

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE NUMBER OF BENEFICIARIES
WHO RECEIVED MEDICARE
PART B CLINICAL LABORATORY
TESTS DECREASED DURING THE
FIRST 10 MONTHS OF THE
COVID-19 PANDEMIC**

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Office of Inspector General

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Report in Brief

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



Why OIG Did This Audit

Clinical laboratory (lab) tests, when used appropriately, are important because they provide health care providers with information to prevent, detect, diagnose, treat, and manage disease (including managing chronic medical conditions). These conditions have health impacts and economic costs, and prevention can reduce costs. To help contain the spread of COVID-19, Federal, State, Tribal, and local government agencies implemented community mitigation activities, including some issuing orders or advisories to residents to stay at home. These and other factors may have contributed to Medicare beneficiaries receiving fewer clinical services, including lab tests. Our preliminary analysis of lab tests billed to and paid by Medicare Part B found decreases in the number of beneficiaries who received lab tests when compared with a similar period before the pandemic.

Our objective was to identify changes in the number of beneficiaries who received Medicare Part B lab tests during the first 10 months of the COVID-19 pandemic—specifically, the number of beneficiaries who received: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries.

How OIG Did This Audit

Our audit covered Part B claims for lab tests provided from March through December 2019 (“pre-pandemic period”) and from March through December 2020 (“pandemic period”).

The Number of Beneficiaries Who Received Medicare Part B Clinical Laboratory Tests Decreased During the First 10 Months of the COVID-19 Pandemic

What OIG Found

During the pandemic period, the number of beneficiaries who received Medicare Part B lab tests decreased for: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries. From March through December in 2016, 2017, and 2018 and for the pre-pandemic period (in 2019), the number of beneficiaries who received lab tests paid for by Medicare decreased by 1 percent or less in each year. However, for the pandemic period (in 2020), the number of beneficiaries who received lab tests decreased by about 9 percent compared with the pre-pandemic period.

Our comparison of the numbers of beneficiaries who received lab tests during the pandemic and pre-pandemic periods identified the following trends: (1) The number of beneficiaries who received lab tests had the highest percentage decreases during the first 3 months of the pandemic period when compared with the same months during the pre-pandemic period; (2) for almost 90 percent of lab tests for which the number of tests performed had decreased during the pandemic period, the number of beneficiaries who received those tests decreased by more than 10 percent; (3) for the gender and residential location (i.e., rural or urban) demographics, during the pandemic period the number of beneficiaries who received lab tests had similar percentage decreases for each category within the corresponding demographic (e.g., the female and male genders had similar percentage decreases); (4) for the race or ethnicity group demographic, during the pandemic period there was more variation in the percentage decreases in the number of beneficiaries who received lab tests for each category (e.g., the Hispanic or Latino category had a higher percentage decrease than the White category); and (5) the number of beneficiaries with diabetes, kidney disease, and heart disease who received common lab tests for those conditions decreased during the pandemic period. The results of our data analysis suggest that the COVID-19 pandemic contributed to these decreases. Lab tests are important for beneficiaries with chronic medical conditions, which are associated with hospitalizations, billions of dollars in Medicare costs, and deaths.

What OIG Recommends

The information in this report is provided for informational purposes only and therefore the report does not contain any recommendations. The Centers for Medicare & Medicaid Services elected not to provide comments on our draft report.

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INTRODUCTION

WHY WE DID THIS AUDIT

Clinical laboratory (lab) tests, when used appropriately, are important because they provide health care providers with information for the prevention, early detection, diagnosis, treatment, and management of disease. Ensuring that people receive necessary lab tests can help to improve health care quality and contain long-term health costs. Lab testing is also important in managing chronic medical conditions, such as diabetes. Chronic medical conditions are common among Medicare beneficiaries, with a significant share of them living with at least one condition.¹ Chronic medical conditions have health impacts and economic costs, and preventing these conditions, or managing symptoms when prevention is not possible, can reduce these costs.²

COVID-19 first appeared in the United States in early 2020. Adults who are 65 years of age and older and people of any age who have certain underlying medical conditions are at higher risk for severe illness from COVID-19. As COVID-19 spread across several countries and affected a large number of people, it was classified as a pandemic.³ To reduce the risk of COVID-19 transmission, some individuals changed their behaviors and some health care providers changed their practices in ways that reduced or delayed use of health care services. Federal, State, Tribal, and local government agencies recommended and implemented various community mitigation activities, including some issuing orders or advisories to residents to stay at home as much as possible and practice physical distancing in public, to help slow and contain the spread of COVID-19.⁴ These and other factors may have contributed to Medicare beneficiaries receiving fewer clinical services, including lab tests.

Our preliminary analysis of lab tests billed to and paid by Medicare Part B during the COVID-19 pandemic found decreases in the number of beneficiaries who received lab tests when

¹ The Lewin Group, *Laboratory Medicine: A National Status Report* (May 2008). Available at <https://www.cdc.gov/labbestpractices/pdfs/2007-status-report-laboratory-medicine-a-national-status-report-from-the-lewin-group-updated-2008-9.pdf>. Accessed on Mar. 8, 2021.

² Centers for Disease Control and Prevention (CDC). Health and Economic Costs of Chronic Diseases. Available at <https://www.cdc.gov/chronicdisease/about/costs/index.htm>. Accessed on Aug. 15, 2021.

³ According to CDC, a pandemic refers to an epidemic (i.e., an increase in the number of cases of a disease above what is normally expected in that population in that area) that has spread over several countries or continents, usually affecting a large number of people. Available at <https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html>. Accessed on Sep. 2, 2021.

⁴ According to CDC, community mitigation strategies can lower the risk for disease by limiting or preventing person-to-person interactions. Each State has authority to enact its own laws and policies to protect the public's health, and States varied widely in the type and timing of orders issued. See <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6935a2-H.pdf>. Accessed on July 5, 2022.

compared with a similar period before the pandemic.⁵ In this report, we present our analysis of the overall decrease in the number of beneficiaries who received lab tests during the first 10 months of the pandemic.⁶ This information may be useful to stakeholders involved in ensuring that beneficiaries avoid the potential bad outcomes that may result from missing or delaying appropriate care.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for the Department of Health and Human Services (HHS), the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.⁷

OBJECTIVE

Our objective was to identify changes in the number of beneficiaries who received Medicare Part B lab tests during the first 10 months of the COVID-19 pandemic. Specifically, we identified changes in the number of beneficiaries who received: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries.^{8, 9}

BACKGROUND

The Medicare Program and the Role of the Centers for Medicare & Medicaid Services

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers Medicare. CMS's goal is to provide a high-quality health care system that ensures better care, access to coverage, and improved health for beneficiaries.

⁵ A prior Office of Inspector General (OIG) data brief report also identified decreases in the spending on lab tests in 2020, specifically the spending on non-COVID-19 tests. See *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](#)), issued Dec. 30, 2021.

⁶ This report's analysis compares data for the period March through December 2020 (the first 10 months of the pandemic) and March through December 2019 (the 10-month period a year earlier).

⁷ OIG's COVID-19 response strategic plan and oversight activities can be accessed at [HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG](#).

⁸ Our audit did not cover COVID-19 tests created in 2020, which included diagnostic tests used to identify active COVID-19 virus infections and antibody tests used to identify the immune response from previous COVID-19 virus infections or immunization.

⁹ We identified Medicare beneficiaries' chronic medical conditions using the Centers for Medicare & Medicaid Services' (CMS's) "Medicare Beneficiaries at a Glance," 2020 Edition. Available online at <https://www.cms.gov/files/document/medicare-beneficiaries-glance-2020-edition.pdf>. Accessed on Mar. 23, 2021.

Medicare Part B provides supplementary medical insurance for medical and other health services.

The COVID-19 Pandemic

On January 31, 2020, the Secretary of HHS declared a national public health emergency as a result of confirmed U.S. cases of COVID-19, a highly contagious disease caused by the SARS-CoV-2 coronavirus.¹⁰ On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. On March 13, 2020, the White House declared a state of national emergency in the United States. Federal, State, Tribal, and local government agencies recommended and implemented various community mitigation activities, including some issuing orders or advisories to residents to stay at home as much as possible and practice physical distancing in public, to help slow and contain the spread of COVID-19.¹¹

When the national emergency was declared, CMS took action nationwide to respond to COVID-19 and ensure continued access to care for beneficiaries. CMS activated several blanket waivers, including expanded telehealth coverage, to ease certain requirements for providers.^{12, 13}

Some people with COVID-19 are more likely than others to become ill. Adults who are 65 years of age and older and people of any age who have certain underlying medical conditions (e.g., heart or lung disease or diabetes) are at higher risk for severe illness from COVID-19.¹⁴ Severe

¹⁰ A public health emergency declaration lasts for the duration of the emergency or for 90 days, but it may be extended by the Secretary. The January 31, 2020, public health emergency was renewed on April 21, July 23, and October 2, 2020; on January 7, April 15, July 19, and October 15, 2021; and on January 14, April 12, July 15, and October 13, 2022.

¹¹ According to CDC, community mitigation strategies can lower the risk for disease by limiting or preventing person-to-person interactions. Each State has authority to enact its own laws and policies to protect the public's health, and States varied widely in the type and timing of orders issued. See <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6935a2-H.pdf>. Accessed on July 5, 2022.

¹² A blanket waiver suspends a regulatory requirement that applies to all providers of a certain type. No individual application is necessary for a blanket waiver.

¹³ In January 2021, CMS released its Pandemic Plan, which detailed the actions that CMS took to support the country's health care system and its beneficiaries during the COVID-19 pandemic. The plan outlined how CMS used waivers and flexibilities to support States, providers, and external stakeholders, ensuring continued access to quality care for beneficiaries. The plan also detailed how CMS provided regulatory relief to health care providers on the front lines, expanded telehealth services, and reduced time-consuming paperwork requirements to allow every available resource to be directed toward patient care. The plan is available online at <https://www.cms.gov/files/document/covid-pandemic-plan.pdf>. Accessed on Sept. 15, 2021.

¹⁴ CDC, "Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (Updated May 22, 2020)." Available at <https://web.archive.org/web/20200525002326/https://www.cdc.gov/coronavirus/2019-ncov/faq.html>. Accessed on Sept. 13, 2021.

illness from COVID-19 is defined as hospitalization, admission to an intensive care unit, intubation or mechanical ventilation, or death.¹⁵

In its early days, the COVID-19 pandemic caused temporary disruptions in health care, as health care providers attempted to preserve equipment (e.g., personal protective equipment, beds, and ventilators) and resources (e.g., staffing availability) and limit beneficiaries' and health care providers' exposure to the coronavirus. Some hospitals postponed certain services, and some physician practices closed their offices or significantly reduced services. Concerns related to contracting the coronavirus prevented some individuals from seeking and receiving medical care.

Lab Tests

Lab tests serve multiple functions, including diagnosis, monitoring, and screening. A diagnostic test is generally used to confirm a diagnosis in someone who has signs, symptoms, or other evidence of a particular disease, condition, or risk. Lab tests can be used for monitoring chronic conditions (e.g., the blood test that measures the hemoglobin A1C level for those with diabetes). Screening tests are lab tests that help to identify people with an increased risk for a condition or disease before they have symptoms or even realize they may be at risk so that preventive measures can be taken. Screening tests are an important part of preventive health care. For example, a routine cholesterol screening might reveal the risk for heart disease. If a person is able to take preventive measures and make lifestyle changes, they can reduce their risk for adverse health outcomes and the costly complications associated with treating and managing heart disease. According to a Lewin Group report (2008) prepared for the Centers for Disease Control and Prevention, lab tests contributed significantly to the prevention of health complications and death associated with heart disease.¹⁶

Medicare Coverage of Lab Tests

Medicare Part B (Medical Insurance) generally covers medically necessary lab tests when a doctor or other practitioner orders them for the diagnosis, prevention, or treatment of a disease or the assessment of a medical condition (42 CFR § 410.32(a)). Lab tests include certain blood tests, urinalysis, tests on tissue specimens, and some screening tests (e.g., cardiovascular disease screening and diabetes screening). Lab tests can be performed in many different settings, including hospital laboratories, physician offices, and independent reference

¹⁵ CDC, "Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19 (Updated Feb. 15, 2022)." Available at <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html>. Accessed on July 5, 2022.

¹⁶ The Lewin Group, *Laboratory Medicine: A National Status Report* (May 2008). Available at https://www.cdc.gov/labbestpractices/pdfs/2007-status-report-laboratory_medicine_-_a_national_status_report_from_the_lewin_group_updated_2008-9.pdf. Accessed on Mar. 8, 2021.

laboratories.¹⁷ There is no beneficiary deductible or coinsurance for Medicare-approved lab tests. According to the American Clinical Laboratory Association, a trade association representing leading laboratories in the United States, Medicare is the single largest purchaser of lab tests.¹⁸

Providers receive payment for lab tests based on amounts listed on the Clinical Laboratory Fee Schedule (CLFS). To receive payment for a lab test, the provider submits a claim for payment (42 CFR § 424.5(a)(5)). The Healthcare Common Procedure Coding System (HCPCS) is the approved system for reporting outpatient procedures, items, and services (45 CFR §§ 162.1002(c)(1) and (a)(5)). For most outpatient services, a provider must use the appropriate HCPCS code or Current Procedural Terminology (CPT) code on the claim form (*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 23, §§ 20 and 20.3).¹⁹ Diagnosis codes on a claim may also be used in determining coverage and payment (*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 23, § 10).²⁰

HOW WE CONDUCTED THIS AUDIT

Our audit covered Medicare Part B claims for lab tests (identified by HCPCS or CPT codes) reimbursed under the CLFS that were provided from March through December 2019 (which we refer to as “the pre-pandemic period”) and from March through December 2020 (which we refer to as “the pandemic period”).²¹ During the pre-pandemic period, Medicare spent a total of \$6.6 billion for 419.9 million lab tests received by 26.1 million beneficiaries, and during the pandemic period, Medicare spent a total of \$5.5 billion for 358.4 million lab tests received by 23.7 million beneficiaries. For the pandemic period (in 2020) compared with the pre-pandemic

¹⁷ A reference laboratory is a laboratory that receives a specimen from another (referring) laboratory for testing and that actually performs the test (*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 16, § 10.1).

¹⁸ American Clinical Laboratory Association, “Protecting Laboratory Access for Medicare Beneficiaries.” Available at https://www.acla.com/wp-content/uploads/2019/04/GAO_Medicare-billing_FactSheet_4.16.pdf. Accessed on June 17, 2021.

¹⁹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. HCPCS codes are divided into two groups: level I and level II. Level I HCPCS codes consist of CPT codes, a numeric coding system maintained by the American Medical Association (AMA), and are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II HCPCS codes are based on a standardized coding system and are used primarily to identify products, supplies, and services not included in the CPT codes. **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2019–2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

²⁰ Diagnosis codes are standardized codes used to describe diagnoses for medical conditions.

²¹ These tests are covered under Medicare Part B and do 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.

period (in 2019), Medicare spending decreased by about 16 percent, lab tests decreased by about 15 percent, and the number of beneficiaries who received lab tests decreased by about 9 percent. Spending for lab tests made up about 4 percent of total Medicare Part B expenditures for both periods. Although lab tests represented only a small percentage of these expenditures, lab tests were received by more than 75 percent of all Part B beneficiaries in both periods.²²

To address the first part of our objective, we compared the number of beneficiaries who received lab tests during the pandemic period with the number of beneficiaries who received lab tests during the pre-pandemic period.²³ To make the number of beneficiaries who received lab tests during the two periods comparable, our audit did not cover COVID-19 tests created in 2020, which included diagnostic tests used to identify active COVID-19 virus infections and antibody tests used to identify the immune response from previous COVID-19 virus infections or immunization. We also identified the number of beneficiaries who received lab tests according to beneficiary demographics, i.e., gender, residential geographic location (urban or rural), and race or ethnicity group. To identify any significant trends before the pre-pandemic and pandemic periods that were relevant to our analysis, we reviewed Medicare Part B claims for lab tests reimbursed under the CLFS that were provided during the same months (March through December) in the 3-year period before the pre-pandemic period (in 2016, 2017, and 2018).

To address the second part of our objective, we compared the number of beneficiaries with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) who received lab tests during the pandemic period with the number of beneficiaries with those same conditions who received lab tests during the pre-pandemic period.²⁴ We also identified lab tests associated with those chronic medical conditions and compared the number of beneficiaries with those conditions who received those lab tests during the pandemic period with the number of beneficiaries with those conditions who received those lab tests during the pre-pandemic period.

²² Medicare Part B enrollment for the pandemic period increased less than 3 percent from the pre-pandemic period, which is consistent with the enrollment increases each year since 2016 for the March through December period.

²³ We compared the number of beneficiaries who received lab tests in the aggregate as well as by individual lab test. For our comparative analysis of the individual lab tests that beneficiaries received during the pandemic period and the number of beneficiaries receiving those individual lab tests during the pre-pandemic period, we removed lab tests associated with 87 CPT codes for which there were no beneficiaries who received those lab tests during the pre-pandemic period (in 2019); 51 of the 87 CPT codes were new codes added in 2020.

²⁴ CMS identified diabetes, kidney disease, and heart disease as among the top 10 chronic medical conditions for Medicare beneficiaries. See <https://www.cms.gov/files/document/medicare-beneficiaries-glance-2020-edition.pdf>. Accessed on Mar. 23, 2021. CDC also identified these chronic medical conditions as among the underlying medical conditions that could put beneficiaries at a higher risk for severe illness if they contracted the coronavirus. See <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html>. Accessed on July 5, 2022.

This audit is not an assessment of CMS's or the labs' response to the COVID-19 pandemic. The information represents a snapshot during a period of time, and it is possible that the trends we present in this report have changed since our audit. We did not confirm that the lab tests were medically necessary or that the number of units were properly billed and paid. We also did not identify all possible underlying reasons for the trends. (Some of the reasons that CMS mentioned to us were claim submission delays; lab tests performed during Medicare Part A hospitalization stays, which would not have been included in this analysis; and the "downstream effect" from temporary health care disruptions caused by the pandemic.) Finally, we did not tie health outcomes to specific beneficiaries or specific missed lab tests.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

RESULTS OF AUDIT

During the pandemic period, the number of beneficiaries who received Medicare Part B lab tests decreased for: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries. From March through December in 2016, 2017, and 2018 and for the pre-pandemic period (in 2019), the number of beneficiaries who received lab tests paid for by Medicare decreased by 1 percent or less in each year. However, for the pandemic period (in 2020), the number of beneficiaries who received lab tests decreased by about 9 percent compared with the pre-pandemic period.

Our comparison of the numbers of beneficiaries who received lab tests during the pandemic and pre-pandemic periods identified the following trends:

- The number of beneficiaries who received lab tests had the highest percentage decreases in March, April, and May 2020, i.e., during the first 3 months of the pandemic period, when compared with the same months during the pre-pandemic period.
- For almost 90 percent of lab tests (represented by individual HCPCS or CPT codes) for which the number of tests performed had decreased during the pandemic period, the number of beneficiaries who received those tests decreased by more than 10 percent.
- For the gender and residential location (i.e., rural or urban) demographics, during the pandemic period the number of beneficiaries who received lab tests had similar percentage decreases for each category within the corresponding demographic (e.g., the female and male genders had similar percentage decreases).

- For the race or ethnicity group demographic, during the pandemic period there was more variation in the percentage decreases in the number of beneficiaries who received lab tests for each category (e.g., the Hispanic or Latino category had a higher percentage decrease than the White category).
- The number of beneficiaries with diabetes, kidney disease, and heart disease who received common lab tests for those conditions decreased during the pandemic period.²⁵

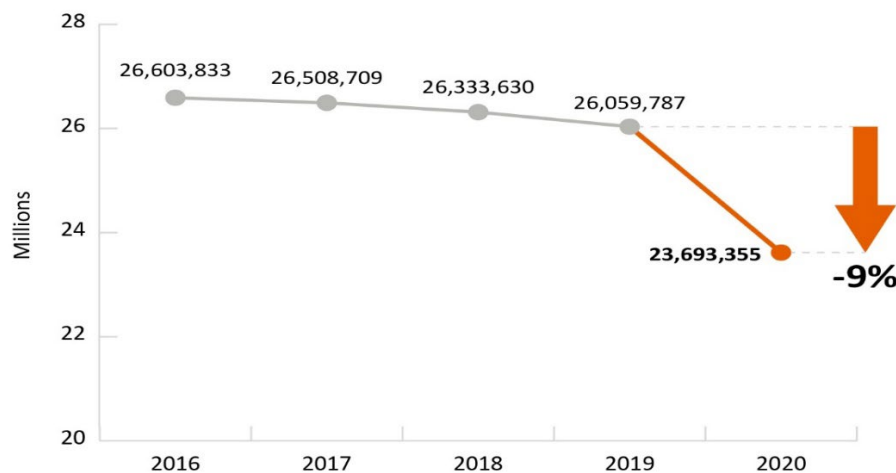
The results of our data analysis suggest that the COVID-19 pandemic contributed to decreases in the number of beneficiaries who received lab tests during the pandemic period compared with the pre-pandemic period.

CHANGES IN THE NUMBER OF BENEFICIARIES WHO RECEIVED MEDICARE PART B LAB TESTS DURING THE FIRST 10 MONTHS OF THE COVID-19 PANDEMIC

The Number of Beneficiaries Who Received Lab Tests Decreased

From March through December in 2016, 2017, and 2018 and for the pre-pandemic period (in 2019), the number of beneficiaries who received lab tests paid for by Medicare decreased by 1 percent or less in each year. However, during the pandemic period (in 2020), the number of beneficiaries who received lab tests decreased by 2.4 million, or about 9 percent, from the pre-pandemic period. Specifically, during the pre-pandemic period, 26.1 million beneficiaries received lab tests, and during the pandemic period, 23.7 million beneficiaries received lab tests. (See Figure 1.)

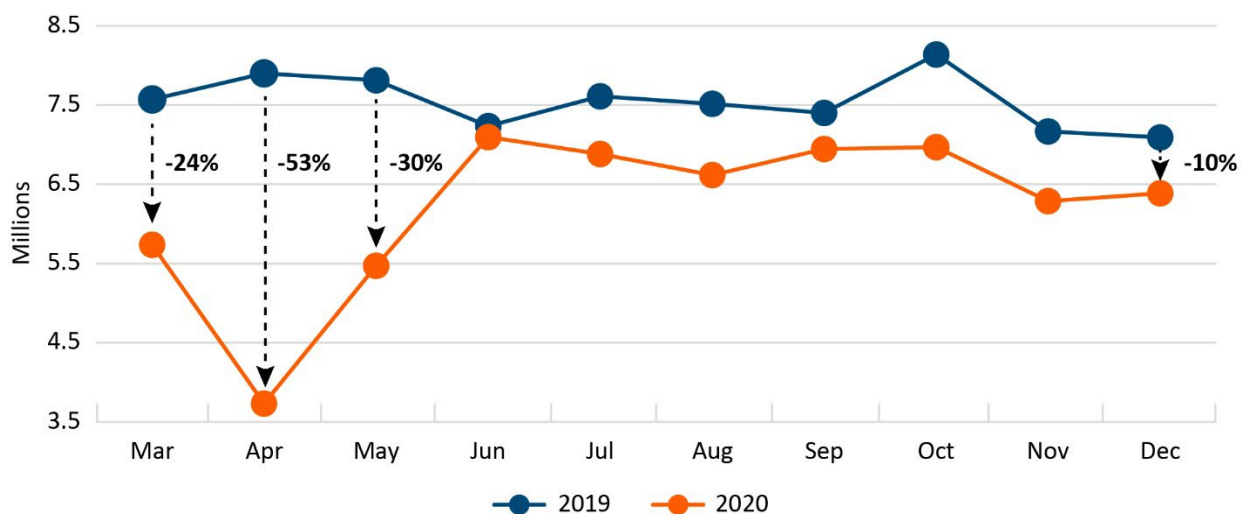
Figure 1: Decreases in the Number of Beneficiaries Who Received Lab Tests (March to December Period for 2016 to 2020)



²⁵ We define “common lab tests” as those tests that were received by more than 25 percent of beneficiaries with diabetes, kidney disease, or heart disease during the pre-pandemic period.

There were steep decreases in the number of beneficiaries who received lab tests in March, April, and May 2020, i.e., during the first 3 months of the pandemic period, when compared with the same months during the pre-pandemic period. Although the number of beneficiaries who received lab tests rebounded somewhat in May and June of the pandemic period (in 2020), the number still remained lower compared with the pre-pandemic period. (See Figure 2.)

Figure 2: Number of Beneficiaries Who Received Lab Tests During the Pre-pandemic and Pandemic Periods (by Month)



The Number of Beneficiaries Who Received Lab Tests Decreased for the Majority of Lab Tests

For 1041 of 1323, or 79 percent, of lab tests (identified by their individual HCPCS or CPT codes), the number of beneficiaries who received these tests decreased during the pandemic period when compared with the pre-pandemic period. For almost 90 percent of these 1041 lab tests, the number of beneficiaries who received the tests decreased by more than 10 percent.

Table 1 on the following page shows the top 10 lab tests with more than 10-percent decreases from the pre-pandemic to the pandemic period.²⁶

²⁶ There was a total of 933 lab tests with more than 10-percent decreases from the pre-pandemic to the pandemic period. Table 1 shows the 10 lab tests that were received by the greatest number of beneficiaries during the pre-pandemic period.

Table 1: The Top 10 Lab Tests With More Than a 10-Percent Decrease in the Number of Beneficiaries Who Received the Tests (Based on the Number of Beneficiaries Who Received the Tests During the Pre-pandemic Period)

Lab Test (CPT Code)	No. of Beneficiaries Who Received Test (Mar.–Dec. 2019)	No. of Beneficiaries Who Received Test (Mar.–Dec. 2020)	Difference	Percentage Change
Blood test, basic group of blood chemicals (80048)*	5,923,982	4,870,775	(1,053,207)	–18%
Manual urinalysis test with examination using microscope (81001)	5,350,459	4,664,731	(685,728)	–13%
Automated urinalysis test (81003)	4,091,396	3,433,975	(657,421)	–16%
Cyanocobalamin (vitamin B-12) level (82607)	3,871,157	3,435,130	(436,027)	–11%
Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	3,692,125	3,210,253	(481,872)	–13%
Bacterial colony count, urine (87086)	3,672,365	3,084,389	(587,976)	–16%
Uric acid level, blood (84550)	2,193,956	1,915,523	(278,433)	–13%
Evaluation of antimicrobial drug (antibiotic, antifungal, antiviral) (87186)	2,110,618	1,745,842	(364,776)	–17%
Folic acid level (82746)	1,975,142	1,731,987	(243,155)	–12%
Urinalysis, manual test (81002)	1,956,054	1,416,689	(539,365)	–28%

* See footnote 19 for the AMA copyright notice.

For a comprehensive list of the top 25 lab tests (based on the number of lab tests received by beneficiaries during the pre-pandemic period) that had any decreases in the number of beneficiaries who received them, see Appendix B.²⁷

²⁷ Among the top 25 lab tests that beneficiaries received in the pre-pandemic period, no lab tests had increases in the number of beneficiaries who received them during the pandemic period.

Actions That CMS Took During the Pandemic Period To Ensure That Beneficiaries Receive Lab Tests During the Pandemic

CMS stated that its priority during the pandemic has been ensuring beneficiary access to care (e.g., expanded telehealth coverage), while also protecting beneficiaries and health care providers from COVID-19. During the pandemic period, CMS provided education and outreach to beneficiaries focused on continuity of preventive care. Although CMS has not done a formal analysis of decreases in the number of beneficiaries who received lab tests, it offered some possible reasons for the trends (e.g., claim submission delays; lab tests performed during Medicare Part A hospitalization stays, which would not have been included in this analysis; and the “downstream effect” from temporary health care disruptions caused by the pandemic).

The Number of Beneficiaries Who Received Lab Tests Decreased for Both the Female and Male Genders

The number of beneficiaries who received lab tests decreased similarly for both the female and male genders during the pandemic period compared with the pre-pandemic period. However, the larger decrease occurred among females, with a decrease of 10 percent vs. a decrease of 8 percent among males. (See Table 2.)

Table 2: Number of Beneficiaries Who Received Lab Tests, by Gender, During the Pre-pandemic and Pandemic Periods

Gender	No. of Beneficiaries (Mar.–Dec. 2019)*	No. of Beneficiaries (Mar.–Dec. 2020)*	Difference	Percentage Change
Female	14,863,212	13,429,017	(1,434,195)	–10%
Male	11,196,572	10,264,336	(932,236)	–8%

* The sum of female and male beneficiaries does not match the total number of beneficiaries who received lab tests during the pre-pandemic period (26,059,787) and pandemic period (23,693,355) because there was an immaterial number of claims on which the gender fields were blank.

The Number of Beneficiaries Who Received Lab Tests Decreased Among Those Residing in Rural and in Urban Counties

The number of beneficiaries who received lab tests decreased similarly among those residing in rural and in urban counties during the pandemic period compared with the pre-pandemic period. However, the larger decrease occurred among beneficiaries who resided in rural counties, with a decrease of 10 percent vs. a decrease of 9 percent among beneficiaries who resided in urban counties. (See Table 3 on the following page.)

Table 3: Number of Beneficiaries Who Received Lab Tests, by Beneficiary Residential Geographic Location at Time of Service, During the Pre-pandemic and Pandemic Periods

Beneficiary Residential Geographic Location*	No. of Beneficiaries (Mar.–Dec. 2019)†	No. of Beneficiaries (Mar.–Dec. 2020)†	Difference	Percentage Change
Rural	4,983,086	4,502,970	(480,116)	–10%
Urban	20,901,029	19,065,322	(1,835,707)	–9%

* Source: The rural and urban classifications are based on a ZIP Code match from CDC’s *National Center for Health Statistics (NCHS) 2013 Urban-Rural Classification Scheme for Counties* file at the time of service.

† The sum of beneficiaries residing in rural and urban counties does not match the total number of beneficiaries who received lab tests during the pre-pandemic period (26,059,787) and pandemic period (23,693,355) because there was an immaterial number of claims on which either: (1) the ZIP Codes were blank or entered incorrectly or (2) beneficiaries were classified in more than 1 location type within the same time period.

The Number of Beneficiaries Who Received Lab Tests Decreased Among All Race or Ethnicity Groups

The number of beneficiaries who received lab tests decreased among all race or ethnicity groups during the pandemic period compared with the pre-pandemic period. The decreases varied by race or ethnicity group, with the largest decreases occurring among the beneficiaries who identified themselves as Hispanic or Latino, American Indian or Alaska Native, and Black or African American. (See Table 4.)

Table 4: Number of Beneficiaries Who Received Lab Tests, by Race or Ethnicity Group, During the Pre-pandemic and Pandemic Periods

Race or Ethnicity*	No. of Beneficiaries (Mar.–Dec. 2019)†	No. of Beneficiaries (Mar.–Dec. 2020)†	Difference	Percentage Change
Hispanic or Latino	537,487	454,184	(83,303)	–15%
American Indian or Alaska Native	107,409	91,951	(15,458)	–14%
Black or African American	2,318,285	1,994,376	(323,909)	–14%
Asian	556,450	482,901	(73,549)	–13%
White	21,558,849	19,736,186	(1,822,663)	–8%
Other or Unknown	981,292	933,736	(47,556)	–5%

* This report uses the 2020 U.S. Census categories for identifying race and ethnicity. Some terms differ from the terms used for beneficiary race obtained from the Medicare Enrollment Database, which was the source for this information for our audit. Specifically, in the Medicare enrollment file, the term used for Hispanic or Latino was “Hispanic,” the term used for American Indian or Alaska Native was “North American Native,” and the term used for Black or African American was “Black.” There were no differences in the terms used for Asian and White.

† The sum of beneficiaries representing all race or ethnicity groups does not match the total number of beneficiaries who received lab tests during the pre-pandemic period (26,059,787) and pandemic period (23,693,355) because there was an immaterial number of claims on which the race or ethnicity fields were blank. This is different from the “Unknown” category, which was used for beneficiaries whose race information was obtained from originating sources that may not have collected race information (such as the Railroad Retirement Board, the Medicare program for railroad workers and their families).

CHANGES IN THE NUMBER OF BENEFICIARIES WITH CERTAIN CHRONIC MEDICAL CONDITIONS WHO RECEIVED MEDICARE PART B LAB TESTS DURING THE FIRST 10 MONTHS OF THE COVID-19 PANDEMIC FOR LAB TESTS ASSOCIATED WITH THOSE CONDITIONS

Diabetes, Kidney Disease, and Heart Disease Are Examples of Three Chronic Medical Conditions That Are Common Among Medicare Beneficiaries

According to CMS, diabetes, kidney disease, and heart disease are chronic medical conditions that are common among Medicare beneficiaries.²⁸ When these conditions are not well managed with lab tests, medications, diets, or lifestyle changes, they may lead to use of high-cost health services, increased Medicare spending, poor health outcomes or death, and, during the COVID-19 pandemic, an increased risk of developing severe illness if a person has COVID-19. Medicare spends billions of dollars for hospitalizations associated with these chronic medical conditions. Because these conditions persist for an extended period and, in many cases, cannot be cured, lab tests used for screening for and monitoring these conditions (e.g., the blood test that measures the hemoglobin A1C level for those with diabetes and various blood tests for those with kidney disease) can play an important role in improving health outcomes and controlling future health care costs.²⁹

²⁸ To identify these chronic medical conditions, we used CMS’s *Medicare Beneficiaries at a Glance*, 2020 Edition. Available online at <https://www.cms.gov/files/document/medicare-beneficiaries-glance-2020-edition.pdf>. Accessed on Mar. 23, 2021. Other chronic medical conditions common among Medicare beneficiaries include high blood pressure, high cholesterol, and arthritis.

²⁹ The hemoglobin A1C test is a blood test that measures the average amount of glucose, or blood sugar, in a person’s bloodstream over the previous 3 months. Glucose is the type of sugar that the body uses as its principal energy source.

Medicare Spent Almost \$604 Million on Lab Tests and \$4.1 Billion on Hospital Services for Type 2 Diabetes, Chronic Kidney Disease, and Chronic Ischemic Heart Disease During the Pre-pandemic Period

During the pre-pandemic period, Medicare spent almost \$604 million on lab tests for up to 7.4 million beneficiaries who had type 2 diabetes mellitus (type 2 diabetes), chronic kidney disease, and chronic ischemic heart disease.^{30, 31} (These three conditions are specific types of diabetes, kidney disease, and heart disease.) Medicare also spent \$4.1 billion in hospital services for beneficiaries with these chronic medical conditions.

Table 5 quantifies the health care costs and health outcomes (e.g., the number of beneficiary deaths) associated with each of these chronic medical conditions (identified by their diagnosis codes). The purpose of the table is to show these conditions’ impact on Medicare and its beneficiaries by using data for the pre-pandemic period, not to compare these data with the same data for the pandemic period.

Table 5: Medicare Part B Lab Test Spending and Number of Beneficiaries Who Received Lab Tests for Type 2 Diabetes, Chronic Kidney Disease, and Chronic Ischemic Heart Disease and Medicare Part A Hospitalizations, Inpatient Costs, and Deaths Associated With Those Conditions During the Pre-pandemic Period

Chronic Medical Condition (Diagnosis Code)	Amount Paid for Lab Tests	No. of Beneficiaries Who Received Lab Tests	No. of Claims for Hospitalizations Associated With Beneficiaries	Amount Paid for Hospitalization Claims	Average Cost of Stay	Average Length-of-Stay (in Days)	No. of Beneficiary Deaths
Diabetes: Type 2 Diabetes Mellitus (E11)	\$416,050,063	5,146,790	137,908	\$1,833,427,504	\$13,297	7.61	1,671
Kidney Disease: Chronic Kidney Disease (Ckd) (N18)	138,879,432	1,379,760	2,942	62,492,413	21,241	7.36	54
Heart Disease: Chronic Ischemic Heart Disease (I25)	49,017,825	826,397	100,480	2,212,317,057	22,018	6.42	1,216
Total	\$603,947,320	7,352,947	241,330	\$4,108,236,975			2,941

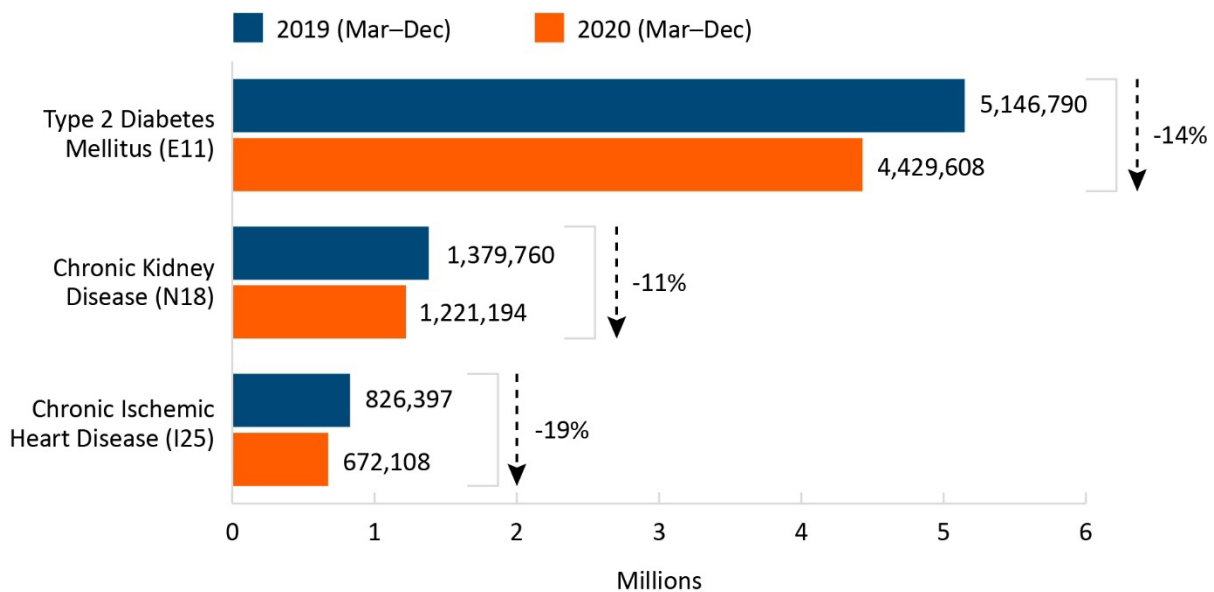
³⁰ Ischemic heart disease, also called coronary heart disease, is one of the most common forms of heart disease.

³¹ We used the information from this period because it was the most current period before the pandemic period.

The Number of Beneficiaries With Type 2 Diabetes, Chronic Kidney Disease, and Chronic Ischemic Heart Disease Who Received Lab Tests Decreased

The number of beneficiaries with type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease who received lab tests decreased from the pre-pandemic to the pandemic period. (See Figure 3.)

Figure 3: Decreases in the Number of Beneficiaries With Type 2 Diabetes, Chronic Kidney Disease, and Chronic Ischemic Heart Disease Who Received Lab Tests (From the Pre-Pandemic to the Pandemic Period)



The Number of Beneficiaries With Type 2 Diabetes Who Received Certain Lab Tests Decreased

The diagnosis of diabetes entails laboratory measurements of blood glucose and hemoglobin A1C. High blood-glucose levels (hyperglycemia) can lead to a number of acute and chronic health problems, some of them life-threatening. Tests for diabetes are used to screen for high blood-glucose levels, detect and diagnose diabetes and prediabetes, monitor and manage glucose levels over time, and detect and monitor complications. Diabetics typically have to manage their blood-glucose levels on a daily basis and over time to avoid health problems and complications. Treatment, which may involve specialized diets, exercise, and medications (including insulin), aims to ensure that the blood-glucose level does not get too high or too low (hypoglycemia).

Diabetes is a group of conditions linked by an inability to produce enough insulin or to respond to insulin, or both. When there is not enough insulin or cells stop responding to insulin, too much glucose (blood sugar) stays in the bloodstream. There are two main types of diabetes. **Type 1 diabetes** begins most often in children and young adults, who then have diabetes for life. **Type 2 diabetes** is the most common type of diabetes, occurring most often in overweight middle-aged and elderly people. Diabetes is the seventh-leading cause of death in the United States.

We identified seven lab tests as “common” for beneficiaries with type 2 diabetes during the pre-pandemic period, i.e., those tests that were received by more than 25 percent of beneficiaries with type 2 diabetes. (We refer to these tests as “the top 7 lab tests.”) During the pandemic period, the number of beneficiaries with type 2 diabetes who received each of the top 7 lab tests decreased by 10 percent or more. (See Table 6.)

Table 6: Decreases in the Number of the Top 7 Lab Tests Received by Beneficiaries With Type 2 Diabetes (From the Pre-pandemic to the Pandemic Period)

Lab Test (CPT Code)*	No. of Beneficiaries With Type 2 Diabetes Who Received Test (Mar.–Dec. 2019)	No. of Beneficiaries With Type 2 Diabetes Who Received Test (Mar.–Dec. 2020)	Difference	Percentage Change
Hemoglobin A1C level (83036)	4,408,235	3,810,950	(597,285)	–14%
Blood test, comprehensive group of blood chemicals (80053)	2,901,489	2,579,037	(322,452)	–11%
Blood test, lipids (cholesterol and triglycerides) (80061)	2,875,883	2,543,067	(332,816)	–12%
Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	1,947,581	1,753,683	(193,898)	–10%
Urine microalbumin (protein) level (82043)	1,640,879	1,430,289	(210,590)	–13%
Blood test, thyroid stimulating hormone (TSH) (84443)	1,638,875	1,461,071	(177,804)	–11%
Creatinine level to test for kidney function or muscle injury (82570)	1,377,658	1,230,194	(147,464)	–11%

* We did not include the CPT code for insertion of needle into vein for collection of blood sample (36415) because it is not specific to type 2 diabetes but is associated with all blood tests.

Type 2 diabetes is associated with hospitalizations, billions of dollars in Medicare costs, and deaths. Lab tests are an important part of preventive health care. Lab tests can be used to screen beneficiaries for type 2 diabetes and monitor disease progression. Worsening of type 2 diabetes could result in increased morbidity and deaths and increased Medicare spending. As shown in Table 5, in addition to hospitalization costs of \$1.8 billion during the pre-pandemic period for beneficiaries who had a diagnosis of type 2 diabetes, there was an average cost per stay of \$13,297, an average length-of-stay of about 7.61 days, and a total of 1,671 deaths.

The Number of Beneficiaries With Chronic Kidney Disease Who Received Certain Lab Tests Decreased

Lab testing is instrumental in determining how well the kidneys are working. Once the kidneys fail, dialysis or a kidney transplant is needed to stay alive. Routine lab tests can help detect early warning signs of kidney disease. Tests used to check, monitor, and manage kidney disease include blood and urine tests. Treatment varies, depending on the cause of the kidney disorder, and may include medications and dietary changes.

We identified eight lab tests as “common” for beneficiaries with chronic kidney disease during the pre-pandemic period, i.e., those tests that were received by more than 25 percent of beneficiaries with chronic kidney disease. (We refer to these tests as “the top 8 lab tests.”) During the pandemic period, the number of beneficiaries with chronic kidney disease who received each of the top 8 lab tests decreased by 7 percent or more. (See Table 7.)

Kidney disease occurs when the kidneys cannot function properly. There is not one type of “kidney disease.” Rather, a number of different conditions can cause kidney disease or a loss in kidney function. **Chronic kidney disease** describes the gradual loss of kidney function. The kidneys filter waste and excess fluids from the blood, which are then excreted in the urine. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes, and waste can build up in the body and may cause health problems. Kidney disease is the eighth-leading cause of death in the United States.

Table 7: Decreases in the Number of the Top 8 Lab Tests Received by Beneficiaries With Chronic Kidney Disease (From the Pre-pandemic to the Pandemic Period)

Lab Test (CPT Code)*	No. of Beneficiaries With Chronic Kidney Disease Who Received Test (Mar.–Dec. 2019)	No. of Beneficiaries With Chronic Kidney Disease Who Received Test (Mar.–Dec. 2020)	Difference	Percentage Change
Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	618,056	564,350	(53,706)	–9%
Creatinine level to test for kidney function or muscle injury (82570)	510,070	471,997	(38,073)	–7%
Parathormone (parathyroid hormone) level (83970)	489,082	445,967	(43,115)	–9%
Blood test, comprehensive group of blood chemicals (80053)	476,160	435,486	(40,674)	–9%
Total protein level, urine (84156)	391,263	359,480	(31,783)	–8%
Kidney function blood test panel (80069)	388,998	353,043	(35,955)	–9%

Lab Test (CPT Code)*	No. of Beneficiaries With Chronic Kidney Disease Who Received Test (Mar.–Dec. 2019)	No. of Beneficiaries With Chronic Kidney Disease Who Received Test (Mar.–Dec. 2020)	Difference	Percentage Change
Blood test, basic group of blood chemicals (80048)	387,369	319,485	(67,884)	-18%
Vitamin D-3 level (82306)	381,630	349,046	(32,584)	-9%

* We did not include the CPT code for insertion of needle into vein for collection of blood sample (36415) because it is not specific to chronic kidney disease but is associated with all blood tests.

Chronic kidney disease is associated with hospitalizations, millions of dollars in Medicare costs, and deaths. Lab tests are an important part of preventive health care. Lab tests can be used to screen beneficiaries for chronic kidney disease and monitor disease progression. Worsening of chronic kidney disease could result in increased morbidity and deaths and increased Medicare spending. As shown in Table 5, in addition to hospitalization costs of \$62.5 million during the pre-pandemic period for beneficiaries who had a diagnosis of chronic kidney disease, there was an average cost per stay of \$21,241, an average length-of-stay of about 7.36 days, and a total of 54 deaths.

The Number of Beneficiaries With Chronic Ischemic Heart Disease Who Received Certain Lab Tests Decreased

Heart disease can lead to blood clots, heart failure, heart attack, stroke, or death. Lab tests for heart disease vary by purpose and type of test—whether to determine risk (e.g., to screen asymptomatic people to help determine their risk of developing coronary heart disease), identify disease (e.g., to determine whether a person is actually having a heart attack and what part of the heart is affected when a patient presents to the emergency room with a possible heart attack), or monitor treatment (e.g., regular blood testing to check how long it takes for blood to clot while a patient is taking heart condition medication). Treatment of heart disease depends on the specific condition and its severity. Some conditions require prompt medical intervention, while for other conditions, diet and lifestyle changes or medication or both may be recommended.

Heart disease is a general term that refers to a variety of medical conditions that affect one or more components of the heart. Anything that damages the heart or decreases its oxygen supply, affects the muscle’s efficiency, or reduces its ability to pump blood will disrupt the coordinated relationship between the heart, kidneys, and blood vessels and can harm not only the heart but the rest of the body. Heart disease may be present at birth or develop over a lifetime. **Chronic ischemic heart disease** occurs when a part of the heart does not receive enough blood. Left untreated, this disease may lead to severe heart damage. Heart disease is the leading cause of death in the United States.

We identified three lab tests as “common” for beneficiaries with chronic ischemic heart disease during the pre-pandemic period, i.e., those tests that were received by more than 25 percent of beneficiaries with chronic ischemic heart disease. (We refer to these tests as “the top 3 lab tests.”) During the pandemic period, the number of beneficiaries with chronic ischemic heart disease who received each of the top 3 lab tests decreased by 13 percent or more. (See Table 8.)

Table 8: Decreases in the Number of the Top 3 Lab Tests Received by Beneficiaries With Chronic Ischemic Heart Disease (From the Pre-pandemic to the Pandemic Period)

Lab Test (CPT Code)*	No. of Beneficiaries With Chronic Ischemic Heart Disease Who Received Test (Mar.–Dec. 2019)	No. of Beneficiaries With Chronic Ischemic Heart Disease Who Received Test (Mar.–Dec. 2020)	Difference	Percentage Change
Blood test, lipids (cholesterol and triglycerides) (80061)	483,659	407,222	(76,437)	–16%
Blood test, comprehensive group of blood chemicals (80053)	330,007	286,279	(43,728)	–13%
Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	262,912	224,249	(38,663)	–15%

* We did not include the CPT code for insertion of needle into vein for collection of blood sample (36415) because it is not specific to chronic ischemic heart disease but is associated with all blood tests.

Chronic ischemic heart disease is associated with hospitalizations, billions of dollars in Medicare costs, and deaths. Lab tests are an important part of preventive health care. Lab tests can be used to screen beneficiaries for chronic ischemic heart disease and monitor disease progression. Worsening of chronic ischemic heart disease could result in increased morbidity and deaths and increased Medicare spending. As shown in Table 5, in addition to hospitalization costs of \$2.2 billion during the pre-pandemic period for beneficiaries who had a diagnosis of chronic ischemic heart disease, there was an average cost per stay of \$22,018, an average length-of-stay of about 6.42 days, and a total of 1,216 deaths.

CONCLUSION

The results of our analysis of Medicare Part B data suggest that the COVID-19 pandemic contributed to decreases in the number of beneficiaries who received lab tests during the pandemic period (March through December 2020) compared with the pre-pandemic period (March through December 2019). For almost 90 percent of lab tests for which the number of tests performed had decreased during the pandemic period, the number of beneficiaries who received those tests decreased by more than 10 percent. The results of our data analysis also showed that for the gender and residential location demographics, the number of beneficiaries who received lab tests had similar percentage decreases for each category within the corresponding demographic (e.g., the female and male genders had similar percentage decreases). However, for the race or ethnicity group demographic, there was more variation in the lab test percentage decreases for each category (e.g., the Hispanic or Latino category had a higher percentage decrease than the White category).

In addition, the results of our data analysis suggest that the COVID-19 pandemic contributed to decreases in the number of beneficiaries with type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease who received lab tests during the pandemic period (March through December 2020) compared with the pre-pandemic period (March through December 2019). While the overall number of beneficiaries who received lab tests decreased by 9 percent during the pandemic period, the number of beneficiaries with type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease who received lab tests decreased by 14 percent, 11 percent, and 19 percent, respectively. These chronic medical conditions are associated with hospitalizations, billions of dollars in Medicare costs, and deaths. Lab tests are an important part of preventive health care. Lab tests can be used to screen beneficiaries for type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease and to monitor disease progression. Failure to properly manage these conditions could result in increased morbidity and deaths and increased Medicare spending.

Because the information in this report is provided for informational purposes only, the report does not contain any recommendations. CMS elected not to provide comments on our draft report.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered Medicare Part B claims for lab tests (identified by HCPCS or CPT codes) reimbursed under the CLFS that were provided during the pre-pandemic period (March 1 through December 31, 2019) and the pandemic period (March 1 through December 31, 2020).³² During the pre-pandemic period, Medicare spent a total of \$6.6 billion for 419.9 million lab tests received by 26.1 million beneficiaries, and during the pandemic period, Medicare spent a total of \$5.5 billion for 358.4 million lab tests received by 23.7 million beneficiaries.³³ Spending for lab tests made up about 4 percent of total Medicare Part B expenditures for both periods. Although lab tests represented only a small percentage of these expenditures, lab tests were received by more than 75 percent of all Part B beneficiaries in both periods.³⁴

We compared the number of lab tests that beneficiaries received during the pandemic period with the number of lab tests received during the pre-pandemic period.³⁵ The information in this report is provided for informational purposes only and therefore the report does not contain any recommendations.

This audit is not an assessment of CMS's or the labs' response to the COVID-19 pandemic. The information represents a snapshot during a period of time, and it is possible that the trends we present in this report have changed since our audit. We did not confirm that the lab tests were medically necessary or that the number of units were properly billed and paid. We also did not identify all the possible underlying reasons for the trends. (Some of the reasons that CMS mentioned to us were claim submission delays; lab tests performed during Medicare Part A hospitalization stays, which would not have been included in this analysis; and the "downstream effect" from temporary health care disruptions caused by the pandemic.) Finally, we did not tie health outcomes to specific beneficiaries or specific missed lab tests.

³² These tests are covered under Medicare Part B and do 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.

³³ Our audit did not cover COVID-19 tests created in 2020, which included diagnostic tests used to identify active COVID-19 virus infections and antibody tests used to identify the immune response from previous COVID-19 virus infections or immunization.

³⁴ Medicare Part B enrollment for the pandemic period increased less than 3 percent from the pre-pandemic period, which is consistent with the enrollment increases each year since 2016 for the March through December period.

³⁵ We compared the number of beneficiaries who received lab tests in the aggregate as well as by individual lab test. For our comparative analysis of the individual lab tests that beneficiaries received during the pandemic period and the number of beneficiaries receiving those individual lab tests during the pre-pandemic period, we removed lab tests associated with 87 CPT codes for which there were no beneficiaries who received those lab tests during the pre-pandemic period (in 2019); 51 of the 87 CPT codes were new codes added in 2020.

We did not assess CMS's internal controls because they were not significant to our audit objective. Our objective did not require us to assess CMS's or specific clinical labs': (1) internal controls related to the reviewed lab tests or (2) response to the COVID-19 pandemic. Additionally, we did not evaluate whether the claims for lab tests complied with applicable Federal requirements.

We conducted our audit from March 2021 to September 2022.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials and reviewed information on the CMS website and written responses from CMS to obtain an understanding of its actions taken during the COVID-19 pandemic;
- used CMS's National Claims History (NCH) Physician/Supplier Part B claim files and NCH Outpatient files to identify paid Medicare Part B claim lines for lab tests with dates of service during the March to December period for 2016, 2017, and 2018 and during the pre-pandemic and pandemic periods;
- analyzed the data in CMS's NCH files for lab tests that were provided during the March to December period for 2016, 2017, and 2018 to identify any significant trends before the pre-pandemic and pandemic periods that were relevant to our analysis;
- analyzed the data in CMS's NCH files by comparing the number of beneficiaries who received lab tests during the pre-pandemic period with the number of beneficiaries who received lab tests during the pandemic period, in total, by individual lab test, and by demographics (i.e., gender, residential geographic location (urban or rural), and race or ethnicity group);
- identified chronic medical conditions that CMS has stated are common among Medicare beneficiaries and identified the lab tests associated with those conditions;
- obtained the diagnosis codes associated with type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease and compared the number of beneficiaries who had these medical conditions and received lab tests during the pre-pandemic period with the number of beneficiaries who had these medical conditions and received lab tests during the pandemic period;

- analyzed data on hospitalizations, payments, and deaths for Medicare beneficiaries who had type 2 diabetes, chronic kidney disease, and chronic ischemic heart disease and received lab tests during the pre-pandemic period; and
- discussed the results of our audit with CMS officials.

We provided our draft report to CMS on September 22, 2022, for review. CMS elected not to provide comments.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: TOP 25 LAB TESTS WITH DECREASES IN THE NUMBER OF BENEFICIARIES WHO RECEIVED THE TESTS (FROM THE PRE-PANDEMIC TO THE PANDEMIC PERIOD)

Lab Test (HCPCS or CPT Code)	No. of Beneficiaries Who Received Test (Mar.– Dec. 2019)	No. of Beneficiaries Who Received Test (Mar.– Dec. 2020)	Difference	Percentage Change
Blood test, comprehensive group of blood chemicals (80053) ³⁶	18,618,401	17,036,720	(1,581,681)	–8%
Blood test, lipids (cholesterol and triglycerides) (80061)	16,995,391	15,358,631	(1,636,760)	–10%
Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	16,263,001	14,784,014	(1,478,987)	–9%
Blood test, thyroid stimulating hormone (TSH) (84443)	12,470,826	11,187,239	(1,283,587)	–10%
Hemoglobin A1C level (83036)	10,042,265	9,222,996	(819,269)	–8%
Blood test, basic group of blood chemicals (80048)	5,923,982	4,870,775	(1,053,207)	–18%
Vitamin D-3 level (82306)	5,740,429	5,293,279	(447,150)	–8%
Manual urinalysis test with examination using microscope (81001)	5,350,459	4,664,731	(685,728)	–13%
Thyroxine (thyroid chemical) measurement (84439)	4,358,237	3,947,361	(410,876)	–9%
Automated urinalysis test (81003)	4,091,396	3,433,975	(657,421)	–16%
Cyanocobalamin (vitamin B-12) level (82607)	3,871,157	3,435,130	(436,027)	–11%
Creatinine level to test for kidney function or muscle injury (82570)	3,705,592	3,383,277	(322,315)	–9%
Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	3,692,125	3,210,253	(481,872)	–13%
Bacterial colony count, urine (87086)	3,672,365	3,084,389	(587,976)	–16%
Urine microalbumin (protein) level (82043)	3,549,944	3,199,045	(350,899)	–10%
PSA (prostate specific antigen) measurement (84153)	2,629,734	2,411,967	(217,767)	–8%
Magnesium level (83735)	2,440,740	2,216,061	(224,679)	–9%
Iron level (83540)	2,327,482	2,087,071	(240,411)	–10%
Ferritin (blood protein) level (82728)	2,209,777	2,016,695	(193,082)	–9%
Uric acid level, blood (84550)	2,193,956	1,915,523	(278,433)	–13%

³⁶ The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2019–2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this report should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

Lab Test (HCPCS or CPT Code)	No. of Beneficiaries Who Received Test (Mar.– Dec. 2019)	No. of Beneficiaries Who Received Test (Mar.– Dec. 2020)	Difference	Percentage Change
Evaluation of antimicrobial drug (antibiotic, antifungal, antiviral) (87186)	2,110,618	1,745,842	(364,776)	-17%
Folic acid level (82746)	1,975,142	1,731,987	(243,155)	-12%
Urinalysis, manual test (81002)	1,956,054	1,416,689	(539,365)	-28%
Prostate cancer screening; prostate specific antigen test (psa) (G0103)	1,801,107	1,675,339	(125,768)	-7%
Iron binding capacity (83550)	1,790,080	1,601,137	(188,943)	-11%