Proskauer

You Can Go Home Again: Tri-Agencies Release New Group Health Plan Coverage Requirements for Over-the-Counter At-Home COVID-19 Tests

Employee Benefits & Executive Compensation Blog on **January 11, 2022**

Looking forward to the weekend? Many employers and plan administrators may also have been . . . up until yesterday, when the government issued new requirements that take effect on Saturday. Specifically, starting this Saturday, January 15, 2022—yes, that's four short days from now—and through the end of the public health emergency, group health plans and issuers are required to cover over-the-counter (OTC) at-home COVID-19 tests without participant cost-sharing, preauthorization, or medical management, even if no health care provider was involved in ordering the test.

How Did We Get Here?

By way of background, almost two years ago, pursuant to the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), group health plans and issuers were required to cover "FDA-approved" COVID-19 testing without participant cost-sharing, preauthorization, or medical management. Until relatively recently, FDA-approved COVID-19 testing required the involvement of a health care provider. Once FDA-approved at-home COVID-19 tests that could be self-administered and self-read became widely available, it was unclear whether these tests were subject to the same coverage requirements that applied to COVID-19 testing involving a health care provider.

In response to a directive issued by the White House on December 2, 2021 to "clarify" the treatment of such at-home COVID-19 tests, the Departments of Labor, Treasury, and HHS released a set of "FAQs" on January 10, 2022, confirming that group health plans and issuers must provide coverage of OTC at-home COVID-19 tests without participant cost-sharing, preauthorization, or medical management. This marks a significant expansion of the prior guidance on COVID-19 testing,[1] which mandated coverage of at-home COVID-19 tests only when required as a result of an individualized assessment or a test order from a health care provider.

What is the Scope of the Coverage Mandate for OTC At-Home COVID-19 Tests?

Group health plans and issuers will now be required to cover FDA-approved OTC at-home COVID-19 tests, regardless of whether a health care provider ordered the test or examined the individual to determine the need for a test (unless the FDA approval for the test requires the provider to have done so). This coverage must be provided without participant cost sharing, preauthorization or medical management.

In the FAQs, the Departments affirmed that the new requirements do not impact prior guidance mandating coverage of COVID-19 testing ordered by an attending health care provider. The Departments also confirmed that the new requirements do not alter prior guidance stating that employment-based COVID-19 testing (*i.e.*, surveillance testing) is not required to be covered by group health plans and issuers.

How Is the Payment Made by the Plan or Issuer?

Group health plans and issuers can choose whether to pay sellers of COVID-19 tests directly (what the agencies call "direct coverage") or require the covered individual to pay for it at the point of sale and then submit a reimbursement request to the plan or issuer. The guidance strongly encourages direct coverage of OTC at-home COVID-19 testing.

Does the Guidance Require Unlimited Coverage of OTC At-Home COVID-19 Tests?

In a word, almost. Coverage may not be limited to preferred pharmacies or retailers and must be provided without participant cost-sharing or medical management.

However, the guidance outlines a limited non-enforcement policy whereby plans and issuers may, under certain circumstances limit (1) the amount paid for at-home COVID-19 tests obtained from non-network pharmacies and retailers, but only if certain safe harbor requirements are met, and (2) the number of tests eligible for reimbursement in a 30-day period. These exceptions are described in more detail below.

In addition, although applying medical management techniques to at-home COVID-19 tests is prohibited, plans and issuers may take steps to prevent, detect, and address fraud and abuse. Examples of permissible actions include requiring participant attestations that tests were purchased for personal use and not for employment-based or resale purposes, and, requiring documentation of a proof of purchase for tests showing the purchase price and date.

Proskauer observation: While the guidance is explicit that these steps cannot be overly burdensome, even an attestation can be somewhat useful (albeit hardly perfect) in mitigating the risk of fraud and abuse.

Can Plans and Issuers Limit the Amount They Reimburse Non-Network/Non-Preferred Pharmacies and Retailers for OTC At-Home COVID-19 Tests?

Generally, no, but the guidance includes a limited non-enforcement policy whereby a plan or issuer that meets certain requirements may limit the amount of reimbursement for tests from non-network pharmacies or retailers to the *lesser of* (1) the actual price of the test, or (2) $12.

This safe harbor may be used only if the plan or issuer makes direct coverage of at-home tests available through its pharmacy network and a direct-to-consumer shipping program at no cost to participants. Moreover, to use this safe harbor, access to an adequate number of tests must be available through direct coverage, based on a facts and circumstances analysis. If there are not adequate tests through direct coverage, the plan or issuer would need to meet the normal requirements and could not set limits on the reimbursement amount for tests obtained from non-network pharmacies or retailers.

Proskauer observation: This safe harbor is an important limitation that helps address the risk of unscrupulous retailers significantly raising prices in order to take advantage of payors. However, the scope and utility of this safe harbor is somewhat unclear in times like the present where there is a shortage of OTC tests. In any case, plans sponsors will want to contact their pharmacy benefit managers or other networks in short order to determine whether they have a direct coverage solution that will satisfy the safe harbor requirements and allow the plan to impose a dollar limitation on out-of-network costs.

Can Plans and Issuers Set Limits on the Number of OTC At-Home COVID-19 Tests Eligible for Reimbursement?

Yes. The guidance provides a limited non-enforcement policy under which a plan or issuer may limit the frequency of at-home COVID-19 tests to 8 tests per 30-day period (or calendar month). This limit is applied on a per-participant or per-beneficiary basis, and cannot be limited to a smaller number of tests over a shorter period (*e.g.*, 4 tests in a 15-day period).

Proskauer observation: While the limitation should still be sufficiently generous to provide coverage where necessary, it is welcome in that it helps limit fraud and abuse, as well as the potential for hoarding, which limits test availability.

Can Plans and Issuers Educate Participants on OTC Testing?

Yes, as long as the educational and informational resources provided by the plan or issuer are consistent with the FDA's authorization for the tests and make clear that OTC testing coverage is provided as required. The information could include an explanation of the differences between OTC tests and those performed/ordered by a provider and/or processed in a lab, quality information for specific tests (*e.g.*, shelf life, expected test performance, etc.), how to obtain tests directly from the plan or network providers and how to submit a claim for reimbursement.

Proskauer observation: Plans and issuers may wish to consider taking the Departments up on this suggestion, as it may make it more likely that OTC testing is used effectively and does not result in duplicative or excess costs.

[1] See Part 43 (https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf) and Part 44 (https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf) of the Affordable Care Act Implementation Frequently Asked Questions, and, in particular, Q4 of Part 43.

View Original

Related Professionals

- **Jennifer Rigterink**
  Senior Counsel
- **Robert M. Projansky**
  Partner