Over-the-Counter COVID-19 Test Demonstration

Payment and Coverage of COVID-19 Laboratory-Conducted Tests Prior to the Public Health Emergency

Clinical diagnostic laboratory tests are covered under section 1861(s)(3) of the Social Security Act (the Act) and are paid for on the Clinical Laboratory Fee Schedule. Beneficiaries do not pay anything for these tests, but a physician or non-physician practitioner order is required before they can receive the test.

Medicare Part B, which includes a variety of outpatient services, generally covers medically necessary clinical diagnostic laboratory tests performed by a laboratory when ordered by a physician or other non-physician practitioner who is treating the beneficiary. There is no benefit under Medicare Part A or Part B for coverage or payment for over-the-counter (OTC) products obtained directly by a beneficiary without a physician's or practitioner's order, such as OTC COVID-19 tests.

Over-the-Counter COVID-19 Test Demonstration

CMS implemented a demonstration project under section 402(a)(1)(B) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(B)) to test the efficacy of Medicare covering over-the-counter COVID-19 tests without cost-sharing during the COVID-19 PHE.

Starting April 4, 2022, and through the end of the COVID-19 public health emergency (PHE) (currently anticipated to be May 11, 2023), Medicare covers and pays for OTC COVID-19 tests under the terms of this initiative at no cost to people with Medicare Part B. This includes people with Medicare Part B through Original Medicare and those enrolled in Medicare Advantage (MA) plans.

COVID-19 testing is a critical part of the broader pandemic response. This initiative was consistent with the Administration's overall strategy to ramp-up access to easy-to-use, at-home COVID-19 tests free of charge during the PHE. Combined with the free over-the-counter tests available through covidtests.gov, this initiative was intended to significantly increase testing access for Americans most vulnerable to COVID-19.

In addition to helping prevent the spread of COVID-19, the goal of this demonstration was to investigate whether Medicare payment for OTC COVID-19 tests improved access to testing and resulted in Medicare savings from a less expensive mode of testing and from more effective utilization of services.

From April 2022 through March 2023, CMS paid approximately $1.1 billion for about 101 million OTC COVID-19 tests given to an estimated 8 million Medicare beneficiaries through the demonstration .

What's Covered in the Demonstration?

During this initiative, eligible pharmacies and health care providers can provide U.S. FDA-approved, authorized, or cleared OTC COVID-19 tests to patients enrolled in Part B. This includes people with Medicare Part B through Original Medicare and those enrolled in MA plans. Eligible Medicare patients will get these tests at no cost, and their annual deductible, coinsurance, and copayment don't apply.

Patients who only have Medicare Part A can get free OTC COVID-19 tests through other government-led programs, like covidtests.gov, which operates through the United States Postal Service. Or, they may have coverage through a private insurance plan, if they're enrolled in a plan.

How Many Tests Are Covered During the Demonstration?

Each eligible Medicare patient can get up to 8 tests per calendar month until the PHE ends (May 11, 2023). Medicare won't pay for more than 8 OTC tests in a month. If a patient gets more than 8 tests in a calendar month, they may pay out-of-pocket for the extra tests unless they have additional health coverage.

Note: The quantity limit of 8 tests per patient per calendar month applies only to the OTC COVID-19 tests, and doesn't apply for laboratory-performed COVID-19 tests and other COVID-19-related services. Providers can continue to order laboratory and other diagnostic tests for their patients, and CMS will continue to cover and pay for them under existing payment policies.

What Does Medicare Pay for these Tests during the Demonstration?

CMS established a fixed national payment rate of $12 per OTC COVID-19 test. If an entity charges less, then Medicare would pay the lesser of $12 or what the entity charges. In other words, the maximum Medicare would pay is $12 per OTC COVID-19 test. During the PHE, the range of Medicare payment rates for COVID-19 tests performed by laboratories ranges from roughly $51-$100. The payment labs receive depends on the type of test run and the speed at which results are returned, in some cases. Beneficiary cost sharing for thesetests is the same – zero dollars.

Note: CMS increased the payment amount labs receive for high-throughput COVID-19 lab tests through an Administrative Ruling (CMS-2020-1-R2). Labs can receive roughly $75 for high-throughput COVID-19 tests, and are eligible to receive an additional $25 if the labs complete a majority of the COVID-19 diagnostic tests run on high-throughput technology within two days, for a total of $100 per test by Medicare. When the PHE ends, this administrative ruling will conclude and lab payment will revert back to the pre-PHE payment rate of $51 for these types of tests.

What is the Authority for the Demonstration?

Section 402(a)(1)(B) of the Social Security Amendments of 1967 authorizes the Secretary of HHS to carry out "demonstration projects" for various stated purposes. One of these is, "to

determine whether payments for services other than those for which payment may be made under" Medicare, "would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under" Medicare, if such services are furnished by an "institution or entity" that has the "capability" of providing "ambulatory health services."

CMS was interested in testing whether making payment for OTC COVID-19 tests for Medicare beneficiaries without cost-sharing would result in more economical provision of Medicare benefits, e.g., by Medicare beneficiaries utilizing a less expensive kind of test, and through avoiding Medicare costs associated with COVID-19 that is not detected in time to provide meaningful treatment to the infected individual or avoid further spread of the disease.

Will the Demonstration be Evaluated?

The purpose of demonstrations functioning under this statutory authority is to test the efficacy of Medicare covering and paying for otherwise non-covered services. When we announced the OTC COVID-19 test demonstration, we stated that it would run through the end of the COVID-19 PHE. Our analysis of the efficacy of this demonstration will cover the time period from April 4, 2022 (when the demonstration was announced) through the end of the public health emergency. An evaluation of the demonstration is expected to be completed in early 2024.

Post-PHE Coverage for COVID-19 Testing

When the initiative was announced we said that the Medicare patient access to free OTC COVID-19 tests through the demonstration will conclude when the COVID-19 PHE ends. Part B covers a variety of outpatient services, including medically necessary clinical diagnostic laboratory tests, but doesn't typically cover or pay for OTC services and tests, including OTC COVID-19 tests, absent this demonstration.

Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted COVID-19 tests when ordered by a provider, but their current access to free OTC COVID-19 tests will end once the PHE concludes (May 11, 2023). Medicare beneficiaries can still get up to 8 OTC COVID-19 tests per calendar month for dates of services through the end of the demonstration (May 11, 2023). This means that Medicare enrolled pharmacies and healthcare providers can still bill Medicare for OTC tests they provided to Medicare beneficiaries between April 4, 2022 and the last day of the PHE (May 11, 2023). Medicare beneficiaries enrolled in a MA plan may also have additional access to tests depending on their MA plan benefits.

As noted above, Medicare Parts A and B generally does not cover and pay for over-the-counter self-administered tests. Medicare covers and pays for most clinical diagnostic laboratory tests on the clinical laboratory fee schedule, and payment generally is made only to the laboratory or another Medicare enrolled provider or supplier that performed or supervised the performance of the test.