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Mandated coverage of over-the-counter COVID-19 tests

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Authors
Richard Stover, FSA, MAAA
Randie Thompson, JD, LLM

The Departments of Labor, Health and Human Services, and the Treasury have issued guidance that requires group health plans to cover in full the cost of over-the-counter COVID-19 tests effective January 15.

Background

The Families First Coronavirus Response Act (FFCRA) included a requirement that group health plans cover COVID-19 diagnostic testing and related items and services without cost-sharing, prior authorization, or other medical management requirements. Subsequently the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), expanded the COVID-19 diagnostic testing mandate provisions. (See our July 1, 2020 *FYI*.) However, coverage of over-the-counter (OTC) COVID-19 tests intended for at-home use was limited to where the test was ordered by an attending health care provider who had determined that the test was medically appropriate for the individual.

With the expanded availability of OTC COVID-19 at-home tests since the passage of FFCRA and the CARES Act, last month President Biden directed the Departments of Health and Human Services, Labor and the Treasury (the departments) to issue guidance by January 15 that would require group health plans and issuers to cover in full the cost of OTC COVID-19 tests. The requirement that the OTC COVID-19 test be ordered by an attending provider would be eliminated.

Departments' FAQs

On January 10 the departments issued FAQs providing guidance on the coverage requirements for OTC COVID-19 tests. Generally, health plans must cover, without cost sharing, OTC COVID-19 tests. The FAQs provide the following guidance:

Q1. Under the FFCRA, are plans required to cover OTC COVID-19 tests without an order or individualized clinical assessment by a health care provider?

Yes. A health care provider does not need to be involved and "coverage must be provided without imposing any cost-sharing requirements, prior authorization or other medical management requirements." The prior requirement for coverage to involve an order of individualized clinical assessment from a health care provider no longer applies.

- While plans are encouraged to provide direct coverage of OTC COVID-19 tests by reimbursing sellers directly, direct coverage is not required. (See Q2, below, for cost incentives to provide a direct coverage program.)
- Importantly, the guidance continues the FFCRA provision that plans are not required to provide coverage of OTC COVID-19 testing for employment purposes, such as return-to-work programs. Instead, the coverage mandate only applies to OTC COVID-19 testing for individualized diagnostic or treatment purposes.

Q2. If a plan provides direct coverage of OTC COVID-19 tests, may it limit coverage to only tests that are provided through preferred pharmacies or other retailers?

No. However, under a direct coverage safe harbor included in the guidance, if a plan establishes a direct coverage program with preferred pharmacies or retailers with a direct-to-consumer shipping program, the plan can limit reimbursement of tests purchased outside of the direct coverage program to the lower of $12 per test or the test's actual price.

Under a direct coverage safe harbor program, the participant cannot have any out-of-pocket costs, and the plan must ensure that participants have adequate access to OTC COVID-19 tests (including both in person and online locations).

Q3. If a plan otherwise provides coverage without cost sharing for COVID-19 diagnostic tests, may a plan set limits on the number or frequency of OTC COVID-19 tests covered under the plan?

Yes. The quantity limit safe harbor allows a plan to limit the number of covered OTC COVID-19 tests to eight tests in any 30-day period (or calendar month). However, this limit does not apply to OTC COVID-19 tests administered with a provider's involvement or prescription.

- In applying the eight-test quantity limit to multi-test packages, each test may be counted separately.
- The eight-test quantity limit applies per covered individual — for example, a family of four would be eligible for coverage of up to 32 OTC COVID-19 tests per calendar month.

Q4. When providing coverage of OTC COVID-19 tests, are plans permitted to address fraud and abuse?

Yes. Plans "may act to prevent, detect and address fraud and abuse." The guidance provides examples of permissible activities.

- A plan could require an attestation that the OTC COVID-19 test was purchased for personal diagnostic or treatment purposes, not for employment purposes, is not for resale, and is not reimbursable by another source.
- Any fraud and abuse program must be reasonable and not unduly burdensome to the participant.

Q5. How can plans facilitate access to, effective use of, and prompt payment for OTC COVID-19 tests?

The guidance acknowledges the benefits of education and consumer support "to access and use OTC COVID-19 tests as intended." The guidance permits plans to provide education and consumer support as long as such resources make clear that the plan provides coverage for, including reimbursement of, all OTC COVID-19 tests that meet the statutory requirements of the FFCRA. The guidance provides examples of permitted resources.

Q6. When must plans begin providing coverage of OTC COVID-19 tests without cost sharing, prior authorization, or other medical management requirements for OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider?

The FAQs also include guidance regarding coverage of preventive services for colonoscopies and contraceptive services.

This requirement is effective January 15, although coverage for OTC COVID-19 tests purchased prior to January 15 may also be covered. The requirement continues through the end of the public health emergency.

In closing

With the January 15 effective date of this new guidance, plan sponsors will need to work quickly with their health plan or pharmacy benefit manager to implement a compliant approach for covering the cost of OTC COVID-19 tests.

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