Agencies Issue Additional Guidance on OTC COVID-19 Tests

February 15, 2022

On February 4, 2022, federal agencies released additional FAQs related to coverage of over the counter ("OTC") COVID-19 tests by group health plans and health insurance carriers. The FAQs are intended to clarify the previous FAQs released on January 10, 2022.

Prior Guidance

On January 10, 2022, the agencies released initial guidance for plans and carriers, which required them to cover FDA approved at-home, OTC COVID-19 tests without cost sharing, prior authorization, or medical management, and without the need for a prescription or recommendation of a health care provider. These requirements apply during the COVID-19 public health emergency. Notably, plans and carriers are not required to cover OTC COVID-19 tests purchased or used for workplace testing/employment purposes.

Plans and carriers may reimburse participants for their purchase upon submission of a claim or by reimbursing the entity who sold the test directly. The guidance provided for two safe harbors, which permit plans and carriers to:

- limit reimbursement to the lower of the actual price or $12 per test if the plan arranges for direct-to-consumer coverage of OTC COVID-19 tests that meet the FFCRA criteria through **both** its pharmacy network (or another entity designated by the plan or carrier) **and** a direct-to-consumer shipping program; and
- limit coverage to no less than eight (8) tests per Individual for a 30-day or one month period.

In order to limit reimbursements for tests purchased from non-preferred providers, plans must ensure there are an adequate number of retail locations (in-person and online) with access to OTC COVID-19 tests and communicate necessary information about the direct coverage program, including when it is available and which retail pharmacies are available.

New Guidance

The guidance issued on February 4, 2022 (which is generally effective prospectively for purposes of the first 5 bullets below), helps clarify some of the requirements in the initial guidance, and provides the following:

- Plans and carriers have flexibility in how they provide access to OTC COVID-19 tests under the first safe harbor. As such, generally the safe harbor applies if the plan provides access to at least one direct-to-consumer shipping mechanism and at least one in-person mechanism. Direct coverage could include the following (and the methods used by the plan must be communicated to participants):
  - Direct-to-consumer shipping that allows orders to be placed by phone or online;
  - directly through the plan's or carrier's pharmacy network retailer;

  - other non-pharmacy network retailers (including through distribution of coupons to receive tests from certain retailers without cost-sharing); and
  - alternative OTC COVID-19 test distribution sites such as a standalone drive-through or walk-up distribution site (even if the site operates independently of a pharmacy or retailer).

- Whether access to OTC COVID-19 tests is adequate is still determined based on all relevant facts and circumstances, including locality, which tests are covered, utilization, and communication of where tests can be purchased.
- Not all OTC COVID-19 tests are required to be covered by the direct coverage program. Depending on the facts and circumstances, plans can limit the number of test manufacturers, such as those with whom the plan has contracted.
- Reasonable shipping costs for direct-to-consumer shipping must be covered by the plan.
- Plans won't be penalized for supply chain shortages. Where there is a shortage of tests, the plan may still be able to limit reimbursement to the lower of $12 or the cost of the test for tests purchased outside the direct coverage program if all other requirements under the safe harbor are met.
- Reimbursement is intended for tests that can be read by participants at home, not those that are intended to be read by a laboratory or health care provider. Tests that are not approved to be self-administered and self-read are not covered by this guidance; however, they may still be required to be covered by the plan if they are FDA approved and ordered by a health care provider.
- Plans can curtail fraud and abuse by limiting coverage of OTC COVID-19 tests that are purchased without involvement of a health care provider to those purchased from established retailers that would typically be expected to sell OTC COVID-19 tests. This means, they could prohibit reimbursement of tests purchased from private individuals (in person or online) or from a seller that uses an online auction or resale marketplace. Further, the plan could require reasonable documentation of proof of purchase that clearly identifies the product and seller, such as a UPC code or other serial number, original receipt from the seller of the test. It is important for plans and carriers to communicate these limitations to participants, and that they do not utilize onerous processes or processes that result in delaying coverage of or access to OTC COVID-19 tests.
- Finally, while coverage of OTC COVID-19 expense is a Section 213(d) medical expense which can be reimbursed under an HSA, health FSA or HRA, participants cannot be reimbursed more than once for the same medical expense. Therefore, the cost (or the portion of the cost) of OTC COVID-19 tests paid or reimbursed by a plan cannot also be reimbursed by an HSA, health FSA or HRA. Plans are encouraged to communicate this to participants and to discourage them from using a health FSA or HRA debit card when purchasing the OTC COVID-19 test if they will be seeking reimbursement from the health plan.

Plans and carriers can use this additional guidance to tailor their OTC COVID-19 test coverage, and employers are encouraged to work directly with their carriers and TPAs to ensure they are adequately communicating their OTC COVID-19 testing coverage requirements to participants.

Dickerson Insurance Services
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About the Author. This alert was prepared for Alera Group by Barrow Weatherhead Lent LLP, a national law firm with recognized experts on the Affordable Care Act. Contact Stacy Barrow or Nicole Quinn-Gato at sbarrow@marbarlaw.com or nquinngato@marbarlaw.com.

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