# EARLY TREATMENT FOR AT-RISK POPULATIONS: PAXLOVID

***A TOOLKIT FOR LONG BEACH LONG-TERM CARE FACILITIES ON IMPLEMENTATION AND ORDERING OF PAXLOVID: A SARS-COV-2 ANTIVIRAL THERAPY***

LONG BEACH HEALTH & HUMAN SERVICES

## TABLE OF CONTENTS

## INTRODUCTION

COVID-19 continues to be amongst the leading cause of death in the United States. The elderly and those with co-morbidities are at significantly higher risk of severe outcomes. The Long Beach Department of Health and Human Services (Health Department) would like to support access to the U.S Food and Drug Administration (FDA) authorized COVID-19 oral antiviral treatment, PAXLOVID™. Studies demonstrated early treatment of Paxlovid reduced the risk of hospitalization and death by 88% in patients who received treatment within five days of symptom onset. In addition to vaccination, early treatment is a core strategy to prevent severe outcomes in residents of long-term care facilities with mild to moderate symptoms of COVID-19.

Outpatient antiviral COVID-19 therapeutics are widely available but underused. The Long Beach Health Department is eager to collaborate to meet the following goals:

- Provide early treatment to at-risk populations in skilled nursing facilities and other inpatient settings, regardless of patient vaccination status.
- Decrease hospitalizations and disease progression through effective, early treatment.

While there are other COVID-19 therapeutics (remdesivir/Veklury and Molnupiravir) on the market, this document will focus on the preferred agent, Paxlovid, for non-hospitalized patients with mild to moderate symptoms. If Paxlovid is determined to not be clinically appropriate for the patient, clinicians can explore the alternative therapies for eligibility and administration. See US Department of Health and Human Services (HHS) Side by Side Overview of Therapeutics for additional information.

### Toolkit Overview

This toolkit will serve to provide standard information on Paxlovid and how to order through the city. Please note, this document contains information as of March 2023, and guidelines, recommendations, and other information may adapt over time. Please continue to refer to credible sources to stay in accordance with any new changes.

## WHAT IS PAXLOVID?

Paxlovid (nirmatrelvir co-packaged with ritonavir) is a preferred oral antiviral authorized for the treatment of mild-moderate COVID-19 illness. Paxlovid should be initiated as soon as possible after diagnosis of COVID-19, and within 5 days of symptom onset. Patients take a combination of pills twice a day for 5 days. Paxlovid is available by prescription only.

Note: Paxlovid is not a substitute for vaccination, and the COVID-19 vaccination and booster dose are still highly recommended. Paxlovid is also not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospital

## PAXLOVID RECENT UPDATES

### FDA Briefing Document – March 16, 2023

On March 16, 2023, the U.S Food and Drug Administration (FDA) released information stating that viral rebound may be the natural course of COVID-19 infection, rather than a side effect of antiviral treatments. We hope that this news will help counter widespread public and provider misconceptions about viral rebound. Refer to the FDA briefing document for more information.

### Emergency Use Authorization Update – February 1, 2023

A positive COVID-19 test is no longer required to prescribe Paxlovid treatment. On February 1, 2023, the FDA revised the Emergency Use Authorization (EUA) and removed this requirement in effort to limit barriers to treatment and to support timely treatment administration.

The authorized prescriber can make a diagnosis by determining if the patient had a recent COVID-19 exposure, reports mild-to-moderate symptoms of COVID-19, and is at high-risk for progression to severe COVID-19, including hospitalization or death.

## ELIGIBILITY CRITERIA

Paxlovid is for adults and children 12 years (weighing at least 40kg/at least 88 pounds) and older who are at higher risk for developing serious COVID-19 disease that may lead to hospitalization and/or death. Paxlovid should be considered for patients who meet the following criteria (regardless of COVID-19 vaccination status):

- Have symptoms consistent with mild-to-moderate COVID-19 and onset no more than 5 days, AND
- Have one or more **risk factors** for severe COVID-19

  Some risk factors include:

  - Being over 50 years or age, with risk increasing substantially at age ≥ 65 years
  - Being unvaccinated or not being up to date on COVID-19 vaccinations
  - Specific medical conditions and behaviors (including obesity, smoking (former or current), disabilities, and depression

Please see the FDA's Eligibility Screening Checklist for additional details on criteria.

Clinical considerations for usage in specific populations (e.g pregnancy, *mild* renal/hepatic impairment, individuals of reproductive potential) are found in the FDA's Fact Sheet for Healthcare Providers (see sections 8, Use in Specific Populations).

## PRESCRIBING PAXLOVID

Paxlovid can be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

Paxlovid can also be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider patient relationship with the individual patient, to assess renal and hepatic function; and
- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

### Paxlovid Sample Prescriptions

**Prescription for patients with normal renal function:**

**SAMPLE PRESCRIPTION FOR PAXLOVID – FOR PATIENTS WITH NORMAL RENAL FUNCTION**

PRESCRIPTION AS FOLLOWS

| | | |
|---|---|---|
| Written: | 04/27/2022 | EScript Expiration Date: |
| Medication NDC Prescribed: | Paxlovid Co-Pack (eua) | NDC: 00069 -1085-30 |
| Medication Prescribed: | Paxlovid 20x 150 mg & 10x 100 mg Oral Tablet Therapy Pack | Days Supply: |
| Quantity: | 30 Each (30 Tablet) | Refills: 0 (additional refills) |
| Directions: | take 2 nirmatrelvir 150 mg + 1 ritonavir 100 mg tablet bid x 5 days | |
| Diagnosis/use: | (not specified) | Diagnosis Codes: U07.1 |

**Prescription for patients with reduced renal function:**

**SAMPLE PRESCRIPTION FOR PAXLOVID – FOR PATIENTS WITH REDUCED RENAL FUNCTION**

PRESCRIPTION AS FOLLOWS

| | | |
|---|---|---|
| Written: | 04/27/2022 | EScript Expiration Date: |
| Medication NDC Prescribed: | Paxlovid Co-Pack (eua) | NDC: 00069 -1085-30 |
| Medication Prescribed: | Paxlovid 10x 150 mg & 10x 100 mg Oral Tablet Therapy Pack | Days Supply: |
| Quantity: | 20 Each (20 Tablet) | Refills: 0 (additional refills) |
| Directions: | take 1 nirmatrelvir 150 mg + 1 ritonavir 100 mg tablet bid x 5 days | |
| Diagnosis/use: | (not specified) | Diagnosis Codes: U07.1 |

## PATIENT/FAMILY CONSENT

Healthcare providers must communicate to patient or parents/caregivers, as appropriate, information consistent with the Fact Sheet for Patients and Parent/Caregivers (and provide a copy of the fact sheet) prior to the patient receiving Paxlovid. The patient or parent/caregiver has the option to accept or refuse Paxlovid treatment.

## ORDERING

### Long Beach Health Department Order

The Long Beach Department of Health and Human Services currently does not house any therapeutics in the city but will be able to connect interested prescribers to the LA County therapeutics team. The LA County therapeutics team will enroll your facility or pharmacy to the **Health Partner Order Portal (HPOP).** This provider portal is used for managing, monitoring, and reporting key metrics associated with the distribution and administration of vaccines, therapeutics, and diagnostics.

If interested, please contact LA's therapeutics team *directly* to get onboarded:

Email: dph-therapeutics@ph.lacounty.gov and CC' gabriela.hurtado@longbeach.gov *(Medical Countermeasures and Vaccine Preventable Disease Supervisor)* and mckailey.walters@longbeach.gov *(Healthcare-Associated Infections (HAI) Supervisor)*

Subject line: Covid Therapeutics Request for [Name of Facility].

Body of email: include Paxlovid AND the number of courses requested.


For questions, please email LBHAI@longbeach.gov or call 562-570-4302 for the Healthcare Associated Infections (HAI) program.

### Other locations:

COVID-19 treatments can also be provided at the following sites:

Paxlovid can also be found using the U.S Department of Health and Human Services (HHS) COVID-19 Therapeutics Locator.

Alternatively, HHS has launched the Test-to-Treat initiative* to help appropriate patients access COVID-19 testing and treatment options in one location.

## PACKAGE PRESENTATION

Paxlovid is available in two package presentations:

1. **Standard dose:**

   Paxlovid Standard Dose that includes 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.


2. **Dose (reduction) for patients with renal impairment:**

   Paxlovid Renal Dose for people with moderate renal impairment (eGFR > 30 mL/min to < 60 mL/min) that includes 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for 5 days. Paxlovid is not recommended for people with severe renal impairment (eGFR <30 mL/min).


Note: Paxlovid is not recommend in patients with *severe* hepatic impairment (Child-Pugh Class C)

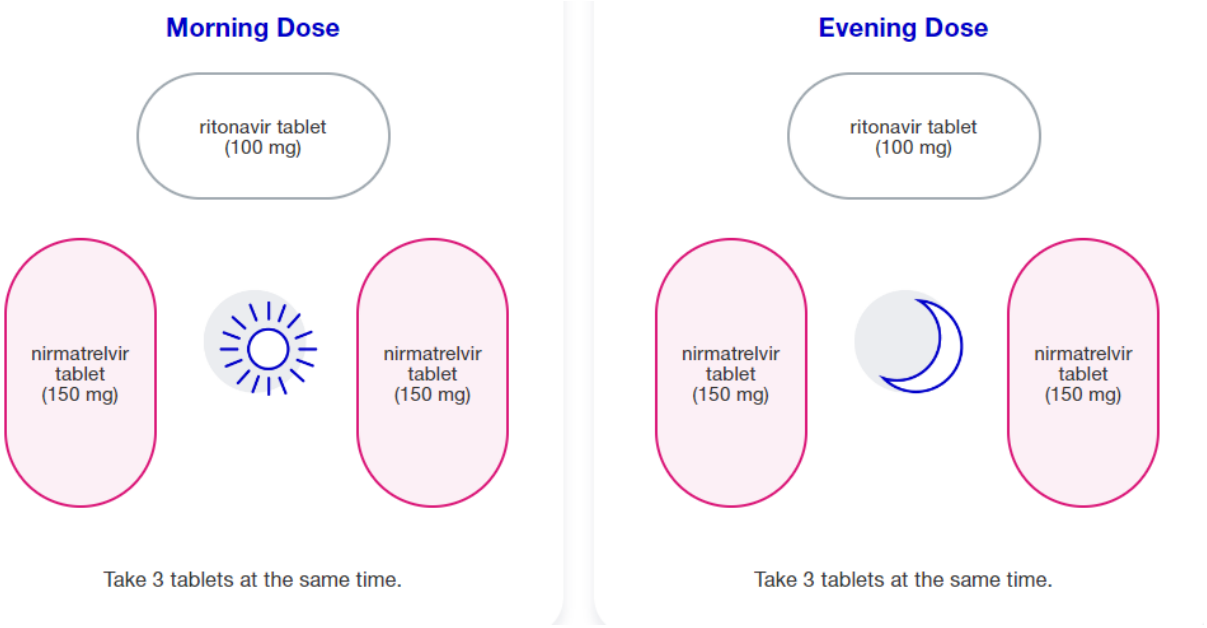
## ADMINISTRATION

The 5-day treatment course of Paxlovid should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset. Should a patient require hospitalization due to severe or critical COVID-19 after starting treatment with Paxlovid, the patient should complete the full 5-day treatment course per the healthcare provider's discretion.

If the patient misses a dose of Paxlovid within 8 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule. If the patient misses a dose by more than 8 hours, the patient should not take the missed dose and instead take the next dose at the regularly scheduled time. The patient should not double the dose to make up for a missed dose. Paxlovid (both nirmatrelvir and ritonavir tablets) can be taken with or without food.

The tablets should be swallowed whole and not chewed, broken, or crushed

Patients should complete the entire course of treatment as prescribed, which consists of:




## STORAGE AND HANDLING

Paxlovid is nirmatrelvir tablets co-packaged with ritonavir tablets. It is supplied in two different dose packs. Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same blister card

Store at USP controlled room temperature 20°C *to* 25°C (68°F *to* 77°F); excursions permitted between 15°C *to* 30°C (59°F *to* 86°F).

## DRUG INTERACTIONS

Paxlovid has been shown to be safe, including in fragile, elderly people. However, drug-drug interactions are important to consider before prescribing Paxlovid. Clinicians should carefully review the patient's concomitant medications, including over-the-counter-medications, herbal supplements, and recreational drugs. Nevertheless, many commonly used medications can still safely be coadministered with Paxlovid. Guidance is available on simple steps (such as brief suspension or dose reduction) to avoid significant interactions with commonly prescribed medications.

For information about and assistance managing drug interactions, healthcare providers should consult to the following resources:

- Fact Sheet for Healthcare Providers (see sections 4: Contraindications, 5: Warnings and Precautions, and 7: Drug Interactions)
  Pfizer Medical Information's PAXLOVID product page, which includes a Drug Interaction tool.

- The National Institute of Health (NIH) offers a quick reference list of Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications

Additional resource:

- The University of Liverpool also offers a COVID-19 Drug Interactions checker to assess the likelihood on interactions. Please note if a drug is not listed it cannot automatically be assumed to be safe to coadminister and clinicians must use their own judgement to assess safety of interactions.

## ADVERSE EVENTS AND REPORTING

### Reactions

Anaphylaxis and other hypersensitivity reactions have been reported with PAXLOVID. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue Paxlovid and initiate appropriate medications and/or supportive care.

### Reporting

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to PAXLOVID within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500.

*See sections 6.4 of Fact Sheet for Healthcare Providers for definition on serious adverse events

To report, submit Form 3500 to FDA MedWatch using one of the following methods:

1. Complete and submit the report online
2. Complete and submit a postage-paid FDA Form 3500 and return by:
    a. Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
    b. Fax to 1-800-FDA-0178
3. Call 1-800-FDA-1088 to request a reporting form

## ALTERNATIVE THERAPUETICS

If a patient is not clinically eligible to take Paxlovid, Veklury (Remdesivir) and Lagevrio (molnupiravir) are alternative COVID-19 therapies.

Veklury (remdesivir) is another preferred treatment for mild-moderate COVID-19. Veklury is given intravenously, once daily for three consecutive days.

Lagevrio (molnupiravir) (oral antiviral) is an alternative treatment when Paxlovid or Veklury therapies are not clinically appropriate or available.

## RESOURCES AND SUPPORT

### Clinical Resource/Warmline

The California Department of Public Health offers a free a COVID-19 therapeutics warmline. California health care providers can now call (866) 268-4322 (1-866-COVID-CA) to receive confidential consultation on COVID-19 testing and treatment. The COVID-19 Therapeutics Warmline is a real-time resource available to all California health care providers and is managed by the University of California, San Francisco (UCSF) National Clinician Consultation Center.

1. Health care providers of any experience level can call to speak with a clinician or pharmacist about drug-drug interactions or any other clinical challenges.
2. No protected health information will be collected, only basic provider contact and facility information will be collected.

The COVID-19 Therapeutics Warmline is available Monday through Friday, 6 a.m. – 5 p.m. Voicemail messages left after hours will be returned on the next business day. An online case submission form will be available soon.

### General Resources

The California Department of Public Health (CDPH) COVID-19 Treatments Webpage also offers general treatment information for providers, in addition to graphics to increase awareness for treatment options.

### Fact Sheets

Paxlovid Fact Sheet for Healthcare Providers

Paxlovid Fact Sheet for Patients, Parents, and Caregivers

CDPH: Best Practices for Skilled Nursing Facilities

CDPH: Best Practices for Long Term Care Facilities

## REIMBURSEMENT

Develop a process for reimbursement for administrative costs. Because the federal government has purchased a supply of some treatments, there would be no cost to patients for the antiviral product itself. Depending on patients' insurance coverage, patients may or may not need to pay for a provider to administer the treatment/assessment.

### Department of Health Care Services (DHCS)

The Department of Health Care Services (DHCS) is providing guidance for pharmacy providers regarding the billing of Paxlovid, when independently initiated and furnished by a pharmacist. Providers can submit their COVID-19 testing, testing-related, and treatment claims to DHCS for claims processing.

- DHCS will reimburse pharmacists for the prescribing (consultation and assessment of need for treatment) and/or the dispensing of Paxlovid.
- Since the initial supply of Paxlovid is purchased by the federal government and distributed free to providers, providers will not be reimbursed the ingredient cost but will be reimbursed the professional dispensing fee.
    - Claims for reimbursement of the dispensing fee must be submitted to Medi-Cal Rx for processing.

**Paxlovid is expected to hit the private market in mid-2023, according to the U.S Department of Health and Human Services (HHS) plans shared in an October meeting with state health officials and clinicians. This means fewer people will get the potentially lifesaving treatments. Further information regarding reimbursement for Paxlovid and other SARS-CoV-2 therapeutic treatments will be shared as this information is made available.**

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