

COMPLIANCE ALERT

January 2022, Issue 1



Administration Releases Guidance on At-Home Testing Coverage Requirements

On January 10, the Administration released guidance clarifying the announced expanded coverage requirement for at-home COVID-19 tests. The expanded coverage requirement will apply to tests purchased on or after January 15, 2022.

Background

As a refresher, the Families First Coronavirus Response Act (“FFCRA”) requires group health plans and health insurance issuers to provide coverage for COVID-19 diagnostic testing without cost-sharing, prior authorization or other medical management.

Previous guidance has included at-home tests in the FFCRA coverage requirement, where the test is ordered by an attending health care provider who has determined that the test is medically appropriate.

New Guidance

This week’s guidance provides clarification and expansion of coverage for at-home, or OTC, tests. Under this new guidance, OTC tests must be covered without the involvement of a health care provider, an order or individualized clinical assessment, for those OTC tests for which the FDA does not require a health care provider’s order. This applies to those OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider purchased on or after January 15, 2022, and during the public health emergency.

These tests must be covered without imposing any cost-sharing requirements, prior authorization, or other medical management. The agencies interpret the requirement for no cost-sharing to require coverage without out-of-pocket expense to the participant for the cost of the test, subject to certain safe harbors (see below).

KEY DATES AND NUMBERS:

January 15, 2022:
**OTC Test Coverage
Requirement Applies to OTC
test purchases.**

8 Tests:
**Plans must cover a minimum
of 8 OTC tests per month
for each covered person.**

***New guidance requires
coverage for at-home
COVID-19 tests with no
cost sharing for tests
obtained without involving
a health care provider.***



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The guidance does not require a plan to provide coverage by reimbursing sellers of OTC COVID-19 tests directly - a plan or issuer may instead require a participant who purchases an OTC test to submit a claim for reimbursement to the plan. However, the agencies strongly encourage plans to provide direct coverage for OTC COVID-19 tests by reimbursing sellers directly without requiring participants to provide upfront payment and seek reimbursement.

Preferred Pharmacies or Retailers

Plans providing direct coverage may not limit direct coverage to only tests that are provided through preferred pharmacies or retailers. However, the Departments will not take enforcement action related to coverage of OTC tests against any plan that provides coverage of OTC tests purchased by participants during the public health emergency by arranging for direct coverage of OTC tests under the FFCRA through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limits reimbursement for OTC tests from nonpreferred pharmacies or other retailers to no less than the actual price, or \$12 per test (whichever is lower). Plans may elect to provide more generous reimbursement up to the actual price of the test.

Plans Must Cover a Minimum Number of OTC Tests

The guidance allows plans to limit the number or frequency of OTC COVID-19 tests covered without cost sharing under a plan. The Departments will not take enforcement action against any plan that, during the public health emergency, provides coverage without cost sharing for (and does not impose prior authorization or other medical management requirements on) such OTC tests, if the plan or issuer limits the number of OTC tests covered for each person covered under the plan to no less than 8 tests per 30-day period (or per calendar month). For a family of 4, this would be 32 tests per calendar month. Plans and issuers may set more generous limits.

This applies only with respect to the coverage of OTC tests that are administered without a provider's involvement; plans and issuers must continue to provide coverage for COVID-19 tests that are administered with a provider's involvement or prescription as required under the FFCRA.

COVID Testing Requirements

Families First Coronavirus Response Act

- Requires group health plans and health insurance issuers to provide coverage for COVID-19 diagnostic testing and related items and services
- Coverage must be without cost-sharing or prior authorization or other medical management requirements.
- Coverage requirement in effect from March 18, 2020 through the end of the declared public health emergency for the COVID-19 pandemic, which is currently ongoing.