Departments Clarify Guidance on Coverage of OTC COVID-19 Tests

February 2022

On February 4, 2022, the Departments of Labor, Treasury, and Health and Human Services (the Departments) issued further guidance (frequently asked questions (FAQs) Part 52) on the requirement that health plans offer first-dollar coverage of over-the-counter (OTC) COVID-19 tests without a prescription, individualized clinical assessment from a provider, prior authorization, or other medical management requirements.

This Aon bulletin discusses:

- Background on coverage of OTC COVID 19 tests, including the two safe harbors for implementing this coverage;
- Employer flexibility in designing direct coverage of the OTC COVID-19 tests for plan participants under the safe harbor;
- Compliance with the safe harbor when faced with a shortage of OTC COVID-19 tests;
- Issues of fraud and abuse in reimbursing OTC COVID-19 tests;
- Miscellaneous issues, including prohibitions against double-dipping; and
- What employers should do now.

Background on Coverage of OTC COVID-19 Tests

On January 10, 2022, the Departments issued FAQs Part 51, which require group health plans and issuers to provide first-dollar coverage of OTC COVID-19 tests starting January 15, 2022, and continuing through the end of the public health emergency period. Coverage of the OTC COVID-19 tests must be provided without:

- A prescription;
- An individualized clinical assessment from a health care provider;
- Cost-sharing;
- Prior authorization; or
- Other medical management requirements.

The Departments established two safe harbors for plans to use when covering OTC COVID-19 tests. The first safe harbor allows plans to cover OTC COVID-19 tests by arranging for direct coverage of OTC COVID-19 tests through both its pharmacy network and a direct-to-consumer shipping program,

while otherwise limiting reimbursement for OTC COVID-19 tests from non-preferred pharmacies or other retailers to at least the actual price or $12 per test (whichever is lower). The second safe harbor allows plans to limit the number of OTC COVID-19 tests for each participant (including spouses and dependents) to eight tests per 30-day period.

New FAQs Offer Plans Flexibility in Designing Direct Coverage Safe Harbor

In FAQs Part 52, the Departments offered plans some flexibility in establishing a direct-to-consumer shipping program and direct coverage through an in-person network, while still providing participants with "adequate access" to OTC COVID-19 tests. While "adequate access" will depend on the facts and circumstances, OTC COVID-19 tests generally must be made available through at least one direct-to-consumer shipping mechanism and at least one in-person mechanism.

Plans may provide "direct coverage" through multiple mechanisms, including:

- A "direct-to-consumer shipping" program that allows for orders to be placed online or by telephone;
- The plan's pharmacy network;
- Other non-pharmacy retailers (including through distribution of coupons for participants to receive tests from certain retailers without cost-sharing); and
- Alternative OTC COVID-19 test distribution sites (e.g., drive-through or walk-up sites), including sites that are independent from a pharmacy or other retailer.

Plans must ensure that participants receive clear communications regarding where to receive tests under the direct coverage option at no cost and which tests are available at the specified locations or other specified mechanisms (e.g., distribution sites).

A "direct-to-consumer shipping" mechanism is any program that does not require the individual to obtain the test at an in-person location. This can include an online order or a telephone order and may be provided by a pharmacy or other retailer or through the plan directly or by an entity on its behalf. The mechanism does not have to provide exclusive access through one entity, provided the test is shipped directly to the participant. A direct-to-consumer shipping program must cover reasonable shipping costs related to the tests in a manner consistent with other items or products provided by the plan via mail order. Presumably this means that if a plan generally covers shipping costs for other mail order coverage (e.g., prescription drugs), the plan also will need to cover shipping for OTC COVID-19 tests.

Plans must ensure that participants have access to OTC COVID-19 tests through an adequate number of locations, including pharmacies and other retailers or independent distribution sites set up by or for the plan. Whether or not there is adequate access will be determined based on all relevant facts and circumstances, such as the locality of participants under the plan, current utilization of the pharmacy network by plan participants when making coverage available through a pharmacy network, and how the plan notifies participants of retail locations, distribution sites, or other mechanisms for distributing the tests. Again, plans also need to communicate which tests are available under the direct coverage

program. The Departments may request information from plans to ensure that participants have adequate access to OTC COVID-19 tests, such as the number and location of in-person options.

A plan may meet the “adequate coverage” safe harbor even if the plan does not make all OTC COVID-19 tests available through its direct coverage program. For example, depending on the facts and circumstances, plans may be able to limit tests through its direct coverage program to a limited number of manufacturers, such as those with whom the plan has a contractual relationship.

Inadequate Access to OTC COVID-19 Tests Due to Short Supply

The Departments will not take enforcement action against employers who otherwise meet the direct coverage requirements but are unable to provide adequate access due to a temporary supply shortage of tests. In that case, plans may still impose the $12 limit per test (or the full cost of the test, whichever is lower) for OTC COVID-19 tests purchased outside of the direct coverage option.

Fraud and Abuse in Reimbursing OTC COVID-19 Tests

Employers are permitted to address suspected fraud and abuse related to tests purchased by participants from private individuals, via online auctions, resale marketplaces, or resellers. For example, the plan does not have to cover tests that occur online in person-to-person sales or resale or online markets. However, the plan must clearly communicate to participants which retailers will be covered by the plan and which resellers for which the participant will not receive reimbursement.

Miscellaneous Issues, Including Prohibitions Against Double-Dipping

OTC COVID-19 tests that use a self-collected sample but require processing by a laboratory or other health care provider to return results (such as home-collection polymerase chain reaction tests that can be purchased by consumers) are not covered by FAQs Part 51 and Part 52. However, these tests may be covered by the plan, in accordance with other guidance, at no cost when ordered by an attending health care provider and otherwise meeting the requirements of the Families First Coronavirus Response Act.

OTC COVID-19 tests are medical expenses and therefore generally are reimbursable by health flexible spending accounts (FSAs) and health reimbursement accounts (HRAs). However, participants cannot receive duplicative reimbursements from both the group health plan and/or a health FSA or HRA for an OTC COVID-19 test. A participant also is not permitted to seek a qualified reimbursement for the OTC COVID-19 test from a health savings account if the participant has been reimbursed from the group health plan or the plan has otherwise covered the test. In short, participants are not allowed to double-dip and obtain reimbursement or coverage from two different sources with respect to coverage or reimbursement of the COVID-19 OTC tests.

What Employers Should Do Now

Plan sponsors should continue to work with their pharmacy benefit managers, carriers, and third-party administrators to effectively administer plan coverage for OTC COVID-19 testing in accordance with FAQs 51 and 52. Additionally, plans should make sure that participant communications are clear

regarding how the plan will provide coverage for OTC COVID-19 tests to participants and any actions participants may need to take for direct coverage or reimbursement.

Resources

FAQs Part 52 can be found here.

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