California Department of Public Health

COVID-19 Test-to-Treat Playbook

CDPH Therapeutics Task Force

June 2022

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Executive Summary

The role of therapeutics in COVID-19 response has changed drastically with the arrival of **highly effective** oral therapeutics and launch of "test-to-treat" programs, which facilitate **expedited and simplified** access to treatment as soon as someone tests positive for COVID-19. This is critical since therapeutics must be given within 5-7 days of symptom onset to be effective and each additional step in getting a **test**, a **prescription**, and **medication** may lead to a drop off in patients getting treatment.

"Test-to-treat" as a concept applies to any effort to expedite the key elements of (1) **testing**, (2) **prescriber** access, and (3) **medication dispensing**. This may include streamlined steps that take place outside of a physical provider office or clinic site, such as at-home tests, telehealth, and/or mail-order medication. These pathways save lives—CDPH estimates that since approximately 123K Paxlovid courses have been administered in California, between 1,000 - 7,000 hospitalizations and 130 - 1,400 deaths have been averted.

The products currently authorized for treating mild-to-moderately ill COVID-19 patients include:

Drug	Type	Information
Paxlovid	Oral pills	EUA for patients ≥12 y/o; highly effective in reducing deaths/hospitalizations; drug-drug interaction risk; not recommended for severe renal or hepatic impairment
Molnupiravir	Oral pills	EUA for patients ≥18 y/o; moderately effective in reducing deaths/hospitalizations; not recommended for pregnant people
Remdesivir	IV	FDA-approved for patients ≥12 years; EUA in patients younger than 12; highly effective in reducing deaths/hospitalizations; multi-day treatment
Bebtelovimab	IV	EUA for patients ≥12 y/o; moderately effective; given in single dose
Evusheld	Injection	Indicated for immunocompromised individuals who cannot mount an immune response to COVID-19 vaccinations; taken *before* getting sick or exposed

These products are **currently not in shortage** and should be used whenever clinically appropriate. Paxlovid and molnupiravir can only be prescribed for individual patients by physicians, advance practice RNs, or physician assistants. Since the federal government provides these medications to states for free, providers cannot bill insurance for therapeutic ingredient costs, but they may bill for dispensing fees or provider visits.

All entities in public health and health care (including health plans, healthcare delivery systems, and providers) have a role in expanding test-to-treat access. **Best practice tips** are found in Section 4, including:

- **Patient Flows**: Update all patient access points with information that streamlines symptomatic patients to same-day or next-day **testing** and relays how to quickly connect with a provider if they

test positive. Update these points to funnel positive/symptomatic patients to same-day **provider visits** (in-person or telehealth).

- **Provider Education:** Providers should review the **clinical algorithms and treatment flows** in Appendix 2, sign up for CDPH Provider Office Hours and CDPH therapeutics updates, and expand COVID-19 therapeutics eligibility to incorporate more clinical decision-making—including prescribing to all individuals age 50+ and to populations who face structural barriers to health that have contributed to disproportionate rates of hospitalization and death from COVID-19. Familiarize providers with online drug interaction tools (see Section 2.7) and create pharmacy consultation lines to support clinicians.
- **Prescribe to Pharmacies with Therapeutics**: Regularly review and confirm that prescribing workflows connect patients to pharmacies carrying oral COVID-19 therapeutics. Utilize mail-order options if needed.
- **Dispensing Rules**: Clinics and health care centers should ask their legal counsel to review the Board of Pharmacy's lawbook to understand medication dispensing.
- **Monitoring for Equity**: Develop metrics and tracking systems to regularly review COVID-19 utilization data to identify disparities and help prioritize resources.

1 Introduction

The COVID-19 pandemic is still rapidly and frequently evolving, as is the case with COVID-19 therapeutics. The majority of COVID-19 therapeutics currently available are still under Emergency Use Authorization (EUA). The role of COVID-19 therapeutics has changed drastically due to the availability of oral therapeutics as well as emerging resistance to therapeutics previously introduced. For much of the pandemic, the COVID-19 therapeutics typically available to patients were either inpatient medications or outpatient monoclonal antibodies given at infusion centers. With the introduction of oral antiviral pills that can be dispensed at outpatient pharmacies—and the associated roll-out of a federal "test-to-treat" program—the therapeutics landscape requires new strategies for improving equitable patient access.

1.1 Playbook Scope

This playbook provides information about several different aspects of COVID-19 therapeutics: clinical guidance and tools, distribution and logistics information, data applications and availability, and best practices for increasing access. It also focuses primarily on Paxlovid and molnupiravir, the two COVID-19 therapeutics best suited for seamless test-to-treat experiences. It does not cover inpatient therapeutics.

Noting that the pandemic landscape changes constantly, all of the information contained in this playbook is most relevant to the current situation as of June 2022.

The primary intended audiences for this playbook are local health jurisdictions (LHJs), health care providers and pharmacists, and health care delivery systems and health plans working to stand up test-to-treat models.

1.2 COVID-19 Therapeutics are a Crucial Component of Pandemic Response

The first line of protection against severe COVID-19 outcomes is vaccination against the disease. As the Omicron wave made clear, vaccines do not prevent 100% of infections. Additionally, as of June 2022, approximately 15% of Californians aged five years and older have not received *any doses* of the COVID-19 vaccine, putting them at higher risk for infection, hospitalization, and death.

Outpatient COVID-19 therapeutics can help fill this gap, offering another line of defense that is highly effective in reducing the risk of death and hospitalization due to COVID-19. Both the CDC and NIH emphasize the importance of rapidly connecting people who test positive for COVID-19 with treatment as an effective way to decrease morbidity and mortality.

Since Paxlovid, the most frequently prescribed COVID-19 therapeutic, can reduce someone's risk of death or hospitalization by up to 90%, CDPH estimates that if everyone who was eligible for treatment was treated, the state would observe a significant reduction in hospitalizations and death. **CDPH**

estimates that since approximately 123,000 Paxlovid courses have been administered in California, between 1,000 to 7,000 hospitalizations and 130 to 1,400 deaths have been averted.

1.3 COVID-19 Therapeutics Overview

Several COVID-19 outpatient therapeutic options are available in the United States, including those for treatment of acute infection, pre-exposure prophylaxis, and post-exposure prophylaxis. Treatments are available for eligible patients based on exposure status, symptoms, and risk factors for severe disease progression. Ultimately, COVID-19 treatments play an important role in preventing illness and helping people recover from COVID-19, with the goal of saving lives, reducing hospitalizations, and relieving pressure on stressed hospital systems.

As of the time of this writing, the therapeutics authorized or approved by the FDA to treat COVID-19 include:

- ritonavir boosted nirmatrevir (Paxlovid, authorized under Emergency Use Authorization (EUA))
- molnupiravir (Lagevrio, authorized under EUA)
- remdesivir (Veklury, approved for use in individuals 12 years of age and older and authorized under EUA for children younger than 12 years of age)
- bebtelovimab (authorized under EUA).

Bebtelovimab and remdesivir must be infused in a health care setting. Paxlovid and molnupiravir are the only COVID-19 drugs that can be dispensed to patients at pharmacies, which is why Paxlovid and molnupiravir are the primary focus of test-to-treat pathways.

These products, with the exception of remdesivir, are being allocated to states by the federal government and are available to patients at no cost. All products are **no longer in shortage** and should be used whenever clinically appropriate. This may change in the event of a future surge. CDPH recommends considering social determinants of health (such as unstable housing, lack of access to health care, experiencing racism, built environment factors, etc.) and their influence on disproportionately poor COVID-19 outcomes when evaluating patients for these medications.

1.4 Test-to-Treat

"Test-to-treat" is a concept of facilitating expedited access to treatment as soon as someone tests positive for a disease. From decades of advancement in HIV and sexually transmitted infections care, we know that each successive logistical step from 1) obtaining a test to 2) accessing a prescriber to 3) accessing medication leads to drop off in patients accessing treatment. Thus, we are applying similar principles to reinforce the importance of expediting treatment so that all those who test positive for COVID-19 are expeditiously funneled into assessment for a therapeutic. Importantly, "test-to-treat" as a concept generally applies to any efforts to ensure the key elements of (1) testing, (2) prescriber, and (3) medication occur expeditiously. This is particularly critical for COVID-19 as therapeutics must be given within 5-7 days of symptoms onset in order to be effective. With the advent of at-home antigen

tests and telehealth, expedited access may include streamlined steps that take place outside of a physical provider office or clinic site.

Plans and providers should optimize workflows, processes, and communications to expedite each step of COVID-19 care delivery, particularly to prescribers and medication as at-home testing has become more accessible. In instances where providers have capability to dispense on-site, efforts should be made to link patients immediately to dispensing of therapeutics. Those sites that do not have mechanisms to dispense should provide linkages to pharmacies who can prioritize expedited prescription fulfillment and delivery. For more detailed tips and best practices for health care providers, health systems, and health plans, see Section 4: For Health Plans, Health Systems, Practice Managers, and Providers: Best Practices to Facilitate Access to Therapeutics.

1.5 Background Through June 2022

Prior to December 2021, the only COVID-19 therapeutics available to patients were infused or injected monoclonal antibodies that had to be delivered in an appropriate health care setting by a health care practitioner.

In December 2021, both the oral medications Paxlovid and molnupiravir received EUA designations from the FDA. Initial supplies of both medications were extremely limited, and states were responsible for managing the federal supply chain for orders to all pharmacies in their jurisdiction, including chain pharmacy locations that had received their own vaccine supply directly from the federal government.

As production rates quickened, supply of both products outpaced demand starting in early March 2022. Healthcare delivery systems faced the challenge of creating new operational workflows to facilitate testing, prescribing, and treatment, leading to public difficulties accessing COVID-19 antivirals in a timely manner. In answer to this gap, the federal government announced the federal test-to-treat initiative, which included an online test-to-treat locator to help the public find sites with testing, prescribing, and dispensing of oral therapeutics all at one location. This test-to-treat locator includes the federal government's initial sites (primarily large chain pharmacies with embedded clinics) as well as other health care centers and delivery systems that have stood up their own test-to-treat pathways for patients.

Since March 2022, CDPH and LHJs have encouraged health care providers to create operational workflows that facilitate connection to therapeutics. Eventually, every health care provider should have a streamlined pathway to connect eligible patients to therapeutics if they test positive for COVID-19. While this practice transformation is underway in all healthcare delivery systems, the federal test-to-treat locator helps patients identify alternative solutions if they cannot readily access therapeutics through their regular health care provider.

CDPH and LHJs have been encouraging sites that offer testing, prescribing, and dispensing to contact their LHJs to get added to the federal test-to-treat locator and close equity gaps in therapeutics access. However, many of the clinics that treat low-income, BIPOC (Black, Indigenous, and People of Color),

uninsured, and/or underinsured patients still have not developed operational workflows to facilitate access to therapeutics or coordinated with LHJs to make their services visible on the federal test-to-treat locator. Access is particularly poor for people experiencing homelessness and people in rural areas of the state that are far from licensed pharmacies.

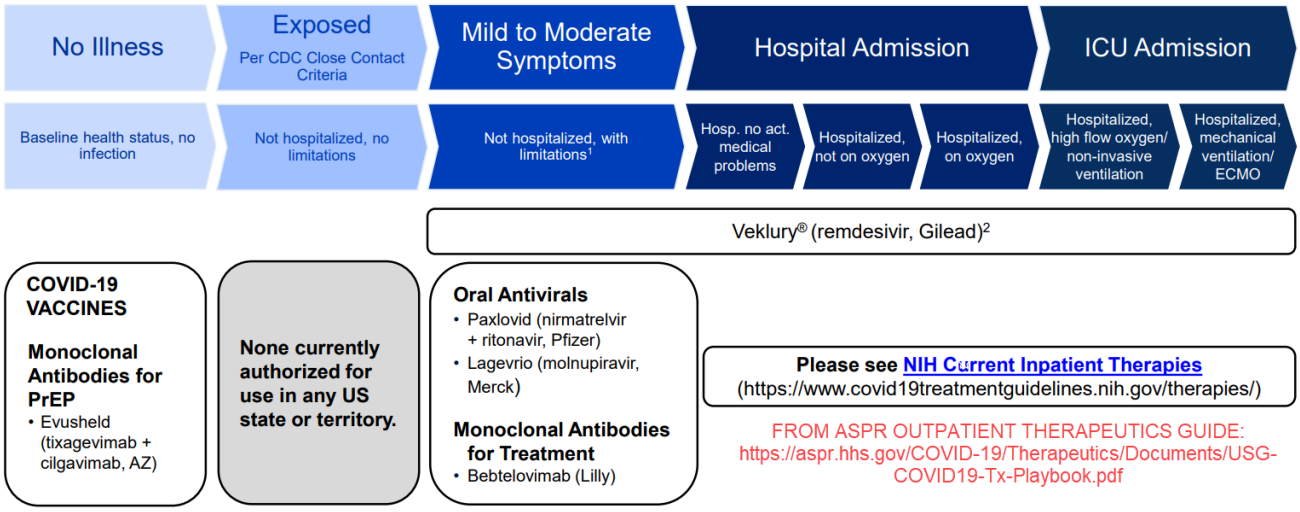
To help remedy ongoing inequities in therapeutics access—especially for the uninsured—CDPH partnered with Optum Serve to operate 146 test-to-treat sites in high-need, low-access areas of the state. The Optum Serve test-to-treat sites offer an "end to end" service with antigen testing, telehealth prescribing for COVID-positive patients, and on-site Paxlovid and molnupiravir dispensing. However, the California Board of Pharmacy waiver that allows dispensing at Optum Serve locations is set to expire December 31st, at which point these sites will no longer be able to provide end-to-end service. Instead, prescribers at Optum Serve sites will have to prescribe to nearby pharmacies for patient pick-up or to pharmacies that can provide same or next-day mail order.

California's Emergency Medical Services Authority has also set up test-to-treat sites in health care settings in low-access areas of the state. These involve in-person encounters with clinicians and do not require a waiver to operate and so will continue to stay open past December 31st.

2 For Clinicians: Clinical Information

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 FDA-issued EUAs. Providers should review product EUAs as well as the NIH Treatment Guidelines prior to using outpatient therapeutics.

Summary of COVID-19 Preventative Agents & Therapeutics



[1] Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/
[2] Therapeutic Management of Hospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/

2.1 Paxlovid

Paxlovid is a highly effective oral antiviral medication for COVID-19-positive patients that reduced the relative risk of hospitalization or death by 89% in clinical trials. This is more effective than molnupiravir. Patients must start taking Paxlovid **within five days of symptom onset** for the medication to be effective. Since there are two dosing packages of Paxlovid available, prescriptions for Paxlovid should specify the numeric dose of each active ingredient within Paxlovid. Paxlovid is not recommended for individuals with severely impaired renal function (eGFR<30 mL/min) or severe hepatic impairment (Child-Pugh Class C). Because Paxlovid contains ritonavir, there may be risk of significant drug-drug interactions and providers should run a drug interaction screen when clinically appropriate. The most commonly reported side effects of Paxlovid are altered taste or loss of taste, gastrointestinal side effects, and dizziness. The dosage for Paxlovid when renal function is normal is 300 mg nirmatrevir (two 150 mg tablets) and 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice a day for 5 days. The packaging is 30 tablets divided in five daily dose blister cards, where each blister card contains four nirmatrevir tablets and two ritonavir tablets. Nirmatrevir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

There is a different packaging of Paxlovid that should be used in patients with moderately impaired renal function (eGFR ≥30 to <60ml/min); this is called Renal Paxlovid. The dosing for Renal Paxlovid is 150 mg nirmatregvir (one 150 mg tablet) and 100 mg ritonavir (one 100 mg tablet) with both tablets taken together orally twice a day for five days. The packaging is 20 tablets divided in five daily dose blister cards, where each blister card contains two nirmatrevir tablets and two ritonavir tablets. Nirmatrevir tablets and ritonavir tablets are again supplied in separate blister cavities within the same

child-resistant blister card. If Renal Paxlovid packaging is not available, regular Paxlovid can be used for renal dosing by disposing of one of the 300 mg nirmatrevir tablets daily (two 150 mg tablets are contained in the regular Paxlovid package instead of one)

Paxlovid should be stored at USP-controlled room temperatures of 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F).

Health care providers can use a checklist to help them decide when to prescribe Paxlovid, and the FDA and Pfizer both have tools to help physicians identify potential drug-drug interactions for their patients. More resources can be found in Appendix 1.

2.2 Molnupiravir (Lagevrio)

Molnupiravir (Lagevrio) is an oral antiviral medication for COVID-19 positive patients that reduced the risk of hospitalization or death by 30% in a clinical trial. It is the least effective of the currently available COVID-19 outpatient treatment options and should only be used if other treatment options are not available or clinically appropriate. Patients must start taking molnupiravir **within five days of symptom onset** for the medication to be effective. As a mutagenic RNA antiviral agent, there is a theoretical risk that molnupiravir could be incorporated into human DNA; however, no assays have shown evidence for mutagenicity. The FDA recommends **against** using molnupiravir in pregnant patients. The drug cannot be used in patients under the age of 18. The most common side effects of molnupiravir are diarrhea, nausea, and dizziness.

The dosage for Lagevrio is 800 mg of molnupiravir (in four 200 mg capsules) taken twice a day for five days. Molnupiravir is supplied in 40-count bottles.

Molnupiravir should be stored at 20° to 25°C (68° to 77°F); excursions are permitted between 15° to 30°C (59° to 86°F).

2.3 Monoclonal Antibodies

Monoclonal antibodies (mAbs) are medications that mimic the immune system's natural defense system against infection. They can help prevent the COVID-19 virus from attaching to human cells, making it more difficult for the virus to reproduce and worsen symptoms. mAbs are most effective when taken within seven days of symptom onset and are delivered in a one-time intravenous (IV) dose. Bebtelovimab is the only mAb that is currently authorized under EUA to treat acute COVID-19. It has shown efficacy against recent variants of the COVID-19 virus.

Test-to-treat providers should have a plan for referring patients to mAb infusion centers if patients are beyond the five-day window for receiving oral antivirals.

2.4 Remdesivir

Remdesivir (Veklury) is an intravenous antiviral medication. As an outpatient treatment, it is given daily for three consecutive days. Treatment must be started within seven days of symptom onset. Compared to placebo, a clinical trial showed a relative risk reduction of 87% in hospitalizations or deaths. Similar to monoclonal antibodies, remdesivir is another option that can be provided at an infusion center for patients who are not candidates for Paxlovid. The requirement for daily doses over three days does make the logistics of administration more complicated than other options.

2.5 Other Therapeutics

Evusheld is an injectable monoclonal antibody that is authorized as a pre-exposure prophylaxis, helping prevent people from getting sick before they've been exposed to COVID-19. It is recommended *only* for 1) people who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination or 2) people who have a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s). Evusheld is not authorized as a treatment for acute COVID-19. Vaccines provide greater and longer-lasting protection than Evusheld. Because Evusheld is taken before someone gets sick, it's not part of the test-to-treat pathway.

2.6 How Variants Impact Available Treatments

Viruses continuously mutate as they circulate among the population, creating new variants. COVID-19 therapeutic products vary in their vulnerability to new variants depending on their mechanism of action. Monoclonal antibodies, for example, are created to bind to a specific viral protein so are very sensitive to any change at the binding site.

Paxlovid and molnupiravir, on the other hand, interfere with the virus's replication mechanisms. Paxlovid binds to a specific part of the virus and inhibits replication, and molnupiravir causes viral RNA to mutate until it malfunctions. It is still possible that these oral antivirals may lose efficacy against future COVID variants, but their mechanisms of action may help extend the value of these drugs.

2.7 Decision-Making Processes and Algorithms

Multiple factors must be considered when selecting the appropriate treatment for outpatients with COVID-19. These include patient-specific factors—such as clinical/medical conditions and potential drug-drug interactions—and healthcare system factors like drug availability and feasibility of drug administration.

The below links can be used to assist in clinical decision making.

Treatment Guidelines

- COVID-19 Treatment Guidelines (nih.gov)
- Non-hospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines (nih.gov)
- HHS Clinical Implementation Guide (PDF)

Treatment Algorithms (Flow Charts)

- HHS Outpatient Therapeutics Decision Aid (PDF)
- IDSA Outpatient Treatment Roadmap (PDF)

Drug Interaction Checkers

- Liverpool COVID-19 Interactions (covid19-druginteractions.org)
- Pfizer's Drug Interaction Tool
- FDA's Paxlovid prescribing guide
- NIH's Paxlovid interaction guide

Other product information, including links to EUA text, can be found in the Appendix 1 and 2.

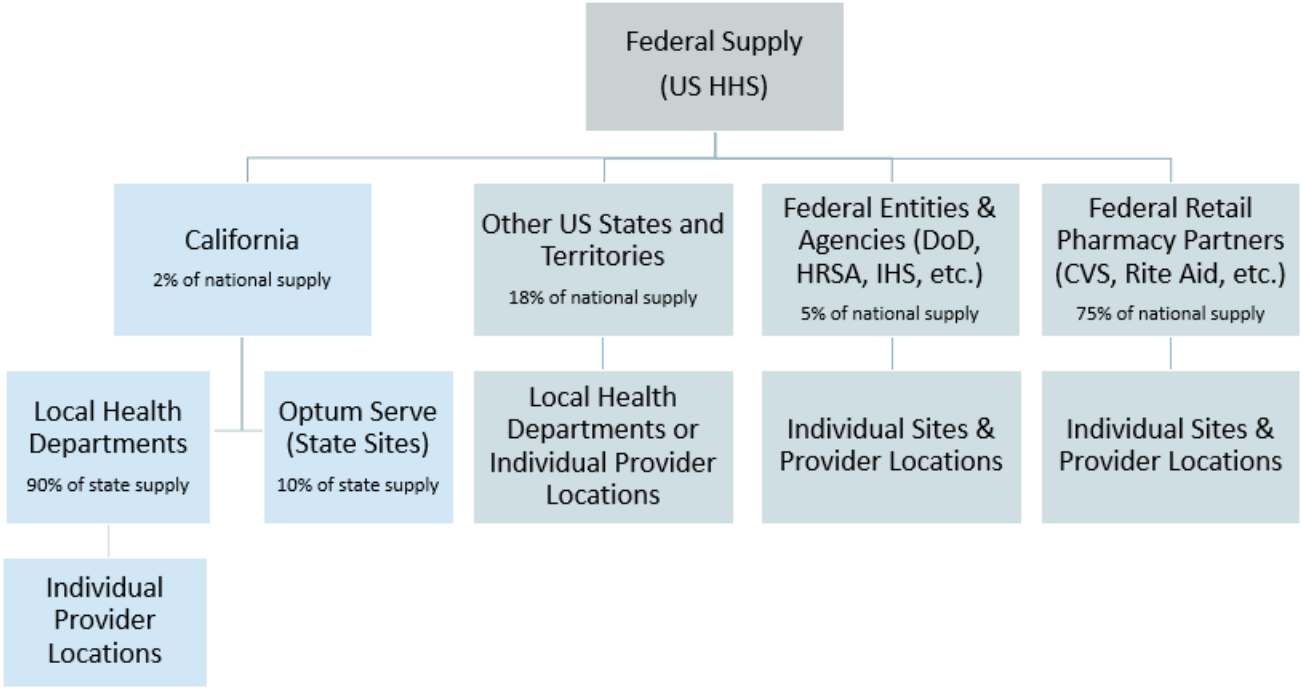
3 For Local Health Jurisdictions: Paxlovid and Molnupiravir Logistics and Distribution

3.1 Allocation & Flow of Products

Allocation and distribution of COVID-19 oral antivirals are still being managed by local, state, and federal governments. Therapeutics under EUA are available at no cost.

Flow from Federal Government to State Governments & Other Partners

HHS sets ordering thresholds for COVID-19 therapeutics for each US state and territory; federal programs like the Department of Defense, Health Resources and Services Administration (HRSA), and Indian Health Service; and some retail pharmacy chains (known as Federal Retail Pharmacy Partners, or FRPPs). Ordering thresholds are determined by each state's population, and each week states receive "new" supply that resets them back to their ordering threshold. The current thresholds for California's ordering are approximately 10,500 Paxlovid courses, 950 Renal Paxlovid courses, and 4,700 molnupiravir courses, but these do vary slightly each week and may increase or decrease in the future.



Flow from CDPH to Local Health Jurisdictions

Ten percent of the state's ordering threshold is allocated to state-supported test-to-treat sites (currently operated by Optum Serve). With the remaining amount, CDPH uses a population- and equity-based formula to allocate certain amounts to each county. Half of the total state's supply is

allocated according to each county's share of the past two weeks' COVID-19 cases, and half of the total state's supply is allocated according to population where people in in lower health equity quartiles (i.e., areas with less healthy community conditions) are weighted more than people in higher health equity quartiles (i.e., healthier community conditions). Quartiles are measured using zip code-level Healthy Places Index scores. The Healthy Places Index is a tool created by the Public Health Alliance of Southern California that measures social determinants of health. LHJs are not required to accept the therapeutics allocation assigned to them by CDPH, which sometimes occurs due to the challenges of prescribing outpatient COVID-19 therapeutics at the local level.

Flow from Local Health Jurisdictions to Individual Sites

LHJs are responsible for managing all COVID-19 therapeutic provider sites in their jurisdiction. If a site wants to dispense antivirals and requests antivirals from the LHJ, the LHJ vets the site and sends information about that site to CDPH. CDPH then registers that site in an HHS system called the Health Partner Ordering Portal (HPOP). Once the site is registered and verifies their information in the HPOP system by logging in and filling out a form, that site becomes eligible to receive and dispense antivirals. Antiviral providers must meet federal reporting requirements to report into HPOP each day they are open with (1) how many courses they have administered that day and (2) how many courses they have available on hand.

When LHJs receive their allocation totals each week, they fill out an ordering sheet to send specific amounts to each of their site locations. This means that LHJs determine how much product each site in their area receives, *except* for chain pharmacy locations. As mentioned above, chain pharmacies receive their own allocation from the federal government and these organizations control where their product goes. Tribal clinics can receive allocations from the federal government through IHS as well as from LHJs.

Future Supply Estimations

The federal government has purchased approximately 20 million courses of Paxlovid from Pfizer and three million courses of molnupiravir from Merck. HHS has estimated that this supply will ensure free access at least until the end of summer 2022. CDPH does not know whether HHS plans to purchase more of either product, and it is difficult to estimate how supply projections would change in a surge. However, both Pfizer and Merck have continued to ramp up production of these products.

3.2 Provider Network

Site Types and Test-to-Treat vs. Alternate Models

Test-to-treat providers ideally have three components: (1) rapid testing; (2) either in-person or telehealth prescribing capabilities with a physician, advanced practice registered nurse, or physician assistant (these are the only individuals able to prescribe COVID-19 oral antivirals); and (3) the ability to dispense COVID-19 oral antivirals according to California state law.

While some therapeutics sites offer a full range of testing, prescribing, and dispensing services, some therapeutics locations are only able to dispense the product. This means that in order to access Paxlovid or molnupiravir at many locations, patients need to first obtain a prescription from a health care provider. The federal government differentiates between test-to-treat and dispensing-only sites with two different online locators: one locator includes just test-to-treat sites, and one includes all locations that can either dispense oral COVID-19 therapeutics or administer monoclonal infusions.

Sites also differ in terms of where their allocations come from and the organization responsible for registering them. The largest **pharmacy chains** in California—including CVS, Walgreens, Rite Aid, Walmart, Safeway, Albertsons, and MedShoppe/LederNet—get their own supply directly from the federal government. While CDPH and LHJs originally helped prioritize some of these locations for earlier access to product based on equity, these major chains now generally decide where to send Paxlovid and molnupiravir. These chains have agreed to maintain plentiful supply in the locations that CDPH and LHJs flagged as equity priorities. Several **federal entities** like the Department of Defense, Indian Health Service, and HRSA maintain test-to-treat sites for the priority populations they serve and are also directly supplied by the federal government. In partnership with LHJs, CDPH is supporting several **state** sites operated by Optum Serve and the Emergency Services Medical Authority in low-access areas. Lastly, LHJs have been identifying, recruiting, and registering **LHJ-supported test-to-treat** locations.

Process for Adding New Sites

LHJs are responsible for vetting additional test-to-treat facilities (that are not state or federally supported) in their area. Local health jurisdictions should email CDPH with the following information to get local test-to-treat sites added to the HHS locator:

- Provider name
- Provider address (including street, city, zip code, and county)
- Provider contact information (including point of contact name, email and phone)
- Provider type (i.e., hospital, pharmacy, health center, etc.)
- Provider setting (i.e., hospital, school, pharmacy, etc.)
- Populations served (i.e., general public, pediatrics, military, etc.)

When CDPH receives the new site request from the LHJ/Medical Health Operational Area Coordinator (MHOAC), CDPH enters it into the HPOP system, and the provider receives an email notification to finish verifying their account. Therapeutic orders are then coordinated through the LHJ/MHOAC, and product is shipped directly to the site. New sites requests must be submitted by Wednesday at close of business each week in order to make it into the allocation cycle ordering sheets the following Monday.

CDPH suggests that all test-to-treat sites have the following characteristics:

- Offer services to all individuals, regardless of insurance status or ability to pay.

- Have hours of operation and language translation services that accommodate local community needs.
- Be able to provide comprehensive end-to-end testing, treating, and prescription-dispensing services to support a seamless patient experience.
- Either be able to conduct rapid COVID-19 testing (result available at time of visit) on-site or provide an evaluation of at-home testing results.
- Have health care providers available to provide timely and thorough assessment and discussion relevant to treatment option(s), consistent with FDA requirements regarding these therapeutic options.
- Have a mechanism to readily dispense oral medications to eligible patients; if necessary, direct prescriptions to pharmacies that have expedited home delivery services.
- Have a plan to refer patients to a provider able to offer infusion services should oral medications be contraindicated, and the patient needs to receive either an anti-SARS-CoV-2 monoclonal antibody (for example, Bebtelovimab) or IV remdesivir.

If providers meet these qualifications and are interested in becoming a test-to-treat provider, they should contact their LHJ or county MHOAC.

Sites are automatically taken down from the HHS Test-to-Treat locator if they do not report inventory or administration data into HPOP for two months. If sites do not report this data for two weeks, a cautionary note for the site pops up instructing patients to call the provider to ensure inventory before arriving at the location. If a LHJ needs a site taken down more urgently, LHJs should email the CDPH Therapeutics inbox with that request.

Requesting to be Added to the Federally Supported Program

The federal government is offering testing, contracting, and reimbursement support to some test-to-treat sites that meet specific criteria. These sites must provide end-to-end test and treat services on-site (this can include telehealth accessed on-site), offer services to all individuals regardless of insurance status, accept test-to-treat patients for priority same-day or next-day visits, provide services at no charge to patients, and be located in counties with high Social Vulnerability Index (SVI) scores. LHJs should coordinate with their MHOAC to request federal support for sites in their area.

Mobile Sites

Several LHJs and organizations are working to create mobile test-to-treat sites, which are not currently supported by the federal government's test-to-treat site locator. The federal website requires a single location for a site to be "pinned" to and does not yet allow states to submit webpage information so that the public can check a program's website to find the mobile site's current location. CDPH has requested a feature change in the federal government site submission system to allow webpage additions, at which point CDPH will be able to start uploading mobile sites. Mobile sites may also be possible to show in My Turn with upcoming My Turn updates (see Section 9.1 for more information).

3.3 Packaging, Storing, and Transferring Information

Packaging and Storage Information

Packing, storage, and handling information is detailed in Section 2 (Clinical Information) of this playbook.

Destroying Product

The COVID-19 environment is dynamic. As such, product return and/or destruction is **NOT** recommended as these drugs may be effective against future variants. Any returned product must be destroyed since it's integrity cannot be verified. If you have storage concerns, consider transferring product to another location/site in your region or health system. The only products that should be destroyed are ones that are no longer usable (i.e., expired, broken packaging, etc.).

If product must be returned from your site, please follow the below guidance:

Guidelines for Product Return

- All therapeutic products are property of the USG and must be used in accordance with EUA guidance.
- Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S.
- All sites should first check with respective state and local health jurisdiction to ensure product cannot be used/stored elsewhere in the state or region
- Doses discarded on site (compromised vials, unused diluted vials, etc.) should be recorded in HPOP.

Transferring Product

All product transfers should be coordinated with MHOACs and Regional Disaster Medical and Health Specialists (RDMHS), and transfers should be kept within the operational area or region when practicable. Transfers can only be made to another registered HPOP provider. Sending and receiving providers must follow the HPOP transfer procedures and the receiving provider will assume all inventory reporting responsibility for the therapeutic(s) transferred. Please ensure cold chain procedures are followed.

4 For Health Plans, Health Systems, Practice Managers, and Providers: Best Practices to Facilitate Access to Therapeutics

Below are some best practices to facilitate test-to-treat pathways and expedite access to 1) testing, 2) prescribing, and 3) medication dispensing.

4.1 Testing

- Update all points of access for patients and employees (i.e., phone tree, website, app, in-person urgent care) with information that streamlines symptomatic patients to same-day or next-day testing. Message that therapeutics are available if they test positive and provide instructions for how to access a same-day prescriber if they test positive.
- To facilitate care, accept self-attestation of a positive COVID-19 test. If providers desire a re-test or verification of test, offer onsite antigen or rapid NAAT test in the office.

4.2 Prescribing

- **Provider education**
    - Ensure medical directors, practice managers, and other relevant staff receive up to date information about therapeutics via webinars, CME opportunities, provider ECHOs, and joining relevant listservs including CDPH's weekly therapeutics update. Individuals can sign up CDPH therapeutics updates here: https://www.surveymonkey.com/r/PK5NBHM
        - Additional information can be found at the CDPH Therapeutics website: COVID-19 Treatments (ca.gov)
        - Providers can also sign up for CDPH Provider Office Hours: COVID-19 Vaccine – California Vaccines for Children (VFC) (eziz.org). The primary topics covered are COVID-19 vaccines, but COVID-19 therapeutics is also covered.
    - Set a regular cadence to share updates, such as a monthly provider meeting.
    - Clinical considerations
        - Point providers to helpful tables reviewing therapeutic options such as those described in Appendix 2 of this playbook.
        - Given that the FDA's latest EUAs provide greater flexibility for clinical judgment in prescribing therapeutics, encourage providers to expand eligibility for therapeutics to:
            - those over the age of 50 regardless of the presence of other risk factors, given those over 50 have a 25-fold risk of death compared to 18–29-year-olds
            - populations who have structural barriers to health and/or faced disproportionate rates of hospitalization and death from COVID-19
        - Clarify to providers that verification of oxygen saturation is not a pre-requisite to prescribing COVID-19 therapeutics and providers can use clinical judgement in

assessing whether patients have mild-to-moderate COVID-19 that would qualify them for therapeutics. This is particularly relevant for telemedicine visits.
    - Remind providers that based on the initial Paxlovid trial data, approximately 18 patients would need to be treated in order to prevent one hospitalization and 87 patients would need to be treated to prevent one death.
    - Clarify to providers that regarding reports of Paxlovid rebound cases to date:
        - Nearly all have been mild-to-moderate (in one study, <1% of cases presented to the ED or hospital)
        - No evidence currently exists to suggest that rebound is due to mutations causing Paxlovid resistance
        - Reports of rebound should not be considered as treatment failures and should not deter use
- **Develop workflows to facilitate access to a prescriber/prescription**
    - Update all points of access for patients and employees (i.e., phone tree, nurse advice lines, website, app, in-person urgent care) to funnel those who have a positive test and are symptomatic to discuss with a same-day provider, either in-person or via telehealth to minimize the number of places a patient has to go to eventually access medications. See Appendix 2 for tools regarding clinical workflows.
    - Provide a member/patient call center line to assist with access to COVID-19 treatment options.
    - Use population health management approaches to identify all in a practice setting who might qualify based on age or other comorbidities. Designate a status in their chart such as "COVID therapeutic eligible" so that if they develop COVID later they are more quickly identified as eligible.
    - Use population health management approaches to identify and contact all immunocompromised individuals who would qualify for Evusheld as pre-exposure prophylaxis (see description of immunocompromised in Section 2.5).
- **Navigating drug interactions**
    - Make providers aware of the websites to check drug-drug interactions (DDIs) in Section 2.7 of this playbook. This is particularly relevant for Paxlovid which contains ritonavir, a CYP3A4 inhibitor
    - Make clinical consultation advice lines available for providers and pharmacists to support COVID-19 treatment guidance, including having an on-call pharmacist or pharmacy hotline that providers can call to discuss difficult cases.
    - Find alternative ways to verify patients' medication list if you do not have access to their full medical record. This can include calling the patient's pharmacy or their usual doctor's office for their medication list
    - Review Electronic Health Record (EHR) e-prescribing function to ensure access to medication reconciliation through Surescripts or other third-party entity when possible.

- **Prescribing to a pharmacy that has therapeutics**
  - Clinicians must prescribe to a pharmacy that carries COVID-19 therapeutics, which can be identified at: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/.
  - Regularly review and confirm that prescribing workflows accurately connect patients to pharmacies carrying oral COVID-19 therapeutics. This could include ensuring the default or "preferred" pharmacy is able to accommodate prescription fulfillment.
  - Promote prescription options with same-day home delivery through courier and/or expedited mail order. For example, Walgreens has ample Paxlovid supply through the federal government and provides free same-day or 1-2-day delivery (depending on specific addresses and Rx timing) to Medi-Cal patients.
  - If e-prescribing is a barrier, develop alternative prescribing workflows such as phone and/or fax. See Section 7.2 on Alternatives to Electronic Prescribing.
  - If a patient is not eligible for an oral therapeutic and/or infusion is preferred, regularly review and confirm ordering workflows that accurately connect patients with COVID-19 infusion network(s) in a timely manner. Attention should be given to how providers can best support scheduling appointments and coordinating patient transportation to and from the appointment, if necessary.

4.3 Dispensing

See Section 7 for more information about dispensing. In addition, ask your legal counsel to review the Board of Pharmacy's lawbook to understand dispensing limitations. If you do not have counsel on hand, consider hiring counsel to review these regulations and to provide you with risk assessment of any dispensing pathways you are interested in pursuing.

4.4 Other best practices

- Member/patient education: Support robust consumer marketing and awareness campaigns that include information about COVID-19 treatment and how to access.
- Caring for uninsured patients and/or a patient new to your clinic or system.
  - Lower barriers to seek urgent care for evaluation and treatment for COVID-19, including shortening or bypassing standard enrollment processes.
  - Become a Medi-Cal Qualified Provider to access the COVID-19 Uninsured Group Program. This program allows uninsured patients get coverage for their COVID-19 care.
    - Step 1: Make sure you are a Medi-Cal provider (in some cases you may also need to be a provider for a separate Health Access Program). Information about how to sign up as a Medi-Cal provider can be found at the Provider Application and Validation for Enrollment (PAVE) page on the DHCS website
    - Step 2: Become a COVID-19 Uninsured Group Qualified Provider by enrolling in any of the following Presumptive Eligibility programs. **Note: you do not need

to treat the specific populations listed in these programs in order to become a Qualified Provider.**

- Hospital Presumptive Eligibility
    - Hospital Presumptive Eligibility (HPE): Provider Enrollment Instructions
    - Hospital Presumptive Eligibility (HPE) Program Provider Election Form and Agreement
- Presumptive Eligibility for Pregnant Women
    - Presumptive Eligibility for Pregnant Women Provider Enrollment Instructions
    - Qualified Provider Application and Agreement for Participation in the Presumptive Eligibility for Pregnant Women (PE4PW) Program
- Child Health and Disability Prevention
    - CHDP

- Step 3: Once you are a Qualified Provider of the COVID-19 Uninsured Group, assist uninsured patients to enroll into the COVID-19 Uninsured Group. (Patient applicants do not have direct access to the portal which is only available to Qualified Providers)
    - Option 1: Paper transcription
        - Download a paper version of the application at: MC 374 Application for Coverage of Coronavirus (COVID-19) Testing Costs
        - Have the patient fill out the application
        - Transcribe the individual's information directly into the COVID-19 Uninsured Group Application Web Portal (Coronavirus (COVID-19) Uninsured Group Application Web Portal User Guide (COVID19 Uninsured Group)based on their answers to the paper application
    - Option 2: Online entry with patient
        - Navigate to the COVID-19 Uninsured Group Application Web Portal (Coronavirus (COVID-19) Uninsured Group Application Web Portal User Guide (COVID19 Uninsured Group) with the patient in the room. Providers can log into the online portal using the user guide provided
        - Fill out the application based on the patient's verbal answers
- After the application is submitted online, the eligibility results are immediate (approval or denial). Providers will be able to see a real-time eligibility response on their web browser.
- A Medi-Cal ID number is generated for the patient which can then be used for billing and claims.

  - For more information, see: https://www.dhcs.ca.gov/services/medi-cal/eligibility/Pages/COVID-19-Presumptive-Eligibility-Program.aspx

- Follow-Up: Provide for follow-up with the member/patient to confirm access to therapeutics and address questions or concerns about side effects
- Equity and Reporting: Develop metrics and tracking systems to regularly review COVID-19 utilization data, identify disparities to help prioritize resources. Example metrics include:
  - Time from symptom onset to receipt of therapeutic
  - Time from initial contact with member to receipt of therapeutic
  - Member demographics accessing treatment, including: SDOH, race, ethnicity, zip code, and age
  - Percent of symptomatic and COVID-19 positive patients that are evaluated by a prescriber
  - Percent of symptomatic and COVID-19 positive patients that receive a prescription for a therapeutic and/or referral for mAb infusion
  - Reasons why a patient was *not* prescribed a therapeutic
- Provide CDPH with recommendations to improve access to COVID-19 outpatient treatment options. You can provide information, feedback, and recommendations to CDPH at this link: https://www.surveymonkey.com/r/PL3FHZ9.

5 Patient Pathways to Treatment

Ideally, patients access therapeutics via their regular healthcare clinic and/or system—either in person or through telehealth—by scheduling an urgent care/walk in appointment. The patient can show their at-home rapid test/PCR results or take a rapid test at the clinic. If clinically appropriate, the health care practitioner submits the patient's prescription to the patient's pharmacy of choice (which may or may not be located on-site with the clinic), confirming that pharmacy has product using the HHS Therapeutics Locator. The patient may opt for mail delivery or go to the pharmacy to pick up their medication.

While this pathway is most familiar to people, reports indicate that many patients are not able to quickly access their regular care providers and/or their providers are not yet prescribing therapeutics to eligible COVID-positive patients. If patients cannot quickly access therapeutics through their usual healthcare provider, patients can look for test-to-treat facilities using the HHS Test-to-Treat locator, California's My Turn website, or by talking to a provider or other trusted messenger who directs them to a test-to-treat site. These sites should then be able to test the patient (or patient can report/show their positive test result) and connect the patient to a health care provider either in-person or via a telehealth platform who can then prescribe medication if clinically appropriate. This prescription is dispensed at the location, sent to the patient's pharmacy of choice, or mailed to the patient. location, sent to the patient's pharmacy of choice, or mailed to the patient.

5.1 Special Populations

People Experiencing Homelessness

People experiencing homelessness (PEH) face additional barriers to accessing COVID-19 therapeutics. One successful outreach program for PEH—Housing for Health—has found that therapeutics should be paired with on-site shelter health clinics and outbreak response teams that already have pre-existing and trusting relationships with their patients.

These teams also recommend that prescribing clinicians use a self-report model of assessment for patient drug histories and health conditions, given that lab and medical records access may be sparse for this group. If unable to confirm medication history, clinicians may consider prescribing molnupiravir, which does not have the same drug-drug interaction risks that Paxlovid does but is less effective. Clinical care teams for people experiencing homelessness should review the dispensing regulations in Section 7 to determine whether they can carry oral antivirals and directly dispense them on-site as soon as a patient receives their prescription.

6 Billing and Reimbursement

Because the federal government provides COVID-19 therapeutics at no cost to providers and pharmacies, organizations cannot bill insurance for the drugs' ingredient cost. However, providers may bill insurance for dispensing fees and physician visits to evaluate patients and prescribe therapeutics. HHS has stated that "costs should not be a barrier to patient access" and indicated that patients should never be charged for medications. This federal guidance has not been translated into enforced regulations, and as a result, patients may need to pay out of pocket or get prior approval from their health plan to access out-of-network test-to-treat sites.

6.1 Commercial Insurance & General Info

At present, there are no federal rules or regulations mandating that private insurance plans cover COVID-19 treatment. Any existing cost-sharing under these plans like copayments and deductibles may apply to treatment services, although some health insurance plans are temporarily waiving cost-sharing fees for COVID-19 treatment. Patients can find more information about their health plan's policies by calling the patient services number on the back of their health insurance card.

6.2 Medi-Cal

During the public health emergency (PHE) and through one year after the PHE ends, Medi-Cal and other state Medicaid programs are required to cover treatment for most enrollees without cost sharing.

6.3 Medicare

Medicare Part D coverage does not typically include drugs that are not FDA-approved such as EUA medications. However, the Centers for Medicare and Medicaid Services (CMS) issued a memo regarding Paxlovid and Molnupiravir coverage in November 2021 strongly encouraging Part D sponsors to offer oral antiviral coverage to their enrollees. Again, because the federal government is providing these medications for free to states, Medicare patients cannot be charged any ingredient costs for the drug. The CMS memo allows Part D sponsors to pay dispensing fees to pharmacies for issuing the drug and asks Part D sponsors to consider paying higher dispensing fees to encourage more dispensing. Lastly, HHS Outpatient Treatment Guide instructs Part D sponsors that they should not charge enrollee cost-sharing on dispensing fees paid to pharmacies.

6.4 Uninsured

The California Department of Health Care Services (DHCS) COVID-19 Uninsured Group Program covers COVID testing, treatment, and all medically necessary care (including health care provider visits necessary for prescribing COVID-19 therapeutics) at no cost to the individual until the end of the COVID-19 PHE. Eligible individuals must enroll through a qualified provider which usually occurs in the hospital setting where these enrollment pathways have been established. More information is

available on DHCS website. Uninsured patients can also get treatment services from FQHCs and county public hospital systems, which provide care to all individuals, regardless of insurance status, immigration status, or ability to pay.

The HRSA Uninsured Program previously paid provider claims for COVID-related care for the uninsured. This program no longer has funding and will not accept claims.

7 Regulatory and Legal

7.1 Prescribing Personnel and Settings

As of the publication of this playbook, the FDA's EUAs for Paxlovid and Molnupiravir state that these medicines can only be prescribed for an individual patient by physicians, advanced practice registered nurses, or physician assistants that are authorized under state law to prescribe anti-infectives (the class of drugs that Paxlovid and Molnupiravir belong to). Because the Emergency Use Authorization (EUA) for these drugs specifies that they must be prescribed to individual patients, California cannot issue a standing order allowing pharmacists to prescribe at this time.

7.2 Alternatives to Electronic Prescribing

Statement Regarding Dispensing Prescriptions Not Transmitted Electronically (Email from Board of Pharmacy to California Pharmacies from January 7, 2022)

"The California State Board of Pharmacy (BOP) has received reports of pharmacists refusing to fill prescriptions not transmitted electronically since provisions of Business and Profession Code (BPC) section 688 – which requires most prescriptions to be issued and received as electronic data prescriptions (or e-prescriptions) – took effect January 1, 2022.

Licensees are reminded that 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. In addition, BPC section 688(i) states pharmacists may continue to dispense medications from legally valid written, oral, or faxed prescriptions pursuant to law. Thus, under BPC section 688, pharmacists can fill a legally valid written, oral or faxed prescription if the only issue is that the prescription was not received electronically. 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."

7.3 Dispensing

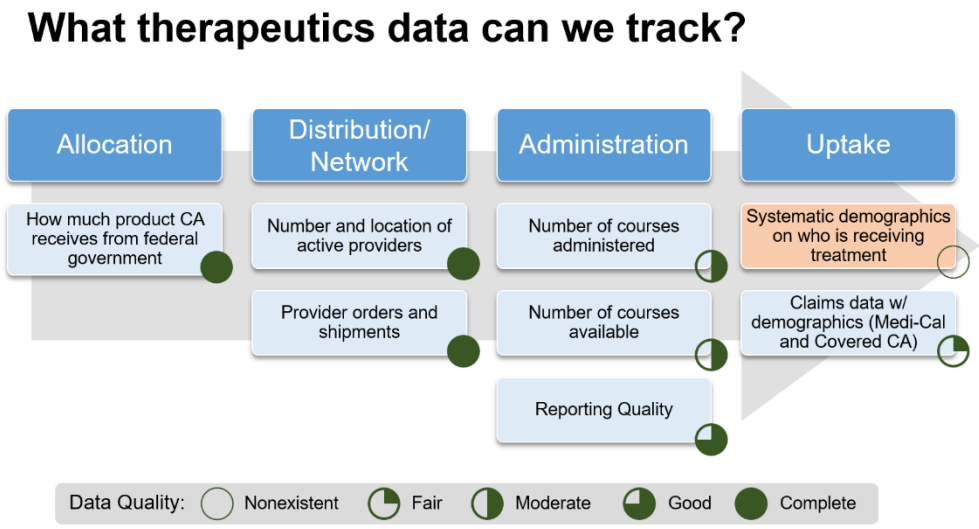
Disclaimer: The content of this section has been prepared by the Office of Legal Services for the California Department of Public Health. This document is to be used for informational purposes only and does not constitute legal advice. None of the legal references contained in this document shall be construed as an offer to represent you, nor does the receipt of such information constitute an attorney-client relationship. The code sections referenced are to serve as a guide and are not representative of all laws that may apply. Nothing contained in this document is intended to provide legal advice or create a contractual or attorney-client relationship. Please consult with your own legal counsel to determine the applicability of the code sections.

There are five general pathways to dispensing COVID-19 therapeutics:

1. **Licensed pharmacies and pharmacists** as described and regulated by California state law and regulations.
2. **Physician dispensing** under BPC 4170: Physicians may dispense drugs to patients under their California state medical license as long as they meet certain criteria and follow state regulations. Physicians can only dispense drugs to their own patients, and drugs must be "necessary in the treatment of condition" for which the physician is seeing the patient. Physicians must also meet labeling, storage, and other requirements as laid out in state regulations. Additional information and requirements are included in Appendix 11 under Physician Dispensing (note that the information included is not exhaustive of all relevant regulations).
3. **Clinics licensed under 4180**: Several types of licensed clinics may dispense drugs under the direction of a physician or surgeon to patients registered for care at that clinic. These clinics include community clinics, primary care clinics, tribal health clinics, and student health clinics. The clinics must comply with records-keeping regulations. Additional information and requirements are included in Appendix 11 under 4180 Clinics and Additional Rules (note that the information included is not exhaustive of all relevant regulations).
4. **Mobile site dispensing** under state-of-emergency rules: Pharmacies or 4180-licensed clinics may establish a licensed "mobile pharmacy or clinic" during a declared federal, state, or local emergency. These mobile pharmacies must retain records of dispensing, and a pharmacist (or professional director of a 4180 clinic) must be on site. Additional information and requirements are included in Appendix 11 under Special Rules During an Emergency (note that the information included is not exhaustive of all relevant regulations). For more information on mobile site dispensing to determine whether your facility may apply, please contact the Board of Pharmacy directly with your specific request at Amber.Dillon@dca.ca.gov.
5. **Temporary waivers** issued by the CA Board of Pharmacy (BOP): During the public health emergency, BOP has limited ability to waive some regulations regarding dispensing in California. These waivers have allowed some dispensing in different settings and with different personnel if certain conditions are met. More information is in Appendix 11 under Waivers.

8 For Local Health Jurisdictions: Data

There are two datasets of COVID-19 therapeutics available to CDPH and LHDs: 1) shipping and ordering data and 2) utilization data. While the California Immunization Registry provided a wealth of demographic and geographic information about who was getting COVID-19 vaccines in the state, there is no similar registry for prescription medications. This means CDPH has access to information about how many treatment courses are being administered and the providers administering them, but CDPH does not have significant insight into who is *receiving* treatment courses—making it difficult to infer how equitable the distribution of COVID-19 treatment is.



8.1 Available Data

The Therapeutics Shipping and Ordering dataset pulls together ordering information from HPOP and shipping and delivery information from AmerisourceBergen. HPOP is the system CDPH uses for entering site-level therapeutics orders for all state- and LHJ-coordinated therapeutics sites. AmerisourceBergen is the shipping company that the federal government has contracted with to deliver COVID-19 therapeutic products. This dataset includes ordering and shipment data for all COVID-19 therapeutics providers (i.e., pharmacy chain locations and federal entities as well as state- and LHJ-coordinated sites), so it is a complete record of all COVID-19 medications coming into the state. Delivery status information for this data may be on a slight delay (up to 24 hours).

The Therapeutics Utilization dataset is based off of provider reporting. The federal government requires that all COVID therapeutics providers report into the HPOP system each day they are open with 1) the number of courses they have administered of each product type and 2) the number of courses they have available for each product type. This information is what HHS uses to indicate where product is available on the HHS therapeutics locator. Unfortunately, the utilization dataset is at times

difficult to use depending on the rate providers are reporting. As of May 2022, percent of Paxlovid and molnupiravir providers that reported utilization data in the previous week was 70%. Active reporting rates are higher for chain pharmacies like CVS and Walgreens, and lower for state- and LHJ-coordinated sites like local health clinics and pharmacies. This bias in reporting rates can make utilization data difficult to accurately analyze.

Both datasets are housed in the federal COVID-19 data tracking system (called Tiberius) and are currently in the process of being piped into Snowflake, the same platform that LHJs currently use to access vaccination data.

8.2 Data Gaps

Neither of the above datasets include any information about the recipients of COVID therapeutics, and providers are not required to collect this information. CDPH has tried to access therapeutics claims data from Medi-Cal and Covered California to measure equitable distribution, but because the ingredient cost of the drug is free, many providers are not submitting claims information to insurance plans. Electronic health record data and health information exchange data also appear to be missing these records. CDPH is currently investigating other methods to obtain demographic data on therapeutics recipients.

9 What's Next

9.1 Additional Investments to Support Equitable Access to Therapeutics

CDPH is exploring additional investments to support equitable access to therapeutics, including funding to support safety net providers and communications.

9.2 Test-to-Treat Playbook 2.0

Later in Summer 2022, CDPH plans on updating this playbook to include:

- Any updated clinical information
- The results of therapeutics data exploration
- Updates to best practices for expanding equitable access to test-to-treat sites and therapeutics, highlighting innovations and themes from additional LHJs
- Feedback and ongoing questions we receive from LHJs, health systems, and providers

10 APPENDICES

- Appendix 1: Online Resources
- Appendix 2: Therapeutic Treatment Options & Clinical Decision Aids
- Appendix 3: Therapeutics Pathways to Access
- Appendix 4: EMSA Monoclonal Antibody Therapeutics Model
- Appendix 5: EMSA Therapeutics Dosing Regimens
- Appendix 6: EMSA Monoclonal Antibody Consent Form
- Appendix 7: EMSA Paxlovid Protocol
- Appendix 8: EMSA Therapeutics Start-up Site
- Appendix 9: Paxlovid Providers Checklist from NY DPH
- Appendix 10: Dispensing Regulations
- Appendix 11: Optum Serve Talking Points
- Appendix 12: Acronyms

10.1 Appendix 1: Online Resources

Federal Resources

- NIH Treatment Guidelines – Provides clinical guidance as well as drug and patient prioritization guides
- Health Care Provider Fact Sheets:
  - Paxlovid
  - Sotrovimab
  - Bebtelovimab
  - Remdesivir
  - Remdesivir (For patients <12 years)
  - Molnupiravir
  - Evusheld
- Patient Fact Sheets
  - Paxlovid
  - Molnupiravir
  - Sotrovimab
  - Bebtelovimab
  - Evusheld
- ASPR/HHS COVID-19 Therapeutics website – Federal level information on allocation and use
  - Side-by-side comparison table for available drugs: Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19 (hhs.gov)
  - ASPR HPoP Direct Ordering Fact Sheet
- HHS' regularly updated Outpatient Treatment Guide: contains a clinical decision aid, dosing and packaging information, and other resources
- A drug-drug interaction checker for COVID-19 therapeutics

California Department of Public Health (CDPH) Resources

- CDPH COVID-19 Treatment's webpage – information for patients and providers and CDPH allocation process. The CDPH Therapeutics webpage provides general information for the public and providers regarding outpatient therapeutic options for COVID-19.
  - CDPH COVID-19 Therapeutics Product Guide (2/24/2022)
  - CDPH COVID-19 Oral Antiviral Info Sheet and FAQ for California Pharmacists

Payment Information

- CMS payment information: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
- Association of America's Health Insurance Plans information page on payment for covid 19 services: https://www.ahip.org/news/articles/health-insurance-providers-respond-to-coronavirus-covid-19

10.2 Appendix 2: Therapeutics Treatment Options and Clinical Decision Aids

Available Outpatient COVID-19 Therapeutics

SARS-CoV-2 Negative (-) Patients

Not Exposed	Exposed
Pre-Exposure Prophylaxis (PrEP)	Post-Exposure Prophylaxis (PEP)
Long-Acting Monoclonal Antibody • Tixagevimab/cilgavimab (Evusheld)	Currently no authorized treatments

SARS-CoV-2 Positive (+) Patients

Mild to Moderate Illness in Individual at High Risk for Disease Progression
Treatment options, in order of preference: 1. Nirmatrelvir/ritonavir (Paxlovid) 2. Remdesivir (Veklury) **If above options are unavailable or not medically appropriate, can consider (in alphabetical order):** 3. Bebtelovimab 4. Molnupiravir (Lagevrio)

Summary of Outpatient COVID-19 Therapeutics

Treatment of Acute Disease

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Treatment Effectiveness	Activity Against Variants Currently Circulating
Bebtelovimab 175 mg given as a single intravenous injection	Intravenous	12 years and older and weighing at least 40 kg	As soon as possible, but within 7 days of symptom onset	In low-risk adults, 34% relative reduction in viral load compared to placebo and a relative reduction in time to sustained symptom resolution compared to placebo. Currently there is no trial data to determine difference in clinical outcomes between placebo and treatment arms.	Effective against Omicron, including BA.2 subvariant

Drug	Route	Age groups authorized for treatment	Timing of Treatment	Effectiveness	Activity Against Variants Currently Circulating
Nirmatrelvir with ritonavir (Paxlovid) Orally twice daily for 5 days • For patients with normal/mild renal impairment (eGFR > 60 mL/min): **300 mg nirmatrelvir with 100 mg ritonavir** • For patients with moderate renal impairment (eGFR ≥ 30 to < 60 mL/min): 150 mg nirmatrelvir with	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, a relative risk reduction of 89% in hospitalizations or deaths.	Effective against Omicron, including BA.2 subvariant

100 mg ritonavir					
Remdesivir (Veklury) • For adults and pediatric patients weighing ≥ 40 kg: 200 mg IV on Day 1, followed by 100 mg IV daily on Days 2 and 3 • For pediatric patients ≥ 28 days old and weighing ≥ 3 kg to < 40 kg: 5 mg/kg IV on Day 1, followed by 2.5 mg/kg IV daily on Days 2 and 3.	Intravenous	FDA approved for use: 12 years and older and weighing at least 40 kg FDA EUA for use: pediatric outpatients <12 years and/or children weighing 3.5 kg to 40 kg	As soon as possible, but within 7 days of symptom onset	Compared to placebo, a relative risk reduction of 87% in hospitalizations or deaths.	Effective against Omicron, including BA.2 subvariant
Molnupiravir (Legevrio) 800 mg	Oral	18 years and older	As soon as possible, but within 5	Compared to placebo, a relative risk	Effective against Omicron,

Orally twice daily for 5 days			days of symptom onset	reduction of 30% in hospitalizations or deaths.	including BA.2 subvariant

Pre-Exposure Prophylaxis

Drug	Route	Age groups authorized for treatment	Pre-Exposure Prophylaxis Effectiveness	Activity Against Variants Currently Circulating
Tixagevimab 300 mg / 300 cilgavimab mg (Evusheld) Given as two separate, consecutive injections	Intramuscular	12 years and older and weighing at least 40 kg	Reduced the risk of developing symptomatic COVID-19 by 77% compared to placebo.	Effective against Omicron, including the BA.2 subvariant

Treatment Guidelines

- COVID-19 Treatment Guidelines (nih.gov)
- Non-hospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines (nih.gov)
- HHS Clinical Implementation Guide (PDF)

Treatment Algorithms (Flow Charts)

- HHS Outpatient Therapeutics Decision Aid (PDF)
- IDSA Outpatient Treatment Roadmap (PDF)

10.3 Appendix 3: Therapeutics Pathways to Access

COVID-19 Therapeutics Pathways to Access

	COVID-19 Test		Health Care Provider Visit		Prescription Dispensing			
	Results from at-home or PCR test	Rapid test on-site	In-Person	Telehealth	On-Site	Partner Pharmacy[2]	Patient pharmacy of choice[3]	Mail order
Test-to-Treat[1]	✓	✓	✓	✓	✓	✓	✓	✓
"Traditional" Rx Journey	✓	✓	✓	✓	✗	✗	✓	✓
Telehealth-Based Pathway	✓	✗	✗	✓	✗	✗	✓	✓

[1] In order to be mapped on HHS' Test-to-Treat locator, T2T facilities must have a physical location. T2T facilities must also accept all patients, regardless of insurance type. Patients can find Test-to-Treat locations using the HHS Test-to-Treat locator.

[2] "Partner Pharmacies" must be located in same office, building, or area as the T2T clinic. If dispensing medication to patients in-person, they cannot be located > .25 miles of safe walking distance (i.e., no major highways to cross) away from the T2T clinic. They do not have to be officially affiliated with T2T clinic but must be prepared to direct interested T2T patients to the clinic. Partner pharmacies may dispense medication via mail/delivery service if the pharmacy can guarantee delivery within 12 hours.

[3] Providers can check COVID-19 Tx on stock using the HHS Therapeutics Locator.

Types of Oral Antiviral Providers

Federal

Chain Retail Pharmacies

Federal Agencies

Some Federally Qualified Health Centers

State

Optum Serve Test-to-Treat Sites

Emergency Medical Services Authority Sites

Local

LHD-Selected Sites and Locations

Includes Primary Care Offices, Community Clinics, and Some FQHCs

10.4 Appendix 4: EMSA Monoclonal Antibody Therapeutics Model

SharePoint Link: EMSA Monoclonal Antibody Therapeutics Model.pdf

EMSA COVID-19 Therapeutics Model

Introduction

Patient Flow, Stations, and Staffing

This Monoclonal Antibody Therapeutics model is designed as a point-to-point model flow. This model includes patient intake, administration of Monoclonal Antibody therapeutics, and post-infusion observation areas.

The Monoclonal Antibody Therapeutics Model is designed to be scalable to facility size, community needs, and level of staffing for 12-hour workdays.

Staffing breakdown for oral or IV Monoclonal Antibody Start up sites

Entrance or Check-in	Infusion MAB Area	Oral Therapeutics Area	Post Infusion Observation	Pharmacy (Optional)
1 MEDICAL SCREENER (LEVEL: LVN OR CNA) 1 RUNNER (LEVEL: LVN OR CNA)	1 EMERGENCY MEDICINE PHY SICIAN 2-4 RN 1-2 EXTENDERS (LEVEL: LVN OR CNA)	1 EMERGENCY MEDICINE PHY SICIAN 2 RN 1-2 EXTENDERS (LEVEL: LVN OR CNA)	1-2 LVN	1 PHARMACIST 1 PHARMACY TECHNICIAN

Note: If the site is offering both oral and IV therapeutics only, 1 physician on-site can support both departments

Facility Layout

Entrance or Check-in Station

- Staffing: Medical Screener (LVN or CNA)
- Critical Functions: At this station, patients will be greeted, provided a surgical mask, medically evaluated (e.g., history, vitals, known medication allergies, other medical criteria). Patients will be masked for the duration of their course of treatment.
- Runner: an identified runner will escort the checked-in patient to the identified infusion station and conduct a hand-off. No visitors will be allowed in the infusion or observation area.
- Note: Donning and Doffing areas along with hot and cold zones are dependent on facility layout.

Infusion Area

- Staffing: emergency medicine physician, registered nurses and extenders (LVN or CNA).
- Critical Functions: Identified treatments spaces including a chair/cot/bed
- Minimum Infusion Times can range from 16 minutes to 70 minutes depending on the product and the product EUA. *Current approved MAB Bebtelovimab is administered IV push over 30 seconds.*
  - All infusions must be followed by an observation period of 60 minutes per the EUA.
  - Patients may spend their observation period in the same chair/bed/cot space they were infused in.
- All chairs, beds, cots, stations, and equipment should be cleaned and disinfected between patients.
- Staff should have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Post-Infusion Observation

- Staffing: LVN
- Critical Functions: Identified area for patients to complete their observation period for 60 minutes per the EUA.
- Staff will have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

  At the conclusion of post-infusion monitoring, patients will have their final medical evaluation for clearance to leave the facility and will receive post-procedure instructions for proper follow-up with a primary care provider.

- Runner: Escort the patient directly to the facility exit.
- All beds, stations, and equipment should be cleaned and disinfected between patients.

Additional Areas On-site:

- Pharmacy: A Pharmacist or Pharmacy Technician is optional. Per the EUA, monoclonal antibodies can be prepared by a qualified healthcare professional using aseptic technique, and do not require a laminar flow hood for preparation.
    - A refrigerator with temperature monitoring is required for onsite monoclonal antibody product storage.

Supply List:

IV THERAPEUTICS	QTY	KIND
25G X 5/8 SAFETY HYPODERMIC NEEDLES	500	EACH
18G HYPODERMIC NEEDLES	500	EACH
3ML LUER LOCK	500	EACH
ZIP LOCK BAG WITH COPY OF PATIENT EDUCATION SHEET	500	EACH
INFUSION SUPPLIES	**QTY**	**KIND**
IV STARTER KIT	500	EACH
IV EXTENSION SET	500	EACH
3ML LUER LOCK	500	EACH
18G HYPODERMIC NEEDLES	500	EACH
20G IV INSERTION NEEDLES	200	EACH
22G IV INSERTION NEEDLES	200	EACH
24G IV INSERTION NEEDLES	200	EACH
NORMAL SALINE 10ML FLUSH	500	EACH
SITE SUPPLIES AND PATIENT ASSESSMENT (REQUIRED FOR BOTH ORAL & INFUSION THERAPY)	**QTY**	**KIND**
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH
HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH

HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH
HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
OFFICE SUPPLIES (STAND ALONE SITES ONLY)	**QTY**	**KIND**
PENS	100	EACH
CLIP BOARDS	5	EACH
HIGHLIGHTERS	1	PACK
PEN HOLDER	2	EACH
STAPLER	2	EACH
STAPLES	2	PACK
STAPLER REMOVER	1	EACH
TAPE DISPENSER	2	EACH
REFILLABLE TAPE	2	PACK
MASKING TAPE	2	PACK
PAPER CLIPS	2	PACK
BOX CUTTER	1	EACH
COPY PAPER	500	EACH
AA BATTERIES	2	PACK
AAA BATTERIES	2	PACK
WALKIE TALKIE	4	EACH
HAND SANITIZER	5	EACH
SHEET PROTECTOR	50	EACH
MANILA FOLDERS	100	EACH
NOTE PADS	10	PACK
FOLDER TABS	2	PACK
3 INCH BINDER	2	EACH
HANGING FOLDERS	100	EACH
3 HOLE PUNCHER	1	EACH
FLASHLIGHT	1	EACH
DISINFECTANT WIPES	10	EACH
PAPER TOWELS	TBD	OES Wrap Around Service
HAND SOAP	TBD	OES Wrap

		Around Service
FACIAL TISSUES	TBD	OES Wrap Around Service
TOILET PAPER	TBD	OES Wrap Around Service
TOILET SEAT COVERS	TBD	OES Wrap Around Service
FIRST AID KIT	1	EACH
BROOM	1	EACH
DUSTPAN	1	EACH
RECYCLING BIN	TBD	
WASTE BASKET	TBD	
TRASH BAGS 40-45 GALLON	TBD	
BIOHAZARD BAGS	TBD	
SHARP CONTAINERS	TBD	
MAB FURNITURE (DEPENDS ON FACILITY)	**QTY**	**KIND**
CHAIRS	TBD	IV or Oral
MED CART	TBD	IV or Oral
FAST BEDS	TBD	IV only
IT SUPPLIES (STAND ALONE SITES ONLY)	**QTY**	**KIND**
LABTOP WITH MOUSE	2	EACH
LAND LINE PHONE	2	EACH
PRINTER	1	EACH
TONER CARTRIDGES	2	EACH
OUTSIDE VENDOR (STAND ALONE SITES ONLY)	**QTY**	**KIND**
SET UP PHONE LINE AND WIFI	1	SERVICE
SET UP JANITORIAL SERVICE	1	SERVICE
SET UP SHREDDING SERVICE	1	SERVICE
SET UP BIOHAZARD WASTE SERVICE	1	SERVICE
PPE SUPPLIES (STAND ALONE SITES ONLY)	**QTY**	**KIND**
GLOVES - SMALL	TBD	OES
GLOVES - MEDIUM	TBD	OES

GLOVES - LARGE	TBD	OES
GLOVES - XLARGE	TBD	OES
N95 MASK	TBD	OES
SURGICAL MASK	TBD	OES
FACE SHIELD	TBD	OES
HAIR NET	TBD	EMSA
SHOE COVERS	TBD	EMSA
GOWNS	TBD	OES
MEDICATION ON HAND (ORAL & IV SITES) - REQUIRED	**QTY**	**KIND**
DIPHENHYDRAMINE 50MG/ML	12	EACH
DIPHENHYDRAMINE 25MG (PO)	1	BOTTLE
SOLUMEDROL 120MG IV PUSH	12	EACH
ONDANSETRON 4MG ODT	30	EACH
ONDANSETRON 4MG/2ML VIAL	12	EACH
GLUCAGON	6	EACH
D50	3	EACH
ADRENALINE 1ML/1ML VIAL	6	EACH
EPI-PEN (ADULT)	6	EACH
EPI-PEN (PEDS)	3	EACH
ALBUTEROL INHALER	6	EACH
NORMAL SALINE 1000ML IV BAG	1	CASE
THERAPEUTICS PROVIDING	**QTY**	**EACH**
BEBTELOVIMAB (IV PUSH)	TBD	
PAXLOVID (ORAL)	TBD	
LAMINATED SIGNS (STAND ALONE SITES ONLY)	**QTY**	**EACH**
TREATMENT ROOM 1	1	EACH
TREATMENT ROOM 2	1	EACH
TREATMENT ROOM 3	1	EACH
TREATMENT ROOM 4	1	EACH
TREATMENT ROOM 5	1	EACH
TREATMENT ROOM 6	1	EACH
TREATMENT ROOM 7	1	EACH
TREATMENT ROOM 8	1	EACH
HOT ZONE	1	EACH
CLEAN AREA	1	EACH
DIRTY AREA	1	EACH
PPE REQUIRED BEYOND THIS POINT	2	EACH

NO PHOTOS OR VIDEO ALLOWED	2	EACH
DO NOT ENTER	2	EACH
STAFF ONLY	2	EACH
MEDICATION ONLY	2	EACH
MAB PARKING SPACE 1	1	EACH
MAB PARKING SPACE 2	1	EACH
MAB PARKING SPACE 3	1	EACH
MAB PARKING SPACE 4	1	EACH
MAB PARKING SPACE 5	1	EACH
MAB PARKING SPACE 6	1	EACH
MAB PARKING SPACE 7	1	EACH
MAB PARKING SPACE 8	1	EACH
MAB FORMS & BINDER (ALL FACILITIES - REQUIRED)	**QTY**	**KIND**
EMSA MAB POLICY AND PROCEDURE BINDER	2	BINDERS
EMSA MAB CONSENT FORMS	1	EACH PT
EMSA MAB PATIENT DISCHARGE FORMS	1	EACH PT
EMSA MAB INTAKE RECORD FORMS	1	EACH PT
EMSA MAB PATIENT EDUCATION FORMS	1	EACH PT
EMSA MAB FLYER (SPECIFIC FOR EACH FACILITY)	1000	EACH
EMSA MAB PARENT/GUARDIAN CONSENT (12-17YR)	STANDBY	IF NEEDED
EMSA MAB MEDICATION TRACKING LOG (PHARMACY ONSITE)	1	BINDER

Emergency Medical Services Authority COVID-19 Therapeutics

10.5 Appendix 5: EMSA Therapeutics Dosing Regimens

SharePoint Link: Dosing Regimens MAB Therapeutics.pdf

CALIFORNIA EMERGENCY MEDICAL SERVICES AUTHORITY

Dosing Regimens for the Drugs Recommended for High-Risk, Non-hospitalized Adults with Mild to Moderate COVID-19.

Drug Name	Dosing Regimen	Time From Symptom Onset
Ritonavir-Boosted Nirmatrelvir (Paxlovid)	**eGFR ≥60 mL/min:** Nirmatrelvir 300 mg with RTV 100 mg PO twice daily for 5 days **eGFR ≥30 to <60 mL/min:** Nirmatrelvir 150 mg with RTV 100 mg PO twice daily for 5 days **eGFR <30 mL/min:** **Not recommended** **Severe Hepatic Impairment (Child-Pugh Class C):** **Not recommended**	≤5 days
Remdesivir	RDV 200 mg IV on Day 1, followed by RDV 100 mg IV once daily on Days 2 and 3. Each infusion should be administered over 30–120 minutes. Patients should be observed for ≥1 hour after infusion as clinically appropriate.	≤7 days
Bebtelovimab	BEB 175 mg as a single IV injection, administered over ≥30 seconds. Patients should be observed for ≥1 hour after injection.	≤7 days
Molnupiravir	Molnupiravir 800 mg PO twice daily for 5 days	≤5 day

Updated: 13 May 2022 Emergency Medical Services Authority COVID-19 Therapeutics

10.6 Appendix 6: EMSA Monoclonal Antibody Consent Form

SharePoint Link: MAB Consent Form.pdf

CALIFORNIA EMERGENCY MEDICAL SERVICES AUTHORITY

Monoclonal Antibody Consent Form

You have been diagnosed with mild-to-moderate COVID-19 and have been identified as someone at risk of developing severe COVID-19 or have been exposed to someone infected with SARS-CoV-2 and are at high risk for progression to severe COVID-19. There is currently no treatment approved by the U.S. Food and Drug Administration (FDA) for mild-to moderate COVID-19. Because you are at risk of developing severe disease, you are being offered treatment with a monoclonal antibody.
Monoclonal antibodies are made in a laboratory and are like the natural antibodies normally made by your body to fight infection. In the past, approximately 100 different monoclonal antibodies have been approved by the FDA to treat different illnesses, and now some are being developed to treat COVID-19. The FDA has granted Emergency Use Authorization (EUA) for monoclonal antibodies that may decrease the likelihood of people like you, with mild-to-moderate COVID-19, developing severe disease.

The purpose of this form is to confirm that you understand:

1) You are being offered treatment under Emergency Use Authorization.
2) The treatment involves starting an IV and infusing antibodies into your blood or taking an oral treatment course.
3) The purpose of this treatment is to decrease the risk that you will develop severe COVID-19 symptoms.

POSSIBLE BENEFITS: It is possible the treatment will help control your symptoms, slow growth of the virus, shorten the duration of your illness, or lessen the severity of your illness.

POSSIBLE RISKS AND KNOWN SIDE EFFECTS: The treatment may have side effects but NOT common. These were not common in trials of antibodies to COVID-19. Side effects reported with monoclonal antibodies include allergic reactions: rash, itching, flushing, swelling of the lips, face, or throat, fever, chills, nausea, headache, muscle aches, chest tightness, wheezing, shortness of breath, low blood pressure, lightheadedness, and dizziness.

CERTIFICATION AND SIGNATURES

BY SIGNING THIS FORM, I ACKNOWLEDGE THAT I HAVE READ OR HAVE HAD THIS FORM READ AND/OR EXPLAINED TO ME; THAT I FULLY UNDERSTAND ITS CONTENT; THAT I HAVE BEEN GIVEN A FACT SHEET ABOUT THE TREATMENT; THAT I HAVE BEEN GIVEN THE OPPORTUNITY TO ASK QUESTIONS; AND THAT MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION.

Patient Name: _____ Medical Staff: _____

Patient Signature: _____ Staff Signature: _____

Today's Date: _____

10.7 Appendix 7: EMSA Paxlovid Protocol

SharePoint Link: PAXLOVID Protocol.pdf

EMSA CALIFORNIA EMERGENCY MEDICAL SERVICES AUTHORITY

PAXLOVID

Policy and Administration Protocol

PAXLOVID is used to treat mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Eligibility Criteria:

The Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for Paxlovid for the treatment of COVID-19 in individuals who meet all the following criteria:

- ✓ Test positive for COVID-19 on a nucleic acid amplification (NAA) including PCR or antigen test, including an FDA-authorized home-test kit
- ✓ Are age 12 or older and weigh at least 88 pounds (40 kilograms)
- ✓ Are age 65 or older or have a medical condition or other factor that increases their risk for severe COVID-19.
- ✓ Have mild to moderate COVID-19 symptoms
- ✓ Can start treatment within five days of symptom onset
- ✓ Are not hospitalized due to COVID-19 when treatment is initiated

Information to Review Prior to Prescribing:

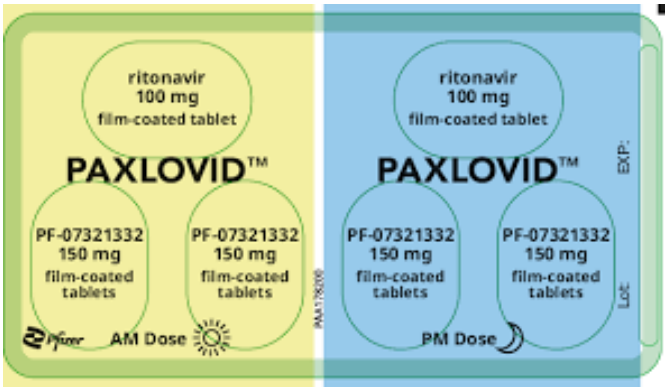
- ✓ Health care practitioners must communicate information consistent with the EUA Fact Sheet for Patients, Parents, and Caregivers and provide them with a paper or electronic copy prior to administration of Paxlovid.
    - Access the fact sheet at fda.gov/media/155051/download.

Important prescribing instructions:

- ✓ Prescriptions should specify the numeric dose of each active ingredient within Paxlovid: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for five days with or without food.

Dosing information in patients with renal impairment:

- Mild renal impairment (eGFR ≥60 to <90ml/min): No dosage adjustment needed.
- Moderate renal impairment (eGFR ≥30 to <60ml/min): Reduce dosage to 150mg nirmatrelvir (one 150mg tablet) with 100mg ritonavir (one 100mg tablet) taken together twice daily for five days.



DOSAGE FORMS AND STRENGTHS

Morning Dose – 3 tablets

Tablet 1	Ritonavir 100mg
Tablet 2	Nirmatrelvir 150mg
Tablet 3	Nirmatrelvir 150mg

HOW SUPPLIED/STORAGE AND HANDLING

- Nirmatrelvir tablets, 150 mg are oval, pink immediate-release, film-coated tablets debossed with “PFE” on one side and “3CL” on the other side.
- Ritonavir tablets, 100 mg are white film-coated ovaloid tablets debossed with the "a" logo and the code NK.
- Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card. Each carton contains 30 tablets divided in 5 daily-dose blister cards (NDC number: 0069-1085- 30).
- Each daily blister card (NDC number: 0069-1085-06) contains 4 Nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each) and indicates which tablets need to be taken in the morning and evening.

- Storage and Handling 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).

Guidance for Prescribers and Pharmacist

Identify drug to drug interaction:

- Before prescribing ritonavir-boosted Nirmatrelvir, clinicians should carefully review the patient's concomitant medications, including over-the-counter medicines, herbal supplements, and recreational drugs.
- Clinicians should refer to resources such as the Liverpool COVID-19 Drug Interactions website.
- Drug classes of particular concern are those that include drugs that are prone to concentration-dependent toxicities.

Management Strategies for Drug-Drug Interactions

- Before administering ritonavir-boosted nirmatrelvir to a patient, clinicians should assess the potential risks and benefits of using this combination in that patient. In particular, clinicians should assess the availability of other equally effective COVID-19 treatment options that have lower risks of drug interactions.
- Clinicians should consider the magnitude and significance of the potential interaction when choosing management strategies for patients who are receiving ritonavir-boosted nirmatrelvir. Potential strategies include:

  a) Adjusting the dose of the concomitant medication,
  b) Using an alternative to the concomitant medication,
  c) Increasing monitoring for potential adverse reactions to the concomitant medication, *or*
  d) Temporarily withholding the concomitant medicaion

Prescribe an Alternate COVID-19 Therapy
For cases where drug-drug interaction management strategies are not possible or feasible, or the potential risks of such strategies outweigh the potential benefits.

Amiodarone	Flecainide	Propafenone
Apalutamide	Gecaprevir/pibrent asvir	Quinidine
Bosentan	Ivabradine	Rifampin
Carbamazepine	Lumacaftor/ivacaft or	Rifapentine
Clopidogrel[a]	Lumateperone	Sildenafil for PH
Closapine	Lurasidone	St. John's wort
Disopyramide	Meperidine (pethidine)	Tadalafil for PH

Dofetilide	Midazolam (oral)	Tolvaptan
Dronedarone	Phenobarbital	Vardenafil for PH
Enzalutamide	Phenytoin	Voclosporin
Ergot derivatives	Primidone	

Temporarily Withhold Concomitant Medication, If Clinically Appropriate For guidance on restarting the concomitant medication, consult the primary care physician or the MAB physician for guidance. If withholding is not clinically appropriate, use an alternative concomitant medication or COVID-19 therapy.

Alfuzosin	Estazolam[d]	Rosuvastatin
Aliskiren	Everolimus[f]	Salmeterol
Atovastatin	Finerenone	Silodosin
Avanafil	Flibanserin	Simvastatin
Chemotherapy[c]	Flurazepam[d]	Sirolimus[f]
Clonazepam[d]	Lomitapide	Suvorexant
Clorazepate[d]	Lovastatin	Tacrolimus[f]
Colchicine[e]	Naloxegol	Ticagrelor
Diazepam[d]	Ranolazine	Triazolam[d]
Eletriptan	Rimegepant	Ubrogepant
Erythromycin	Rivaroxaban[g]	Vorapaxar

Adjust Concomitant Medication Dose and Monitor for Adverse Effects Consult with the primary care physician or MAB physician. If the dose of the concomitant medication cannot be adjusted, withhold the medication (if clinically appropriate) or use an alternative concomitant medication or COVID-19 therapy.

Alprazolam[d]	Digoxin	Quetiapine
Amlodipine	Elexacaftor/tezacaftor/	Rifabutin
Apixaban	ivacaftor	Riociguat
Aripiprazole	Eluxadoline	Saxagliptin
Brexpiprazole	Fentanyl	Sildenafil for ED
Buspirone	Iloperidone	Ruxolitinib
Cariprazine	Itraconazole	Tadalafil for ED
Chlordiazepoxide[d]	Ivacaftor	Tamsulosin
Cilostazol	Ketoconazole	Tezacaftor/ivacaftor
Clarithromycin	Maraviroc	Trazodone
Clobazam[d] Cyclosporine[f]	Mexiletine Oxycodone	Vardenafil for ED
Darifenacin	Pimavanserin	

Reporting Adverse Events and Medication Errors:

Under the EUA, all serious adverse events and all medication errors potentially related to PAXLOVID

must be reported. Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- Complete and submit a postage-paid Form FDA 3500 (https://www.fda.gov/media/76299/download) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 208529787, or by fax (1-800- FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form. Please provide a copy of all FDA MedWatch forms to Pfizer via fax (1-866-635-8337), telephone (1- 800-438-1985) or website www.pfizersafetyreporting.com

Emergency Medical Services Authority COVID-19 Therapeutics

10.8 Appendix 8: EMSA Start Up Site

SharePoint Link: EMSA START UP SITE.pdf

EMSA THERAPEUTICS START-UP SUPPLY LIST

IV THERAPEUTICS	**QTY**	**KIND**
25G X 5/8 SAFETY HYPODERMI C NEEDLES	500	EACH
18G HYPODERMI C NEEDLES	500	EACH
3ML LUER LOCK	500	EACH
ZIP LOCK BAG WI TH COPY OF PATI ENT EDUCATI ON SHEET	500	EACH
INFUSION SUPPLIES	**QTY**	**KIND**
I V STARTER KIT	500	EACH
I V EXTENSI ON SET	500	EACH
3ML LUER LOCK	500	EACH
18G HYPODERMI C NEEDLES	500	EACH
20G I V INSERTI ON NEEDLES	200	EACH
22G I V INSERTI ON NEEDLES	200	EACH
24G I V INSERTI ON NEEDLES	200	EACH
NORMAL SALINE 10ML FLUSH	500	EACH
SITE SUPPLIES AND PATIENT ASSESSMENT (REQUIRED FOR BOTH ORAL & INFUSION THERAPY)	**QTY**	**KIND**
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH
HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH
HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH
STETHOSCOPE	2	EACH
PULSE OX	2	EACH
HEART RATE MONITORS	2	EACH
MANUEL BLOOD PRESSURE CUFFS	2	EACH
BLOOD PRESSURE MONITOR	2	EACH

OFFICE SUPPLIES (STAND ALONE SITES ONLY)	QTY	KIND
PENS	100	EACH
CLIP BOARDS	5	EACH
HIGHLIGHTERS	1	PACK
PEN HOLDER	2	EACH
STAPLER	2	EACH
STAPLES	2	PACK
STAPLER REMOVER	1	EACH
TAPE DISPENSER	2	EACH
REFILLABLE TAPE	2	PACK
MASKING TAPE	2	PACK
PAPER CLIPS	2	PACK
BOX CUTTER	1	EACH
COPY PAPER	500	EACH
AA BATTERIES	2	PACK
AAA BATTERIES	2	PACK
WALKIE TALKIE	4	EACH
HAND SANITIZER	5	EACH
SHEET PROTECTOR	50	EACH
MANILA FOLDERS	100	EACH
NOTE PADS	10	PACK
FOLDER TABS	2	PACK
3 INCH BINDER	2	EACH
HANGING FOLDERS	100	EACH
3 HOLE PUNCHER	1	EACH
FLASHLIGHT	1	EACH
DISINFECTANT WIPES	10	EACH
PAPER TOWELS	TBD	OES Wrap Around Service
HAND SOAP	TBD	OES Wrap Around Service
FACIAL TISSUES	TBD	OES Wrap Around Service
TOILET PAPER	TBD	OES Wrap Around Service
TOILET SEAT COVERS	TBD	OES Wrap

		Around Service
FIRST AID KIT	1	EACH
BROOM	1	EACH
DUSTPAN	1	EACH
RECYCLING BIN	TBD	
WASTE BASKET	TBD	
TRASH BAGS 40-45 GALLON	TBD	
BIOHAZARD BAGS	TBD	
SHARP CONTAINERS	TBD	
MAB FURNITURE (DEPENDS ON FACILITY)	**QTY**	**KIND**
CHAIRS	TBD	IV or Oral
MED CART	TBD	IV or Oral
FAST BEDS	TBD	IV only
IT SUPPLIES (STAND ALONE SITES ONLY)	**QTY**	**KIND**
LABTOP WITH MOUSE	2	EACH
LAND LINE PHONE	2	EACH
PRINTER	1	EACH
TONER CARTRIDGES	2	EACH
OUTSIDE VENDOR (STAND ALONE SITES ONLY)	**QTY**	**KIND**
SET UP PHONE LINE AND WIFI	1	SERVICE
SET UP JANITORIAL SERVICE	1	SERVICE
SET UP SHREDDING SERVICE	1	SERVICE
SET UP BIOHAZARD WASTE SERVICE	1	SERVICE
PPE SUPPLIES (STAND ALONE SITES ONLY)	**QTY**	**KIND**
GLOVES - SMALL	TBD	OES
GLOVES - MEDIUM	TBD	OES
GLOVES - LARGE	TBD	OES
GLOVES - XLARGE	TBD	OES
N95 MASK	TBD	OES
SURGICAL MASK	TBD	OES
FACE SHIELD	TBD	OES
HAIR NET	TBD	EMSA
SHOE COVERS	TBD	EMSA
GOWNS	TBD	OES

MEDICATION ON HAND (ORAL & IV SITES) - REQUIRED	QTY	KIND
DIPHENHYDRAMINE 50MG/ML	12	EACH
DIPHENHYDRAMINE 25MG (PO)	1	BOTTLE
SOLUMEDROL 120MG IV PUSH	12	EACH
ONDANSETRON 4MG ODT	30	EACH
ONDANSETRON 4MG/2ML VIAL	12	EACH
GLUCAGON	6	EACH
D50	3	EACH
ADRENALINE 1ML/1ML VIAL	6	EACH
EPI-PEN (ADULT)	6	EACH
EPI-PEN (PEDS)	3	EACH
ALBUTEROL INHALER	6	EACH
NORMAL SALINE 1000ML IV BAG	1	CASE
THERAPEUTICS PROVIDING	**QTY**	**EACH**
BEBTELOVIMAB (IV PUSH)	TBD	
PAXLOVID (ORAL)	TBD	
LAMINATED SIGNS (STAND ALONE SITES ONLY)	**QTY**	**EACH**
TREATMENT ROOM 1	1	EACH
TREATMENT ROOM 2	1	EACH
TREATMENT ROOM 3	1	EACH
TREATMENT ROOM 4	1	EACH
TREATMENT ROOM 5	1	EACH
TREATMENT ROOM 6	1	EACH
TREATMENT ROOM 7	1	EACH
TREATMENT ROOM 8	1	EACH
HOT ZONE	1	EACH
CLEAN AREA	1	EACH
DIRTY AREA	1	EACH
PPE REQUIRED BEYOND THIS POINT	2	EACH
NO PHOTOS OR VIDEO ALLOWED	2	EACH
DO NOT ENTER	2	EACH
STAFF ONLY	2	EACH
MEDICATION ONLY	2	EACH
MAB PARKING SPACE 1	1	EACH
MAB PARKING SPACE 2	1	EACH
MAB PARKING SPACE 3	1	EACH
MAB PARKING SPACE 4	1	EACH
MAB PARKING SPACE 5	1	EACH

MAB PARKING SPACE 6	1	EACH
MAB PARKING SPACE 7	1	EACH
MAB PARKING SPACE 8	1	EACH
MAB FORMS & BINDER (ALL FACILITIES - REQUIRED)	**QTY**	**KIND**
EMSA MAB POLICY AND PROCEDURE BINDER	2	BINDERS
EMSA MAB CONSENT FORMS	1	EACH PT
EMSA MAB PATIENT DISCHARGE FORMS	1	EACH PT
EMSA MAB INTAKE RECORD FORMS	1	EACH PT
EMSA MAB PATIENT EDUCATION FORMS	1	EACH PT
EMSA MAB FLYER (SPECIFIC FOR EACH FACILITY)	1000	EACH
EMSA MAB PARENT/GUARDIAN CONSENT (12-17YR)	STANDBY	IF NEEDED
EMSA MAB MEDICATION TRACKING LOG (PHARMACY ONSITE)	1	BINDER

10.9 Appendix 9: Paxlovid Providers Checklist from NY DPH

SharePoint Link: Paxlovid-providers-checklist.pdf

Paxlovid Checklist Tool for Prescribers

The National Institute of Health (NIH) COVID-19 Treatment Guidelines recommends ritonavir-boosted nirmatrelvir (Paxlovid), as the preferred treatment for most high-risk, non-hospitalized patients with mild to moderate COVID-19. Paxlovid is currently free for all eligible patients. Visit https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/ to read the guidelines.

Eligibility Criteria

The Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for Paxlovid for the treatment of COVID-19 in individuals who meet all the following criteria:

- ☑ Test positive for COVID-19 on a nucleic acid amplification (NAA) or antigen test, including an FDA-authorized home-test kit
- ☑ Are age 12 or older and weigh at least 88 pounds (40 kilograms)
- ☑ Are age 65 or older or have a medical condition or other factor that increases their risk for severe COVID-19. More information on underlying medical conditions can be found by visiting cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.
- ☑ Have mild to moderate COVID-19 symptoms
- ☑ Can start treatment within five days of symptom onset
- ☑ Are not hospitalized due to COVID-19 when treatment is initiated

Drug Interactions to Review Prior to Prescribing Paxlovid

Co-administration of Paxlovid can alter the plasma concentrations of other drugs, and other drugs may alter the plasma concentrations of Paxlovid.

- ☑ Carefully review concomitant medications, including over-the-counter medicines, herbal supplements, and recreational drugs, to evaluate the potential for drug-drug interactions.
- ☑ Important drug-drug interactions with Paxlovid:
  - Ritonavir can increase concentrations of certain drugs that are highly dependent on CYP3A4 for clearance, increasing the potential for drug toxicities.
  - Drugs that induce CYP3A4 (such as rifampin) can lead to significant reductions in nirmatrelvir and ritonavir concentrations, which may decrease the therapeutic effect of Paxlovid.

- Refer to the Paxlovid EUA Fact Sheet for Healthcare Providers (Sections 4 and 7) and the NIH Treatment Guidelines on Potential Paxlovid Drug-Drug Interactions for details on identifying and managing drug-drug interactions. To read the fact sheet, visit fda.gov/media/155051/download.
- For additional decision support, access the University of Liverpool's COVID-19 Drug Interactions Checker by visiting covid19-druginteractions.org/checker.

☑ Hormonal contraceptives:

- Patients on combined hormonal contraceptives (i.e., ethinyl estradiol) should use an effective alternative contraceptive method or an additional barrier method, or not have sexual activity during treatment with Paxlovid.

☑ Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

Information to Review Prior to Prescribing

☑ Health care practitioners must communicate information consistent with the EUA Fact Sheet for Patients, Parents, and Caregivers and provide them with a paper or electronic copy prior to administration of Paxlovid. Access the fact sheet at fda.gov/media/155051/download.

☑ Important prescribing instructions:

- Prescriptions should specify the numeric dose of each active ingredient within Paxlovid: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for five days.

☑ Dosing information in patients with renal impairment:

- Mild renal impairment (eGFR ≥60 to <90ml/min): No dosage adjustment needed.
- Moderate renal impairment (eGFR ≥30 to <60ml/min): Reduce dosage to 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for five days.
  - More information on renal dosing can be found by visiting fda.gov/media/155071/download.
- Severe kidney impairment (eGFR <30 mL/min): Paxlovid is not recommended. To learn more about alternative treatments, visit nyc.gov/health/covidprovidertreatments.

☑ Use in patients with hepatic impairment:

- Mild (Child-Pugh Class A) to moderate (Child-Pugh Class B) liver impairment: No dosage adjustment needed.
- Severe liver impairment (Child-Pugh Class C): Therapy is not recommended.

Additional Prescribing Information For Home Delivery

Paxlovid can be prescribed in New York City through Alto Pharmacy, who will deliver to the patient's preferred address at no cost. Visit nyc.gov/health/covidprovidertreatments for detailed instructions. Other pharmacies that have Paxlovid in stock can be found on the COVID-19 Therapeutics Locator at covid-19-therapeutics-locator-dhhs.hub.arcgis.com.

☑ Before sending the prescription, verify the patient's phone number and address for delivery.

☑ In the note for pharmacist section, indicate the patient's date of symptom onset.

☑ Submit e-prescription to Alto Pharmacy. Prescriptions can also be sent by phone at 800-874-5881, or by fax at 415-484-

7058.

- ☑ Advise patient that they will receive a call or text message from the pharmacy (800-874-5881) and they must respond to schedule the delivery.
- ☑ Contact Alto Pharmacy at 800-874-5881 for questions on medicine interactions or other concerns.

The NYC Health Department may change recommendations as the situation evolves. 3.28.22

10.10 Appendix 10: Dispensing Regulations

Disclaimer: The content of this section has been prepared by the Office of Legal Services for the California Department of Public Health. This document is to be used for informational purposes only and does not constitute legal advice. None of the legal references contained in this document shall be construed as an offer to represent you, nor does the receipt of such information constitute an attorney-client relationship. The code sections referenced are to serve as a guide and are not representative of all laws that may apply. Nothing contained in this document is intended to provide legal advice or create a contractual or attorney-client relationship. Please consult with your own legal counsel to determine the applicability of the code sections.

Physician Dispensing

Bus. & Prof. Code § 4170

(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the

supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the California State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the California Board of Podiatric Medicine, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the California State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the California Board of Podiatric Medicine.

Bus. & Prof. Code § 4171

(a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

Bus. & Prof. Code § 4172

A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure. The Medical Board of California shall, by regulation, define the term "secure" for purposes of this section.

Bus. & Prof. Code § 4173

This chapter does not prevent the dispensing of drugs or devices by registered nurses functioning pursuant to Section 2725.1.

Bus. & Prof. Code § 4174

Notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6.

4180 Clinics

The statute regarding the appropriate settings for dispensing drugs is Business and Professions Code § 4180.

Bus. & Prof. Code § 4180

(a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than the number of hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

Additional Circumstances for Licensed Clinics

In addition, Business and Professions Code § 4126.5 provides that a licensed clinic can furnish dangerous drugs to certain entities under specific circumstances.

Bus. & Prof. Code § 4126.5

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

(b) Notwithstanding subdivision (a), or any other law, a clinic licensed under Section 4180 may furnish dangerous drugs to any of the following during a proclaimed state of emergency:

(1) Another clinic or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A clinic furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(2) A patient pursuant to a prescription or as otherwise authorized by law.

(3) A health care provider that is not a clinic but that is authorized to purchase dangerous drugs.

(4) To another clinic under common control, including a mobile clinic, as described in subdivision (c) of Section 4062.

Special Rules During an Emergency

According to Business and Professions Code § 4062, there are also special rules that may apply in a declared federal, state, or local emergency, that allow dispensing in a different setting.

Bus. & Prof. Code § 4062

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as

soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

Labelling and Storage Requirements for Drugs and Requirements for Prescriptions

The Business and Professions Code also contains various requirements for the labeling and storage of drugs and the prescriptions itself.

Bus. & Prof. Code § 4076

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 , the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1 , the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5 , or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1 , 4052.2 , or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients

may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 , the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1 , the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5 , or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1 , 4052.2 , or 4052.6 .

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information, or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

Bus. & Prof. Code § 4076.6

(a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076 .

(f) For purposes of this section, a dispenser does not include a veterinarian.

Bus. & Prof. Code § 4077

(a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all information required in Section 4076 except the prescription number.

(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a _____," or words of similar meaning, are exempt from the requirements of Section 4076 , and Section 111480 of the Health and Safety Code , when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."

(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

Bus. & Prof. Code § 4172

A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure. The Medical Board of California shall, by regulation, define the term "secure" for purposes of this section.

Waivers

The Board of Pharmacy's limited authority to issue waivers of the Pharmacy Law and its implementing regulations is based on Business and Professions Code § 4062. For information on the waiver process

and current waivers issued by the Board of Pharmacy related to COVID-19, please consult: https://www.pharmacy.ca.gov/licensees/covid19_info.shtml.

Bus. & Prof. Code § 4062

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter, or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

10.11 Appendix 11: Optum Serve Talking Points

COVID-19 Treatments, Test to Treat, & Optum Serve Rollout Talking Points & Social Media for LHJs

Talking Points

Treatments/General

- DON'T WAIT. If you have COVID-19 symptoms, get tested. Treatment works best when started *as soon as possible* after symptoms start and before symptoms worsen.
- COVID-19 treatments can lower risk of severe illness and hospitalization and work best when taken soon after symptoms begin.
- How to get COVID-19 treatments:
    - If you have symptoms, call your health care provider right away to ask about testing and if you qualify for COVID-19 treatments.
    - Stay home and isolate away from others to avoid making them sick.
    - If you don't have a health care provider or don't hear back from your provider within a few days, visit a Test to Treat location to get rapid testing and find out if treatments are right for you.
    - If you are uninsured, get free care at an OptumServe Test to Treat location.
- COVID-19 treatments are not a substitute for COVID-19 vaccines. While treatments are an essential tool in the fight against COVID-19, vaccines are how we get through the pandemic. Go to MyTurn to book your appointment to find a walk-in clinic near you.

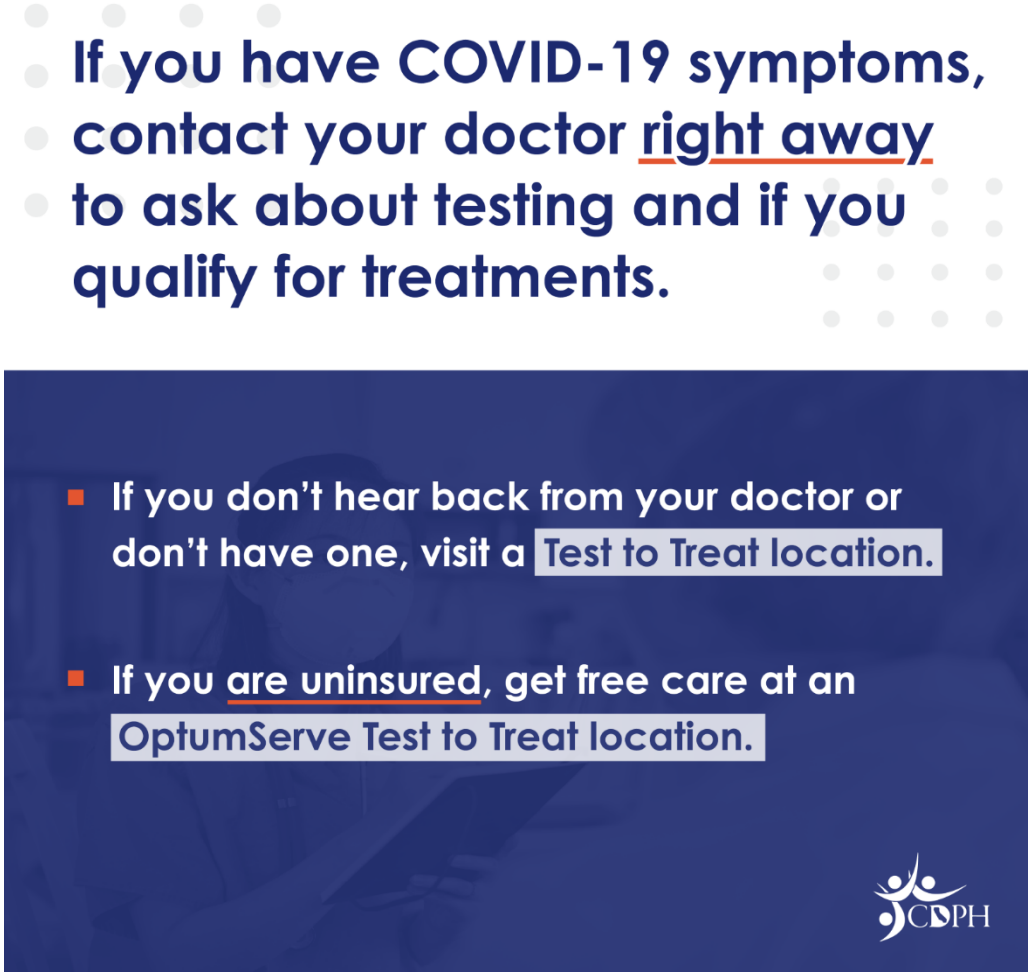
Test to Treat Initiative

- The United States government launched the Test to Treat initiative as part of the federal government's National COVID-19 Preparedness Plan. Through this program, individuals can get tested, assessed by a medical provider, and (if appropriate) given prescription antiviral pills (Paxlovid or molnupiravir) all in the same location.
- Most COVID-19 medications are currently free, but some testing and treating facilities may charge an administration or visit fee that may be covered by insurance. People should ask about these fees when they call a Test to Treat site.
- Test to Treat sites can be found on the Test to Treat Locator.

California OptumServe Test to Treat Launch

- Testing and treatment provided at OptumServe Test to Treat sites are intended to provide access for people without insurance or who are unable to obtain timely testing and treatment through their usual health care provider. Services will be free of cost.
- OptumServe will implement a Test to Treat model at all 146 testing California locations which can be found here: OptumServe locations
- Once all OptumServe test sites are converted to Test to Treat sites, approximately 90% of the population will live within a 30-minute driving distance of a site.
- Not all Test to Treat sites in California are OptumServe. People should ask about fees when they call a non-OptumServe Test to Treat site.

Social Media



Messaging

COVID-19 is still circulating in our communities. If you have COVID-19 symptoms, contact your doctor right away to ask about testing and if you qualify for COVID-19 treatments.

If you don't hear back from your doctor or don't have one, visit a #TestToTreat location for rapid testing and #COVID19 treatments (if you are eligible) by going to: https://bit.ly/TestToTreatCOVID19

If you are uninsured, get free care at an OptumServe Test to Treat location by going to: https://lhi.care/covidtesting

10.12 Appendix 12: Acronyms

ASPR – Office of the Assistant Secretary for Preparedness & Response

BIPOC - Black Indigenous People of Color

BOP - Board of Pharmacy

BPC - Business and Professions Code

CDC - Centers for Disease Control

CDPH - California Department of Public Health

CMS - Centers for Medicare and Medicaid Services

DHCS - Department of Health Care Services

EMSA - Emergency Medical Services Authority

EUA - Emergency Use Authorization

FDA - Food and Drug Administration

FRPP - Federal Retail Pharmacy Partners

FQHC - Federally Qualified Health Centers

HCP - Health Care Provider

HHS - Health and Human Services

HPOP - Health Partner Orde4ring Portal

HRSA - Health Resources and Services Administration

IV – Intravenous

LHJ - Local Health Jurisdiction

LVN – Licensed Vocational Nurse

mAb - Monoclonal Antibodies

MHOAC - Medical Health Operational Area Coordinator

NIH – National Institutes of Health

PCR – Polymerase Chain Reaction

PEP - Post-Exposure Prophylaxis

PHE - Public Health Emergency

PrEP - Pre-Exposure Prophylaxis

RDMHS - Regional

RN – Registered Nurse

RNA – Ribonucleic Acid

RX - Prescription

SVI - Social Vulnerability Index

T2T - Test-to-Treat

US - United States

USG – Ultrasound Sonography

USP – United States Pharmacopeia