

Medicare Coverage of Over-the-Counter COVID-19 Tests: Frequently Asked Questions April 4, 2022

Does Medicare cover over-the-counter COVID-19 tests?

CMS launched a new initiative on April 4, 2022, that provides direct payment to participating eligible pharmacies and health care providers for up to eight free over-the-counter COVID-19 tests per calendar month per beneficiary when provided to people with Medicare Part B, including those enrolled in Medicare Advantage plans, for the duration of the COVID-19 public health emergency (PHE).

When can people with Medicare get the free over-the-counter COVID-19 tests that are covered by Medicare?

Starting on April 4, 2022, people with Medicare Part B, including those who are enrolled in a Medicare Advantage plan, will be able to go to eligible pharmacies and health care providers that are participating in this initiative to receive up eight free over-the-counter COVID-19 tests per calendar month. People with Medicare Part B coverage can get up to eight free over-the-counter tests for the month of April any time before April 30, and then get up to eight more free over-the-counter tests during each subsequent calendar month through the end of the COVID-19 PHE. Note that there can be multiple tests per box, so eight tests may come in fewer than eight boxes.

A list of pharmacies that have committed publicly to participate is available <u>here</u> (<u>https://www.medicare.gov/medicare-coronavirus</u>). Because this initiative is voluntary, more eligible pharmacies and health care providers may also participate. Medicare beneficiaries should check with their pharmacy or health care provider to find out whether they are participating in this initiative. If so, they can provide the tests under this initiative and will bill Medicare on the beneficiary's behalf. Information about where to find a test is also available by calling 1-800-MEDICARE (1-800-633-4227).

In addition, people with Medicare can also access free tests through a number of other channels established by the Biden-Harris Administration. Medicare beneficiaries can:

- Request free over-the-counter tests for home delivery at <u>covidtests.gov</u>. Every home in the U.S. is eligible to order two sets of four at-home COVID-19 tests.
- Access no-cost COVID-19 tests through health care providers at over 20,000 testing sites nationwide. A list of community-based testing sites can be found <u>here</u>.
- Access lab-based PCR tests and antigen tests performed by a laboratory when the test is ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional at no cost through Medicare.
- In addition to accessing a COVID-19 laboratory test ordered by a health care professional, people with Medicare can access one lab-performed test without an order, also without cost-sharing, during the PHE.



Does this initiative apply to people in original Medicare, Medicare Advantage, or both? This initiative applies to all individuals with Medicare Part B, including individuals enrolled in a Medicare Advantage plan. Please note that individuals should present their red, white and blue Medicare card to get their free over-the-counter COVID-19 tests, even if they are enrolled in a Medicare Advantage plan. If a Medicare card is lost or misplaced, call 1-800-MEDICARE. It is possible that a pharmacy might be able to get the information it needs to bill Medicare if individuals do not have their red, white and blue card.

People with Medicare who are only entitled to Part A, and not enrolled in Part B, are not eligible to receive over-the-counter tests under the initiative, but can receive free over-the-counter COVID-19 tests provided through other government programs such as covidtests.gov.

Will people with Medicare pay anything for these tests?

No. People with Medicare will be able to obtain up to eight over-the-counter COVID-19 tests per calendar month without cost-sharing from a participating eligible pharmacy or health care provider. This means that there is no applicable co-payment and the beneficiary's annual deductible does not apply.

If a person with Medicare wants to obtain more than eight over-the-counter COVID-19 tests per calendar month, then that person can obtain the additional the additional tests at retail prices or through another available resource. Note there may be more than one over-the-counter test per box, so eight tests may come in fewer than eight boxes.

Are the free over-the-counter COVID-19 tests available only to existing customers of the participating pharmacy location or chain?

No, people with Medicare Part B can get up to eight over-the-counter COVID-19 tests per calendar month without cost-sharing from any participating eligible pharmacy, whether or not they are an existing customer of that particular location or chain. People with Medicare Part B should present their red, white and blue Medicare card (even if you have a Part D prescription card or Medicare Advantage plan card) in order to obtain these tests at no cost from the participating eligible provider.

Does this initiative apply to any over-the-counter tests or only specific types or brands of tests for COVID-19?

This initiative will pay eligible pharmacies and health care providers that are participating in this initiative for over-the-counter COVID-19 tests that are approved, authorized or cleared by the U.S. Food and Drug Administration (FDA) when furnished to eligible Medicare beneficiaries within the limit of eight tests per beneficiary per calendar month.

Participating eligible pharmacies and health care providers are not required to carry all types of FDA approved, authorized or cleared over-the-counter COVID-19 tests, but are encouraged to provide equitable access to these tests for their consumers.



Will people with Medicare need to buy the tests first and then be reimbursed?

No. Medicare will only make payment directly to eligible pharmacies and health care providers that are participating in this initiative, which will allow people with Medicare Part B coverage, including individuals enrolled in a Medicare Advantage plan, to receive up to eight tests per calendar month at no cost at the point of sale and without needing to be reimbursed. Participating eligible pharmacies and health care providers under this initiative will then bill Medicare in a manner similar to the way they currently bill for other Medicare covered services. Medicare beneficiaries will not need to submit a bill or receipt to Medicare for payment under this initiative.

Will Medicare pay for over-the-counter COVID-19 tests purchased from pharmacies and health care providers prior to the start of the initiative on April 4, 2022?

No. Medicare only will provide coverage and payment for over-the-counter COVID-19 tests starting April 4, 2022. Medicare will continue providing payment for up to eight tests per beneficiary per calendar month for individuals with Medicare Part B, including those enrolled in a Medicare Advantage plan, through the end of the COVID-19 PHE. This initiative will enable payment directly to eligible pharmacies and health care providers that are participating in this initiative to allow people with Medicare Part B to get up to eight tests per calendar month at no cost.

People with Medicare will not be eligible to be reimbursed through this initiative for tests purchased before April 4, 2022. However, a person enrolled in a Medicare Advantage plan that currently covers such tests as an additional benefit may be reimbursed through their plan for tests they get before this initiative begins.

If the retail price of the over-the-counter COVID-19 tests is more than \$12, can a participating eligible pharmacy or health care provider charge or bill for the balance of the test?

No. A participating eligible pharmacy or health care provider must agree not to balance bill or charge a Medicare beneficiary anything for tests that fall within the established per beneficiary per calendar month quantity limit of eight tests. However, if a Medicare beneficiary has exceeded the per calendar month quantity limit, a participating eligible pharmacy or health care provider may seek payment from the beneficiary for such tests. If a participating eligible pharmacy or health care provider tries to charge a beneficiary for any difference between the retail price and the Medicare payment before the beneficiary has exceeded the monthly quantity limit, the beneficiary should report the incident to 1-800-MEDICARE or to https://oig.hhs.gov/fraud/report-fraud/.

For people with Medicare who are blind or have another disability that makes some tests difficult to use, will Medicare cover tests that accommodate their needs?

Medicare will pay for all types of over-the-counter COVID-19 tests that are approved, authorized or cleared by the FDA, subject to the calendar month quantity limit established under this initiative. This includes tests that are adapted for people with disabilities. CMS is encouraging participating eligible pharmacies and health care providers to make sure they provide tests that can be used by people with varying abilities.



What happens if a Medicare beneficiary would like more than the eight over-thecounter tests per calendar month permitted under this initiative?

If a person with Medicare exceeds the per calendar month quantity limit of eight tests, Medicare will deny the claim and no payment will be made to the participating eligible pharmacy or health care provider for the additional tests. The participating eligible pharmacy or health care provider can then charge the beneficiary for the retail price of the over-the-counter COVID-19 tests. Because the participating eligible pharmacy or health care provider would need to submit a claim to Medicare prior to learning that the beneficiary is over the quantity limit, beneficiaries may receive requests for payment from the participating pharmacy or health care provider at a later date for tests that exceeded the limit. Also, if a Medicare beneficiary has other coverage, such as Medicaid, then they should check with that plan to see whether it offers a benefit for tests over the Medicare monthly quantity limit.

Will there be options for people with Medicare to order tests online?

CMS is encouraging participating eligible pharmacies and health care providers to provide tests under this initiative to people with Medicare through a variety of convenient means, including online ordering.

Participating eligible pharmacies and health care providers can elect to use online ordering mechanisms, such as a direct-to-consumer shipping program, to furnish these tests to people with Medicare so long as the beneficiary or their designee requests the tests. A direct-to-consumer shipping mechanism can include online or telephone ordering, and may only be operated by a participating eligible pharmacy or health care provider under the initiative. The availability of tests through these means will help beneficiaries obtain access to these tests in harder to reach communities.

CMS may ask to see documentation showing a beneficiary's request for tests. The agency could recoup payment and may take other administrative actions if this documentation is not produced.

Can family members get free COVID-19 tests if they don't have Medicare?

Only people with Medicare Part B, including those enrolled in a Medicare Advantage plan, are eligible to receive up to eight tests per calendar month under this initiative. Over-the-counter COVID-19 tests obtained through this initiative are intended for eligible Medicare beneficiaries only. However, people without Medicare Part B have access to other government programs that are providing over-the-counter COVID-19 tests for free. For example, every home in the U.S. is eligible to order two sets of four free, at-home COVID-19 tests delivered by the U.S. Postal Service. These free at-home tests for home delivery can be ordered at <u>covidtests.gov</u>.

Those who have difficulty accessing the internet or need additional support placing an order can call 1-800-232-0233 to get help in English, Spanish, and more than 150 other languages. This call-line is open 8 a.m. to midnight ET, 7 days a week. There's also a TTY line (1-888-720-7489) to support access by hearing impaired callers.



In addition, most people with a group health plan or private health insurance coverage, and who are not enrolled in Medicare Part B or a Medicare Advantage plan, can go online or to a pharmacy or store to obtain an over-the-counter COVID-19 diagnostic test approved, authorized or cleared by the FDA without cost-sharing, either through reimbursement or covered directly through their plan or insurance.

Additional information is available here: <u>https://www.cms.gov/how-to-get-your-at-home-OTC-</u> <u>COVID-19-test-for-free</u>.

Why did this take so long to set up?

This is the first time in the history of the Medicare program that Medicare will be paying for any over-the-counter test without cost sharing for Medicare beneficiaries.

The law does not generally cover over-the-counter services and tests. Given the importance of ensuring access to free, at-home testing for every American during the pandemic, CMS is using an innovative approach that requires multiple elements of this initiative be designed, tested and evaluated.

In addition to designing this initiative to meet statutorily required benchmarks, there are several operational changes that needed to be made to ensure this new and unprecedented pathway runs smoothly and that program integrity guardrails are established.

What authority is CMS using for this initiative?

CMS is using its authority under section 402(a)(1)(B) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(B)) to engage in demonstration projects testing the efficacy of Medicare covering otherwise non-covered services in order to conduct this initiative.

If I have questions about this initiative, where should I go for more information?

People with Medicare can get additional information about this initiative here: <u>https://www.medicare.gov/medicare-coronavirus</u>

Information for Eligible Pharmacies and Health Care Providers

Who is included as an eligible pharmacy or health care provider that can participate in this initiative?

Health care providers eligible to participate in the initiative include institutional and noninstitutional Medicare ambulatory health care providers and suppliers that are able to bill Medicare on a standard claims format. This can include, but is not limited to, physicians and other non-physician practitioners in private practice, hospital outpatient departments, skilled nursing facilities (SNF), home health agencies, federally qualified health centers, rural health clinics, opioid treatment programs, independent laboratories, mass immunizers that bill on a standard claim format, and certain pharmacies depending on how they are enrolled in Medicare.



Only participating eligible pharmacies and health care providers are able to bill Medicare under the initiative for furnishing these over-the-counter COVID-19 tests. If a pharmacy or health care provider is currently enrolled in Medicare and is able to bill Medicare on a standard claims format for ambulatory health care services, such as preventive vaccines, clinic visits or laboratory tests, they may participate in this initiative by billing for over-the-counter COVID-19 tests provided to eligible Medicare beneficiaries.

Do eligible pharmacies and health care providers need to sign up to participate in this initiative?

No. For eligible pharmacies and health care providers, voluntary participation in the initiative is initiated by submission of a Medicare claim for over-the-counter COVID-19 tests furnished to an eligible Medicare beneficiary. CMS will not require eligible pharmacies and health care providers to sign participation agreements in order to participate in the initiative.

Do health care providers currently enrolled in Medicare and interested in participating need to enroll in this initiative?

No. Health care providers currently enrolled in Medicare and that are able to furnish ambulatory health care services, such as preventive vaccines, clinic visits or lab tests, may bill Medicare for providing eligible beneficiaries with over-the-counter COVID-19 tests under this initiative. Participating eligible pharmacies and health care providers must bill Medicare using the applicable standard claim format (i.e., the 837 Professional or Institutional format).

Health care providers eligible to participate in this initiative include, but are not limited to, physicians and other non-physician practitioners in private practice, hospital outpatient departments, skilled nursing facilities (SNF), home health agencies, federally qualified health centers, rural health clinics, opioid treatment programs, independent laboratories, mass immunizers that bill on a standard claim format and certain pharmacies depending on how they are enrolled in Medicare.

Health care providers not currently enrolled in Medicare, but who wish to participate, will need to first enroll in Medicare. [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification]

How may eligible pharmacies and health care providers who elect to participate in this initiative make customers aware of their participation?

CMS is producing several educational materials for beneficiaries, as well as participating eligible pharmacies and health care providers. We encourage participating eligible pharmacies and health care providers to join CMS in producing educational materials for their customers. One example could be providing a voluntary Advanced Beneficiary Notice of Non-coverage (ABN) so that beneficiaries are further aware of the per calendar month quantity limit of eight for over-the-counter COVID-19 tests. Our hope is that the use of educational materials (produced by CMS and others) will inform the beneficiary of the initiative, the established quantity limits and potential financial consequences for exceeding



that limit.

Are health care providers enrolled in Medicare as solely Durable Medical Equipment Prosthetics, Orthotics, & Supplies (DMEPOS) suppliers eligible to participate in the initiative?

No. Health care providers enrolled in Medicare solely as DMEPOS suppliers are not eligible to participate in the initiative because the authority for the initiative extends only to eligible pharmacies and health care providers that are capable of providing ambulatory health care services (for example, laboratory testing, vaccines and other clinical services, but not solely selling DMEPOS items). If a DMEPOS supplier provides ambulatory health care services, then they typically are enrolled in Medicare in multiple ways and may be able to bill Medicare under that other enrollment pathway.

Can an institutional provider, such as an inpatient hospital, submit claims for overthe-counter COVID-19 tests furnished to beneficiaries during an inpatient stay?

Payment under the initiative cannot be made for over-the-counter COVID-19 tests furnished by an eligible institutional provider to an eligible Medicare beneficiary during an inpatient stay, such as an inpatient hospital stay or Part A SNF stay. This is because the inpatient facility should provide any needed testing during that inpatient stay. However, payment could be made under the initiative when eligible institutional providers, such as hospitals, furnish Medicare beneficiaries with over-the-counter COVID-19 tests on the day of discharge from an inpatient stay.

Will pharmacies and health care providers be able to submit claims for over-thecounter COVID-19 tests under the initiative using roster billing?

No. At this time, all participating eligible pharmacies and health care providers under this initiative are required to submit claims to Medicare using the standard claims format. Participating. P eligible providers may not submit a roster bill under this initiative.

Can claims be submitted electronically?

Yes. All participating eligible pharmacies and health care providers are required to bill for providing over-the-counter COVID-19 tests on the applicable standard claim format (i.e., the 837 Professional or Institutional format).

Can a Medicare beneficiary submit claims on their own behalf?

No. Only participating eligible pharmacies and health care providers can submit claims to Medicare under this initiative. Medicare beneficiaries should inquire with their local pharmacy or health care provider to learn whether they are participating in the initiative. If they are participating, they can provide tests to the beneficiary and will bill Medicare on the beneficiary's behalf for these tests. If a Medicare beneficiary submits a claim for an over-the-counter COVID-19 test, the beneficiary will receive a letter explaining that they must have the participating eligible pharmacy or health care provider that gave them the tests submit the claim on their behalf.

Was a billing code established for over-the-counter COVID-19 tests?



Yes. CMS established a Healthcare Common Procedure Coding System (HCPCS) Level II code, *K1034*, that is payable for all participating eligible pharmacies and health care providers under the initiative. This HCPCS code is for a single test and is inclusive of all FDA-approved, authorized or cleared COVID-19 tests where the specimen is self-collected and the test is self-administered by an individual. All payer types, including private insurance and Medicaid programs, may utilize this code.

How much will Medicare pay participating eligible pharmacies and health care providers for over-the-counter COVID-19 tests under this initiative?

CMS established a fixed national payment rate of \$12 per over-the-counter COVID-19 test. If a participating eligible pharmacy or health care provider usually charges (such as the retail price) less than \$12 per test, then Medicare pays the lesser of the two amounts. This payment amount applies to all over-the-counter FDA-approved, authorized or cleared COVID-19 tests where the specimen is self-collected and the test is self-administered by an individual for tests obtained within the quantity limit established under this initiative.

Do participating eligible pharmacies and health care providers submit claims to original Medicare for over-the-counter COVID-19 tests furnished to beneficiaries enrolled in a Medicare Advantage plan through this initiative?

Yes. For the length of the initiative, participating eligible pharmacies and health care providers in the initiative will submit claims to original Medicare for over-the-counter COVID-19 tests provided to eligible beneficiaries whether they are enrolled in original Medicare or a Medicare Advantage plan.

Can a participating eligible pharmacy or health care provider bill a Medicare beneficiary for the difference between the Medicare payment amount and the retail price for the tests?

No. As a condition of receiving Medicare payment under the initiative, participating eligible pharmacies and health care providers agree not to charge beneficiaries anything for the tests that fall within the established per beneficiary per calendar month quantity limit of eight tests. However, if a beneficiary has exceeded that per calendar month quantity limit, participating eligible providers may then seek payment from the beneficiary for the customary retail charge for any additional over-the-counter COVID-19 tests.

What happens if a Medicare beneficiary would like more than the established quantity limit of eight over-the-counter tests per calendar month?

If a beneficiary exceeds the per calendar month quantity limit of eight tests, a claims processing edit will automatically deny claims that exceed the established limit and no Medicare payment will be provided. The participating eligible pharmacy or health care provider may seek reimbursement directly from the beneficiary in this circumstance. If beneficiaries are aware that they have exceeded the per calendar month quantity limit, a participating eligible pharmacy or health care provider does not need to wait to receive a claim denial to charge the beneficiary the customary retail charge for the over-the-counter COVID-19 test. If a Medicare beneficiary has other coverage, such as Medicaid, then the participating eligible pharmacy or health care provider can submit a claim to that issuer



if/when the Medicare claim is denied because the Medicare beneficiary has exceeded the monthly quantity limit.

Who is keeping track of whether a beneficiary has met or exceeded the per calendar quantity limit?

Once a participating eligible pharmacy or health care provider submits a claim to Medicare, a claims processing edit will automatically deny claims that exceed the per beneficiary per calendar month quantity limit of eight tests. Medicare will pay claims in the order in which they are submitted; participating eligible pharmacies and health care providers are encouraged to submit claims promptly. We are asking Medicare beneficiaries to also keep track of how many tests they have acquired within a calendar month because they will be financially responsible for any over-the-counter COVID-19 tests they obtain over the per-calendar-month quantity limit (unless they have additional health coverage). A participating eligible pharmacy or health care provider may also inquire if the beneficiary has reached their monthly quantity limit before providing tests.

Will CMS require Medicare Advantage plans to cover over-the-counter COVID-19 tests for Medicare Advantage enrollees?

No. Original Medicare will pay for over-the-counter COVID-19 tests covered under the initiative for all Medicare beneficiaries, including Medicare Advantage beneficiaries, for the duration of the COVID-19 PHE.

Where can pharmacies and health care providers find additional information about this initiative?

Pharmacies and health care providers who are looking for additional information should see: <u>https://www.cms.gov/COVIDOTCtestsProvider</u>