# COVID-19 Test-to-Treat program



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# Test-to-Treat (T2T)

- As part of the federal government's National COVID-19 Preparedness Plan the United States government has launched a nationwide Test to Treat Initiative
- The goal of the program is to provide a new way to quickly access free lifesaving orals treatments for COVID-19.
- If a patient tests positive and treatment is appropriate for them, they can receive medications through this program.
- This does <u>NOT</u> replace the already existing federal allocation of COVID-19 therapeutics to states. This is in addition.



## Test-to-Treat sites need to have three components:

- (1) Rapid testing;
- (2) Either in-person <u>or telehealth</u> prescribing capabilities with a physician, advanced practice registered nurse, or physician assistant (these are the only individuals able to prescribe anti-infectives); and
- (3) The ability to dispense COVID-19 oral antivirals according to California state law. Patients can also bring their own test results from an at-home test to access Test-to-Treat.

# Test-to-Treat and Long-term Care Facilities/Skilled Nursing Facilities:

The current process for getting T2T medications directly to LTCFs/SNFs is murky

The best process currently, as this process is ongoing and evolving rapidly, would be to go through your managed care pharmacy partner if you would like your site to be added as a T2T site.



## Available Anti-SARS-COV-2 Treatments: Antivirals

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Effectiveness	Activity Against Variants Currently Circulating	Clinical considerations
Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid)  Orally twice daily for 5 days	Oral 📩	12 years and older and weighing at least 40 kg	As soon as possible, but within 5 days of symptom onset	Compared to placebo, <u>a</u> relative risk reduction of 89% in hospitalizations or deaths.	Effective against Delta and Omicron	Drug interactions: Caution if concern for undiagnosed HIV; Renally dosed; Caution if severe hepatic impairment
Remdesivir (Veklury)  200 mg IV on Day 1, followed by 100 mg IV daily on Days 2 and 3	Intravenous	FDA approved in 12 years and older and weighing at least 40 kg; EUA for <12 years of age weighing 3.5 to 40 kg  Only product currently available to <b>all age</b> groups	As soon as possible, but within 7 days of symptom onset	Compared to placebo, <u>a</u> relative risk reduction of <u>87%</u> in hospitalizations or deaths.	Effective against Delta and Omicron	Caution in renal or hepatic impairment
Lagevrio (molnupiravir) 800 mg Orally twice daily for 5 days	Oral	18 years and older	As soon as possible, but within 5 days of symptom onset	Compared to placebo, <u>a</u> relative risk reduction of <u>30%</u> in hospitalizations or deaths.	Effective against Delta and Omicron	Caution in individuals of reproductive age; require use of reliable method of contraception



## Paxlovid Renal: New formulation

#### Paxlovid (nirmatrelvir and ritonavir) Formulation and Packaging

FDA updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with **moderate** renal impairment.



#### Standard Dose

300 mg nirmatrelvir;100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Minimum Order Quantity: 20



#### **Renal Dose**

150 mg nirmatrelvir;100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Minimum Order Quantity: 5



## What is Mild to Moderate Illness?

#### Mild Illness

#### **Moderate Illness**

Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.

Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO2) ≥94% on room air at sea level.



## Who is High Risk?

- CDC list of conditions: https://www.cdc.gov/coronavirus/201 9-ncov/hcp/clinicalcare/underlyingconditions.html
- Age is the strongest risk factor for severe COVID-19 outcomes, people aged 65 years or older accounted for 81% of U.S. COVID-19 related deaths in 2020

#### Conditions Listed in Sotrovimab EUA

- Older age (for example age ≥65 years of age)
- <1 year old</p>
- Obesity or being overweight
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or treatment
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation)

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of sotrovimab under the EUA is not limited to the medical conditions or factors listed above



# Current Supply of COVID-19 Outpatient Therapeutics

- Supply of therapeutic products in California is currently not limited;
   we are currently not in a state of scarcity
- At this time, all patients who are eligible for treatment with COVID-19 treatments should be offered treatment
- Should product ever be scarce in the future, the NIH Treatment Guidelines provide direction on patient prioritization: https://www.covid19treatmentguidelines.nih.gov/management/clinic al-management/nonhospitalized-adults--therapeutic-management/



## COVID-19 Test to Treat Locator



English



Need help finding a place to get medication? Call <u>1-800-232-0233</u> (TTY <u>888-720-7489</u>)

#### **Get medication for COVID-19**

COVID-19 medications are now available through your doctor, local pharmacies, and health clinics.

If you have COVID-19 symptoms and test positive, do not wait to get treated.

You must take oral COVID-19 medication within 5 days of your first COVID-19 symptoms.

Use the tool below to find a location that is right for you.

Find COVID-19 Medication	ı	Beaufort Sea
Enter address or zip code	Q	
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Welcome!	×	Gulf of
Search for an address to learn more about the location and its surrounding If you don't know the address, use one of these search methods:	area.	Alaska C A N A D A



#### New! Clinical Resources for Paxlovid

- Paxlovid is now widely available in community pharmacies.
- Although the number of COVID-19 hospitalizations has decreased dramatically since early 2022, some high-risk patients are still getting sick enough to require hospital admission.
- Early treatment with Paxlovid and other available authorized or approved therapeutics could make a difference.

#### FDA Paxlovid clinical resources now available

Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers

Q&A with FDA Director of the Office of Infectious Diseases



# **Summary Points**

- Effective treatment for outpatients with mild to moderate COVID-19 is available and should be offered to all high-risk patients if they meet criteria for treatment based on EUAs
- We are not in a state of scarcity, all patients at high risk for disease progression with a COVID-19 positive test (PCR or antigen) who are within the treatment window should be offered treatment
- Providers should review product EUAs as well as the NIH Treatment Guidelines prior to using outpatient therapeutics
- Clinical guidance is available to assist in the selection of an appropriate COVID-19 therapeutic as well the navigation of some of the clinical complexities of using these drugs (i.e. Paxlovid drug interactions)
- LTCFs/SNFs may utilize the Test-to-Treat program or keep using their regular route for therapeutic ordering/administration

