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Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests

Key Results

Medicare Part B spent \$9.3 billion on laboratory tests in 2021, a 17 percent increase from 2020. The spending increase resulted from increased volume for three types of tests: COVID 19 tests, genetic tests, and chemistry tests. Genetic tests exceeded pre pandemic spending levels, while chemistry test spending increased from 2020 but did not fully return to pre pandemic levels.

Medicare Part B spending on laboratory (lab) tests increased by \$1.3 billion in 2021, from \$8.0 billion in 2020 to \$9.3 billion in 2021. The 17-percent increase was the biggest change in spending since OIG began monitoring payments in 2014.

In 2021, Medicare Part B spent \$2.0 billion on COVID-19 tests, a 29-percent increase from 2020. Medicare Part B paid for 26 different procedure codes for COVID-19 tests, including code U0005, a new code that incentivized faster test turnaround times. More than 10 million enrollees received at least 1 COVID-19 test paid for by Medicare Part B.

Medicare Part B spending on non-COVID-19 tests also increased. Total spending on four categories of high-priced genetic tests increased by 56 percent, from \$1.2 billion in 2020 to \$1.9 billion in 2021, exceeding pre-pandemic spending levels. Spending on chemistry tests—the largest category of tests by both spending and volume—increased from \$1.9 billion in 2020 to \$2.1 billion in 2021, but remained below pre-pandemic levels.

Medicare Part B spent \$5.5 billion in 2021 on the top 25 tests, which accounted for 59 percent of total test spending. The factors that affected overall spending also contributed to the increase in spending on the top 25 tests. These factors were the increased volume for COVID-19 tests, the continued growth of high-priced genetic tests, and the increased volume for panel and chemistry tests.

Why OIG Did This Review

The Protecting Access to Medicare Act of 2014 (PAMA) changed the way the Medicare program sets payment rates for lab tests by aligning Medicare payment rates with rates paid by private payers. The Centers for Medicare & Medicaid Services (CMS) calculated new rates that took effect in 2018, lowering Medicare payment rates for many tests. As part of PAMA, Congress also mandated that the Office of Inspector General (OIG) publicly release an annual analysis of the top 25 tests based on Medicare spending and that it conduct analyses that OIG determines appropriate. OIG issued the first report in 2015, analyzing Medicare Part B payments for lab tests in 2014. This data brief provides an analysis of Medicare payments for lab tests in 2021.

How OIG Did This Review

We analyzed claims data for lab tests performed in 2021 that CMS paid for under the Clinical Laboratory Fee Schedule (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 identified the top 25 lab tests based on Medicare spending for tests performed in 2021. We also identified key statistics and emerging trends, including Medicare spending by procedure code and test category.

RESULTS

Medicare Part B spent \$9.3 billion on laboratory tests in 2021, a 17-percent increase from 2020

Medicare Part B spending on laboratory (lab) tests increased by \$1.3 billion in 2021, from \$8.0 billion in 2020 to \$9.3 billion in 2021. The 17-percent increase was the biggest change in spending since OIG began monitoring payments in 2014. The increase in spending in 2021 resulted from higher spending in three groups of tests: COVID-19 tests, genetic tests, and chemistry tests, as shown in Exhibit 1. See the Appendix for a list of prior OIG reports on Medicare Part B spending and payment rates for lab tests.

Exhibit 1: Overall Medicare Part B spending increased by 17 percent in 2021, driven by increased spending on COVID-19 tests, genetic tests, and chemistry tests.



Source: OIG analysis of Medicare Part B claims data, 2022. Groups may not add up to total because of rounding.

Legislation related to the COVID-19 pandemic delayed the changes to payment rates for lab tests that were mandated by PAMA.¹ Under the provisions of PAMA, payment rates for procedure codes that were on the CLFS prior to PAMA's implementation in 2018 are based on the volume-weighted median of lab-reported data, which resulted in lower payment rates for many of these tests. PAMA also limited how much payment rates for tests could fall for the first 6 years of its implementation. However, legislation related to the COVID-19 pandemic delayed the reductions to payment rates in 2021 and 2022. Thus, payment rates did not change in 2021.

Medicare Part B spending on COVID-19 tests increased by 29 percent in 2021, to \$2.0 billion

In 2021, Medicare Part B spent \$2.0 billion on COVID-19 tests, a \$440 million increase from \$1.5 billion in 2020. Medicare paid for COVID-19 tests across 26 procedure codes, including antibody tests, high-throughput tests, panel tests, and a new code

About U0005. CMS introduced a new procedure code, U0005, in 2021 to incentivize faster test turnaround times. Labs that returned results within 2 calendar days could bill CMS for an additional \$25 using procedure code U0005. This code is an add-on code and can only be included on claims with procedure codes U0003 and U0004. Medicare Part B paid for procedure code U0005 12.3 million times in 2021 and spent a total of \$305 million for this code. Although these payments do not represent additional tests, they indicate that labs returned at least 12.3 million COVID-19 test results within 2 calendar days.

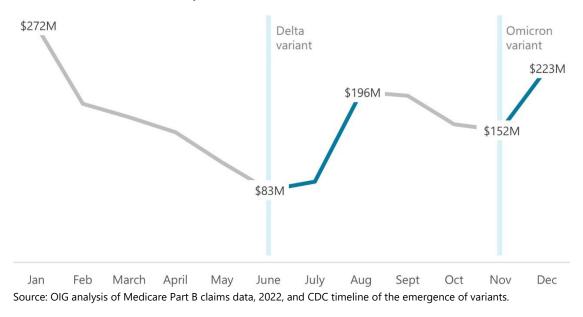
used to incentivize faster test turnaround times (see sidebar).² The volume of COVID-19 tests that Medicare Part B paid for also increased in 2021, from 18.8 million tests in 2020 to 25.8 million tests in 2021, a 37-percent increase.³

The increase in volume was driven by more tests received by more people. In 2021, more than 10.1 million people received at least one COVID-19 test paid for by Medicare Part B, a 19-percent increase from 2020, when 8.5 million enrollees received a COVID-19 test paid for by Medicare Part B. On average, Medicare Part B paid for 2.6 COVID-19 tests per person, an increase from 2.2 tests per person in 2020.⁴

Medicare spending on COVID-19 tests fluctuated throughout 2021, as shown in Exhibit 2. Testing in the United States declined notably during the first half of the

year and increased in August and December 2021, which coincided with two new variants: the Delta variant and the Omicron variant, respectively.⁵

Exhibit 2: Medicare Part B spending on COVID-19 tests decreased early in 2021 but increased in response to the Delta and Omicron variants.

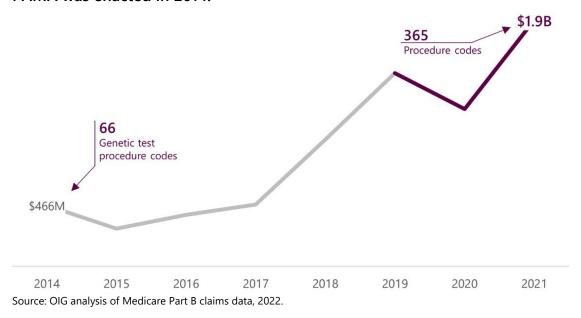


Medicare Part B spending on genetic tests increased by 56 percent in 2021, to \$1.9 billion, continuing a long-term trend

Medicare Part B spending on genetic tests increased to \$1.9 billion in 2021, a \$677 million increase from \$1.2 billion in 2020. Genetic tests, as a group, comprise four categories of tests: molecular pathology tests, multianalyte algorithmic assays, genomic sequencing procedures, and proprietary lab analysis tests. Total spending on these genetic tests accounted for 20 percent of Medicare spending for lab tests in 2021.

Medicare Part B spending for genetic tests continued its upward trend, as shown in Exhibit 3. Since OIG began monitoring Medicare Part B spending on lab tests in 2014, spending on genetic tests has more than tripled. The increase in spending was driven by both an increase in the volume of claims for genetic tests and an increase in the number of procedure codes eligible for payment.

Exhibit 3: Total spending on genetic tests has increased significantly since PAMA was enacted in 2014.



The volume of genetic tests that Medicare Part B paid for increased by 55 percent, from 1.8 million in 2020 to 2.8 million in 2021. Compared to volume from 2019, the volume of genetic tests increased 24 percent from 2.3 million. These are all high-priced tests, with an average payment of \$666 per test in 2021. In 2021, the number of procedure codes for genetic tests increased to 365, an additional 31 codes to the 334 procedure codes that Medicare Part B paid for in 2020.

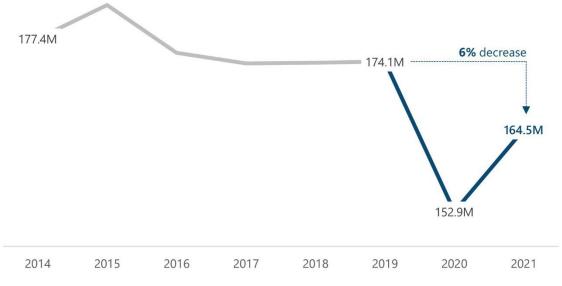
Medicare Part B spending on chemistry tests increased by 10 percent in 2021, but did not return to pre-pandemic levels

Medicare Part B spending on chemistry tests increased in 2021, following a decline in 2020. This is the largest category on the CLFS, by both spending and volume. In

2021, Medicare Part B spent \$2.1 billion on 165 million chemistry tests, compared to \$1.9 billion spent on 153 million tests in 2020. Chemistry tests—which averaged about \$13 per test in 2021—measure the level of a chemical such as a protein, electrolyte, or hormone in a specimen. These are among the most common types of tests, and providers use the results to monitor a person's organ function and general health status. The increase in spending on these tests in 2021 was driven by an increase in volume, which could indicate that Medicare enrollees resumed at least some medical care they had postponed during the height of the pandemic in 2020.

However, volume for chemistry tests in 2021 was 6 percent lower than it was in 2019, as shown in Exhibit 4. Volume for chemistry tests remained fairly stable until 2020, when volume declined by 12 percent. Although volume increased from 2020, the decrease in volume from 2019 raises questions about the continuing impact of the COVID-19 pandemic on the healthcare system. If fewer Medicare Part B enrollees received these tests, it could indicate that they may not have accessed healthcare at the same level as they did before the COVID-19 pandemic began.

Exhibit 4: Volume of chemistry tests in 2021 was 6 percent lower than it was in 2019, following fairly stable volume prior to the COVID-19 pandemic.



Source: OIG analysis of Medicare Part B claims data, 2022.

Medicare Part B spent \$5.5 billion on the top 25 tests, which accounted for 59 percent of total spending in 2021

Medicare Part B spent \$5.5 billion on the top 25 tests, a 10-percent increase from \$4.99 billion in 2020. Spending on the top 25 tests accounted for 59 percent of total spending in 2021. Three factors that contributed to the increase in spending included increased spending on COVID-19 tests; continued growth of genetic tests; and increased volume for panel and chemistry tests.

COVID-19 tests in the top 25. Medicare Part B spent a total of \$1.7 billion on COVID-19 tests in the top 25. For the second year in a row, the top procedure code paid for by Medicare Part B was a COVID-19 test that used high-throughput technology (procedure code U0003, line 1 in Exhibit 5). Despite a 22-percent increase in volume for this test in 2021, spending decreased due to a decrease in the payment rate that CMS set for the test. When CMS introduced U0005, it reduced the payment rates for U0003 and U0004 from \$100 to \$75.7 In 2021, five procedure codes related to COVID-19 tests, including procedure code U0005, were in the top 25.

Genetic tests in the top 25. Medicare Part B spent \$803 million on genetic tests in the top 25. Five procedure codes for high-priced genetic tests were in the top 25 in 2021. As shown in Exhibit 5, these procedure codes had the highest payment rates—ranging from \$509 to \$3,873—but accounted for the lowest volume (lines 7, 9, 19, 20, and 24 in Exhibit 5). Medicare Part B paid for a total of 809,671 tests across three molecular pathology procedure codes and two multianalyte assays with algorithmic analyses procedure codes.

Although these tests represented a notable portion of spending for the top 25 tests, they accounted for the lowest volume. For example, Medicare Part B spent \$282.2 million on 141,146 units of a specific molecular pathology code (procedure code 81408, line 7 in Exhibit 5). Volume for this test increased by 36 percent in 2021 and had the highest change in volume and spending for genetic tests.

Organ- and disease-oriented panel tests and chemistry tests in the top 25.

Medicare Part B spent \$1.8 billion on two categories of tests: organ- and disease-oriented panel tests and chemistry tests. For example, the number 2 test by spending is an organ- or disease-oriented panel test. Spending for this test, the comprehensive group of blood chemicals test (procedure code 80053, line 2 in Exhibit 5), increased by 6 percent, from \$402.7 million in 2020 to \$425.3 million in 2021. However, spending for this test was still 13 percent lower than the \$491.6 million spent in 2019. Similarly, spending for the top chemistry test, the thyroid stimulating hormone test (procedure code 84443, line 4 in Exhibit 5), was 15 percent lower in 2021 than it was in 2019. Historically, volume for these tests has been relatively steady, with changes in spending driven mostly by PAMA-related changes to payment rates. Declines in spending on these tests are driven by declines in volume, which could reflect lower healthcare utilization for people enrolled in Medicare Part B. In 2021, there were 5 chemistry tests and 3 organ- or disease-oriented panel tests in the top 25.

Exhibit 5: Medicare Part B spent \$5.48 billion on the top 25 lab tests in 2021.

	Test Description (Procedure Code)	2021 payment rate	2021 volume (millions)		Volume change om 2020	2021 spending (millions)	
1	COVID-19 test: Infectious agent detection by nucleic acid for COVID-19, high-throughput (U0003)	\$75.00	12.5	↑	22.2%	\$935.9	
2	Blood test, comprehensive group of blood chemicals (80053)	\$10.56	39.5	1	4.7%	\$425.3	
3	Blood test, lipids (80061)	\$13.39	26.5	1	4.9%	\$355.2	
4	Blood test, thyroid stimulating hormone (84443)	\$16.80	19.9	1	5.3%	\$334.4	
5	COVID-19 test: Add-on payment for high throughput tests completed within 2 calendar days of specimen collection (U0005)	\$25.00	12.3	New in 2021		\$305.4	
6	Complete blood cell count, automated test (85025)	\$7.77	37.8	1	3.1%	\$300.2	
7	Genetic test: Molecular pathology procedure level 9 (81408)	\$2,000.00	0.1	1	36.4%	\$282.2	
8	Vitamin D-3 level (82306)	\$29.60	9.1	1	11.8%	\$267.2	
9	Genetic test: Gene analysis (colorectal cancer) (81528)	\$508.87	0.5	1	20.6%	\$252.6	
10	COVID-19 test: Any technique, high-throughput technologies (U0004)	\$75.00	2.9	↑	20.7%	\$220.8	
11	Detection test for organism (87798)	\$35.09	6.1	1	16.2%	\$213.7	
12	Drug test(s), definitive, 22 or more drug class(es) (G0483)	\$246.92	0.8	Ψ	-9.2%	\$203.0	
13	Hemoglobin A1C level (83036)	\$9.71	18.6	1	5.9%	\$182.3	
14	Testing for presence of drug (80307)	\$62.14	2.5	Ψ	-3.6%	\$156.4	
15	Drug test(s), definitive, 15-21 drug class(es) (G0482)	\$198.74	0.7	1	1.3%	\$130.2	
16	COVID-19 test: Amplified probe technique (87635)		2.0	1	46.9%	\$104.8	
17	COVID-19 test: ELISA detection of severe acute respiratory	-	2.6	New to		\$101.5	
12	syndrome coronavirus 2 (COVID-19) (87426)			top 25		****	
18	Parathormone (parathyroid hormone) level (83970)	\$41.28	2.5	<u>↑</u>	8.6%	\$101.4	
19	Genetic test: Gene analysis (breast cancer 1 and 2) (81162)	\$1,824.88	0.05	<u>↑</u>	7.7%	\$94.0	
20	Genetic test: Test for detecting genes associated with breast cancer (81519)	\$3,873.00	0.02	↑	20.1%	\$92.7	
21	Blood test, basic group of blood chemicals (80048)	\$8.46	10.3	Ψ	-0.1%	\$90.3	
22	Cyanocobalamin (vitamin B-12) level (82607)	\$15.08	5.8	↑	11.4%	\$87.9	
23	Drug test(s), definitive, 1-7 drug class(es) (G0480)	\$114.43	0.8	Ψ	-2.6%	\$86.6	
24	Genetic test: Molecular pathology procedure level 8 (81407)	\$846.27	0.1	New to top 25		\$81.6	
25	Drug test(s), definitive, 8-14 drug class(es) (G0481)	\$156.59	0.5	Ψ	-2.5%	\$79.1	
	Total 2021 spending on the top 25 tests: \$5.48 billion						

Sources: OIG analysis of 2020–2021 spending on lab tests in Medicare Part B, 2022. Payment rates are from the 2021 CLFS. Local Medicare Administrative Contractors are responsible for developing the payment amount for claims they receive for some newly created procedure codes until Medicare establishes national payment rates.

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 systems, 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 non-physician services not covered by CPT codes.

CONCLUSION

The COVID-19 pandemic continued to have an impact on Medicare Part B spending on lab tests. In 2021, more people received more COVID-19 tests than in 2020, driving an overall increase on spending for COVID-19 tests. However, looking to 2022, it is likely that the increased availability of at-home COVID-19 tests could affect overall Medicare Part B spending for lab-performed tests.⁹

Another category increasing in Medicare Part B spending is genetic tests, which have been continuing an upward trend since OIG began monitoring spending on lab tests in 2014. The number of genetic test procedure codes on the CLFS continues to grow and total spending on genetic tests has more than tripled since OIG began monitoring payments in 2014.

However, the second year in a row of low volume for chemistry tests raises questions about the pandemic's long-term impact on Medicare enrollee health. Although volume increased from 2020 to 2021, it did not fully return to pre-pandemic levels, which could indicate that people are not seeking the routine or preventive care appointments where these tests are ordered. Research suggests that delays of such tests could have a long-lasting impact on people's health.

The COVID-19 pandemic also affected CMS's long-term timeline for implementing PAMA. In addition to the pause in payment rate reductions, pandemic-related legislation delayed the next set of payment rates, which are scheduled to take effect on January 1, 2024. These new rates will be based on data that labs collected in 2019, meaning that procedure codes added to the CLFS in 2020 and after—including codes for COVID-19 tests and new genetic tests—will not be based on private payer data until the next set of payment rates, currently scheduled for 2027, takes effect.¹⁰

METHODOLOGY

Data Analysis: We based this report on our analysis of Medicare claims data for lab tests performed in 2021 and reimbursed under the CLFS. Through our analysis, we identified key statistics and emerging trends for Medicare spending on lab tests. We analyzed Medicare spending and test volume by procedure code and category. Test volume is based on the number of units for which labs billed Medicare. We calculated total spending for 2021 and compared that to the results from 2014 to 2021.

- COVID-19 tests. We used Current Procedural Terminology (CPT) test codes and HCPCS codes to identify 26 COVID-19 tests that were authorized for payment in 2021. This set of codes includes viral tests, antibody tests, and respiratory panel tests that include COVID-19 in the panel. We included only tests paid for by Medicare Part B in our analysis. Tests that Medicare Part B enrollees received through other programs, such as community testing efforts, were not included, unless they were paid for by Medicare Part B. For analysis by Medicare enrollee, we identified enrollees by using the Health Insurance Claim Numbers on the claims.
- Analysis by test category. We used CPT categories for all tests on the CLFS, except tests used to diagnose COVID-19, which were analyzed as a group. For HCPCS Level II codes that are unique to the CLFS, we used categories previously assigned by CMS.
- Top 25 lab tests. We identified the top 25 lab tests (based on total spending for each procedure code) in 2021 and calculated total spending for these tests. For this group of tests, we calculated the change in the volume of test units paid for from 2020 to 2021.

Data Source: 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. 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. We did not include claims for physician interpretation
of tests.

Limitations: Analysis for this report was conducted on claims that Medicare Part B had processed by June 2022. Data from past reports used the 16-month or 17-month files and, thus, may be marginally different from the set of claims used in 2022. However, this set of claims is comparable to the 16-month and 17-month files.

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.

APPENDIX

Prior Office of Inspector General Reports on Medicare Part B Spending and Payment Rates for Lab Tests

COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly	OEI-09-21-00240	December 2021
Federal COVID-19 Testing Report: Data Insights from Six Federal Health Care Programs*	PRAC Health Care Subgroup	January 2021
Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests	OEI-09-20-00450	December 2020
Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions	OEI-09-19-00100	August 2020
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
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 Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data	OEI-09-16-00040	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

^{*}This report was released by the Pandemic Response Accountability Committee Health Care Subgroup and included analysis of Medicare Part B claims for COVID-19 tests performed between February 1, 2020, and August 31, 2020.

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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.

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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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ENDNOTES

- ¹ On December 10, 2021, the "Protecting Medicare and American Farmers from Sequester Cuts Act," 117 Pub. L. No. 71, was passed and delayed the reporting requirement under Section 1834A of the Protecting Access to Medicare Act of 2014 (the Act) and delayed the application of the 15% phase-in reduction.
- ² To bill using procedure code U0005, the lab had to meet two requirements. First, the lab had to complete the test within 2 calendar days of the specimen being collected. Additionally, the lab must have completed the majority of its COVID-19 tests that use high-throughput technology within 2 calendar days for all patients, not just its Medicare patients, during the prior calendar month. CMS Ruling 2020-1-R2.
- ³ We excluded code U0005 from this analysis, as it does not represent actual tests. Rather, it represents additional payments for tests included in volume for other procedure codes.
- ⁴ We excluded code U0005 from this analysis, as it does not represent actual tests. Rather, it represents additional payments for tests included in volume for other procedure codes.
- ⁵ The Centers for Disease Control and Prevention (CDC) designated Delta as a Variant of Concern (VOC) on June 15, 2021, and Omicron as a VOC on Nov. 30, 2021. <u>SARS-CoV-2 Variant Classifications and Definitions (cdc.gov)</u>.
- ⁶ Additional genetic test procedure codes may be on the CLFS but may not have been included on any Medicare Part B claims for payment.
- ⁷ CMS Ruling 2020-1-R2. See also CMS Press Release, CMS Changes Medicare Payment to Support Faster COVID-19 Diagnostic Testing, CMS Changes Medicare Payment to Support Faster COVID-19 Diagnostic Testing | CMS. Accessed on September 10, 2022.
- ⁸ Because payment rates did not change from 2020 to 2021, all declines in spending were driven by declines in volume.
- ⁹ Medicare Part B began covering over-the-counter tests in April 2022, in addition to tests available by mail. <u>Medicare Covers Over-the-Counter COVID-19 Tests | CMS</u>.
- ¹⁰ On December 10, 2021, the "Protecting Medicare and American Farmers from Sequester Cuts Act," 117 Pub. L. No. 71, was passed and delayed the reporting requirement under Section 1834A of the Act.