January 2022

COVID-19 Over-the-Counter Testing FAQs

Employer FAQs: COVID-19 OTC Testing

Introduction

On January 10, 2022, the Departments of Labor, Health and Human Services (HHS), and the Treasury issued Frequently Asked Questions Part 51 (FAQ Part 51) that requires group health plans and insurers to generally cover over-the-counter (OTC) COVID-19 tests at no-cost and without a prescription as part of the Families First Coronavirus Response Act (FFCRA). As a reminder, the FFCRA requires group health plans and health insurance issuers (including grandfathered plans) to cover certain COVID testing beginning March 18, 2020 and lasting through the end of the COVID-19 Public Health Emergency. FAQ Part 51 builds upon existing guidance in light of the Food and Drug Administration's (FDA) authorization of at-home tests.

Q1. Is the Occupational Safety and Health Association Emergency Temporary Standard (OSHA ETS) that requires large employers with 100+ employees to implement a "vaccine or test" policy currently in effect?

A. No, the United States Supreme Court halted enforcement of this rule pending the outcome of litigation in the Sixth Circuit. For now, employers do not need to comply with the OSHA ETS.

Q2. Do state or local mandates on testing or vaccines still apply?

A. Yes, regardless of the OSHA ETS, states or municipalities may have their own testing and vaccine requirements. Employers should continue to work with employment law counsel to ensure compliance with these rules. This is especially important for employers with operations in multiple jurisdictions.

Q3. What type of plans are required to comply with covering OTC test without cost sharing?

A. The requirement applies to all group health plans (i.e., self-insured and fully insured plans), including grandfathered plans.

Q4. What type of OTC tests must be covered?

A. A plan must cover all over-the-counter (OTC) COVID-19 tests authorized or otherwise approved by the FDA.

Q5. What is the effective date for coverage of OTC tests?

A. Plans must comply with the rule starting January 15, 2022 through the end of the Public Health Emergency.

Q6. How many OTC tests are required per participant?

A. The guidance requires plans to cover up to eight OTC tests per month (or per 30 days) per participant. For example, a family of four covered under the plan could have up to 32 OTC tests covered per month.

Q7. How should plans reimburse participants for OTC tests?

A. A carrier or third party administrator (TPA) can provide coverage directly through the plan (i.e., by reimbursing sellers of OTC COVID-19 tests directly and setting up "in-network" vendors) or by reimbursing participants. However, the guidance strongly encourages plans to offer direct coverage as opposed to reimbursement.

Q8. Can plans limit the cost reimbursed for the OTC tests?

A. The amount that must be reimbursed depends on whether the plan provides direct coverage (and meets the applicable safe harbor) or participant reimbursement. When a plan directly covers the tests and meets the safe harbor, plans must reimburse participants up to $12 per "out-of--network" test; participants pay no cost for tests obtained "in-network." If there is no established network or the plan cannot satisfy the safe harbor, the plan must reimburse participants for the full cost of the OTC test.

Q9. What are the safe harbor conditions that a plan providing direct coverage must meet in order to limit out-of-network OTC tests to $12 per test?

A. The plan must meet all of the following conditions to satisfy the safe harbor.

1) The plan must provide coverage of 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 (through one or more in-network provider(s) or another designated entity).

2) The reimbursement limit from non-preferred pharmacies or other retailers is not less than the lower of the actual price or $12 per test; however, plans can voluntarily reimburse up to the actual price of the test.

3) The plan needs to take reasonable steps to ensure that participants and beneficiaries have adequate access to OTC COVID-19 tests available through a sufficient number of retail locations (including both online and brick and mortar stores). Whether or not access is adequate is determined based on all the relevant facts and circumstances such as the locality of participants and beneficiaries, current utilization of the plan's pharmacy network, etc.

4) Participants and beneficiaries are aware of key information needed to access OTC COVID-19 testing, such as dates of availability of the direct coverage program and participating retailers.

Q10. Can a plan require a provider's recommendation or a prescription before OTC tests will be covered?

A. No, plans may not require any individualized clinical assessment, prior authorization, or impose other medical management rules.

Q11. Can a plan require cost sharing for OTC tests?

A. No, covers OTC tests cannot be subject to cost sharing (i.e., deductibles, copayments, coinsurance).

Q12. What about testing for employment purposes (e.g., to make sure an employee does not have COVID before entering the workplace)?

A. The guidance does not require coverage of OTC tests for employment based purposes. However, there is likely to be some difficulty in verifying whether a test is being done for a medical purpose versus an employment purpose. Employers with mandatory COVID testing policies may want to consult with legal counsel on this point.

Q13. What documentation can a plan require before it reimburses the cost of an OTC test?

A. Plans may impose reasonable documentation requirements to prevent fraudulent claims. Carriers/TPAs/PBMs will likely establish procedures in this regard, which may include completion of an attestation from the participant that the test is for medical purposes (and not for employment purposes), proof of purchase (e.g., receipt), and that the test purchased is one authorized by the FDA .

Q14. What if a provider orders a test?

A. The OTC guidance and testing limit does not apply; there is no limit on tests ordered by a physician. Any such test ordered by a physician must also be covered without cost sharing.

Q15. How should we notify participants about the new rule?

A. Plans should provide participant and beneficiaries with information on how to obtain OTC tests at no cost directly from the plan and/or how to submit a claim for reimbursement. Notices will vary from plan to plan based on how tests are provided or reimbursed.

Q16. How does a plan reimburse OTC tests when purchased in multiples (e.g., testing kits with 2 or more tests per package)?

A. The rule provides a "per test" reimbursement standard, regardless of how a product is packaged. So if a plan provides direct coverage and a participant purchases a testing kit containing 2 tests outside of the network, then the participant would be required to be reimbursed the lower of either $24 or the cost of the testing kit.

Q17. What if a family member is not covered under the group health plan?

A. A plan is not required to cover OTC tests for a non-covered family member.

Q18. What about OTC tests that were purchased before the effective date?

A. A plan is not required to cover OTC tests purchased before the effective date; however, an employee may be able to use an FSA or HSA to reimburse these expenses.

Q19. Should OTC tests be covered under a plan's medical coverage or as part of the pharmacy benefit?

A. Either one. The mandate applies to group health plans and both the pharmacy benefit and major medical plan are part of the group health plan. Importantly, to limit reimbursements amounts to $12 per test the group health plan must meet a safe harbor standard that includes both a direct pay option (the participant does not pay and is then reimbursed but rather the plan pays the seller directly) and a direct

to consumer shipping option (mail order). Plan sponsors should assess which carrier/TPA or pharmacy partner is best able to meet the terms of the safe harbor where pharmacy benefits are administered separately from major medical.

Q20. Does the rule requiring coverage of OTC tests impact HSA eligibility?

A. No, the coverage is treated as preventive care and is permitted coverage that can be provided before the deductible is satisfied.

Q21. Can a plan negotiate an in-network cost that is less than $12 per test?

A. Yes, a plan may be able to negotiate a lower per test cost. However, for tests obtained outside of the network (and when the safe harbor is satisfied), the rule requires reimbursement of the actual cost or $12, whichever is lower.

Q22. Is there a maximum reimbursement amount?

A. It is critically important for plans to try to meet safe harbor requirements. Under the safe harbor, plans can limit reimbursement to $12 per test. Plans that are unable to meet the safe harbor criteria should still work to establish a negotiated rate for reimbursement of OTC tests and adequate access to OTC tests. Plans that fall outside the safe harbor can be protected from paying high prices for OTC tests if they have a direct reimbursement arrangement and negotiated rate with providers under the CARES Act. However, a plan that is unable to meet the requirements of this safe harbor could not deny coverage or impose cost sharing (including setting limits on the amount of reimbursement) with respect to any OTC tests, obtained by participants that meet the statutory criteria under the FFCRA during this period, including those purchased from non-preferred sellers.

Q23. What are next steps for employers?

A. Employers should consult with carriers, TPAs and/or PBMs about how coverage for OTC tests will be administered and paid. Employers should continue to work with employment law counsel on any testing and vaccine requirements that may be imposed by state or local agencies or as part of the employer's employment policies.

Q24. Can at home or OTC tests still be reimbursed by a HRA, H-FSA, or HSA?

A. Yes, but this will be of limited applicability now that group health plans are required to cover most OTC tests. Reimbursement from an account based plan may be appropriate if an individual is not covered by a group health plan or would like to use an OTC test for a non-covered purpose.