

AHIP COVID-19: OTC Testing Coverage

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Biden Administration Updates Guidance Regarding Health Insurance Provider Coverage of OTC COVID-19 Tests

Feb. 4: Tri-Agencies release updated [guidance](#) on requirement for plans to cover OTC COVID-19 tests

Types of Tests That Must be Covered

Tests must be authorized by FDA to be self-administered **and** self-read tests without the involvement of a health care provider. Tests that go to a lab for processing (such as a test where a consumer collects a specimen at home and sends the specimen to be processed in a laboratory) are outside the scope of this policy.

Permissible Activities to Prevent Fraud and Abuse

Plans may act to prevent, detect, and address fraud and abuse.

Limited retailers. New guidance states plans can restrict coverage to established retailers that would typically be expected to sell OTC COVID-19 tests (e.g., reimbursement may be denied for tests purchased from an individual, on-line auction, or resale marketplace)

- Note: plan must ensure enrollees are clear on what types of retail sites are generally covered and not covered.)

Requiring documentation. As previously conveyed, plan can require members to submit “reasonable documentation” including proof of the product and seller, and/or attestation stating reimbursement has not been received from another source including resale.

- Note: process may not unduly burden or discourage enrollees from participation.

OTC COVID Tests: Safe Harbor Updates

In Jan. 2022 guidance, Tri-Agencies created a non-enforcement “safe harbor” where plans can limit the amount reimbursed for OTC COVID-19 tests from non-network retailers to the lesser of \$12 per test or the actual test cost.

To meet safe harbor, plan must provide **direct coverage** by ensuring adequate access to OTC COVID-19 tests with no upfront out-of-pocket expenditures.



Providing “direct coverage” generally requires plans to make tests available **through at least one DTC shipping program and one in-person mechanism (e.g., pharmacy network)**

Agencies will “not take enforcement action” for plans that arrange for direct coverage of OTC COVID-19 tests “through both its pharmacy network and a [DTC] shipping program and otherwise limits reimbursement for OTC COVID-19 tests from non-preferred pharmacies or other retailers” to the lesser of \$12 or the actual price

OTC Test Coverage: Safe Harbor Updates Tests

Non-exhaustive list of examples on how plans can provide “direct coverage” under safe harbor

Pharmacy network

Alternative test distribution sites established by, or on behalf of, plan

Non-pharmacy retailers

DTC shipping program

Allows for orders to be placed online or by telephone (e.g., allows member to obtain test without having to go to in-person location)

Can be supplied by plan directly, through pharmacy/other retailer, or by another entity on plan’s behalf

Plans that use a DTC program must cover reasonable shipping costs related to covered OTC tests in “manner consistent with other items or products provided by the plan or issuer via mail order.”

Additional guidance on safe harbor

- Plans have flexibility in how they provide access to OTC COVID-19 tests
- Depending on facts and circumstances, may be able to limit direct coverage program to tests from a limited number of manufacturers (eg, those with which the plan has a contract with)
- Tri agencies will not take “enforcement action” if plan is temporarily unable to provide adequate access through direct coverage program due **to a supply shortage**. Plan **may continue to limit reimbursement to \$12** for OTC tests purchased **outside** of the direct coverage program.

Biden Administration Will Cover Free OTC COVID-19 Tests Through Medicare

- CMS announced on Feb. 3 that “[s]tarting in early spring,” it will begin covering OTC COVID-19 tests for Medicare beneficiaries through eligible pharmacies and other entities that are participating in this initiative. Guidance provides that MA plans may cover OTC tests as a supplemental benefit. CMS issued an [FAQ](#) document, however details are forthcoming.

High-priced out-of-network COVID-19 tests (diagnostic, antigen, and antibody)

