

Plan Coverage of At-Home COVID-19 Testing

The Bottom Line

- Effective January 15, 2022, plan coverage of FDA-approved over-the-counter at-home COVID-19 diagnostic tests is mandatory.
- Plan sponsors should immediately contact their pharmacy benefit managers to set up mechanisms for direct coverage of at-home tests.
- If any questions remain, plan sponsors should contact their ERISA counsel regarding how to implement the necessary changes and provide notice of the changes.

The Departments of Labor, Health and Human Services and the Treasury issued joint guidance mandating plan coverage of FDA-approved over-the-counter at-home COVID-19 diagnostic tests beginning January 15, 2022. The joint guidance was issued on January 10, 2022 in the form of FAQs.

Background of At-Home Testing

Under the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), group health plans and issuers must cover approved COVID-19 diagnostic testing without any cost-sharing requirements, prior authorizations, or other medical management requirements.

When the FFCRA and CARES Act were enacted, COVID-19 diagnostic tests had to be administered by a healthcare provider. Nevertheless, when the Departments of Labor, Health and Human Services and the Treasury (collectively, the Departments) issued FAQs Part 43 in June 2020, they indicated that plans and issuers had to cover FDA-approved over-the-counter at-home COVID-19 tests (commonly called at-home COVID tests) "when the test is ordered by an attending healthcare provider who has determined that the test is medically appropriate for the individual."

Since June 2020, at-home COVID tests that can be self-administered and self-read have become widely available through pharmacies, retail stores and online retailers without the need for a healthcare provider. In recognition of the importance of testing to help reduce the spread of COVID-19, and the financial barriers to obtaining at-home COVID tests, on December 2, 2021, President Biden announced that the Departments would issue guidance no later than January 15, 2022 to allow individuals to seek reimbursement from their group health plan or issuer for at-home COVID tests. The FAQs provide this guidance.

Important Updates on At-Home Testing

The FAQs address the following key issues, among others:

Can a plan/issuer require an order or clinical assessment?

No. Plans and issuers must cover at-home COVID-19 tests even if those tests are obtained without a healthcare provider's involvement, unless the FDA approval requires this type of order or assessment.

Must plans/issuers cover tests for employment purposes?

No. The FAQs do not modify prior guidance providing that plans and issuers are not required to cover testing if they are for employment purposes (e.g., periodic or systematic testing to be admitted to a jobsite) rather than diagnostic purposes (e.g., because one was exposed to COVID-19 or has presented symptoms of COVID-19). As a practical matter, it may be difficult to determine whether the tests are being purchased for diagnostic or employment purposes, but the FAQs do allow plans/issuers to take certain steps to combat fraud and abuse, as described below.

Can a plan/issuer take action to address suspected fraud and abuse?

Yes. In order to combat fraud and abuse, a plan or issuer can require an attestation that the at-home COVID test is being purchased for personal use and not for employment purposes, will not otherwise be reimbursed, and is not for resale. Plans and issuers can also require reasonable proof of purchase with the claim for reimbursement, such as a receipt. However, plans and issuers cannot require extensive documentation or numerous steps in order to obtain a reimbursement.

When must coverage be provided?

Plans and issuers must begin covering at-home COVID tests no later than January 15, 2022 and must continue to cover the tests until the end of the COVID-19 public health emergency.

How will plans/issuers pay for the testing?

The FAQs permit plans and issuers to:

- 1. Reimburse participants, beneficiaries and enrollees for tests they purchase themselves, or
- 2. Pay their preferred pharmacy/retailer network directly for the tests (referred to as "direct coverage").

The FAQs strongly encourage plans and issuers to provide for direct coverage. As described below, providing direct coverage is critical in order for plans/issuers to impose limits on the cost of the tests.

Can a plan/issuer impose limits on the reimbursement amount?

If certain conditions are satisfied, the Departments will not take enforcement action against plans or issuers for imposing cost limits on the amount they will reimburse. Specifically, the reimbursement amount can be limited to the lesser of the actual cost or \$12 per test. However, in order to impose these cost limits, plans and issuers must arrange for direct coverage through both its pharmacy network and a direct-to-consumer shipping program.

Given the current scarcity of at-home tests, it may be difficult for these conditions to be satisfied so that the cost limits can be imposed. Nevertheless, plans should work with their pharmacy benefit managers to set up a direct coverage option that will allow the cost limits to be imposed.

Can a plan/issuer limit the number of tests that will be reimbursed?

The Departments will not take enforcement action if the plan or issuer limits the number of covered at-home tests to no less than eight tests per 30-day period (or per calendar month). This limit is for each participant, beneficiary or enrollee. This means, for example, that if an enrollee covers their spouse, the limit would be eight tests for each of the enrollee and spouse.

Shorter limits (such as four tests in a 15-day period) are prohibited. This limit is only for at-home COVID tests obtained without an order or clinical assessment and does not apply if the at-home COVID tests are administered with a healthcare provider's involvement or prescription.

When must plans/issuers notify participants of the change?

The Departments will not take enforcement action if the changes are implemented before satisfying applicable modification notice requirements, provided that notice of the change is provided as soon as reasonably practicable.

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