

e-Alert

01.19.22

Insurers and Health Plans Required to Cover OTC COVID-19 Tests

Background

From the early days of the COVID-19 pandemic, and until the related public health emergency ends, health plans and health insurance issuers have been required to cover the costs of COVID-19 tests, without imposing any cost-sharing requirements, prior authorization, or other medical management requirements.

Under guidance issued in June 2020, at-home COVID-19 diagnostic tests required an order by an attending physician who determined that the test was medically appropriate in order to be covered. The FDA at this time had not yet authorized any at-home COVID-19 diagnostic tests. Since then, the FDA has approved several OTC tests, and under the new guidance, a physician's order is no longer required for OTC tests to be covered.

Summary

On January 10, 2022, the Departments of Health and Human Services (HHS), Labor, and Treasury issued [FAQs](#) outlining new requirements for group health plans and health insurance issuers to cover over-the-counter (OTC) COVID-19 diagnostic tests. The new

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requirements apply to all group health plans (fully insured and self-funded). The new requirements go into effect for tests purchased on or after January 15, 2021.

The [FAQs](#) make it clear that the Departments want to ensure plans remove financial barriers that might otherwise prevent participants from accessing tests. Plans are encouraged but not required to provide direct coverage, where the plan pays the provider directly, eliminating the need for participants to pay for the tests and be reimbursed.

Plans are not permitted to limit coverage to tests purchased through network pharmacies or other in-network providers. Plans may be able to limit reimbursement levels to out-of-network providers if they meet the conditions of the safe harbor requirements outlined in the guidance.

Safe Harbor Requirements

The guidance provides a cost-management option for plans and issuers to create a “direct-to-consumer” program using its pharmacy network and a direct-to-consumer shipping program, which will allow the plan to limit the reimbursement they must pay for tests purchased from out-of-network providers.

Plans and issuers that comply with the safe harbor may limit the reimbursement of OTC COVID-19 tests purchased from out-of-network providers to the lesser of the actual price or \$12 per test. If the package contains more than one test, the plan or issuer must calculate the reimbursement based on the number of tests in a package.

Plans who elect to rely on the direct-to-consumer safe harbor must meet certain requirements, including:

- Participants cannot be required to pay for the tests and then seek reimbursement after purchase;
- Plans must ensure claims systems can process payments directly with no upfront out-of-pocket costs to the plan participants; and
- Taking reasonable steps to ensure that participants have adequate access to OTC COVID-19 tests, through an adequate number of retail locations (in-person and online).

If a plan or issuer is unable to ensure adequate access to OTC COVID-19 tests, such as if there are significant shipping delays, the plan cannot limit the amount it reimburses participants who choose to purchase tests elsewhere when access is limited.

Limit on Number or Frequency of Tests

No limits can be placed on traditional COVID-19 tests that are ordered by a health care provider. However, plans and issuers may limit the number of OTC COVID-1 tests covered for each participant, if the participant purchases the tests without a provider's order.

Plans may limit the number of covered tests to no less than 8 tests per 30-day period (or per calendar month) but must not limit tests to a smaller number over a shorter period of time. For example, it would be impermissible to limit a participant to four tests over a 15-day period.

Prevention of Fraud and Abuse

Plans and issuers may implement measures to prevent, detect, and address fraud and abuse as long as they do not create significant barriers to access. Examples of permissible activities include:

- Requiring an attestation that the OTC COVID-19 test was purchased by the participant for personal use, not for employment purposes, has not been (and will not be) reimbursed by another source, and is not for resale.
- Requiring reasonable documentation of proof of purchase with a claim for reimbursement, such as a receipt or a UPC code for the OTC COVID-19 test.

Educational Programs

The Departments recognize that participants may benefit from education and information resources to support them in accessing and using the OTC COVID-19 tests as intended. Plans may create educational programs on the effective use of the tests, so long as the materials make clear that the plan provides coverage for the tests as required. Educational materials may include:

- Guidance on how to access and effectively use the tests, information explaining the different types of tests and when they are appropriate;
- Quality information about specific OTC COVID-19 tests and information about reliability of their test results;

- Information on obtaining the tests directly from the plan, through designated lower-cost sellers, or through direct-to-consumer programs; and
- Instructions on claim filing options, information required to file a claim and documentation requirements.

Employer Next Steps

- Plan sponsors should check with their insurance carriers and third-party administrators to find out how they plan to meet these new coverage requirements.
- Be prepared for an evolving process to roll out in the upcoming days and weeks as these entities develop and launch their programs.
- Reach out to your Client Account Manager (CAM) with any questions.

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