From: <u>DMHC Licensing eFiling</u>

Subject: APL 22-005 – Federal Requirement to Cover At-Home COVID-19 Tests

Purchased Over-the-Counter

Date: Tuesday, January 25, 2022, 2:40 PM

Attachments: APL 22-005 – Federal Requirement to Cover At-Home COVID-19

Tests Purchased Over-the-Counter (1.25.22).pdf

Dear Health Plan Representative:

Please find attached All Plan Letter (APL) 22-005, regarding how to implement the requirements to cover OTC COVID-19 tests as well as how those requirements interact with the requirements of recently effective Senate Bill 510.

Thank you.



Gavin Newsom, Governor State of California Health and Human Services Agency DEPARTMENT OF MANAGED HEALTH CARE 980 9th Street, Suite 500 Sacramento, CA 95814 Phone: 916-324-8176 | Fax: 916-255-5241

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ALL PLAN LETTER

DATE: January 25, 2022

TO: All Full-Service Commercial Health Care Service Plans

FROM: Sarah Ream

Chief Counsel, DMHC

SUBJECT: APL 22-005 – Federal Requirement to Cover At-Home COVID-19 Tests

Purchased Over-the-Counter

On January 10, 2022, the federal Departments of Labor, Health and Human Services, and the Treasury issued guidance regarding commercial health plan coverage of athome, over-the-counter COVID-19 tests (OTC COVID-19 tests) authorized by the U.S. Food and Drug Administration. The federal guidance can be found on the <u>FAQ's Information sheet regarding implementation of the FFCRA, CARES Act, and the Affordable Care Act</u>.

The DMHC anticipates health plans will have questions regarding how to implement the requirements to cover OTC COVID-19 tests as well as how those requirements interact with the requirements of recently effective Senate Bill 510.

As soon as possible, health plans should submit their questions to Amanda Levy, the DMHC's Deputy Director of Health Policy and Stakeholder Relations, so the DMHC can address those questions in forthcoming guidance.²

The remainder of this APL summarizes the federal guidance.

I. Commercial health plans must cover at least eight OTC COVID-19 tests per month for each enrollee who wants such tests.

Beginning January 15, 2022, health plans must cover at least to eight (8) OTC COVID-19 tests per enrollee per month. Health plans can arrange with a network of distributors (e.g., pharmacies and retailers) to provide direct coverage of the tests, in which case

¹ CMS's guidance does not apply to Medicare Advantage or Medi-Cal health plan products.

² Ms. Levy's email address is Amanda.Levy@dmhc.ca.gov.

enrollees would be able to obtain the tests from an in-network source without paying out-of-pocket and then seeking reimbursement from the plan. The federal guidance refers to this model as "direct coverage."

Alternatively, enrollees may purchase the tests themselves and seek reimbursement up to the amount allowed by the federal guidance. As discussed below, the amount a plan must reimburse an enrollee who purchases an OTC COVID-19 test depends on whether the plan is using a direct coverage model and has a sufficient network of distributors to provide tests to the plan's enrollees.

Plans may not impose any prior authorization or cost-sharing requirements as a prerequisite for an enrollee obtaining OTC COVID-19 tests as allowed by CMS's guidance. Likewise, an enrollee does not need to first have an order or individualized clinical assessment from a provider to obtain coverage for OTC COVID-19 tests.

II. Reimbursement for OTC COVID-19 tests

The amount a health plan must reimburse an enrollee for the purchase of an OTC COVID-19 test depends on whether the plan uses the direct coverage model and has an adequate network of retailers to provide tests to enrollees at no up-front cost to enrollees.

A. Direct coverage with an adequate network v. reimbursement model

If the health plan does not use the direct coverage model, enrollees can obtain their OTC COVID-19 tests from any authorized retailer. Enrollees then submit claims for reimbursement to the plan and the plan must reimburse the enrollees for the full amount the enrollees spent for the tests.

If a plan uses the direct coverage model, the expectation is that an enrollee will typically obtain OTC COVID-19 tests from retailers in the plan's direct coverage network. In that case, the enrollee will not pay anything out-of-pocket for the test. However, the enrollee also has the option to purchase OTC COVID-19 tests out of network. In that case, the plan must reimburse the enrollee for the *lesser* of: (1) the actual cost of the tests; or (2) \$12/test.

If a plan uses the direct coverage model *but does not have an adequate network of retailers*, the plan must reimburse enrollees for the actual cost of at least eight OTC COVID-19 tests per month for which the enrollees seek reimbursement. The plan's reimbursement to the enrollee is not capped at \$12/test. Instead, the plan must reimburse the enrollee for the full amount the enrollee spent out-of-pocket.

B. What constitutes an "adequate" network for the direct coverage model?

The federal guidance requires plans to take "reasonable steps" to ensure enrollee have "adequate access" to OTC COVID-19 tests by having an adequate number of retail locations, including both in-person and online locations. Adequate access is determined based on "all relevant facts and circumstances, such as the locality of…enrollees under the plan or coverage and current utilization of the plan's or issuer's pharmacy network

by its...enrollees." A network may be inadequate if enrollees seeking tests are subject to delays that are "significantly longer than the amount of time it takes to receive other items under the plan's or issuer's direct-to-consumer shipping program."

C. Timing and requirements for reimbursing enrollees who purchase OTC COVID-19 tests

The federal guidance does not set a time frame in which plans must reimburse enrollees for OTC COVID-19 tests the enrollees purchase, other than to say the plans should follow their "internal claims procedures, consistent with applicable federal and state law." Accordingly, if an enrollee purchases an OTC COVID-19 test pursuant to the federal guidance and seeks reimbursement from the plan, the plan must reimburse the enrollee within the time frames set forth in Health and Safety Code section 1371.

Specifically, if the enrollee is in an HMO product, the plan must reimburse the enrollee within 45 working days of the plan's receipt of the claim. For all other enrollees, the plan must reimburse the enrollee within 30 working days of receipt of the claim.

The federal guidance and state law allow a plan to require reasonable evidence of payer liability before the plan must pay a claim. The federal guidance suggests plans may request "reasonable documentation of proof of purchase," including a Universal Product Code or "UPC Code" for the tests the enrollee purchased or a receipt for the purchase. However, the federal guidance prohibits plans from requiring enrollees to submit multiple documents or take numerous steps to obtain reimbursement.

III. Plans must continue to cover COVID-19 tests in addition to OTC COVID-19 tests enrollees obtain on their own

The federal guidance expressly states that "health plans must continue to provide coverage for COVID-19 tests that are administered with a provider's involvement or prescription." Accordingly, the requirement that plans cover at least eight OTC COVID-19 tests per month does not relieve health plans from covering additional or other COVID-19 tests an enrollee may need.

Likewise, health plans must continue to cover COVID-19 tests as required by Senate Bill 510, including tests for "diagnostic or screening purposes" as defined by that bill.

As stated above, if your health plan has questions regarding the requirement to cover OTC COVID tests, please direct those questions to Amanda Levy, the DMHC's Deputy Director of Health Policy and Stakeholder Relations, at Amanda.Levy@dmhc.ca.gov.