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Guidance Issued Expanding Coverage for COVID-19 Testing

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On January 10, 2022, the Departments of Labor, Health and Human Services, and the Treasury (together, the "Departments") issued FAQ Part 51 requiring group health plans to cover, without cost-sharing, over-the-counter ("OTC") COVID-19 diagnostic tests obtained without the involvement of a health care provider. This provision is effective for OTC COVID-19 tests purchased on or after January 15, 2022, and continues for the duration of the Public Health Emergency (currently set to expire January 16, 2022 – however another 90-day extension is expected).

Briefly:

- Group health plans (and health insurance carriers) must cover diagnostic OTC COVID-19 tests obtained without the involvement of a health care provider without cost-sharing, prior authorization, or other medical management requirements.

- Plans can either reimburse members for their OTC COVID-19 test purchases after manually submitting a claim, or the plan may arrange to pay the merchant directly ("direct coverage") allowing plan members to receive the OTC COVID-19 tests with no cost sharing at the point-of-sale.

  - If the plan provides direct coverage, reimbursement for OTC COVID-19 tests purchased outside a preferred network may be limited to the lesser of $12/test or the actual cost of the test.
  - Plans that do not provide for direct coverage must reimburse the individual for the full cost of the test.

- Plans must cover 8 individual at-home OTC COVID-19 tests per person enrolled in the plan per month. That means a covered family of 4 can obtain 32 tests per month for free.

- Plans are not required to cover the cost of OTC COVID-19 tests for employment and surveillance purposes.

Frequently Asked Questions

Q: Are group health plans required to cover OTC COVID-19 tests without an order or individualized clinical assessment by a health care provider?

A: Yes. Beginning January 15, 2022, group health plans (and health insurance carriers) must cover diagnostic OTC COVID-19 tests obtained without the involvement of a health care provider without cost-sharing, prior authorization, or other medical management requirements.

Under the existing law, diagnostic OTC COVID-19 tests are covered without cost-sharing when an individual has an order or individualized clinical assessment from a health care provider. Such coverage remains in effect. The limits described in this article as they relate to OTC COVID-19 tests obtained without a health care provider (e.g., 8 tests/month, $12/test when direct coverage is an option) do not apply when an individual has an order or individualized clinical assessment from a health care provider.

Q: How is the coverage provided?

A: Plans and carriers may choose whether to provide "direct coverage" for OTC COVID-19 tests to participants by reimbursing sellers directly without requiring individuals to provide upfront payment or require participants to purchase the OTC COVID-19 test and then submit a claim for reimbursement from the plan.

The Departments strongly encourage plans and carriers to adopt a "direct coverage" approach.

Q: What is "direct coverage"?

A: Direct coverage for OTC COVID-19 tests means that a participant is not required to submit a claim to seek reimbursement from the plan for the purchase of the test. Instead, the plan makes systems and technology changes necessary to process the plan's payment to the preferred pharmacy or retailer directly (including direct-to-consumer shipping programs) with no upfront out-of-pocket expenditure.

A plan must take reasonable steps to ensure that participants have sufficient access to OTC COVID-19 tests, through an adequate number of retail locations (including both in-person and online). Whether there is adequate access should be determined based on all relevant facts and circumstances, such as the locality of participants under the plan and current utilization of the plan's pharmacy network. Plans should communicate with members to ensure that participants are aware of key information needed to access OTC COVID-19 tests, such as dates of availability of the direct coverage program and participating retailers or other locations.

If the plan is unable to meet the requirements of the direct coverage safe harbor, the plan must provide for the full reimbursement of OTC COVID-19 tests. This may occur, for example, when there are substantial delays for obtaining a COVID-19 test through a direct-to-consumer shipping program versus obtaining other items through this same program.

Q: Can the plan limit coverage only to OTC COVID-19 tests that are provided through preferred pharmacies or other retailers?

A: No. Generally, a plan or carrier may not limit coverage only to tests that are provided through preferred pharmacies and other retailers.

A plan that provides for direct coverage of OTC COVID-19 tests in accordance with the guidance may

limit reimbursement for OTC COVID-19 tests from non-preferred pharmacies and other retailers to the lesser of (1) the actual price, or (2) $12/test.

Example:

Plan provides direct coverage

If a plan has set up a network of preferred stores, pharmacies, and online retailers at which a participant can obtain a test with no out-of-pocket expense at the point-of-sale, the participant can still obtain tests from other retailers outside of that network. The plan may reimburse at a rate of up to $12 per individual test (or the cost of the test, if less than $12).

Plan does not provide direct coverage

If a plan has not set up a network of preferred stores, pharmacies, and online retailers at which a participant can obtain a test with no out-of-pocket expense at the point-of-sale, the participant will be reimbursed the full cost of the test. For example, the participant buys a two-pack of tests for $34, the plan would reimburse $34 (as opposed to $24 had the plan set up a network for individuals to obtain the test without an out-of-pocket expense).

Q: How many OTC COVID-19 tests must the plan provide without cost-sharing?

A: A plan or carrier may limit the number of OTC COVID-19 tests purchased by a participant without the involvement of a health care provider to no less than 8 tests per 30-day period (or per calendar month). For a covered family of 4, this means the plan must provide for up to 32 tests in a month.

Q: What is the effective date?

A: Plans and carriers are required to cover OTC COVID-19 tests purchased on or after January 15, 2022. Plans and carriers may, but are not required to, provide such coverage for OTC tests purchased before January 15, 2022.

The guidance confirms that the non-enforcement relief for mid-year changes to an SBC remains available with respect to this change.

Q: Are plans permitted to address suspected fraud or abuse?

A: Yes. Plans and carriers may take reasonable steps to prevent, detect, and address fraud and abuse.

For example, a plan may require:

- 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.

- Documentation of proof of purchase with a claim for reimbursement for the cost of an OTC COVID-19 test (e.g., the UPC code for the OTC COVID-19 test and/or a receipt from the seller of the test, documenting the date of purchase and the price of the OTC COVID-19 test).

Q: Are plans required to cover OTC COVID-19 tests that are for employment purposes?

A: No. Consistent with earlier guidance, plans are not required to provide coverage of testing (including an OTC COVID-19 test) that is for employment purposes.

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

A: Plans and carriers may provide education and information resources to support consumers seeking OTC COVID-19 testing, provided the resources make clear that the plan or carrier provides coverage for, including reimbursement of, all OTC COVID-19 tests under the guidance. This may include:

- information on the difference between OTC COVID-19 tests and other tests ordered by a provider or processed in a laboratory,
- quality and reliability information for specific testing products,
- how to obtain a test directly from the plan without cost-sharing (the direct coverage option, if applicable), and
- how to submit a claim (paper or electronically) and receive reimbursement directly from the plan.

Employer Action

Employers should:

- Discuss this expanded coverage with their carriers and TPAs, including whether the carrier or plan will provide for direct coverage of OTC COVID-19 tests.
- Consider notifying participants of the expanded coverage and how to obtain free OTC COVID-19 tests.