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

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Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern

Key Takeaways:

For calendar years 2016 through 2019, our data analysis showed the following:

- ✓ Medicare payments for genetic tests quadrupled.
- ✓ The number of genetic-testing procedure codes Medicare covered increased by 161 percent. The number of genetic tests Medicare paid for increased by 230 percent.
- ✓ The average amount Medicare paid per beneficiary who received at least one genetic test increased by 75 percent. The average number of genetic tests paid per beneficiary increased by 43 percent.
- ✓ The number of laboratories that received more than $1 million in Medicare payments per year for genetic tests almost tripled, and the number of providers ordering genetic tests for beneficiaries more than doubled.

Although there are legitimate reasons for these increases, the increases indicate areas of possible concern, such as excessive and fraudulent genetic testing, which may negatively affect beneficiaries (e.g., the beneficiary may be responsible for the cost of genetic tests if Medicare denies claims). In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among Medicare contractor jurisdictions.

Purpose of This Data Brief

Genetic testing plays a vital role in determining the risk of developing certain diseases and assisting providers in determining medical treatment. Genetic test results can provide awareness of potential future health problems and help people make informed decisions about their health care.

Because use of and spending on genetic tests have grown rapidly, we analyzed Medicare Part B genetic-testing data for calendar years 2016 through 2019 (audit period). This data brief offers the Centers for Medicare & Medicaid Services (CMS) and other stakeholders insights into trends and areas of possible concern related to genetic testing.

Our objective was to analyze nationwide trends in genetic tests provided and payments made under Medicare Part B.

Background

Genetic Testing

Genetic testing is the use of laboratory procedures to analyze genes, chromosomes, or gene products (i.e.,

proteins). 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 his or her 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 sickle cell disease). 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.

In addition to clinical genetic tests ordered by physicians (called ordering providers in this data brief) for specific medical reasons, there are direct-to-consumer (DTC) genetic tests. DTC tests, which Medicare does not cover, are usually purchased by individuals who are interested in learning more about genetic traits, such as their ancestry or responses to medications. DTC tests are marketed directly to individuals, without the involvement of health care providers.

In 2003, researchers completed mapping of the human genome.[1] Since then, the use of and spending on genetic tests have grown rapidly. Genetic testing has evolved from the use of single-gene tests, which analyze only one gene, to the use of more complex tests, which analyze multiple genes (called panel tests):

- Single-gene tests are used when a physician believes a person has symptoms of a specific condition, such as sickle cell disease.

- Panel tests are used when a physician wants to look at changes in many genes in one test. Panel tests may be grouped into categories based on different medical concerns, such as low muscle tone. They may also be grouped by genes that are associated with a higher risk of developing a certain type of cancer, such as breast cancer.

As of August 2017, there were approximately 75,000 genetic tests on the U.S. market, and about 10 new tests entered the market daily.

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

[1] The human genome comprises all the genes in the human body. Researchers made maps of the genome showing the locations of genes for major sections of all the chromosomes, including "linkage" maps, through which inherited traits (such as those for genetic diseases) can be tracked over generations.

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 (MACs) for 12 jurisdictions to, among other things, process and pay Medicare Part B claims, conduct reviews and audits, safeguard against improper payments, and educate providers on Medicare billing requirements.

Medicare Part B Coverage of Genetic Tests

Medicare Part B does not cover genetic tests used for predictive purposes. However, it does cover genetic tests used for diagnostic purposes under certain conditions.

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 this requirement, 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. As of December 31, 2019, Medicare covered for payment 310 unique codes related to genetic testing, including Healthcare Common Procedure Coding System alphanumeric codes and Current Procedural Terminology[2] codes (which we refer to collectively as "procedure codes").[3]

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) who is treating a beneficiary for a specific medical problem and who uses the results in the management of that problem (42 CFR § 410.32(a)). The test must be related to the beneficiary's illness or injury (or symptom or complaint) (*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 16, § 10). Beneficiaries pay no coinsurance or deductible for Medicare-covered laboratory tests.

Medicare pays laboratories for genetic tests based on amounts listed on the Clinical Laboratory Fee Schedule (CLFS). To receive Medicare payment for a genetic test, a laboratory submits a

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[2] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2016–2019 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.**

[3] Procedure codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. In general, each of the 310 genetic-testing procedure codes represents a unique genetic test; however, for some tests, the same code may be used on a claim form to bill for separate tests for different genes.

claim (42 CFR § 424.5(a)(5)).[4] Providers, such as laboratories, must use the appropriate procedure codes on claim forms for most outpatient services, including genetic tests (*Medicare Claims Processing Manual*, chapter 23, §§ 20 and 20.3).

Three categories of procedure codes on the CLFS are specific to genetic testing: molecular pathology tests, Multianalyte Assays with Algorithmic Analyses (MAAAs), and Genomic Sequencing Procedures (GSPs).[5] Another category on the CLFS, proprietary laboratory analyses (PLAs), includes some genetic tests. In 2019, Medicare payment amounts for genetic-testing procedure codes on the CLFS ranged from about $15 to $12,000.

Categories of Genetic Tests on the Clinical Laboratory Fee Schedule

Molecular pathology tests detect variants in genetic material and often help doctors determine how patients will respond to treatment.

MAAAs combine multiple test results with patient information to yield a score, such as the chances that cancer will recur or a patient will respond to treatment.

GSPs identify structural changes in genetic material and are often used to diagnose or manage inherited diseases, such as hereditary breast cancer.

PLAs were established by the American Medical Association as alphanumeric procedure codes that provide corresponding descriptors for laboratories or manufacturers that want to more specifically identify their tests.

CMS and Medicare Contractor Oversight of Coverage and Payment for Genetic Testing

CMS and the MACs have issued requirements and guidance related to coverage of genetic testing. Specifically, CMS has issued two National Coverage Determinations (NCDs) related to genetic testing: one for next generation sequencing and one for pharmacogenomic testing for warfarin response.[6, 7] MACs have issued Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) related to genetic testing as well as MAC articles that provide coverage

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

[5] We determined these categories based on procedure code category definitions.

[6] 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.

[7] 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.

direction.[8] Some LCDs explain that certain tests are not covered by Medicare, and others explain the requirements for certain tests to be covered by Medicare.

In addition to issuing requirements and guidance, CMS has several methods to prevent improper payments before CMS processes a claim, such as using claims system processing edits, and to detect and recover improper payments after paying a claim.[9] To combat Medicare fraud, CMS uses many different techniques, such as analyzing claims data to identify high-risk providers, performing medical reviews of claims to determine the medical necessity of services, and conducting interviews of beneficiaries about services they received. CMS has special initiatives related to identifying genetic testing fraud and works closely with law enforcement, including the Office of Inspector General (OIG), to investigate providers for potentially fraudulent claims, such as claims for medically unnecessary genetic tests.

Data Used To Develop This Data Brief

Our primary source of data for this data brief was Medicare Part B claims for genetic tests included on CMS's CLFS. We obtained these data from the National Claims History (NCH) Physician/Supplier Part B claim files. These files primarily included claims from independent laboratories and physician office laboratories. We identified approximately $3 billion in Medicare payments for 5.1 million paid genetic tests that had dates of service from January 1, 2016, through December 31, 2019.

We used these claims data to perform our analysis of nationwide trends in genetic tests provided and payments made under Medicare Part B. We did not review supporting documentation associated with these data to determine the accuracy of coding or medical necessity of the genetic tests. In addition, we did not determine the underlying reasons for trends related to genetic tests provided and payments made under Medicare Part B.

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.

[8] An LCD is a decision by a MAC whether to cover a particular item or service on a contractor-wide basis in accordance with 1862(a)(1)(A) of the Act (the Act § 1869(f)(2)(B)), and CMS considers LCDs as Medicare requirements. MACs may also develop and issue LCAs, which generally contain billing, coding, or other guidance that complement LCDs. CMS considers LCAs as guidance rather than as Medicare requirements. MACs issue LCDs and LCAs specific to their jurisdiction.

[9] An edit is programming within the standard claim processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and, depending on the evaluation, takes action on the claims, such as paying them in full or in part, denying payment for them, or suspending them for manual review.

Appendix A describes our audit scope and methodology.

RESULTS OF ANALYSIS

By analyzing nationwide trends in genetic tests provided and payments made under Medicare Part B during our audit period, we determined that, among other trends, payments for genetic tests, the number of genetic tests performed, the number of laboratories that received more than $1 million for performing genetic tests, and the number of ordering providers for genetic tests all increased during our audit period. Although there are legitimate reasons for these increases, the increases indicate areas of possible concern, such as excessive genetic testing and fraud, which may negatively affect beneficiaries (e.g., the beneficiary may be responsible for the cost of genetic tests if Medicare denies claims and a signed Advance Beneficiary Notice of Noncoverage (ABN) is on file).

The information in this data brief may help CMS and other stakeholders to identify changes in the Medicare program that could prevent fraud, waste, and abuse and protect Medicare beneficiaries. The information also complements OIG's report on trends in Medicare expenditures for laboratory tests in 2018, which highlighted the increased spending on genetic tests.[10]

Trends in Payments for Genetic Tests and the Numbers of Genetic Tests Performed, Laboratories Providing These Tests, and Ordering Providers

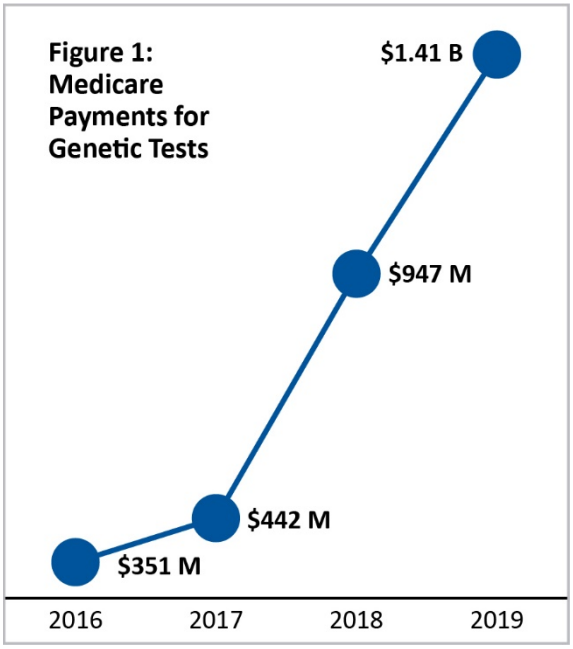
We determined that, among other trends, payments for genetic tests, the number of genetic tests performed, the number of laboratories that received more than $1 million for performing genetic tests, and the number of ordering providers for genetic tests all increased during our audit period.

[10] *Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions* (OEI-09-19-00100), issued Aug. 6, 2020.

Medicare payments for genetic tests quadrupled.

During our audit period, Medicare payments to laboratories for genetic tests quadrupled, from $351 million to $1.41 billion, an increase of 302 percent (Figure 1).

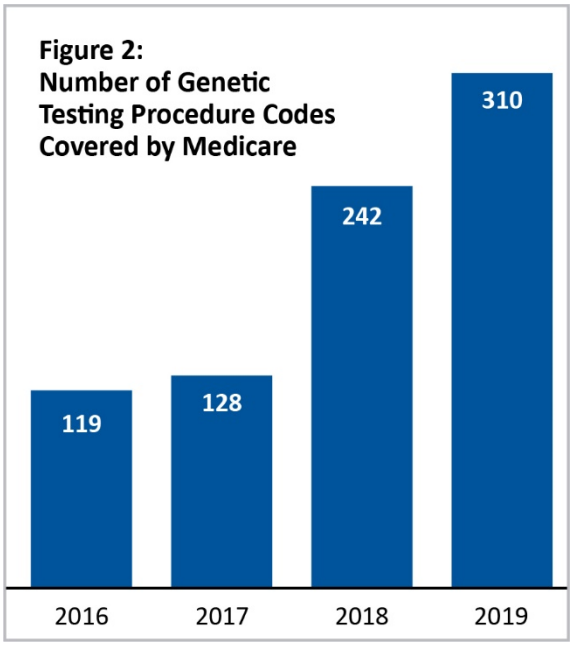
Payments for the five genetic tests with the highest total Medicare Part B payments during our audit period ($1.65 billion) made up 52 percent of the total payment ($3.15 billion) for genetic tests. These five tests were a colorectal cancer screening test, two tests related to breast cancer, a test related to rheumatoid arthritis, and a high-complexity, molecular pathology procedure test. (See Appendix B for payment information on the 25 genetic tests with the highest total Medicare Part B payments for our audit period.)



The number of genetic-testing procedure codes that Medicare covered increased by 161 percent.

During our audit period, the number of genetic-testing procedure codes covered by Medicare increased from 119 to 310, or 161 percent (Figure 2).

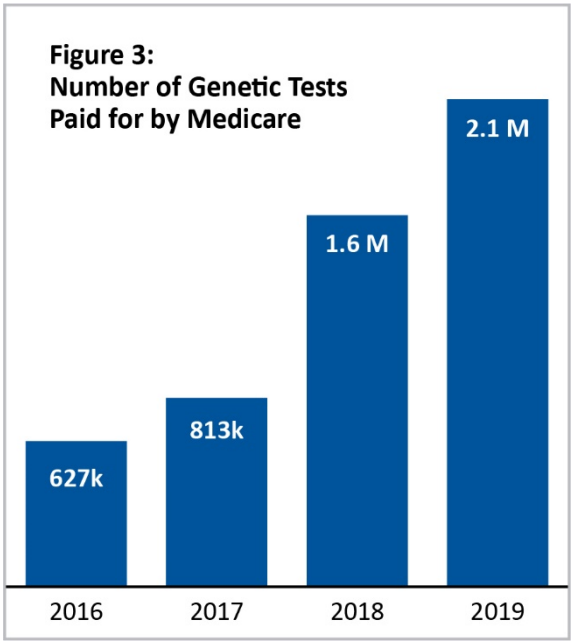
In 2019, the 310 genetic-testing procedure codes on the CLFS consisted of 201 molecular pathology test codes, 38 PLA codes, 37 MAAA codes, and 34 GSP codes.[11]



[11] For information on the categories of genetic-testing procedure codes on the CLFS, see the box on page 4.

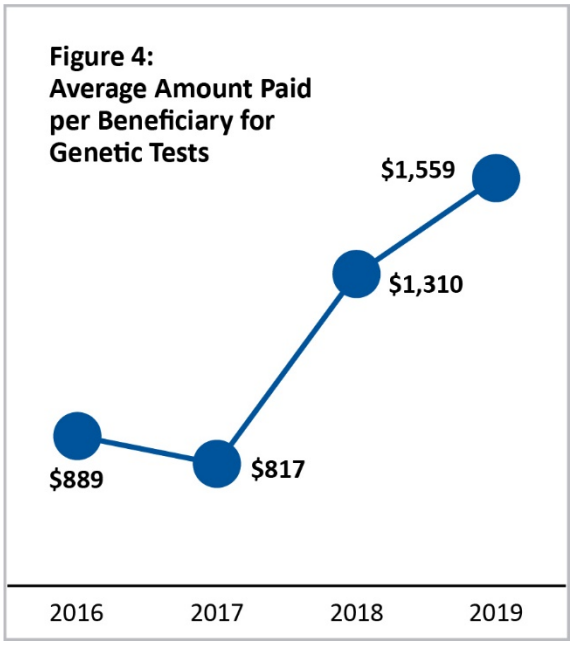
The number of genetic tests that Medicare paid for increased by 230 percent.

During our audit period, Medicare paid laboratories for performing approximately 5.1 million genetic tests. In 2016, Medicare paid laboratories for about 627,000 genetic tests performed. In 2019, this number had increased to about 2.1 million tests, an increase of 235 percent (Figure 3).



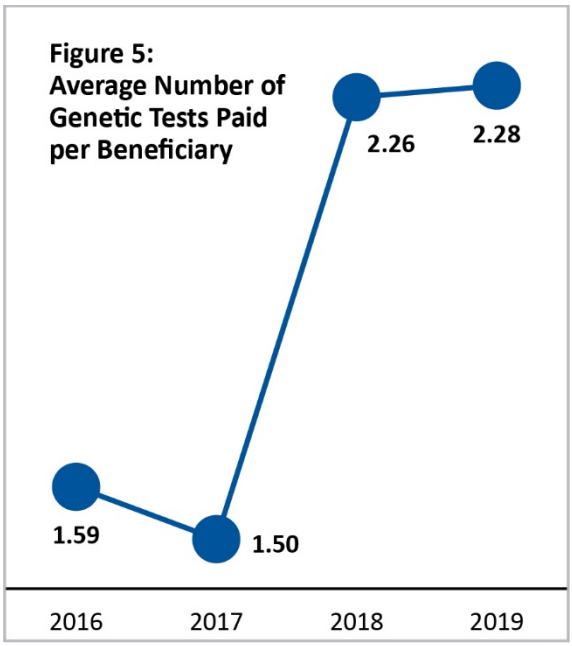
The average amount that Medicare paid per beneficiary who received at least one genetic test increased by 75 percent.

As the overall payment for genetic tests increased from year to year during our audit period, the average amount that Medicare paid per beneficiary who received at least one genetic test (referred to in this data brief as "per beneficiary") also increased. In 2016, the average amount paid for genetic tests per beneficiary was $889. In 2019, this amount was $1,559, an increase of $670, or 75 percent (Figure 4).



The average number of genetic tests per beneficiary that Medicare paid for increased by 43 percent.

In 2016, Medicare paid for an average of 1.59 genetic tests per beneficiary who received a genetic test. This number decreased slightly in 2017 but increased in both 2018 and 2019, to 2.28 genetic tests per beneficiary in 2019 (Figure 5). This increase was 43 percent during our audit period, and the number will likely continue to increase as more genetic tests become available.



As the average number of genetic tests per beneficiary increased, the total number of beneficiaries who received a genetic test increased as well, from approximately 395,000 in 2016 to approximately 905,000 in 2019.

Furthermore, of the approximately 930,000 beneficiaries who received at least 1 cancer genetic test (CGx) test during our audit period, approximately 163,000 beneficiaries (18 percent) received the same CGx test more than once during the same period, with $449 million in payments.[12] Of these beneficiaries, 194 received at least 15 different CGx tests more than once. CMS stated that, in general, it is not necessary to perform the same genetic test more than once in a lifetime for the same beneficiary.[13]

CGx genetic tests are used to diagnose genetic conditions or determine treatment in the presence of signs and symptoms of disease, such as hereditary breast cancer, and may be covered by Medicare. Of the 310 genetic tests that Medicare covered in 2019, 172 were CGx tests.

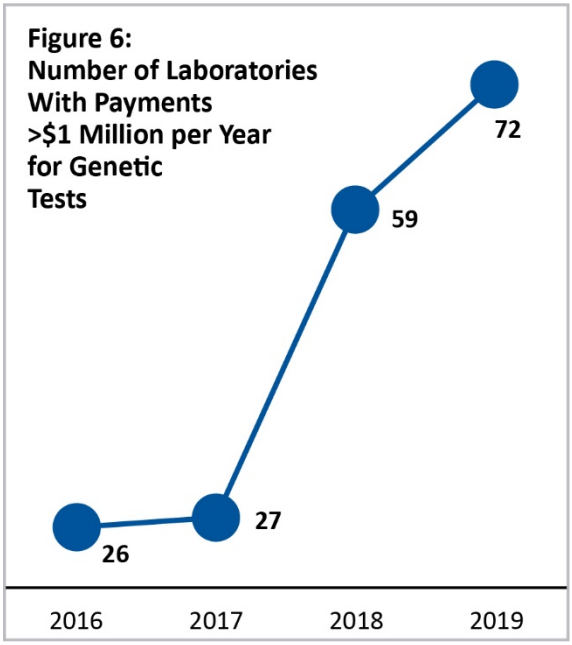
[12] Some of the beneficiaries who received the same genetic test more than once may have received the same test for different diagnoses.

[13] There are some situations in which the same genetic test might be performed more than once for the same beneficiary. According to a Healthcare Fraud Prevention Partnership (HFPP) publication, these situations could include: (1) changes in the testing panel, (2) advancement of knowledge, and (3) the evolution of results interpretation. *Healthcare Fraud Prevention Partnership Genetic Testing Fraud, Waste, and Abuse White Paper*, issued July 2020. Available at https://www.cms.gov/files/document/hfpp-genetic-testing-fwa-white-paper.pdf. Accessed on Nov. 23, 2020.

The number of laboratories that received more than $1 million in Medicare payments per year for genetic tests almost tripled.

As the overall payment for genetic tests increased from year to year during our audit period, the number of laboratories performing genetic tests increased as well (from 706 in 2016 to 836 in 2019). The number of laboratories that received more than $1 million in Medicare payments per year for genetic tests also increased each year during our audit period. In 2016, only 26 laboratories received more than $1 million. In 2019, this number had almost tripled, to 72 laboratories (Figure 6).

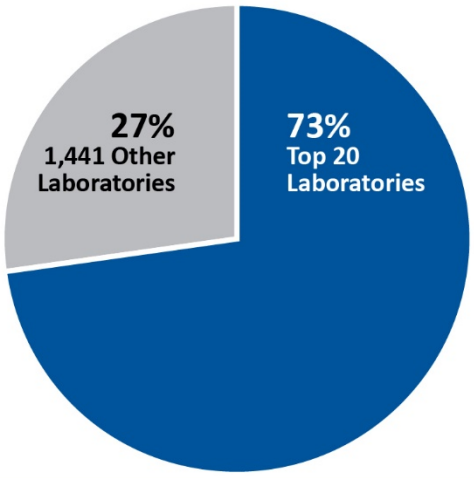
Figure 6:
Number of Laboratories With Payments >$1 Million per Year for Genetic Tests



The 20 laboratories that received the most in Medicare payments accounted for 73 percent of the total amount that Medicare paid for genetic tests.

During our audit period, Medicare paid $3.2 billion to more than 1,400 laboratories for genetic tests. Twenty of those laboratories (1.4 percent) made up 73 percent of the total payment for this period (Figure 7), receiving more than $2.3 billion. During our audit period, the amount paid to the top 20 laboratories ranged from $37 million to $585 million. The types of genetic tests provided by each laboratory varied, with many laboratories specializing in certain genetic tests. For example, the highest paid laboratory, which received $585 million during our audit period, specialized in a colorectal cancer screening test.

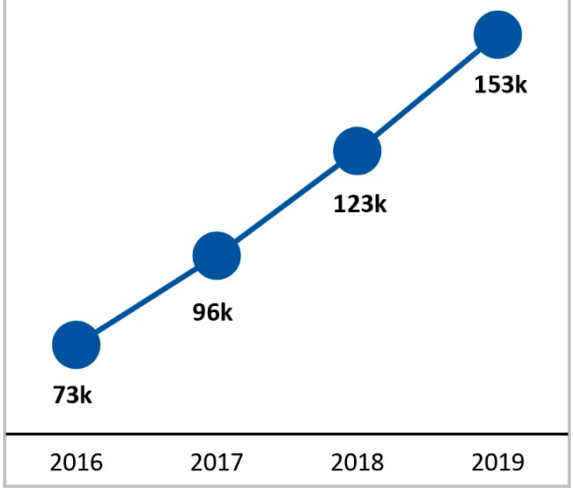
Figure 7:
Percentage of Total Payment for Genetic Tests Received by Top 20 and Other Laboratories



The number of ordering providers for genetic tests more than doubled.

The number of ordering providers for genetic tests increased steadily during our audit period. In 2016, approximately 73,000 providers ordered genetic tests for beneficiaries. By 2019, this number had more than doubled, to approximately 153,000 (Figure 8).

Figure 8:
Number of Ordering Providers for Genetic Tests



The increases shown throughout the trends described above demonstrate the importance of oversight by CMS and the MACs, which is critical to prevent fraud, waste, and abuse related to genetic testing and to protect Medicare beneficiaries. CMS informed us that potential reasons for the increases could include: (1) increased numbers of available genetic tests, (2) an increased number of laboratories available to perform these tests, (3) increased public awareness of and demand for these tests, (4) changes in the practice of medicine because of the availability of these tests, and (5) new therapies that depend on the results of these tests.

Increases in Genetic Testing Indicate Areas of Possible Concern

Our analysis of nationwide trends in genetic testing under Medicare Part B showed that payments for genetic tests, the number of genetic tests performed, the number of laboratories that received more than $1 million for performing genetic tests, and the number of ordering providers for genetic tests all increased during our audit period. Although there are legitimate reasons that genetic testing has increased, these increases indicate areas of possible concern, such as excessive genetic testing and fraud, which may negatively affect beneficiaries. In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among MAC jurisdictions.

Excessive and fraudulent genetic testing could negatively affect beneficiaries.

Excessive Genetic Testing

One beneficiary received 38 different genetic tests in 2018 and 2019, including multiple instances of the same tests being performed 6 or more times.

Excessive genetic testing may result in unnecessary and costly tests being performed. Beneficiaries who received genetic tests received an average of 2.16 genetic tests over the 4 years in our audit period. However, of the 2.4 million beneficiaries that received at least 1 genetic test during that period, more than 67,000 beneficiaries received 10 or more different genetic tests, and more than 3,000 received 20 or more different genetic tests, which was well above the average number of 2.16 genetic tests per beneficiary for our audit period.

The May 2018 publication from the Healthcare Fraud Prevention Partnership (HFPP), a voluntary public-private partnership that helps detect and prevent health care fraud through data and information sharing, noted that most genetic tests are applicable only in specific circumstances.[14] The publication also noted that the same genetic tests generally need to be performed only once because the results would typically not be expected to change in the absence of a new disease.

HFPP partners have found the following problems with the use of genetic testing:[15]

- genetic testing that is not related to actual or potential medical diagnoses,
- overuse of genetic testing in cases where the tests have no clinical value (possibly related to an actual or a potential medical diagnosis but not relevant to treatment decisions), and
- repeated genetic testing of the same person for the same genes by the same provider.

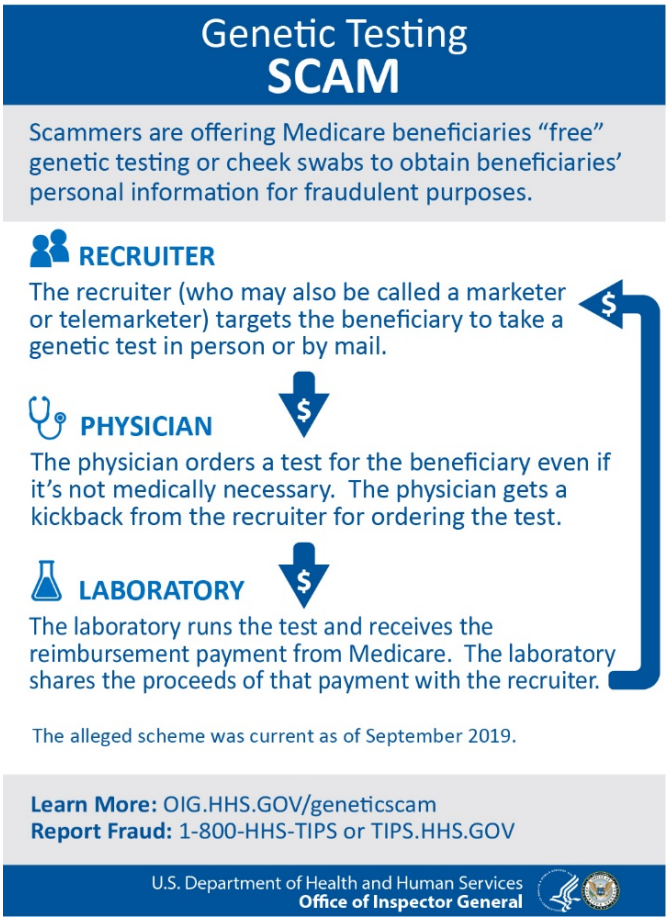
[14] *Examining Clinical Laboratory Services: A Review by the Healthcare Fraud Prevention Partnership.* Available at https://www.cms.gov/files/document/download-clinical-laboratory-services-white-paper.pdf. Accessed on Nov. 23, 2020.

[15] HFPP includes Federal, State and local, law enforcement, private payer, and association partners.

Fraud in Genetic Testing

Fraud in genetic testing is prevalent. In September 2019, OIG issued a fraud alert about a fraud scheme involving genetic testing in which recruiters (also known as marketers) offered Medicare beneficiaries "free" screenings or cheek swabs for genetic testing to obtain their Medicare information for identity theft or fraudulent billing purposes. In the alleged scheme, a recruiter got a Medicare beneficiary to provide a sample for a genetic test. The recruiter then had a physician sign off on the genetic test so that a laboratory would process it. The recruiter paid the physician a kickback in exchange for ordering the test. Then the laboratory processed the test and billed Medicare. Medicare reimbursed the laboratory for the test, and the laboratory shared the proceeds of that payment with the recruiter (Figure 9).

Figure 9:
Genetic Testing Scam



As a result of efforts to target genetic-testing fraud schemes nationwide, OIG and its law enforcement partners charged 35 individuals for their alleged participation in genetic-testing fraud schemes, involving $2.1 billion in losses to the Medicare program.[16] Recruiters are targeting beneficiaries through telemarketing calls, booths at public events, health fairs, and door-to-door visits.

As of summer 2019, the OIG Hotline was receiving about 50 to 60 complaints a week, approximately 20 to 24 percent of which were related to genetic testing.[17]

[16] Additional information available at https://oig.hhs.gov/newsroom/media-materials/media-materials-nationwide-genetic-testing-fraud/. Accessed on Aug. 12, 2021.

[17] The OIG Hotline (1-800-HHS-TIPS or tips.hhs.gov) accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services programs.

In July 2020, HFPP issued a publication that focused on genetic-testing fraud, waste, and abuse.[18] HFPP identified the following categories of fraudulent billing practices:

- **Billing for services not provided or performed** occurs when a laboratory or an ordering provider falsifies a bill or a beneficiary's medical records, or both, to bill insurance for services that were not provided. One example is a "gang visit," in which an improbable number of genetic tests is performed on a single day in a single location, such as a nursing home, an assisted living facility, a health fair, or another place where there are many insured individuals.

- **Unbundling of claims** occurs when a laboratory bills each genetic test separately, rather than using an appropriate panel of bundled tests, to maximize reimbursement. For example, a laboratory may inappropriately bill multiple procedure codes for molecular pathology tests that involve analyzing multiple genes simultaneously on a single piece of equipment using next generation sequencing when it should bill a panel code that results in one payment for all of the tests.

- **Blanket ordering** occurs when an ordering provider indiscriminately orders a number of tests for a beneficiary without considering the beneficiary's specific needs.

The COVID-19 pandemic has created additional opportunities for fraudulent laboratory billing. In addition to COVID-19 tests, laboratories can perform add-on tests—for example, to confirm or rule out a diagnosis other than COVID-19. OIG has program integrity concerns related to add-on tests, including genetic tests, provided in conjunction with COVID-19 testing. OIG is analyzing Medicare claims data for laboratory testing to identify trends in the use of certain add-on laboratory tests, including genetic tests, and to identify laboratory billing patterns that may indicate fraud and abuse.[19]

Negative Effects on Beneficiaries From Inappropriate Billing of Genetic Tests

Beneficiaries could be negatively affected by inappropriate billing of genetic tests. If a beneficiary is a victim of genetic testing fraud and the genetic test was not ordered by a physician or was not medically necessary, the beneficiary could be responsible for the entire cost of the test if Medicare denies the claim. For some tests, this cost could be thousands of dollars. (See Appendix C for the 20 genetic tests with the highest Medicare Part B reimbursement rates for 2019.)

[18] *Healthcare Fraud Prevention Partnership Genetic Testing Fraud, Waste, and Abuse White Paper.* Available at https://www.cms.gov/files/document/hfpp-genetic-testing-fwa-white-paper.pdf. Accessed on Nov. 23, 2020.

[19] Trend Analysis of Medicare Laboratory Billing for Potential Fraud and Abuse With COVID-19 Add-on Testing, Work Plan Item. Available at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000489.asp. Accessed on July 26, 2021. The report (OEI-09-20-00510) is expected to be issued in 2022.

In addition, as mentioned earlier in this data brief, CGx tests are generally necessary only once in a beneficiary's lifetime. In many cases, beneficiaries who received fraudulent CGx tests never received their test results. If a fraudulent claim is submitted to Medicare for a CGx test and later the beneficiary has a legitimate need for the test, the claim for the later test may be denied, and the beneficiary may be responsible for the entire cost of the test (with a signed ABN on file).

Finally, beneficiaries who are victims of genetic testing fraud may also become victims of medical identity theft when they provide their Medicare information to fraudsters. Medical identity theft occurs when someone uses another person's name or insurance information to get medical treatment or when someone uses that information to submit false bills to Medicare or other health insurers. Medical identity theft can result in treatment delays, misdiagnosis, and inappropriate care and can also result in financial harm.

Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among MAC jurisdictions.

As the number and prevalence of genetic tests has increased, so has the need for requirements and guidance from CMS and the MACs. CMS has issued two NCDs related to genetic testing: one for next generation sequencing and one for pharmacogenomic testing for warfarin response. As of April 2021, CMS was not considering issuing any other NCDs related to genetic testing. As of July 2020, the 7 MACs had issued approximately 50 LCDs related to genetic testing.

We found the following variations in the LCD requirements and LCA guidance related to genetic tests:

- **The number of these LCDs issued by each MAC varies.** For example, one MAC had issued only one LCD for genetic testing, and another MAC had issued nine LCDs for genetic testing. Because MACs issue LCDs that limit coverage for a particular item or service only in their jurisdictions, these differences can result in varying Medicare coverage for genetic testing across the Nation.

- **MACs have issued LCDs related to genetic testing for specific diseases; however, not all MACs have issued LCDs for the same diseases.** For example, four of the seven MACs have issued LCDs for genetic testing for thrombophilia (a condition related to blood clotting), but the other three MACs have not issued LCDs related to this test.

- **MACs have issued LCAs with different guidance on certain tests.** For example, all seven MACs issued LCAs with guidance on a high-complexity, molecular pathology procedure test.[20] One MAC's LCA stated that the test would be denied as not medically

[20] This test had the second-highest total payment amount for our audit period and had increased total payments each year.

necessary, and other MACs' LCAs stated that the test is allowed only once in a beneficiary's lifetime.

These inconsistencies could lead to possible confusion among laboratories and ordering providers, which may result in further increases in Medicare payment for genetic tests and the number of genetic tests performed.

A previously issued OIG report identified inconsistencies in LCDs across MACs.[21] For example, LCDs limited coverage for Medicare Part B items and services differently across the Nation, and LCDs defined similar topics inconsistently. The report recommended that CMS consider requiring MACs to jointly develop a single set of coverage policies across all MACs.

CONCLUSION

During our audit period, total Medicare Part B payments to laboratories for genetic tests quadrupled, and the number of genetic tests that Medicare paid for increased by 230 percent. In addition, the number of laboratories performing genetic tests increased (including an almost threefold increase in laboratories that received more than $1 million), and the number of ordering providers for genetic tests also increased.

Although there are legitimate reasons that genetic testing has increased, the increases indicate areas of possible concern, such as excessive testing and fraud, which may negatively affect beneficiaries (e.g., the beneficiary may be responsible for the cost of genetic tests if Medicare denies claims and a signed ABN is on file). In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among MAC jurisdictions. Oversight by CMS and the MACs is critical to prevent fraud, waste, and abuse related to genetic testing and to protect Medicare beneficiaries. The information in this data brief may help CMS and other stakeholders to identify changes in the Medicare program, such as increased oversight, that could prevent fraud, waste, and abuse and protect Medicare beneficiaries.

The information in this data brief presents nationwide trends in genetic tests provided and payments made under Medicare Part B and is intended for informational purposes only; therefore, the data brief does not contain any recommendations.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS provided technical comments on our draft data brief, which we addressed as appropriate. CMS did not submit comments other than those technical comments.

[21] *Local Coverage Determinations Create Inconsistency in Medicare Coverage* (OEI-01-11-00500), issued Jan. 7, 2014.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

Scope

Our primary source of data for this data brief was Medicare Part B claims for genetic tests included on CMS's CLFS. We obtained these data from the NCH Physician/Supplier Part B claim files. These files primarily included claims from independent laboratories and physician office laboratories. We identified $3,151,235,293 in Medicare payments for 5,139,642 genetic tests that had dates of service from January 1, 2016, through December 31, 2019.

We used these claims data to perform our analysis of nationwide trends in genetic tests provided and payments made under Medicare Part B. We did not review supporting documentation associated with these data to determine the accuracy of coding or medical necessity of the genetic tests. In addition, we did not determine the underlying reasons for trends related to genetic tests provided and payments made under Medicare Part B.

We did not perform an overall assessment of CMS's internal control structure. Rather, we interviewed CMS officials about the oversight in place for genetic testing and reviewed CMS requirements and guidance and claims processing system edits related to coverage of and billing for genetic testing.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file. Historically, OIG has utilized NCH data, which has been determined to be reliable based on tracing claims data to supporting documentation. We did not test the NCH data for completeness. (The NCH file contains all claims submitted to Medicare for payment.)

We conducted our audit from May 2020 to September 2021.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, NCDs, LCDs, and guidance related to genetic testing covered under Medicare Part B;

- reviewed HFPP's 2018 publication *Examining Clinical Laboratory Services* and 2020 publication *Genetic Testing Fraud, Waste, and Abuse White Paper* to understand fraud, waste, and abuse schemes related to genetic testing;

- met with CMS officials to obtain an understanding of the oversight in place for genetic testing and reviewed CMS requirements, guidance, and claims processing system edits related to coverage of and billing for genetic testing;

- obtained Medicare Part B claims data for genetic tests;

- analyzed these data to identify trends in genetic testing during our audit period by year, genetic test, provider, beneficiary, etc.; and

- discussed the results of the 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: THE 25 GENETIC TESTS WITH THE HIGHEST TOTAL MEDICARE PART B PAYMENTS (2016–2019)

Genetic Test Procedure Code	Genetic Test Description	2016 Payment	2017 Payment	2018 Payment	2019 Payment	2016–2019 Total Payment
81528[22]	Oncology colorectal screening	$61,674,430	$116,384,905	$167,217,776	$240,683,647	**$585,960,758**
81408	Level 9 molecular pathology procedure	0[23]	0	121,133,327	283,984,828	**405,118,155**
81519	Oncology breast MRNA	59,652,541	59,961,202	76,642,691	83,227,098	**279,483,532**
81162	BRCA1&2 gene full sequence duplication or deletion	40,608,568	51,427,040	50,027,841	118,516,721	**260,580,170**
81490	Autoimmune rheumatoid arthritis	28,548,695	26,308,681	34,376,677	30,391,878	**119,625,931**
81317	PMS2 gene full sequence analysis	4,259,488	2,761,627	31,685,796	53,574,445	**92,281,356**
81493	Coronary artery disease MRNA	23,105,795	28,815,051	29,940,566	233,583	**82,094,995**
0037U	Target gene sequence DNA 324 genes	0	0	0	78,485,774	**78,485,774**
81545	Oncology thyroid	14,010,896	16,515,145	22,341,196	25,357,454	**78,224,691**
81201	APC gene full sequence	0	0	29,877,601	47,249,802	**77,127,403**
81298	MSH6 gene full sequence	924,651	2,224,093	26,368,899	42,449,772	**71,967,415**
81406	Level 7 molecular pathology procedure	0	0	22,014,168	42,215,107	**64,229,275**
81595	Cardiology heart transplant MRNA	12,920,229	12,707,821	18,054,755	19,590,098	**63,272,903**
81226	CYP2D6 gene common variants	11,975,189	11,721,550	17,261,763	11,980,842	**52,939,344**

[22] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2016–2019 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.**

[23] Genetic tests with a $0 payment indicate that the test was not covered by Medicare under the CLFS during that year.

Genetic Test Procedure Code	Genetic Test Description	2016 Payment	2017 Payment	2018 Payment	2019 Payment	2016–2019 Total Payment
81211	BRCA1&2 sequence and common duplication or deletion	$20,777,229	$8,388,352	$14,875,106	0	**$44,040,687**
81432	Hereditary breast cancer-related disorders	3,515,631	10,925,306	15,884,200	12,795,332	**43,120,469**
81295	MSH2 gene full sequence	612,445	1,274,409	15,937,719	25,205,436	**43,030,009**
81539	Oncology prostate probability score	0	14,737,138	18,998,215	3,597,914	**37,333,267**
81541	Oncology prostate MRNA 46 genes	0	0	15,708,174	16,068,257	**31,776,431**
81225	CYP2C19 gene common variants	6,334,790	5,253,889	10,103,713	7,374,517	**29,066,909**
81455	Targeted genomic sequence analysis	672,831	2,745,583	21,334,418	2,289,096	**27,041,928**
81292	MLH1 gene full sequence	2,199,926	5,059,695	8,306,039	10,203,749	**25,769,409**
81538	Oncology lung	3,773,762	5,933,586	9,181,880	6,354,726	**25,243,954**
81407	Level 8 molecular pathology procedure	0	0	5,930,426	17,739,701	**23,670,127**
81404	Level 5 molecular pathology procedure	0	0	10,893,941	12,754,409	**23,648,350**

APPENDIX C: THE 20 GENETIC TESTS WITH THE HIGHEST MEDICARE PART B REIMBURSEMENT RATES FOR 2019

Genetic Test Procedure Code	Genetic Test Description	2019 Reimbursement Rate
81416[24]	Exome sequence analysis	$12,000
81425	Genome sequence analysis	5,031
81415	Exome sequence analysis	4,780
0036U	Exome tumor and sequence analysis	4,780
81518	Oncology breast MRNA 11 genes	3,873
81519	Oncology breast MRNA	3,873
81521	Oncology breast MRNA 70 genes	3,873
81541	Oncology prostate MRNA 46 genes	3,873
0045U	Oncology breast ductal carcinoma 12 genes	3,873
0047U	Oncology prostate MRNA 17 genes	3,873
81540	Oncology tumor unknown origin	3,750
81545	Oncology thyroid	3,600
0026U	Oncology thyroid DNA and MRNA 112 genes	3,600
0037U	Target gene sequence DNA 324 genes	3,500
81440	Mitochondrial gene	3,324
81595	Cardiology heart transplant MRNA	3,240
81525	Oncology colon MRNA	3,116
81455	Targeted genomic sequence analysis	2,920
81538	Oncology lung	2,871
81520	Oncology breast MRNA 58 genes	2,789

[24] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2016–2019 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.**