



U.S. Department of Health and Human Services
Office of Inspector General

DATA BRIEF

Medicare
Payments for
Clinical Diagnostic
Laboratory Tests
in 2017: Year 4
of Baseline Data

OEI-09-18-00410

September 2018

oig.hhs.gov

Suzanne Murrin
Deputy Inspector General





Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data

What **OIG** Found

Medicare paid \$7.1 billion under Part B for lab tests in 2017, a total that has changed very little in the 4-year period from 2014 through 2017. The top 25 tests by Medicare payments totaled \$4.5 billion and represented 64 percent of all Medicare payments for lab tests in 2017. The top five tests, which remained consistent with the top five from the previous 3 years, totaled \$2.2 billion in 2017.

Key Takeaway

Total Medicare spending for lab tests in 2017 was concentrated among a small number of tests and labs. Changes in the Medicare payment rates for the top 25 tests could have a significant impact on overall Medicare spending for lab tests in 2018.

Although more than 50,000 labs received Medicare payments in 2017, 3 labs received \$1.1 billion of the \$7.1 billion (15 percent) in total payments for lab tests. Spending on the top 25 tests was similarly concentrated among a few labs: 1 percent of labs received 55 percent of all Medicare payments for the top 25 lab tests in 2017.

What **OIG** Concludes

Clinical labs play a critical role in delivering health care to millions of Medicare beneficiaries. The new payment system for lab tests took effect on January 1, 2018, and resulted in significant changes to the Medicare payment rates for lab tests. This data brief, like those before it, will provide baseline statistics that **OIG** will use to measure the effects of changes to the payment system when data from 2018 become available. We will continue to monitor Medicare payments for lab tests and to identify emerging trends in these payments and vulnerabilities to potential cost savings.

Why **OIG** Did This Review

Effective in 2018, the Medicare program changed the way it sets payment rates for clinical diagnostic laboratory (lab) tests. The Centers for Medicare & Medicaid Services (CMS) replaced current payment rates with new rates based on current charges in the private health care market. This is the first reform in 3 decades to Medicare's payment system for lab tests.

As part of the same legislation reforming Medicare's payment system, Congress mandated that the Office of Inspector General (**OIG**) monitor Medicare payments for lab tests and the implementation and effect of the new payment system for those tests. This data brief provides the fourth set of annual baseline analyses of the top 25 lab tests.

How **OIG** Did This Review

We analyzed claims data for lab tests that CMS paid for under Medicare's Clinical Laboratory Fee Schedule. These tests are covered under Medicare Part B, and do not include tests that Medicare paid for under other payment systems, such as the payment system for critical access hospitals or the Outpatient Prospective Payment System. We identified the top 25 tests based on Medicare payments in 2017. We also identified key statistics and emerging trends, including Medicare payments by procedure code, beneficiary, lab, ordering provider, and test category.

TABLE OF CONTENTS

BACKGROUND	1
<hr/>	
FINDINGS	
Medicare Part B paid \$7.1 billion for lab tests in 2017, a total that changed very little over 4 years	2
In 2017, 64 percent of Medicare Part B payments for lab tests were for 25 tests	
<hr/>	
CONCLUSION	
<hr/>	
APPENDIX	
A. Prior OIG reports on Medicare payments and rates for lab tests	6
B. Methodology	7
<hr/>	
ACKNOWLEDGMENTS	8

BACKGROUND

The Protecting Access to Medicare Act (PAMA) of 2014 requires reform of the payment system for clinical laboratory (lab) tests—the first such reform in 3 decades.¹ Effective January 1, 2018, new rates based on rates paid by private payers replaced the previous payment system, which was based on lab charges from 1984 and 1985. The new payment system established a single national fee schedule for lab tests, replacing 57 separate local fee schedules. Both the new payment system and the system it replaced established the set of rates known as the Clinical Laboratory Fee Schedule.

To provide oversight, PAMA mandated that the Office of Inspector General (OIG) monitor Medicare payments for lab tests and the implementation of the new payment system. Specifically, PAMA requires OIG to publicly release an annual analysis of the top 25 tests, based on Medicare payments, and to conduct analyses that OIG determines appropriate regarding the implementation and effect of the new payment system.² This report analyzes payments made in 2017, the final year for which CMS paid for lab tests under the pre-2018 system. This is the fourth annual analysis and final year of baseline data before CMS begins making payments under the new system (see Appendix A).

This data brief analyzes claims data for lab tests that CMS paid for under Medicare’s Clinical Laboratory Fee Schedule. These tests are covered under Medicare Part B, and do not include tests that Medicare paid for under other payment systems, such as the Physician Fee Schedule, the payment system for critical access hospitals, or the Outpatient Prospective Payment System.

Lab test payment rates: 2018 and after

On January 1, 2018, CMS began paying for lab tests under the new system mandated by PAMA.^{3,4} CMS issued the 2018 fee schedule in November 2017 and, under the new system, the fee schedule will be updated every 3 years.⁵

To establish a new payment rate for each test on the fee schedule, CMS used the median of private payments for that test, weighted by the volume of payments reported. These new payment rates are based on private payments that labs received during the first half of 2016 and reported to CMS in 2017. Certain labs were exempt from reporting their private payer data to CMS.

Standards

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

FINDINGS

Medicare Part B paid \$7.1 billion for lab tests in 2017, a total that changed very little over 4 years

Medicare payments for lab tests under the Clinical Laboratory Fee Schedule totaled \$7.1 billion in 2017.⁶ Total payments for tests increased slightly from the totals from 2014, 2015, and 2016, which were \$7.0 billion, \$7.0 billion, and \$6.8 billion, respectively.^{7,8}

Medicare Part B covers most lab tests ordered by physicians and pays 100 percent of allowable charges. Beneficiaries do not have a copay under either the new payment system or the old one. Lab tests are usually performed in independent labs, hospitals, and physicians' offices and provide information integral to preventing, diagnosing, and treating disease.

Exhibit 1: What Medicare's \$7.1 billion for lab tests went toward in 2017



TESTS

433 million tests billed

3.4: Average number of tests a beneficiary received on a day

17: Average number of tests per day for top 1% of beneficiaries



BENEFICIARIES

28 million Medicare beneficiaries received at least 1 test

16: Average number of individual tests per beneficiary

86: Average number of tests in 2017 for the top 1% of beneficiaries



LABS

56,859 labs received Medicare payments

\$125,388: Average payments per lab

\$1.1 billion: Payments made to the top 3 labs



PROVIDERS

655,771 providers ordered lab tests

466: Average number of tests ordered per provider

5,964: Average number of tests ordered by top 1% of providers

Source: OIG analysis of Medicare Part B lab test payments, 2018.

In 2017, 64 percent of Medicare Part B payments for lab tests were for 25 tests

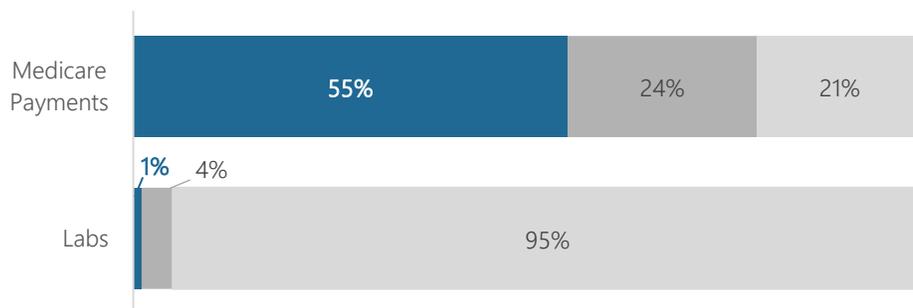
Medicare paid a total of \$4.5 billion for the top 25 lab tests in 2017, representing 64 percent of Medicare payments for lab tests paid for under the Clinical Laboratory Fee Schedule. The 2017 total is slightly higher than the \$4.3 billion that Medicare paid for the top 25 tests in 2016, the \$4.1 billion paid in 2015, and the \$4.2 billion paid in 2014. Exhibit 3 (see page 4) lists the top 25 lab tests based on Medicare payments in 2017.

Seventeen lab tests have remained in the top 25 tests for the last 4 years, reflecting relative stability within this group of high-volume tests. Of these, the top 5 lab tests have maintained their respective positions among the top 25 tests for the last 4 years and accounted for 30 percent (\$2.2 billion) of all payments for lab tests in 2017. These five tests include four common blood tests and a test for Vitamin D₃ levels.

More than half of Medicare payments for tests in the top 25 went to fewer than 300 labs

One percent of labs (272 out of 27,171 labs) received 55 percent of all Medicare payments for the top 25 lab tests in 2017. These labs each received an average of \$9.2 million in 2017. After the top 1 percent of labs, the next 4 percent of labs accounted for 24 percent of Medicare payments for the top 25 lab tests. These labs each received an average of \$1.0 million for these tests in 2017. The remaining 95 percent of labs accounted for just 21 percent of payments for the top 25 lab tests. These labs each received an average of \$36,636 in 2017. Medicare payments were similarly concentrated among a small proportion of all labs in 2014, 2015, and 2016.

Exhibit 2. Fifty-five percent of Medicare payments went to the top 1 percent of labs.



Source: OIG analysis of Medicare Part B lab test payments, 2018.

Exhibit 3. Top 25 lab tests based on Medicare Part B payments in 2017

Test Description (Procedure Code)*	National Limitation Amount**	Number of Tests (Millions)	Medicare Payments (Millions)	Change From 2016 Payments (Millions)
1. Blood test, thyroid-stimulating hormone (TSH) (84443)	\$23.05	21.5	\$484	↑ \$1.6
2. Blood test, comprehensive group of blood chemicals (80053)	\$14.49	41.6	\$473	↑ \$3.0
3. Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	\$10.66	41.5	\$432	↓ \$1.3
4. Blood test, lipids (cholesterol and triglycerides) (80061)	-	28.9	\$415	↑ \$4.4
5. Vitamin D ₃ level (82306)	\$40.61	8.9	\$348	↓ \$1.9
6. Drug test(s), definitive, per day, 22 or more drug class(es), including metabolite(s) if performed (G0483)	\$253.87	1.3	\$307	↑ \$65.3
7. Hemoglobin A1C level (83036)	\$13.32	19.7	\$257	↑ \$6.2
8. Testing for presence of drug (80307)	\$79.81	3.3	\$240	<i>New code in 2017</i>
9. Drug test(s), definitive, per day, 15–21 drug class(es), including metabolite(s) if performed (G0482)	\$204.34	0.8	\$162	↑ \$35.8
10. Blood test, basic group of blood chemicals (80048)	\$11.60	13.2	\$130	↓ \$3.7
11. Parathormone (parathyroid hormone) level (83970)	\$56.62	2.3	\$125	↑ \$4.9
12. Gene analysis (colorectal cancer) (81528)	\$512.43	0.2	\$117	↑ \$55.3
13. Cyanocobalamin (vitamin B ₁₂) level (82607)	\$20.68	5.6	\$114	↑ \$1.0
14. Drug test(s), definitive, per day, 1–7 drug class(es), including metabolite(s) if performed (G0480)	\$117.65	1.0	\$110	↑ \$41.5
15. PSA (prostate specific antigen) measurement (84153)	\$25.23	4.3	\$105	↑ \$1.9
16. Drug test(s), definitive, per day, 8–14 drug class(es), including metabolite(s) if performed (G0481)	\$160.99	0.7	\$101	↑ \$27.6
17. Blood test, clotting time (85610)	\$5.39	17.0	\$92	↓ \$12.9
18. Thyroxine (thyroid chemical) measurement (84439)	\$12.37	7.1	\$86	↑ \$1.5
19. Bacterial colony count, urine (87086)	\$11.07	7.5	\$82	↑ \$0.2
20. Natriuretic peptide (heart and blood vessel protein) level (83880)	\$46.56	1.6	\$70	↑ \$1.3
21. Ferritin (blood protein) level (82728)	\$18.70	3.8	\$70	↑ \$2.5
22. Test for detecting genes associated with breast cancer (81519)	\$3,443.30	0.02	\$60	↓ \$0.2
23. Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	\$8.87	6.6	\$57	↓ \$0.6
24. Folic acid level (82746)	\$20.17	2.8	\$56	↓ \$0.4
25. Gene analysis (breast cancer 1 and 2) full sequence and duplication or deletion variants (81162)***	\$2,503.20	0.02	\$52	↑ \$10.9

Total Medicare payments: \$4.54 billion

Sources: OIG analysis of Medicare Part B payments, 2018.

* See endnote 9 for the American Medical Association (AMA) copyright notice.

** The national limitation amount is a capped rate established by Congress to contain costs. The national limitation amounts listed in this column are from the 2017 Clinical Laboratory Fee Schedule. Medicare pays the lowest of the following three amounts: the lab's charge, the local fee schedule rate, or the national limitation amount.

***Procedure code 81162 ranked as Test 31 in 2016, by Medicare payments.

CONCLUSION

Clinical labs play a critical role in delivering health care to millions of Medicare beneficiaries, and the new method of setting payment rates for lab tests could have significant implications for Medicare spending and for the lab industry. In 2017, Medicare paid \$7.1 billion for tests; the top 25 tests accounted for 60 percent of this amount. About 30 percent of all lab test payments were for five tests.

The new payment system for lab tests took effect on January 1, 2018, and resulted in significant changes to the Medicare payment rates for lab tests. CMS estimated that these changes could save \$670 million in 2018.¹⁰ OIG will use baseline statistics from this OIG data brief and its predecessors to measure the effects of the new payment system in next year's analysis of 2018 payments. We will continue to monitor Medicare payments for lab tests and to identify emerging trends in these payments and vulnerabilities to potential Medicare cost savings.

APPENDIX A: Prior OIG reports on Medicare payments and rates for lab tests

<u>Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies To Ensure Data Quality</u>	OEI-09-17-00050	July 2018
<u>Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data</u>	OEI-09-17-00140	September 2017
<u>Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data</u>	OEI-09-16-00040	September 2016
<u>Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress</u>	OEI-09-16-00100	September 2016
<u>Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data</u>	OEI-09-15-00210	September 2015
<u>Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings</u>	OEI-07-11-00010	June 2013
<u>Variation in the Clinical Laboratory Fee Schedule</u>	OEI-05-08-00400	July 2009

APPENDIX B: Methodology

We based this data brief on our analysis of Medicare’s claims data for lab tests performed in 2017 and reimbursed under the Clinical Laboratory Fee Schedule. For comparison, we also reviewed the same claims data from 2014, 2015, and 2016. As a result of when we accessed claims data, our analysis for 2016 and 2017 used a set of claims that was marginally more complete than the sets we used for our 2014 and 2015 reports. The totals we report for 2017 are thus marginally higher than those reported for 2014 and 2015.

The claims data were from the National Claims History Physician/Supplier Part B claims files and National Claims History Outpatient files. The Physician/Supplier Part B files primarily include lab test claims from independent labs and physician office labs. The Outpatient files primarily include lab test claims from hospital labs. We did not include lab tests that were paid for under other payment systems, such as the payment system for critical access hospitals or the Outpatient Prospective Payment System.¹¹ We also did not include claims for physicians’ interpretations of tests.

We analyzed the claims data to identify key statistics and emerging trends for Medicare Part B payments for lab tests. We analyzed Medicare payments and test volume by procedure code, beneficiary, lab, and ordering provider. Test volume is based on the number of units for which labs billed. We identified the top 25 lab tests based on total payments for each procedure code in 2017, and we calculated total payments for these tests and analyzed payments by lab.

Analysis by beneficiary. We identified beneficiaries by using the Health Insurance Claim Numbers on the claims. We used the dates of service to determine the number of tests that beneficiaries received per day.

Analysis by lab. We used different variables to identify individual labs that billed Medicare. For lab tests in the Physician/Supplier Part B claims files, we used a lab’s Tax Identification Number (TIN) to identify a unique lab. We chose the TIN because the TIN is the highest level identifier in the claims data and includes multiple locations for a lab. For tests in the Outpatient claims files, we identified a unique lab based on the organization’s CMS Certification Number. The Outpatient claims files do not include a variable for a provider’s TIN.

Analysis by ordering provider. We used the ordering provider’s National Provider Identifier (NPI) reported on the claim to identify the physician who ordered the lab test. Because the ordering provider’s NPI is reported only for claims from the Physician/Supplier claims file, our analysis is limited to claims in that file and does not include claims from the Outpatient claims file for lab tests performed by hospital labs.

ACKNOWLEDGMENTS

Chelsea Samuel served as the team leader for this study. Office of Evaluation and Inspections staff who provided support include Berivan Demir Neubert, Christine Moritz, and Michael Novello.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Sarah Ambrose and China Tantameng.

This report was prepared under the direction of Blaine Collins, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Abby Amoroso and Michael Henry, Deputy Regional Inspectors General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ABOUT THE OFFICE OF INSPECTOR GENERAL

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

ENDNOTES

¹ PAMA, P.L. No. 113-93, § 216(a) (adding Social Security Act (SSA), § 1834A, 42 U.S.C. § 1395m-1).

² PAMA, § 216(c)(2).

³ Private payer rates include those paid by private health insurance companies, Medicaid managed care organizations, and Medicare Advantage plans.

⁴ SSA § 1834A(b)(1)(A), 42 U.S.C. § 1395m-1(b)(1)(A), requires CMS to implement the new payment system beginning January 1, 2017; however, CMS moved the implementation date to January 1, 2018. 81 Fed. Reg. 41036, 41037 (June 23, 2016).

⁵ 42 CFR § 414.504(a). In the case of advanced diagnostic lab tests (ADLTs), Medicare will update the payment rates annually. PAMA established advanced diagnostic lab tests as a new category of test. The category includes tests that are performed by a single lab and either (1) analyze multiple biomarkers combined with a unique algorithm to yield a single patient-specific result, (2) are cleared or approved by the Food and Drug Administration, or (3) meet other similar criteria established by the Secretary of Health and Human Services. SSA § 1834A(d)(5), 42 U.S.C. § 1395m-1(d)(5).

⁶ Medicare paid an additional \$229 million in 2017 for specimen collection and validation.

⁷ For lab tests and other Medicare fee-for-service claims dated on or after April 1, 2013, Medicare paid 2 percent less than the payment rate in accordance with the Budget Control Act of 2011, P.L. No. 112-25, Section 302, and the American Taxpayer Relief Act of 2012, P.L. No. 112-240, Section 901 (i.e., sequestration).

⁸ Congress mandated a 1.75-percent reduction in Medicare payments for lab tests under the Clinical Laboratory Fee Schedule in 2011–2015. Patient Protection and Affordable Care Act, P.L. No. 111-148, § 3401(l).

⁹ Labs bill for each test on the Clinical Laboratory Fee Schedule using a Healthcare Common Procedure Coding System (HCPCS) code, which we refer to as a “procedure code.” The HCPCS is divided into two subsystems, referred to as Level I and Level II. Level I HCPCS codes are composed of Current Procedural Terminology codes. The five character codes and descriptions included in this study are obtained from Current Procedural Terminology (CPT®), copyright 2016 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 study should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply. Level II HCPCS codes are established by CMS primarily for items, supplies, and nonphysician services not covered by CPT codes.

¹⁰ *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System*, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>.

¹¹ Many of the lab tests performed in outpatient settings (such as hospitals, skilled nursing facilities, and dialysis facilities) are paid for under Medicare payment systems other than the Clinical Laboratory Fee Schedule. As we have noted, our analysis included only lab tests paid for under Medicare’s Clinical Laboratory Fee Schedule.