

State of California—Health and Human Services Agency California Department of Public Health



February 8, 2023

TO:

Pharmacy and Pharmacy Staff

SUBJECT:

Resource Guide for Pharmacies to Prevent Delayed COVID-19 Treatment



Lagevrio (molnupiravir) and Paxlovid (nirmatrelvir/ritonavir) are oral antiviral drugs that are highly effective for preventing hospitalization and death in patients with mild to moderate COVID-19 infection who are at risk for severe disease. Multiple factors are involved to ensure timely administration of oral antivirals, including adequate drug supply and distribution, acceptance of the therapy by health care providers and the public, and patient access to testing, prescriptions, and drug dispensing sites.

The California Department of Public Health (CDPH) has been made aware of occasions where pharmacists have turned away patient prescriptions for COVID-19 oral antiviral therapy due to misinformation or a lack of information. This document provides recommendations to clarify what information is necessary to dispense these therapeutics.

In all situations, clinical concerns about inappropriate prescriptions or inappropriate dosing should be weighed against the clinical consequences of delaying or denying treatment that prevents severe illness from COVID-19, which has caused <u>98,800 deaths</u> in California as of January 17, 2023. There is also early and increasing evidence that COVID-19 treatment can decrease the risk of developing long COVID symptoms.



This information is intended to aid pharmacies serving as dispensing sites for these critical medications. For more information on COVID-19 therapeutics and California's efforts to increase accessibility, including information on the Test-to-Treat programs, please see the CDPH Test-to-Treat-Playbook.

As we continue to see periodic surges of COVID-19 cases it is important to remain up-to-date on latest clinical guidance to ensure patients receive appropriate and timely access to highly effective COVID-19 treatment. Pharmacies and pharmacists should be aware they may see a rise in prescriptions for COVID-19 medications for a number of reasons including:

- CDPH issued a press release in December 2022 to highlight ongoing underutilization of COVID-19 treatment despite ample supply since Spring 2022: COVID-19 Treatments are Free and Widely Available, but Underutilized (ca.gov).
- CDPH issued a Health Advisory to clinicians in December 2022 to encourage healthcare providers to lower barriers to prescribing COVID-19 therapeutics: <u>Reminder</u> to Lower Barriers to Prescribing COVID-19 Therapeutics to Mitigate the Impact of COVID-19.
- Between December 2022 and January 2023, CDPH released a robust media campaign via TV, radio, and social media to promote the use of COVID-19 oral antiviral therapeutics. Find shareable content in the COVID-19 Treatments page.

While treatments are an important tool in the fight against COVID-19, vaccines are a critical aspect of addressing this pandemic. Vaccines train the immune system to prevent infection and severe illness, and all eligible Californians should <u>get vaccinated or boosted as soon as possible</u>.

The following are intended to clarify topics that pharmacies and pharmacy staff may need to prevent delayed access to critical COVID-19 treatment:

Pharmacies and pharmacy staff should be aware that most insured patients have a right to free and/or reimbursable COVID-19 tests.

- Ensure all staff are knowledgeable about patients' benefits for COVID-19 tests:
 - Pharmacists should order and/or dispense allotted test kits for Medi-Cal beneficiaries at the point-of-sale in accordance with the following: <u>Medi-Cal</u> OTC-COVID19-Antigen-Tests (PDF).
 - Refer to this document for commercial plans: <u>DMHC Know Your Health Care</u> Rights Fact Sheet.
 - o Refer to this webpage for Medicare participating pharmacies.
- For insurance plans that allow patients to pick up tests at pharmacies free of charge, including Medi-Cal, pharmacists should write an order for the COVID-19 tests and submit claim as a pharmacy benefit. If tests are not covered by insurance at point of sale in the pharmacy, patients may elect to pay at the counter and submit the claim for reimbursement from their insurance directly.
- Each beneficiary may receive up to 8 tests (4 kits with 2 tests per kit) every 30 days.
- Uninsured patients can get information on testing at: covid19.ca.gov/get-treated.

There are several ways patients can be evaluated for COVID-19 treatment.

- Pharmacists can prescribe COVID-19 therapeutics. Refer to Paxlovid Fact Sheet.
- California clinicians, including pharmacists, may access the COVID-19 Therapeutics Warmline which is a live clinical consultation line to assist clinicians with prescribing COVID-19 medications: 1-866-268-4322 (866-COVID-CA)
- Direct patient inquiries for information on assessment and treatment to the State's COVID-19 Hotline at 1-833-422-4255 or <u>treatment website</u>. This hotline and website can also help patients get access to telehealth.
- Pharmacy staff may also find additional assessment and treatment information at <u>covid19.ca.gov/treatment</u>.
- If a pharmacy has any additional methods for access, those should also be shared with patients.

Pharmacies should accept all valid hard copy prescriptions; they do not need to be sent electronically.

- The California Business and Professions Code (BPC) section 688(i) states pharmacists are not required to verify that a written, oral, or faxed prescription falls under one of the exceptions of the e-prescription law.
- BPC section 688(i) also states pharmacists may continue to dispense medications from legally valid written, oral, or faxed prescriptions pursuant to law. When deciding whether to refuse to dispense an otherwise legally valid written, oral, or faxed prescription solely because it was not transmitted electronically, a pharmacist should consider the impact on the patient and continuity of care.
- This is also addressed in Question 3 of the California Board of Pharmacy's <u>Electronic Data Transmission Prescriptions Frequently Asked Questions</u>.

Pharmacies should accept uninsured patients and not charge patients for a COVID-19 oral antiviral.

- Organizations must not sell or seek reimbursement for publicly funded COVID-19 therapeutics that the federal government provides at no cost to an organization.
- Uninsured patients in California are encouraged to visit the California Department of Health Care Services (DHCS) COVID-19 Uninsured Group Program for guidance on obtaining coverage as a pathway to no cost vaccines and treatment.
- For information on assessment and treatment options for uninsured patients, direct inquiries to the State's COVID-19 Hotline at 1-833-422-4255 or <u>treatment website</u>.

Pharmacists should not reject COVID-19 prescriptions solely due to the absence of renal function and liver function test results.

- The <u>Paxlovid EUA</u> indicates that these tests are only required for pharmacists when pharmacists are prescribing the medication. These labs are generally not required when dispensing.
- <u>According to ASPR-HHS</u> under "Are lab results required before a patient can be prescribed Paxlovid? - Licensed physicians and advanced practice providers are not required to perform additional laboratory testing when prescribing Paxlovid. Providers

- should use clinical judgement to determine if labs are necessary." Even when prescribing Paxlovid, the provider can use clinical judgment to determine if lab tests are necessary. If a pharmacy is dispensing Paxlovid pursuant to a prescription from a provider, such tests may not be necessary based on the patient's clinical history.
- In making a reasonable attempt to clarify any concerns with the provider and/or patient, pharmacists should use clinical judgement and consider the impact of delayed COVID-19 treatment. Treatment must be started within 5 days of symptom onset.

Pharmacists should not reject COVID-19 prescriptions due to the absence of a "positive test" date or "symptom onset" date written on the prescription.

- These items are not required to be written on the prescription and patients can selfattest to the symptom onset dates.
- The FDA revised its emergency use authorizations on <u>Paxlovid</u> and <u>Lagevrio</u> on February 1, 2023, to no longer require positive results of direct SARS-CoV-2 viral testing before a provider can prescribe them. Additional testing is not required.

Pharmacists should not reject COVID-19 prescriptions due to the presence of only mild symptoms.

 Patients with mild symptoms are, in fact, included in criteria for outpatient treatment according to the FDA EUA and <u>NIH recommendations</u>.

This information should be shared with stores' and facilities' staff to ensure correct information and the best possible patient experience are provided.

The State's COVID-19 Hotline (1-833-422-4255) should also be shared widely as hotline staff are available to respond to all questions related to COVID-19. Additional information can also be found at covid19.ca.gov/treatment.

Additional information for staff and clinicians can be found at the CDPH <u>COVID-19 Test-to-</u> Treat Playbook (ca.gov).

Thank you for all that you do in for your efforts in ensuring a more efficient system for dispensing necessary COVID-19 therapeutic treatments to all.