

December 26, 2021

Happy Holidays Shasta County Providers,

The rapidly moving world of therapeutics to treat COVID-19 means we are sending out this message with equal haste. There are many updates to share with you today.

Paxlovid

On December 22, 2021, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to Pfizer for its oral antiviral drug Paxlovid to treat COVID-19. Paxlovid (nirmatrelvir/PF-07321332 and ritonavir) is **now authorized for the treatment of mild to moderate¹ coronavirus disease 2019 (COVID-19) in adult and pediatric patients age 12 years and older weighing at least 40 kg who are at high risk for progressing to severe COVID-19, including hospitalization or death.**

The timelines for allocation and ordering for Paxlovid have moved quickly. We anticipate that **Paxlovid will be delivered on Monday, 12/27/21** to those sites selected in this first round.

The first allocation to California is 6,180 treatment courses. **Shasta County has been allocated 20 courses of treatment, with a minimum allocation of 20 courses per site**

[PAXLOVID EUA](#)

[FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID \(fda.gov\)](#)

Molnupiravir¹

On December 23, 2021, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization to Merck for its oral antiviral drug Molnupiravir (MD-4482) to treat COVID-19. Molnupiravir is **now authorized for the treatment of mild to moderate COVID-19 in adults age 18 years and older, who are at high risk for progressing to severe COVID-19 and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate.**

The timelines for allocation and ordering for Molnupiravir have moved quickly. Ordering for this product opens at 9 AM tomorrow morning and we have submitted our allocation request. We anticipate that **Molnupiravir will be delivered on Monday, 12/27/21** to those sites selected in this first round.

The first allocation to California is 28920 treatment courses. **Shasta County has been allocated 140 courses of treatment, with a minimum allocation of 20 courses per site.**

[MOLNUPIRAVIR EUA](#)

[FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR MOLNUPIRAVIR](#)

¹ Symptomatic COVID-19 disease criteria as defined by the NIH :

- Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.
- Moderate Illness: Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO₂) ≥94% on room air at sea level.

Considerations for Prescribing Limited Supplies of Outpatient Therapeutics

Medication Prioritization

Because of its lower effectiveness, Molnupiravir should not be used for treatment in patients where any of the below therapies are accessible and clinically appropriate:

- Paxlovid twice daily for 5 days; administered as soon as possible and within 5 days of symptom onset; OR,
- An FDA authorized anti-SARS-CoV-2 monoclonal antibody, in areas where Omicron makes up $\geq 20\%$ of infections, Sotrovimab 500 mg IV as a single infusion administered as soon as possible and within 10 days of symptom onset should be used

Though not written for oral antivirals, the NIH COVID-19 Treatment Guidelines priority groups for treatment with anti-SARS-CoV-2 monoclonal antibodies can be used to guide prioritization of other therapeutics when product supplies are limited: Treatment should be prioritized in:

- Unvaccinated or incompletely vaccinated individuals, and,
- Vaccinated individuals who are not expected to mount an adequate immune response (e.g., individuals who are immunocompromised or on immunosuppressive medications or individuals aged ≥ 65 years).

CDPH recommends additionally prioritizing high-risk patients with moderate illness in the following order:

1. Immunocompromised or on immunosuppressive medications
2. Incompletely vaccinated AND > 65 years of age with risk factors for severe disease
3. > 65 years of age with risk factors for severe disease

Some of the most important risk factors for severe COVID19 include (listed alphabetically): age (risk increases with each decade after age 50), cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromising conditions or receipt of immunosuppressive medications, obesity (body mass index ≥ 30), pregnancy, and sickle cell disease. The likelihood of developing severe COVID-19 increases when a person has multiple comorbidities. (CDC)

Ethical Considerations

While supplies of therapeutics are expected to be limited, the overall aim in distribution and use of should be to achieve the greatest overall clinical benefit to patients infected with COVID-19, avoid bias, and mitigate healthcare disparities.

Clinicians are likely to find that they do not have adequate therapeutics supply for all eligible patients initially. This situation will be challenging for patients and family members, clinicians, and hospital staff. Use of multidisciplinary evidence-based clinical prioritization committee and healthcare system guidelines are recommended.

Oral Antiviral Dispensing Sites

Shasta County has two Rite Aid sites that were selected as Federal Retail Pharmacy Program (FRPP) sites as well as “LHD Selected Sites” that were identified based on several factors (e.g. geographic location, pharmacy capacity, population size, health equity indicators). Both the Federal and LHD selected sites are sourced by the county allocation. The dispensing sites are:

Rite Aid locations:

- **Rite Aid 06099**, 975 East Cypress Avenue, Redding
- **Rite Aid 06714**, 9340 Deschutes Rd, Palo Cedro

LHD Selected Sites:

- **SCHC Urgent Care**, 1035 Placer St, Redding
- **Safeway Pharmacy 273**, 2601 Balls Ferry Rd, Anderson
- **Anderson Family Health Center**, 2965 East St, Anderson
- **Hill Country Health & Wellness Center**, 29632 Highway 299 East, Round Mountain
- **Pit River Health Services**, 36977 Park Ave, Burney
- **Safeway Pharmacy 4178**, 37264 Main St, Burney
- **Mayers Memorial Hospital District RETAIL PHARMACY**, 43563 Highway 299 East, Fall River Mills

Not all sites will receive allocations while supplies remain extremely limited. Allocation minimums have been set at a 20 course minimum and will create a challenges until more product becomes available. New site selections and redistributions are not permitted until the supply chain stabilizes.

We expect the allocations in future weeks to grow significantly. HHS has said that additional courses of Paxlovid are expected in January and Molnupiravir in the coming weeks.

Allocations will be ongoing every 2 weeks. CDPH will apply LHD-determined percentages to biweekly allocation amounts for the two Rite Aid FRPP sites. LHDs will allocate treatment courses biweekly to each LHD selected site location. We are sharing with you the initial allocations so that you may assist you patients in locating these scarce resources. Dispensing sites may be added and allocation amounts may be adjusted to meet the local demand until the supply chain becomes more stable.

Round One Allocations

Site	Address	Paxlovid Allocation	Molnupiravir Allocation	Notes
Rite Aid 6099	975 East Cypress Avenue, Redding	20	40	Retail Pharmacy-open to all patients
Rite Aid 06714	9340 Deschutes Rd, Palo Cedro	0	20	Retail Pharmacy-open to all patients
SCHC Urgent Care	1035 Placer St, Redding	0	20	
Anderson Family Health Center	2965 East St, Anderson	0	20	
Pit River Health Services	36977 Park Ave, Burney	0	20	
Mayers Memorial Hospital District RETAIL PHARMACY	43563 Highway 299 East, Fall River Mills	0	20	Retail Pharmacy-open to all patients
Hill Country Hlth Wellness Ctr	29632 Highway 299 East, Round Mountain	0	0	Please refer to another pharmacy location. No allocations at this time,
Safeway Pharmacy 273	2601 Balls Ferry Rd, Anderson	0		Please refer to another pharmacy location. Site activation in process.
Safeway Pharmacy 4178	37264 Main St, Burney	0		Please refer to another pharmacy location. Site activation in process.

Monoclonal Antibodies

Circulating SARS-CoV-2 viral variants, including Omicron, may be associated with resistance to monoclonal antibodies. FDA updated the Health Care Provider Fact Sheets for [bamlanivimab and etesevimab administered together](#), [REGEN-COV](#), and [sotrovimab](#) with specific information regarding expected activity against the Omicron variant (B.1.1.529/BA.1). These data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant. Based on similar cell culture data currently available, **sotrovimab appears to retain activity against the Omicron variant**.

Based on this information, ASPR will pause any further state allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV pending updated data from the CDC. Shipments of sotrovimab will resume this week.

There may be circumstances, such as lower frequency of Omicron in a region and limited supply of alternative treatment options, in which the use of existing site supply of these monoclonal therapeutics is clinically appropriate. Since whole genome sequencing data are typically delayed, an early indicator of Omicron circulation may be a rapid increase in case counts. Utilize a mAb with efficacy against potential variants given patient's travel and/or exposure history within 2 weeks prior to infection or exposure. It is

recommended that jurisdictions continue use of the Bam/Ete and REGEN-COV monoclonal antibody products while reserving Sotrovimab for treatment of eligible outpatients at highest risk who are either:

- diagnosed with a test that may identify a potential case of the Omicron variant (e.g., by S gene Target Failure in the ThermoFisher TaqPath assay); or
- are present in local settings where reported prevalence of Omicron is greater than 20%.

Until local prevalence of Omicron is greater than 20%, Shasta County will direct Sotrovimab to sites that can provide IV treatment (within 48 hours of collection of a patient sample) to highest risk, eligible individuals diagnosed with a test that may identify a potential case of the Omicron variant.

As additional data become available, we will provide updates and further recommendations if additional actions are warranted.

Information on the authorized products for the treatment of mild-to-moderate coronavirus and other authorized products for treatment or prevention of COVID 19 are available on FDA's [Emergency Use Authorization Drugs and Non-Vaccine Biological Products webpage](#).

AstraZeneca's tixagevimab/cilgavimab (Evusheld) received an emergency use authorization (EUA) for pre-exposure prophylaxis against COVID-19 on December 8, 2021. Evusheld is intended for pre-exposure prophylaxis to protect individuals who are unable to mount an adequate immune response to COVID-19 vaccination or are unable to receive a COVID-19 vaccine due to severe adverse reaction. Evusheld is expected to retain activity against Omicron. Due to the scarcity of this product, allocations and distribution are being coordinated regionally. Supplies remain extremely limited at this time.

Distribution Providers

HPOp Account Verification: *Distribution Providers must* log into HPOp and verify their accounts in order to receive their orders.

Mandatory Reporting

While other mAb products use various reporting platforms depending on the facility type, distribution providers **are required to use HPOP to report *Evusheld, Paxlovid and Molnupiravir*** quantities administered and available **daily**. Update these quantities by the close of business each day. It is only necessary to report on days that your facility is open. Accurate and timely reporting will help CDPH direct patients looking for therapeutics to the right places.

Reporting Process

More detailed instructions on reporting can be found here in Chapter 19: [Central Partner Portal User Guide \(oracle.com\)](#)

1. Log in to HPOP
2. In the Therapeutic Inventory panel, select the Courses Administered and Available tab (if not already selected). The Therapeutic Inventory panel opens and for each therapeutic shows the number of courses administered and available, and the history.
3. In the **Courses Administered and Available** table, find the therapeutic you want to update the data for and do the following:

- a. Select the associated **Courses Administered** cell and enter the number of courses of the therapeutic that were administered.
 - b. Select the associated **Courses Available** cell and enter the number of courses of the therapeutic that are available.
4. Select Save Therapeutic Courses. The updates are saved and appear in the table. It may take some time before the history is updated.

We are working to make available the most updated information to our health care providers, treatment partners and dispensing locations so they you have the appropriate information to provide the best care for your patients. As additional data become available, we will provide updates and further recommendations if additional actions are warranted.

Thank you for your continued commitment to the health of the community.

In health,

Shasta County Public Health

ⁱ Molnupiravir is not recommended for use during pregnancy or breastfeeding. Females of childbearing potential, and males of reproductive potential who are sexually active with females of childbearing potential, are advised to use a reliable method of birth control during and following treatment for a specified period of time.