of tests billed than for any of the Tier 1 MPP codes and more than 4 times as many tests billed as for the top Tier 1 MPP code (81238). The results of our data analysis show that CMS and the MACs' oversight did not adequately address the use of CPT code 81408 in comparison with the use of CPT codes for Tier 1 MPPs.

See the figure for a comparison of the billing volumes for CPT code 81408 and the 10 Tier 1 MPP codes with the highest billing volumes, which ranged from 15,665 to 30,550 tests.

Figure: Comparison of the Billing Volumes for CPT Code 81408 and the 10 Tier 1 Molecular Pathology Procedure Codes With the Highest Billing Volumes (Calendar Year 2021)



NOT ALL MACs COULD IDENTIFY THE SPECIFIC GENE TESTED BY LABORATORIES THAT BILLED CPT CODE 81408

Based on our review of Medicare guidance, we found that the MACs' ability to identify the specific gene tested by laboratories billing CPT code 81408 varied by MAC. Specifically, we found the following:

- Four MACs used a process to identify the specific gene that a laboratory tested before submitting a claim. These MACs had LCAs that directed laboratories to apply for a specific code to be included on claims when billing for genetic tests.[22]

- One MAC had LCAs that state that laboratories should include the specific gene being tested under CPT code 81408 in the narrative description on the Medicare Part B claim; however, the MAC did not enforce this guidance.

- One MAC issued an LCA toward the end of our audit period (in November 2021) stating that laboratories should include the specific gene being tested under CPT code 81408 in the narrative description on the Medicare Part B claim. Before the LCA was issued, there was no requirement to list the gene being tested.

- The remaining MAC did not cover CPT code 81408 and therefore did not have specific guidance related to listing the gene being tested.

If the gene being tested is not identified, there is a risk that the gene tested and billed under CPT code 81408 would not be one of the genes generally tested and billed under that CPT code. To reduce the risk of improper payments, it is important for the MAC to be able to identify the gene being tested because CPT code 81408 covers multiple genes.

ALTHOUGH FIVE OF SEVEN MACs HAD LOCAL COVERAGE ARTICLE GUIDANCE THAT PROHIBITED OR LIMITED USE OF CPT CODE 81408, TWO MACS' LOCAL COVERAGE ARTICLES DID NOT LIMIT ITS USE

Based on our review of Medicare guidance, we found that coverage of CPT code 81408 varied among MAC jurisdictions. Although CMS permits each MAC to provide guidance specific to its jurisdiction or jurisdictions, this may result in different coverage in different jurisdictions. These differences in coverage may lead to confusion among laboratories and provide an opportunity for fraudulent billing, such as billing for tests that are not medically necessary.

During our audit period, five MACs had LCA guidance that prohibited or limited the use of CPT code 81408. Specifically, one MAC had an LCA that specifically stated that performing genetic tests billed under CPT code 81408 was medically unnecessary and denied coverage of that

[22] The Medicare payments for CPT code 81408 for these four MACs made up an immaterial amount (3 percent) of the total Medicare payments for this code during our audit period.

code. The four MACs that had a process for identifying the specific gene tested and billed under CPT code 81408 had LCA guidance that allowed CPT code 81408 to be billed for an enrollee only once in an enrollee's lifetime.

However, for almost the entirety of our audit period, the other two MACs (whose payments made up 97 percent ($865.7 million) of the total Medicare Part B payments for CPT code 81408 during our audit period) had LCAs that stated that there were no diagnosis-code limitations for CPT code 81408. During the last 2 months of our audit period, both MACs issued new LCA guidance that limited the use of CPT code 81408. As a result, there were no longer Medicare payments for CPT code 81408 for either MAC by the end of our audit period. In addition, the LCA for one of these two MACs specifically said that Tier 2 MPP codes, which include CPT code 81408, "should rarely, if ever, be used unless instructed by other coding and billing articles."

CONCLUSION

CMS's oversight of Medicare payments for CPT code 81408 was not adequate to reduce the risk of improper payments. Medicare Part B paid $888.2 million for more than 450,000 genetic tests billed under CPT code 81408 that had dates of service during our audit period. If CMS had had adequate oversight mechanisms in place, the risk of improper payments of up to $888.2 million could have been reduced. Although CMS officials stated that CMS conducts data analysis (e.g., to identify high-risk providers), CMS did not ensure that the MACs provided sufficient oversight over billing of and payments for CPT code 81408.

Two of the seven MACs' payments made up 97 percent of the total payments for CPT code 81408 for our audit period. Because there were no longer payments for CPT code 81408 by the end of our audit period (December 31, 2021), we consider the issues identified by this audit corrected. However, based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment.

RECOMMENDATIONS

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

- review claims billed under CPT code 81408 for our audit period to determine whether they complied with Medicare requirements;

- determine the amount of improper payments for the claims that did not comply with Medicare requirements and, for those that are within the 4-year claim-reopening period, in accordance with CMS's policies and procedures, recover up to $888,169,038 for claims that were at risk of improper payment during our audit period; and

- based upon the results of this audit, notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers 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 COMMENTS

In written comments on our draft report, CMS concurred with our first and third recommendations. CMS did not concur or nonconcur with our second recommendation but provided information on actions that it planned to take to address this recommendation. CMS had the following comments on our three recommendations:

- Regarding our first recommendation, CMS stated that it will direct its Medicare contractors to review a sample of claims to determine whether the coding of claims was accurate. CMS stated that based on the results of the sample review, CMS and its contractors will determine whether additional reviews are warranted.

- Regarding our second recommendation, CMS stated that any identified overpayments resulting from the reviews referenced in its response to the first recommendation will be recovered consistent with statute and agency policy and procedure.

- Regarding our third recommendation, CMS stated that it will identify appropriate providers of potential overpayments and will instruct the MACs to notify those providers of our audit and the potential overpayments and track any returned overpayments made in accordance with this recommendation and the 60-day rule.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Medicare Part B paid $888,169,038 for 450,795 genetic tests billed under CPT[23] code 81408 that had dates of service from CYs 2018 through 2021. These tests were provided to 239,944 enrollees.

To determine whether there was a risk of improper payments, we analyzed Medicare Part A and Part B claims associated with the 239,944 enrollees. Specifically, we analyzed the Medicare Part B claims associated with the $888,169,038 in payments for CPT code 81408 to determine whether there were any services or diagnoses that were related to diseases associated with genes that are generally tested and billed under CPT code 81408. We also analyzed the Medicare Part A and Part B claims associated with the 239,944 enrollees to determine whether the enrollees had established relationships with the ordering providers on the claims billed under CPT code 81408. Finally, we analyzed Medicare Part B summary data for Tier 1 CPT codes to identify the total number of genetic tests billed under each Tier 1 CPT code by year during our audit period and the total payments for those tests, and we compared the total genetic tests billed under each Tier 1 CPT code with the total genetic tests billed under CPT code 81408. We did not review supporting documentation associated with the Medicare Part A and Part B data or use medical review to determine the accuracy of coding or medical necessity of the genetic tests.

We did not perform an overall assessment of the internal control structure of CMS or any of the MACs. Rather, we limited our review to those controls that were significant to our objective. Specifically, we interviewed CMS and MAC officials about the oversight mechanisms in place for payments for CPT code 81408 and reviewed CMS and MAC requirements and guidance related to coverage of and billing for CPT code 81408. 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 November 2021 to April 2023.

[23] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2018–2021 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.**

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, NCDs, LCDs, and guidance related to coverage of and billing for CPT code 81408 under Medicare Part B;

- interviewed CMS officials to obtain an understanding of the oversight mechanisms in place for payments for CPT code 81408;

- met with officials at 4 MACs to obtain an understanding of the oversight mechanisms in place for payments for CPT code 81408;

- extracted from CMS's NCH file Medicare Part B claims data for 239,944 enrollees for 450,795 genetic tests billed under CPT code 81408 that had dates of service during our audit period, with payments totaling $888,169,038;

- analyzed the claims data for the 450,795 genetic tests billed under CPT code 81408 to identify the principal diagnosis codes included on these claims and determined the total number of genetic tests billed using these principal diagnosis codes and the total payments for those tests;

- extracted from CMS's NCH file Medicare Part A and Part B claims associated with the 239,944 enrollees and analyzed the claims to determine whether the enrollees had established relationships with the ordering providers on the claims billed under CPT code 81408;[24]

- extracted from CMS's NCH file summary data for Medicare Part B Tier 1 CPT codes (81161 and 81200 through 81383) and identified the total payment and genetic tests billed under each Tier 1 CPT code by year and compared the total genetic tests billed under each Tier 1 CPT code with the total genetic tests billed under CPT code 81408;

- for CYs 2017 through 2021, judgmentally selected 11 enrollees from the 193,085 enrollees who did not have established relationships with the ordering providers on the claims billed under CPT code 81408 (consisting of 10 enrollees selected based on diagnosis code and 1 enrollee selected based on the ordering provider's lack of an established relationship with other enrollees) to identify any services or diagnoses that were related to diseases associated with genes that are generally tested and billed under CPT code 81408;[25] and

[24] For the purpose of this report, we defined "established relationship" as an enrollee having had at least two visits with the ordering provider in the 6 months before the date of service on the claim.

[25] We used the Beneficiary Claims Export tool, which extracts data from the CMS Integrated Data Repository.

- 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: LOCAL COVERAGE DETERMINATIONS AND ARTICLES RELATED TO GENETIC TESTING

LOCAL COVERAGE DETERMINATIONS

L38274, L38351, L38288, L38429 – MolDX: Repeat Germline Testing
(Effective 5/31/2020, 8/3/2020, 6/7/2020, and 6/14/2020, respectively)
(Related to LCAs A58017, A57331, A57141, and A57100, respectively)

"This contractor does not consider any laboratory test that investigates the same germline genetic content, for the same genetic information, that has already been tested in the same Medicare beneficiary to be reasonable and necessary as it is duplicative."

L35160, L36021, L35025, L36807 – MolDX: Molecular Diagnostic Tests (MDT)
(Effective 10/1/2015, 10/1/2015, 10/1/2015, and 2/16/2017, respectively)
(Related to LCAs A57526, A56973, A56853, and A57772, respectively)

"A Molecular Diagnostic Test (MDT) is any test that involves the detection or identification of nucleic acid(s), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s) . . . all MDT services must include an identifier as additional claim documentation."

L35000 – Molecular Pathology Procedures
(Effective 10/1/2015)
(Related to LCA A56199)

"The following individual Tier 2 genetic tests are unlikely to impact therapeutic decision-making, directly impact treatment, outcome and/or clinical management in the care of the beneficiary and will be denied as not medically necessary: Level 9 Molecular Pathology Procedures."

L35396 – Biomarkers for Oncology
(Effective 10/1/2015)
(Related to LCA A52986)

"Most genomic testing should be done once in a lifetime."

L35062 – Biomarkers Overview
(Effective 10/1/2015)
(Related to LCA A58917)

"All documentation must be maintained in the patient's medical record . . . the record must be legible and . . . must support medical necessity of the services."

L39063 and L39073 – Pharmacogenomics Testing
(Effective 12/12/2021)
(Related to LCAs A58801 and A58812, respectively)

> Pharmacogenomic testing will be considered medically reasonable and necessary if the patient has a condition where clinical evaluation has determined the need for a medication that has a known gene-drug interaction for which the test results would directly impact the drug management of the patient's conditions and the test meets evidence standards . . . Pharmacogenomic testing is not medically reasonable and necessary for genetic testing where either analytical validity, clinical validity, or clinical utility has not been established. Germline testing may be performed once in a lifetime per beneficiary . . . the germline sequence of an individual does not change over time, and therefore repeat testing of the same germline content for the same genetic information does not provide new clinical information.

L34519 – Molecular Pathology Procedures
(Effective 10/1/2015)
(Related to LCAs A57451 and A58918)

In general, diagnostic genetic testing for a disease should be performed once in a lifetime.

LOCAL COVERAGE ARTICLES

A58017, A57331, A57141, A57100 – MolDX: Repeat Germline Testing
(Effective 5/31/2020, 8/3/2020, 6/7/2020, and 6/14/2020, respectively)
(Related to LCDs L38274, L38351, L38288, and L38429, respectively)

"For the following CPT codes associated with germline testing, a beneficiary may only be covered for one test per lifetime: 81408."[26]

A57526, A56973, A56853, A57772 – MolDX: Molecular Diagnostic Tests (MDT)
(Effective 11/1/2019, 9/5/2019, 8/15/2019, 11/1/2019, respectively)
(Related to LCDs L35160, L36021, L35025, and L36807, respectively)

"To report a Molecular Diagnostic Test service, please submit the following claim information . . . enter the appropriate DEX Z-code. The codes listed below fall within the scope of the associated policy but do not automatically imply coverage: 81408."

[26] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2018–2021 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.**

A56199 – Molecular Pathology Procedures
(Effective 1/1/2019)
(Related to LCD L35000)

"The following individual Tier 2 genetic tests are unlikely to impact therapeutic decision-making, directly impact treatment, outcome and/or clinical management in the care of the beneficiary and will be denied as not medically necessary: 81408 . . . the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed."

A52986 – Biomarkers for Oncology
(Effective 10/1/2015)
(Related to LCD L35396)

"Because there are multiple biomarkers represented by each of the Tier 2 codes, when billing for these codes, it will be necessary to report the specific biomarker in the claim narrative/remarks."

Before December 13, 2020, the LCA stated: ". . . because the following CPT codes represent multiple biomarkers, these codes will not have procedure to diagnosis code limitations at this time: 81408." Effective December 13, 2020, the LCA was updated, and this sentence was removed.

A58917 and A58918 – Molecular Pathology and Genetic Testing
(Effective 11/8/2021)
(Related to LCDs L35062 and L34519, respectively)

> Tier 2 molecular pathology procedure codes (81400-81408) are used to report procedures not listed in the Tier 1 molecular pathology codes (88161, 81200-81383). These codes represent rare disease and molecular pathology procedures that are performed in lower volumes than Tier 1 procedures. These codes should rarely, if ever, be used unless instructed by other coding and billing articles. If billing utilizing the following Tier 2 codes, additional information will be required to identify the specific analyte/gene(s) tested in the narrative of the claim or the claim will be rejected: 81408.

A58801 and A58812 – Pharmacogenomics Testing
(Effective 12/12/2021)
(Related to LCDs L39063 and L39073, respectively)

"Consistent with the LCD, the following CPT codes are non-covered for pharmacogenomic testing: 81408."

A57451 – Molecular Pathology Procedures
(Effective 10/3/2018)
(Related to LCD L34519)

"The following . . . CPT codes associated with the services outlined in this Billing and Coding Article will not have diagnosis code limitations applied at this time: 81408."

APPENDIX C: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: May 23, 2023

TO: Amy Frontz
Deputy Inspector General for Audit Services

FROM: Chiquita Brooks-LaSure
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments (A-09-22-03010)

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. 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. Additionally, MACs may develop Articles to educate and assist providers in implementing LCDs and other National policies.

Since 2018, CMS has regularly run genetic testing reports to trend the volume of codes billed and identify static billing patterns of clusters of genetic testing codes and their corresponding diagnoses. Through these analyses, CMS identified an area of concern with CPT code 81408, and policy changes were implemented by the MACs to address the issue. Specifically, while five MACs had LCDs and Article guidance that addressed the use of CPT code 81408, the remaining two MACs did not. CMS notified the two MACs of these findings and both remaining MACs issued new LCDs and Article guidance that addressed the use of CPT code 81408. The ongoing analysis is paired with other information sources to develop leads for referral to the Unified Program Integrity Contractors (UPICs) and law enforcement. CMS is pleased to note that OIG

found that there were no longer payments for this CPT code by the end of the OIG's audit period (December 31, 2021), and that OIG considers the issues identified by this audit corrected.

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 tests were medically necessary. OIG also did not conduct coding reviews to determine whether the tests were properly coded. Without conducting medical or coding reviews, it is important to emphasize that the claims identified by the OIG were identified as being at risk of improper payment and are not confirmed overpayments.

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

OIG Recommendation
The Centers for Medicare & Medicaid Services should direct the Medicare contactors to review claims billed under CPT code 81408 for our audit period to determine whether they complied with Medicare requirements.

CMS Response
CMS concurs with this recommendation. CMS will analyze the OIG's data and direct its contractors to review a sample of claims to determine if the coding was accurate. Based on the results of the sample review, CMS and the Medicare contractors will determine whether additional reviews are warranted.

OIG Recommendation
The Centers for Medicare & Medicaid Services should direct the MACs to determine the amount of improper payments for the claims that did not comply with Medicare requirements and, for those that are within the 4-year claim-reopening period, in accordance with CMS's policies and procedures, recover up to $888,169,038 for claims that were at risk of improper payment during our audit period.

CMS Response
Any identified overpayments resulting from the reviews referenced in the recommendation above will be recovered consistent with statute and agency policy and procedure.

OIG Recommendation
Based upon the results of this audit, the Centers for Medicare & Medicaid Services should direct the MACs to notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers 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 OIG's data to identify appropriate providers of potential overpayments. CMS will then instruct the MACs to notify those providers of the OIG's audit and the potential overpayment and track any returned overpayments made in accordance with this recommendation and the 60-day rule.

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