U.S. Department of Health and Human Services

Office of Inspector General

Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions

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Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions

What OIG Found

Total Medicare spending for clinical diagnostic laboratory (lab) tests increased in 2018, despite lower payment rates for most tests. Medicare spent $7.6 billion for lab tests in 2018, a $459 million increase from $7.1 billion in 2017.

Key Takeaway
Medicare Part B spending for laboratory tests increased by $459 million (6 percent) in 2018, although payment rates for most tests decreased under the new payment system. The spending increase was driven by (1) increased spending on genetic tests, (2) the end of the discount for certain chemistry tests, and (3) the move to a single national fee schedule.

Although payment rates for 75 percent of tests decreased in 2018 under the new payment system, savings that resulted from lower rates were overtaken by increased spending on other tests, including genetic tests and certain chemistry tests. Spending on genetic tests increased from $473 million in 2017 to $969 million in 2018 because of new and expensive tests entering the Clinical Laboratory Fee Schedule (CLFS), as well as an increase in the volume of existing genetic tests. Spending on certain chemistry tests also increased by $82 million in 2018 following the end of a discount on these tests. Finally, a one-time spending increase on some tests occurred in cases in which the national rate was higher than the local payment rates that it replaced.

What OIG Concludes and Recommends

Clinical lab tests play a critical role in delivering necessary health care to Medicare beneficiaries. Although the Protecting Access to Medicare Act of 2014 (PAMA) resulted in lower payment rates, the resulting savings were overtaken by increased spending in other areas.

Genetic tests can provide valuable information to providers and help to identify appropriate treatments for Medicare beneficiaries, but even a small number of inappropriate tests could expose Medicare to extremely high spending. As the spending on genetic tests and the volume of these tests continue to grow, oversight of these tests becomes more important.

Spending on automated chemistry tests increased because a discount that the Centers for Medicare & Medicaid Services (CMS) had previously applied to these tests was not allowed under PAMA. To address this ongoing risk to cost savings, we recommend that CMS seek legislative authority to establish a mechanism to control costs for these tests. Although CMS does not have statutory authority to restore the discount that it previously used, CMS should seek legislative change to regain such authority. CMS neither agreed nor disagreed with our recommendation.

Full report can be found at oig.hhs.gov/oei/reports/oei-09-19-00100.asp

Why OIG Did This Review

Effective in 2018, the Medicare program changed the way it sets payment rates for lab tests. CMS replaced the previous payment rates with new rates based on payments made by private insurers. 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 report also provides the fifth annual analysis of the top 25 lab tests by Medicare spending.

How OIG Did This Review

We analyzed claims data for lab tests that CMS paid for under the Medicare CLFS in 2018. 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 Hospital Outpatient Prospective Payment System. We examined Medicare Part B spending for lab tests in 2018 as compared to 2017 and identified key factors that contributed to increased spending. We identified notable changes to test payment rates and categories and examined factors that affected Medicare spending in certain geographic areas of the lab test marketplace. Additionally, we identified the top 25 tests based on total spending in 2018 for each lab test procedure code.

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BACKGROUND

Objective

To examine the effects of the new payment system required under the Protecting Access to Medicare Act of 2014 (PAMA) and identify factors that affected Medicare spending for lab tests in 2018.

Effective January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) set new rates for clinical diagnostic laboratory (lab) tests to adhere to PAMA.[1] This new rate-setting method replaced the previous system, which set rates based on lab charges from 1984 and 1985 and adjusted for inflation. In 2013, the Office of Inspector General (OIG) found that Medicare paid more for lab tests than other payers because the payment methodology based on historical lab charges was outdated. OIG recommended that CMS seek legislation to establish lower payment rates for lab tests.[2]

In 2014, PAMA required CMS to set payment rates for lab tests using private payer data collected from labs.[3] When CMS published the new fee schedule in 2017, it estimated that the new payment system would generate about $670 million in savings for lab payments in 2018.[4]

The set of payment rates established under the new payment system and the system it replaced are known as the Clinical Laboratory Fee Schedule (CLFS). The CLFS comprises the published fee schedule rate for each test, which is the maximum amount that Medicare is allowed to pay for each lab test. Prior to PAMA, the fee schedule rate was the national limitation amount (NLA), and Medicare paid the lowest of the following: the amount billed, the local fee schedule rate for a geographic area, or the NLA. In other words, Medicare paid the NLA, unless the local fee schedule rate or the lab's charge was lower. Under the new payment system, the fee schedule rate is based on the weighted median of private payer rates determined for each test and applies nationally, replacing the NLA and 57 separate local fee schedules. Because Medicare pays the lower of the amount billed or the fee schedule rate, it pays the fee schedule rate unless the lab's charge is lower.

PAMA also mandated that 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 spending, and to conduct analyses that OIG determines appropriate regarding the implementation and effect of the new payment system. This report analyzes payments made in 2018, the first year that Medicare paid for lab tests under the new system.

Lab test payment rates under the Protecting Access to Medicare Act

On January 1, 2018, Medicare began paying for lab tests under the system mandated by PAMA. CMS issued the 2018 fee schedule in November 2017.[5] To establish a new payment rate for each test on the fee schedule, CMS uses the median of private payer rates for that test, weighted by the volume of payments reported.[6] These new payment rates for 2018 through 2020 were based on private payments that labs received during the first half of 2016 and reported to CMS in 2017. Payment rates for 2021 through 2023 were to be based on private payments that labs received during the first half of 2019 and were to report to CMS in 2020.[7]

PAMA also limited how much payment rates for tests could fall during the first 6 years that the new payment system was in effect.[8] For the first 3 years, from 2018 through 2020, payment rate reductions were to be limited to 10 percent each year. For the following 3 years—2021 through 2023—payment rate reductions were to be limited to 15 percent each year. Beginning in 2024, there was to be no limit to how much payment rates may decrease.

Legislative changes since 2018. Since 2018, Congress has twice delayed the data reporting cycle—once as a result of the Further Consolidated Appropriations Act, 2020 (enacted in December 2019), and once as a result of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (enacted in March 2020). Under the CARES Act, labs will not be required to report private payer data from the first half of 2019 to CMS until 2022.[9] Payment rates based on the volume-weighted median of data reported in 2017 will be in effect through 2022. The 3-year data reporting cycle will resume in 2025.

The same two pieces of legislation also twice delayed the annual limits to payment rate reductions. In 2021, reductions to payment rates will not be permitted, and rates will remain consistent with those paid in 2020. From 2022 through 2024, reductions will be limited to 15 percent each year.[10] Beginning in 2025, there will be no limit to how much rates may decrease.

Oversight of laboratory tests

CMS's Center for Program Integrity (CPI) provides oversight of lab tests, including genetic tests, to prevent inappropriate or fraudulent use. CPI uses a variety of tools to identify patterns of inappropriate use and prevent improper payments. When inappropriate use is identified, CPI partners with law enforcement agencies, including OIG, to investigate fraudulent activity. Additionally, CPI conducts outreach activities to educate providers and beneficiaries about ways to guard against inappropriate use.

Related OIG work

Since Congress passed PAMA, OIG has issued several reports analyzing Medicare payments for lab tests and monitoring CMS's efforts to implement the law.[11] See Appendix D for a list of related reports.

Fraud takedowns by OIG's Office of Investigations. In 2019, OIG collaborated with law enforcement partners to investigate a pattern of fraudulent genetic tests that were ordered using samples collected during "free" cheek-swab screenings.[12] Investigations of fraudulent genetic testing resulted in charges against 35 individuals who fraudulently billed Medicare more than $2.1 billion for genetic tests.[13]

Methodology

We analyzed claims data for lab tests in 2018 that CMS paid for under the CLFS. 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 Hospital Outpatient Prospective Payment System. We examined Medicare spending for lab tests and identified key factors that contributed to increased spending in 2018 as compared to 2017. We identified notable changes to test payment rates and categories and examined factors that affected spending in certain areas of the lab test marketplace. We also identified the top 25 tests based on total spending in 2018 for each lab test procedure code. See Appendix A for a Detailed Methodology.

Standards

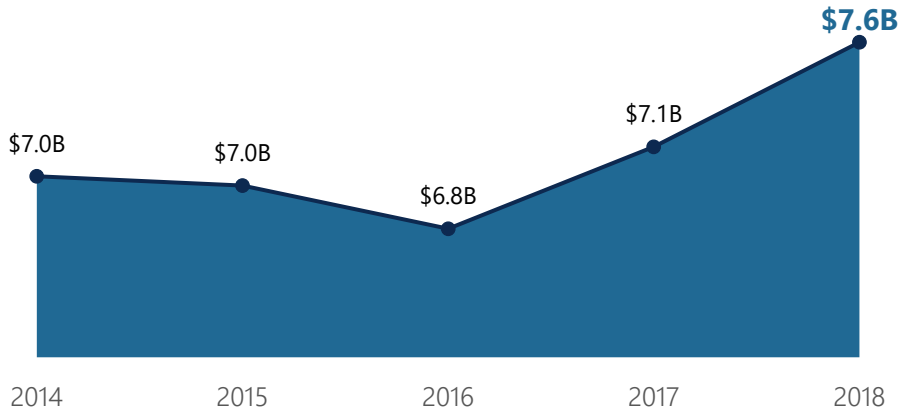
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Total Medicare spending for lab tests increased in 2018, despite lower payment rates for most lab tests

In 2018, payment rates for 75 percent of tests decreased as a result of the new payment system. However, 2018 had the largest increase in Medicare lab test spending since the passage of PAMA in 2014, as shown in Exhibit 1. Medicare spending for lab tests on the CLFS increased by $459 million, or about 6 percent, from $7.1 billion in 2017 to $7.6 billion in 2018.[14]

Exhibit 1: Medicare Part B spending on lab tests reached $7.6 billion in 2018, its highest point since 2014.



Source: OIG analysis of Medicare Part B lab test spending, in billions, 2019.
Note: Dollar values for Medicare spending are rounded.

60% of spending on lab tests goes to the top 25 tests

Although the new payment system resulted in lower payment rates for 23 of the top 25 lab tests, spending on many of the top 25 tests increased in 2018

Payment rates decreased for 23 of the top 25 lab tests in 2018 and increased for 1 test. The remaining test was new to the CLFS in 2018 and therefore did not have a prior fee schedule rate. For 15 of the top 25 tests, these lower payment rates resulted in lower Medicare spending, as shown in the far right column of Exhibit 2 on the next page. Exhibit 2 displays key statistics for the top 25 lab tests by Medicare spending.

Medicare spending increased for 9 of the top 25 tests in 2018. Increased spending resulted primarily from an increase in the volume of six tests, as well as the higher fee schedule rate for one test. In addition, total payments increased for two tests, despite a decrease in both the payment rates and claims volume. These particular tests were affected by the changes made by the payment system, as this report discusses later.

Exhibit 2: Medicare Part B spent $4.57 billion on the top 25 lab tests in 2018, including 3 expensive genetic tests.

	Test Description (Procedure Code)	2017 Fee Schedule Rate	2018 Fee Schedule Rate	2018 Test Volume (Millions)	2018 Medicare Spending (Millions)	Change from 2017 Spending (Millions)
1	Blood test, comprehensive group of blood chemicals (80053)	$14.49	$13.04	41.64	$537.10	↑ $64.37
2	Blood test, lipids (cholesterol and triglycerides) (80061)	$18.37	$16.53	28.58	$463.58	↑ $48.66
3	Blood test, thyroid stimulating hormone (TSH) (84443)	$23.05	$20.75	21.39	$434.71	↓ -$49.26
4	Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	$10.66	$9.59	41.14	$391.09	↓ -$41.09
5	Vitamin D-3 level (82306)	$40.61	$36.55	8.94	$318.95	↓ -$28.97
6	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$253.87	$246.92	1.30	$313.43	↑ $6.90
7	Testing for presence of drug (80307)	$79.81	$71.83	3.38	$236.07	↓ -$3.74
8	Hemoglobin A1C level (83036)	$13.32	$11.99	19.68	$232.32	↓ -$24.34
9	Genetic test: Gene analysis (colorectal cancer) (81528)	$512.43	$508.87	0.34	$167.67	↑ $50.66
10	Drug test(s), definitive, per day; 15-21 drug class(es), including metabolite(s) if performed (G0482)	$204.34	$198.74	0.82	$159.32	↓ -$2.96
11	Blood test, basic group of blood chemicals (80048)	$11.60	$10.44	12.72	$132.52	↑ $2.70
12	Genetic test: Molecular pathology procedure level 9 (81408)	NA	$2,000.00	0.06	$117.92	New to the CLFS
13	Parathormone (parathyroid hormone) level (83970)	$56.62	$50.96	2.34	$115.90	↓ -$9.34
14	Drug test(s), definitive, per day; 1-7 drug class(es), including metabolite(s) if performed (G0480)	$117.65	$114.43	1.05	$113.94	↑ $3.69
15	Cyanocobalamin (vitamin B-12) level (82607)	$20.68	$18.61	5.63	$102.53	↓ -$11.32
16	Drug test(s), definitive, per day; 8-14 drug class(es), including metabolite(s) if performed (G0481)	$160.99	$156.59	0.64	$96.59	↓ -$4.08
17	PSA (prostate specific antigen) measurement (84153)	$25.23	$22.71	4.30	$95.57	↓ -$9.64
18	Thyroxine (thyroid chemical) measurement (84439)	$12.37	$11.13	7.26	$79.42	↓ -$6.76
19	Genetic test: Test for detecting genes associated with breast cancer (81519)	$3443.30	$3,873.00	0.02	$76.62	↑ $16.48
20	Bacterial colony count, urine (87086)	$11.07	$9.96	7.40	$73.31	↓ -$9.08
21	Blood test, clotting time (85610)	$5.39	$4.85	14.84	$72.69	↓ -$19.48
22	Ferritin (blood protein) level (82728)	$18.70	$16.83	3.94	$65.12	↓ -$4.80
23	Natriuretic peptide (heart and blood vessel protein) level (83880)	$46.56	$41.90	1.56	$64.79	↓ -$5.68
24	Detection test for digestive tract pathogen (87507)	$571.72	$514.55	0.12	$56.79	↑ $22.57
25	Detection test for organism (87798)	$48.14	$43.33	1.23	$52.09	↑ $22.68
				Total 2018 Medicare Payments: $4.57 Billion		

Sources: OIG analysis of Medicare Part B lab test spending, 2019. Fee schedule rates are from the 2017 and 2018 CLFS. See endnote 15 for the American Medical Association (AMA) copyright notice.
Note: The column for Medicare spending for lab tests is highlighted in blue.

Spending on genetic tests drove much of the increase in total Medicare spending on lab tests in 2018

Medicare paid $969 million for genetic tests in 2018, a $496 million increase from 2017, as shown in Exhibit 3. Total spending on genetic tests accounted for 13 percent of Medicare spending for lab tests in 2018, as compared to 7 percent of spending in 2017. The spending increase results from an increase in the volume of claims for genetic tests, as well as new and expensive tests entering the market. The volume of Medicare claims for genetic tests almost doubled, from 950,000 units in 2017 to 1.76 million units in 2018. The number of genetic tests for which Medicare made payments also increased dramatically in 2018, almost doubling from 110 in 2017 to 199 in 2018.

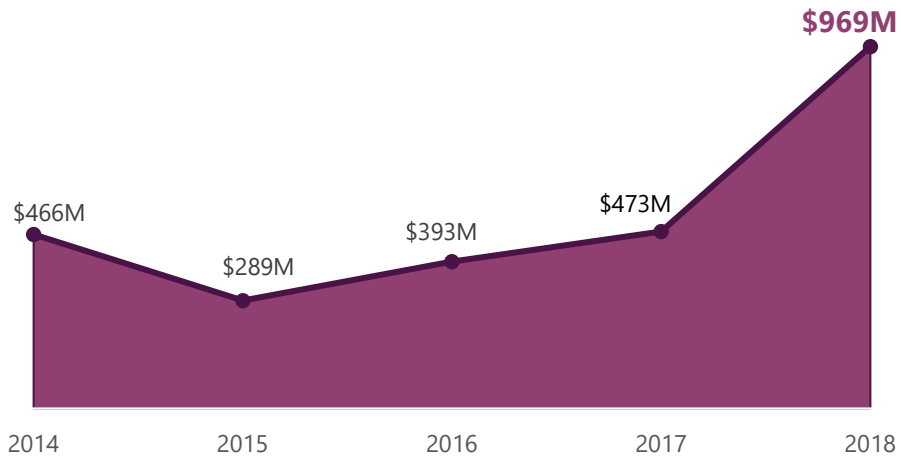
Genetic tests identify changes in a beneficiary's chromosomes, genes, or proteins. They are used to confirm or rule out a genetic condition and determine a chance of developing or passing on a genetic condition. Three categories of genetic tests are on the CLFS:

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

Multianalyte Algorithmic Assays (MAAAs) combine multiple test results with patient information to yield a predictive score, such as recurrence of a cancer or a treatment response.

Genomic Sequencing Procedures (GSPs) identify structural changes in genetic material and are often used to diagnose or manage inherited diseases.

Exhibit 3: Total spending on genetic tests more than doubled to $969 million in 2018 following a steady increase since 2015.



Source: OIG analysis of Medicare Part B lab test spending, in millions, 2019.

Increased volume of claims for high-priced genetic tests contributed to the increase in payments for lab tests in 2018, as did payments for genetic tests that were new to the CLFS in 2018. For example, 3 genetic tests are among the top 25 tests by spending, including 1 new test that entered the CLFS in 2018. Volume for a colorectal cancer test (line 9 in Exhibit 2) increased for the third year in a row, and a breast cancer gene detection test (line 19 in Exhibit 2) increased for the second year in a row. Both tests entered the top 25 in 2016.

In 2018, more new genetic tests were added to the CLFS than in any year since OIG began monitoring payments for lab tests in 2014. In 2018, 106 new genetic tests were added to the CLFS, increasing the number of genetic tests on the CLFS to 216, up from 110 tests in 2017.[16] One of those tests, a genetic panel test, became the number 12 test by Medicare spending.

Most of the growth in genetic test spending was in a particular category of tests: molecular pathology tests. Molecular pathology tests are the most established category of genetic tests on the CLFS. Spending on molecular pathology tests increased from $162 million in 2017 to $488 million in 2018, which accounted for 50 percent of Medicare spending on genetic tests. The increase in spending was

driven by increased volume, which more than doubled from 556,000 units in 2017 to 1.2 million units in 2018. The number of molecular pathology test codes that Medicare paid for also increased, from 79 in 2017 to 149 in 2018.

Two other categories of genetic tests—multianalyte algorithmic assays (MAAAs) and genomic sequencing procedures (GSPs)—also contributed to the overall spending increase for genetic tests in 2018. Spending on MAAAs grew from $291 million in 2017 to $422 million in 2018, reflecting a similar increase in claims for these tests. Although GSPs are a much smaller category of tests, spending nearly tripled in 2018, from $20 million for 25,800 units in 2017 to $59 million for 61,185 units. See Appendix B for historical trends in genetic tests.

Ending discounts for automated chemistry tests contributed to Medicare spending increases in 2018

As a result of changes required by PAMA, Medicare paid more in 2018 than in 2017 for certain chemistry tests, although volume decreased. Beginning in 2018, CMS ended the practice of applying a discount to a set of 23 automated chemistry tests.[17] Without the discount, Medicare paid $82 million more for the same set of tests, increasing spending on these chemistry tests to $194 million in 2018. Concurrently, the volume of these 23 tests decreased by 52,804 units in 2018.

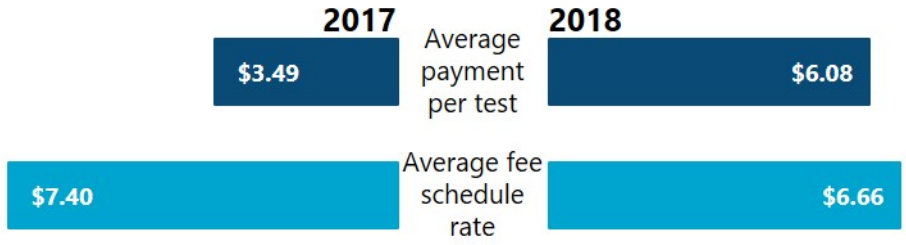
PAMA required CMS to change its policy when reimbursing labs for these tests. Prior to PAMA's implementation, Medicare paid for these tests by applying a discount when multiple codes were billed for the same beneficiary on the same date of service. However, PAMA bars CMS from applying discounts or "bundling" tests.[18] Rather than applying discounts, Medicare began paying either the lab's charge or the fee schedule rate for each test, as it does with other tests on the CLFS.

Automated Chemistry Tests measure the levels of chemicals such as cholesterol, glucose, or potassium in a patient's system. Labs may obtain multiple results from a single sample.

Exhibit 4 provides an illustration of the effect of ending discounts for the group of 23 tests.

- In 2017, the actual average payment amount for the 23 tests, after discounts, was $3.49, which was lower than the average fee schedule rate of $7.40.
- In 2018, however, the actual average payment amount—without the discount—was $6.08, much closer to the 2018 average fee schedule rate of $6.66.

Exhibit 4: Ending the discount for automated chemistry tests narrowed the gap between the average payment per test and the average fee schedule rate.



Source: OIG analysis of Medicare Part B lab test spending, 2019.
Note: The 2017 average fee schedule rate is the average of the NLA, not of all 57 local rates.

The 2018 average fee schedule rate was lower because of the new rate-setting method required by PAMA, but any savings on these 23 automated chemistry tests were more than offset by the PAMA requirement that ended discounts. See Appendix C for a complete list of the 23 automated chemistry tests, including the 2017 and 2018 fee schedule rates and average payments.

Moving to a single national fee schedule in 2018 resulted in a one-time increase in payments for some lab tests

The one-time change from low local payment rates to a single national fee schedule limited cost savings in the first year of PAMA's implementation. Prior to PAMA's implementation, some areas of the United States had lower local payment rates that Medicare paid instead of the national fee schedule rate. Starting in 2018, PAMA replaced 57 local fee schedules with a single payment rate that applies nationally. As a result, 22 of the top 25 tests saw a national payment rate in 2018 that was higher than at least 1 of the 57 local fee schedule rates from 2017. This one-time policy change is not expected to limit Medicare savings in future years.

Exhibit 5 provides an example of how replacing local payment rates with a single national rate resulted in higher payments for the top two tests by Medicare spending, despite the decrease in national fee schedule rates. The fee schedule rates for these tests each decreased by 10 percent in 2018, the maximum allowed that year.

- The fee schedule rate for the comprehensive blood chemical test (code 80053) decreased by $1.45 per test, from $14.49 in 2017 to $13.04 in 2018. However, 4 of the 57 local payment rates were lower than the national payment rate that replaced them. The lowest of these local rates was $11.53, which was $1.51 less than the new national rate. As a result, total Medicare spending for this test increased by about $64 million despite the rate reduction.
- The fee schedule rate for the lipid panel (code 80061) decreased by $1.84 per test, from $18.37 in 2017 to $16.53 in 2018. However, 7 of the 57 local payment rates were lower than the national payment rate that replaced them. The lowest of these local rates was $13.44, which was

$3.09 less than the new national rate that replaced it. As a result, total Medicare spending for this test increased by about $49 million in 2018 despite the rate reduction. See Exhibit 2, lines 1 and 2, for detailed spending data on these tests.

Exhibit 5: The lowest 2017 local rates for the top two tests were replaced by a higher 2018 fee schedule rate, even when it was lower than the 2017 fee schedule rate.

Source: OIG analysis of Medicare Part B lab test spending, 2019.

By contrast, some tests that did not have notable variation across local fee schedules saw Medicare spending decrease under the new payment system. For example, Medicare spending for the number three test by Medicare spending decreased as a result of the lower 2018 payment rate. The fee schedule rate for the thyroid stimulating hormone test (code 84443) decreased by $2.30 per test, from $23.05 in 2017 to $20.75 in 2018. Because 2017 local rates were consistent with the national fee schedule rate, total Medicare spending for this test decreased by about $49 million.

The spending increase caused by moving to a single national fee schedule will not continue in 2019. In 2019, all fee schedule rates applied nationally and rates decreased by 10 percent unless the volume-weighted median was reached. For example, in 2019, the fee schedule rate for the comprehensive blood chemical test fell by 10 percent, to $11.74, which could lead to savings of up to $48 million if volume remained consistent.

CONCLUSION AND RECOMMENDATION

Each year, Medicare beneficiaries and their health care providers use clinical lab tests to diagnose health conditions and to make informed treatment decisions. Given the critical role that lab tests play in health care, it is essential that Medicare ensure beneficiary access to these vital services and protect the integrity of the Medicare trust fund.

PAMA established a way for CMS to tie Medicare payment rates to those paid by private payers and update rates on a regular basis, which resulted in lower payment rates for most tests. However, the resulting savings on some individual lab tests were overtaken by increased spending in other areas.

Medicare spending on genetic tests increased in 2018 as a result of an increased volume of Medicare claims for existing genetic tests and the addition of many new and expensive genetic tests. These tests can provide valuable information for providers and help to identify appropriate treatments for Medicare beneficiaries. However, given how expensive many of these tests are, even a small number of inappropriate tests could expose Medicare to extremely high spending. As spending on genetic tests and the volume of these tests continue to grow, oversight of these tests becomes more important. OIG will continue to monitor payments for genetic tests and encourages CMS to continue oversight efforts to identify and prevent improper payments.

Although the increase in spending on genetic tests was a result of growth in this aspect of the lab test market, spending on automated chemistry tests increased because a discount that CMS had previously applied to these tests was not allowed under PAMA. To address the ongoing risk to cost savings, OIG recommends the following:

CMS should seek legislative authority to establish a mechanism to control costs for automated chemistry tests

CMS should seek legislative authority to establish a way to avoid paying the full fee schedule rate for individual tests when a provider orders multiple results from a single beneficiary sample. Labs that perform automated chemistry tests benefit from the efficiency of obtaining multiple results from a single sample.

The practice of discounting multiple results for a single beneficiary on the same date of service ended due to PAMA's prohibition of discounts and resulted in an $82 million increase in spending on these tests. Because these tests provide bundled results from a single sample, Medicare should consider methods for incorporating test efficiencies when paying for these tests. Although CMS does not currently have statutory authority to discount payments for automated chemistry tests, CMS should consider seeking legislative authority to establish a method of controlling costs, such as:

- reinstating the previous system's policy of discounting automated chemistry tests;
- paying the volume-weighted median immediately for automated chemistry tests instead of phasing in reductions to payment rates until they reach the volume-weighted median of lab-reported data; or
- establishing new test codes that bundle multiple results, similar to how CMS established new tiered bundles for drug tests.[19]

AGENCY COMMENTS AND OIG RESPONSE

CMS did not explicitly agree or disagree with our recommendation that it seek legislative authority to establish a mechanism to control costs for automated chemistry tests. Instead, CMS stated that it would monitor utilization and spending associated with these codes and take the OIG's recommendation into consideration when determining appropriate next steps.

We ask that CMS specify in its Final Management Decision the steps it has taken or plans to take to mitigate excessive spending for the 23 automated chemistry tests. We appreciate the steps that CMS took in 2019 to ensure accurate payments for test panels with specific Current Procedural Terminology (CPT) codes.[20] However, most combinations of automated chemistry tests are not associated with an established test panel. Spending for the set of 23 automated chemistry test codes increased in 2018 because of PAMA's prohibition of discounts, which had previously been applied to these tests. We recommend that CMS seek legislative authority to control costs for these tests when multiple tests are ordered for the same beneficiary on the same date of service.

For the full text of CMS's response, see Appendix E.

APPENDIX A: Detailed Methodology

We based this report on our analysis of Medicare claims data for lab tests performed in 2018 and reimbursed under the CLFS. We compared our analysis for 2018 analysis to results for 2014–2017. For 2014, 2015, and 2018, we analyzed the 16-month file, and for 2016 and 2017, we analyzed the 17-month file. As a result, analysis for 2016 and 2017 used a set of claims that was marginally more complete than sets used for other reports and therefore the totals for 2016 and 2017 are marginally higher than those reported for other years.

The claims data were from the National Claims History Physician/Supplier Part B claim files and National Claims History Outpatient files. The Physician/Supplier Part B files primarily include claims from independent labs and physician office labs. The Outpatient files primarily include claims from hospital labs. We did not include tests paid for under other payment systems, such as the payment system for critical access hospitals or the Hospital Outpatient Prospective Payment System.[21] We did not include claims for physician interpretation of tests.

We analyzed claims data to identify key statistics and emerging trends for Medicare Part B payments for lab tests. We also analyzed Medicare payments and test volume by procedure code and category. Test volume is based on the number of units for which labs billed.

We calculated total spending for 2018 and compared that to similar results from past studies. To identify lower rates, we analyzed the 2018 CLFS and compared 2018 payment rates to 2017 payment rates.

Top 25 lab tests. We identified the top 25 lab tests based on total spending for each procedure code in 2018 and calculated total spending for these tests.

Analysis by category. We used Current Procedural Terminology (CPT) categories for all tests on the CLFS. For Healthcare Common Procedure Coding System (HCPCS) Level II codes that are unique to the CLFS, we had CMS assign CPT categories to those codes. We identified total payments and volume for each category of tests. We used CPT category definitions to identify genetic tests.

Automated Multi-Channel Chemistry Tests. We used the set of 23 Automated Multi-Channel Chemistry Tests for which Medicare pays. We calculated total volume and total spending for each test code and compared spending to 2017 results.

Local fee schedule variation. Using the 2017 fee schedule, we identified the tests within the top 25 where there was variation across fee schedules. We compared the lowest 2017 fee schedule rates to the 2018 fee schedule rates. We also compared average payment per test for 2017 and 2018. We did not identify

whether payments made below the 2017 fee schedule rate resulted from lower lab charges, lower local fee schedule rates, or Medicare's discount policy.

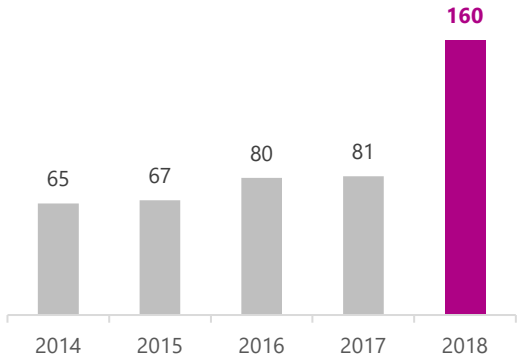
APPENDIX B: Medicare Part B Spending on Genetic Testing

Molecular Pathology Tests

What they are: These tests detect variants in genetic material and often help doctors determine how their patients will respond to treatment.[22]

- **Spending increase:** More than 200 percent, from $162 million in 2017 to $488 million in 2018, a $326 million increase.
- **Volume increase:** 118 percent, from 556,235 in 2017 to 1.2 million in 2018.
- **One test in the top 25:** Molecular pathology procedure, level 9 (81408). It entered the CLFS in 2018 and costs Medicare $2,000 per test.[23]

The number of molecular pathology tests on the CLFS almost doubled to 160 in 2018

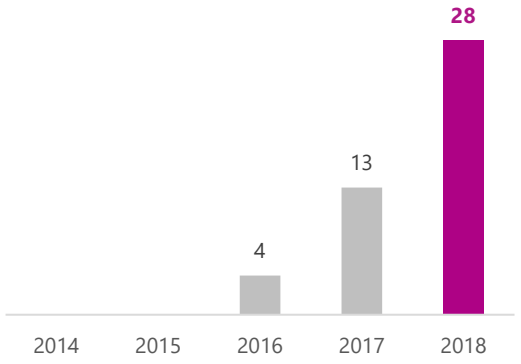


Multianalyte Algorithmic Assays (MAAAs)

What they are: These tests combine multiple test results with patient information to yield a predictive score, such as recurrence of a cancer or a treatment response.[24]

- **Spending increase:** 45 percent, from $291 million in 2017 to $421 million in 2018, a $130 million increase.
- **Volume increase:** 32 percent, from 365,851 in 2017 to 483,912 in 2018.
- **Two tests in the top 25:** Gene analysis for colorectal cancer (81528) and breast cancer detection test (81519). In 2018, the payment rate for the breast cancer detection test increased by 12 percent.

The number of MAAAs on the CLFS more than doubled to 28 in 2018

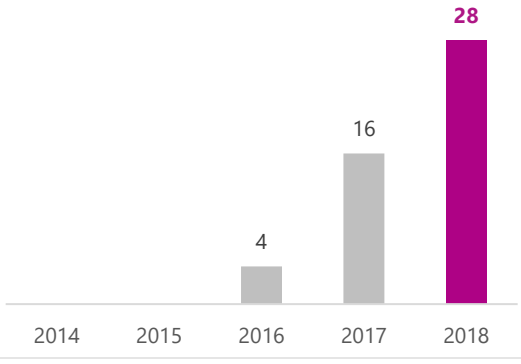


Genomic Sequencing Procedures (GSPs)

What they are: These tests identify structural changes in genetic material and are often used to diagnose or manage inherited diseases.[25]

- **Spending increase**: 200 percent, from $20 million in 2017 to $59 million in 2018, a $39 million increase.
- **Volume increase:** 137 percent, from 25,800 in 2017 to 61,217 in 2018.
- GSPs did not appear in the top 25 for 2018.

The number of GSPs tests on the CLFS almost doubled to 28 in 2018



Source: OIG analysis of Medicare Part B lab test spending, 2019.

APPENDIX C: Changes to Payment Rates for Automated Chemistry Tests

Prior to PAMA's implementation, CMS paid for certain chemistry tests by discounting sets of these codes when multiple results were ordered from a single beneficiary sample. Payment rates for each of these 23 tests, known as Automated Multi-Channel Chemistry Tests or Automated Test Panels, decreased as a result of the new payment system. However, the average payment per test increased because of the end of the discount policy. See below for a list of automated chemistry tests, along with the fee schedule rates in 2017 and 2018 and the average payments for each year.

	2017 fee schedule rate	2018 fee schedule rate	2017 payment per test	2018 payment per test	Change in per-test payment
Albumin (82040)	$6.79	$6.11	$2.22	$5.87	$3.65
Alkaline phosphate (84075)	$7.10	$6.39	$1.82	$6.09	$4.26
ALT (SGPT) (84460)	$7.27	$6.54	$3.77	$6.36	$2.59
AST (SGOT) (84450)	$7.10	$6.39	$2.64	$6.18	$3.54
Bilirubin, total (82247)	$6.88	$6.19	$2.53	$5.86	$3.39
Bilirubin, direct (82248)	$6.88	$6.19	$1.66	$5.91	$4.20
Calcium (82310)	$7.08	$6.37	$3.17	$6.16	$3.00
Calcium ionized (82330)	$18.76	$16.88	$7.24	$16.47	$9.23
Chloride (82435)	$6.31	$5.68	$1.14	$5.46	$4.32
Cholesterol (82465)	$5.97	$5.37	$3.26	$5.24	$1.98
CK, CPK (82550)	$8.93	$8.04	$5.11	$7.94	$2.83
CO_2 (bicarbonate) (82374)	$6.70	$6.03	$1.50	$5.82	$4.32
Creatinine (82565)	$7.03	$6.33	$3.47	$6.15	$2.68
GGT (82977)	$9.88	$8.89	$3.79	$8.58	$4.80
Glucose (82947)	$5.39	$4.85	$3.89	$4.72	$0.84
LDH (83615)	$8.28	$7.45	$4.37	$7.26	$2.89
Phosphorus (84100)	$6.50	$5.85	$3.35	$5.66	$2.31
Potassium (84132)	$6.31	$5.68	$3.55	$5.45	$1.90
Protein (84155)	$5.03	$4.53	$2.89	$4.35	$1.46
Sodium (84295)	$6.60	$5.94	$2.06	$5.74	$3.69
Triglycerides (84478)	$7.88	$7.09	$3.61	$6.87	$3.27
Urea nitrogen (84520)	$5.42	$4.88	$2.12	$4.74	$2.62
Uric acid (84550)	$6.20	$5.58	$3.81	$5.44	$1.63
All automated chemistry tests	**-**	**-**	**$3.49**	**$6.08**	**$2.59**

Source: OIG analysis of Medicare Part B lab test spending, 2019.

APPENDIX D: Prior Office of Inspector General Reports on Medicare Spending and Payment Rates for Lab Tests

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data	OEI-09-18-00410	September 2018
Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies to Ensure Data Quality	OEI-09-17-00050	July 2018
Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data	OEI-09-17-00140	September 2017
Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data	OEI-09-16-00040	September 2016
Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress	OEI-09-16-00100	September 2016
Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data	OEI-09-15-00210	September 2015
Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings	OEI-07-11-00010	June 2013
Variation in the Clinical Laboratory Fee Schedule	OEI-05-08-00400	July 2009

APPENDIX E: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 10, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Lab Test Expenditures Increased in 2018, Despite New Rate Reductions (OEI-09-19-00100)

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 is committed to providing Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

Section 216(a) of the Protecting Access to Medicare Act of 2014 added section 1834A to the Social Security Act, which significantly revised the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule. Beginning on January 1, 2018, Medicare began using certain private payor rate information reported for applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the Clinical Laboratory Fee Schedule. The use of market data to establish Clinical Laboratory Fee Schedule payment rates strengthens Medicare by paying more appropriately for laboratory services while maintaining beneficiaries' access to high quality laboratory services.

CMS notes that the $82 million payment increase for certain chemistry tests identified in the OIG's report accounts for approximately one percent of the overall Medicare spending for laboratory tests in 2018.

CMS appreciates the OIG's review in this area and will consider findings from this report as we continue to evaluate ways to improve the Clinical Laboratory Fee Schedule.

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

OIG Recommendation
The OIG recommends that CMS should seek legislative authority to establish a mechanism to control costs for automated chemistry tests.

CMS Response
The Healthcare Common Procedure Coding System (HCPCS) is divided into two principal subsystems, referred to as level I and level II of the HCPCS. Level I of the HCPCS is composed of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA). Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes.

Prior to implementation of the Protecting Access to Medicare Act of 2014, automated test panels without a CPT code were paid a bundled amount using payment algorithms developed by CMS. However, section 216(a) of the Protecting Access to Medicare Act of 2014 established section 1834A of the Act which generally requires that the Medicare payment rates for each clinical diagnostic laboratory test under the Clinical Laboratory Fee Schedule be an amount that is equal to the weighted median of the private payor rates for the test, based on the applicable information reported for applicable laboratories. Therefore, CMS discontinued the use of these automated test panel payment algorithms that bundled component CPT codes. CMS is monitoring utilization and spending associated with these codes and will take the OIG's recommendation into consideration when determining appropriate next steps.

With regard to panel tests that have their own CPT code, CMS updated Chapter 16, Section 90.2 of the Medicare Claims Processing Manual in May 2019 stating that laboratories must bill the CPT panel test code and not unbundle the individual components if all components of the CPT panel are performed. CMS implemented an edit in October 2019 to reject or return claims as unprocessable if the CPT panel test code is not billed and the individual components were unbundled.

ACKNOWLEDGMENTS

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

We would also like to acknowledge the contributions of other OIG staff, including 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.

ENDNOTES

[1] 81 Fed. Reg. 41036, 41097 (June 23, 2016) (final rule implementing PAMA, P. L. No. 113-93 (April 2014), § 216(a)). See also 42 CFR 414.507(a).

[2] OIG, *Comparing Lab Tests Payment Rates: Medicare Could Achieve Substantial Savings* (OEI-07-11-00010), June 2013. See also OIG, *Variation in The Clinical Laboratory Fee Schedule* (OEI-05-08-00400), July 2009.

[3] 81 Fed. Reg. 41036, 41097 (June 23, 2016) (final rule implementing PAMA, § 216(a)).

[4] CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf. Accessed on February 21, 2020.

[5] CMS, *Information Regarding the Final CY 2018 Private Payor Rate-Based Clinical Laboratory Fee Schedule (CLFS) Payment Rates*. Accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-HCPCS-Median-Calculations.pdf on May 27, 2020.

[6] 42 CFR 414.507(a) and (b).

[7] 81 Fed. Reg. 41036, 41066 (June 23, 2016) (see Table 3, "Final Data Collection and Reporting Periods for CDLTs").

[8] Originally, SSA § 1834A(b)(3)(A) and (B), 42 U.S.C. 1395m-1(b)(3)(A) and (B), as set forth in PAMA 216(a)), provided that clinical diagnostic laboratory test payment would not result in payment reduction greater than the applicable percentage within the first 6 years. See also 81 Fed. Reg. 41036, 41079, and 41100 (June 23, 2016) (changing the phasing in of the payment-reductions timetable to reflect the revised January 1, 2018, implementation date and memorializing the change at 42 CFR 414.507 (d)).

[9] Coronavirus Aid, Relief, and Economic Security Act, P.L. No. 116-136 (March 2020), § 3718(a) (amending SSA §1834A(a)(1)(B), 42 U.S.C. 1395m-1(a)(1)(B), which was added by Further Consolidated Appropriations Act, 2020, P.L. No. 116-94, Division N, § 105(a)(1)(A)(iii)).

[10] SSA § 1834A(b)(3)(B), 42 U.S.C. 1395m-1(b)(3)(B) (as amended by Further Consolidated Appropriations Act, 2020, Division N, § 105(a)(2) and, subsequently, by the Coronavirus Aid, Relief, and Economic Security Act, § 3718(b)).

[11] PAMA also required that the Government Accountability Office (GAO) study a number of aspects of the new payment system, including the implementation of new payment rates. GAO issued the report *Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments* (GAO-19-67) in November 2018.

[12] OIG, *Fraud Alert: Genetic Testing Scam*, https://oig.hhs.gov/fraud/consumer-alerts/alerts/geneticscam.asp, September 2019. Accessed on February 21, 2020.

[13] Department of Justice, *Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged*, https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against, September 27, 2019. Accessed on February 21, 2020.

[14] The percent change was calculated using actual spending totals rather than the rounded dollar values in Exhibit 1. The total Medicare spending for 2017 was $7,129,419.570, and the total Medicare spending for 2018 was $7,588,026,555.

[15] Labs bill for each test on the CLFS 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 CPT codes. **The**

five-character codes and descriptions included in this study are obtained from Current Procedural Terminology (CPT®), copyright 2018 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.

[16] The number of tests on the CLFS includes all tests eligible for payment, and therefore is slightly higher than the number of tests for which Medicare made payments.

[17] These tests are also known as "Automated Panel Tests."

[18] SSA § 1834A(b)(4)(B), 42 U.S.C. 1395m-1(b)(4)(B).

[19] In 2015, CMS established four new HCPCS Level II codes (G0480, G0481, G0482, and G0483) that group multiple drug classes into a single tier, representing multiple codes. For example, G0480 represents 1-7 drug tests, and G0481 represents 8-14 drug tests. CMS could explore establishing similar grouped codes for automated chemistry tests.

[20] See Endnote 15 regarding CPT codes.

[21] 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 CLFS. As we have noted, our analysis included only lab tests paid for under Medicare's CLFS.

[22] Molecular pathology tests analyze DNA or RNA to determine gene variants. These tests are often used to diagnose cancers (e.g., breast and cervical) and detect hereditary and infectious diseases (e.g., HIV, hepatitis B and C). College of American Pathologies, *Molecular Pathology Resource Guide,* http://webapps.cap.org/apps/docs/membership/md_resource_guide.pdf. Accessed on February 21, 2020.

[23] Molecular pathology procedures level 9 (procedure code 81408) perform full DNA sequence analysis to diagnose or manage diseases such as kidney disease, Parkinson's disease, and age-related macular degeneration. BioPortal, *Molecular Pathology Procedure, Level 9,* https://bioportal.bioontology.org/ontologies/CPT?p=classes&conceptid=81408. Accessed on February 21, 2020.

[24] MAAAs combine genetic and demographic information into an algorithm to determine a numeric risk score or probability. MAAAs are commonly used to generate diagnostic or predictive information for certain cancers, such as ovarian, breast, and prostate cancer. Clinical Laboratory News, *Multianalyte Assays with Algorithmic Analysis in Women's Health*, https://www.aacc.org/publications/cln/articles/2018/july/multianalyte-assays-with-algorithmic-analysis-in-womens-health. Accessed on February 21, 2020.

[25] GSPs identify structural changes to DNA or RNA and are used to diagnose and manage inherited diseases. These tests are less frequently used that other genetic tests but are among the most complex and labor-intensive types of tests. NIH, *A Survey of Current Practices for Genomic Sequencing Test Interpretation and Reporting Processes in US laboratories*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5415437/. Accessed on February 21, 2020.

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