

## Subj: COVID-19 Therapeutics Program Updates, 29 08/05/2022

Continuing with our series to give all involved in the allocation, ordering, and dispensing of COVID-19 therapeutics the most current information available on the program.

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### New Updates\*

#### [Bebtelovimab Update](#)

This is an update of last week’s information on Bebtelovimab. The U.S. Department of Health and Human Services purchased an additional 150,000 doses of Bebtelovimab on 29 June. Their supply is expected to be depleted by late August. HSS expects full allocations the week of 15 August and a lower threshold the week of 22 August. To ensure an uninterrupted supply of Bebtelovimab, Lilly, the manufacturer, will make the mAb available through AmerisourceBergen for purchase the week of 15 August and thereafter. The purchasing arrangement will be like that for Remdesivir. Providers will need an existing account with AmerisourceBergen to purchase Bebtelovimab. Providers without an account may initiate the process by emailing AmerisourceBergen at [asdaccountsetup@amerisourcebergen.com](mailto:asdaccountsetup@amerisourcebergen.com). For questions regarding access to Bebtelovimab please contact AmerisourceBergen at [c19therapies@amerisourcebergen.com](mailto:c19therapies@amerisourcebergen.com). HHS estimates the cost at \$2,100 per dose.

#### [Evusheld Small Quantity Ordering](#)

Individual providers that do not currently receive Evusheld through the HPOP distribution process

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\* New updates from our last newsletter are in blue.

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can now order up to 3 patient courses directly from the manufacturer, AstraZeneca. The order link: <https://app.smartsheet.com/b/form/21e4312a2985457f982bb2738cf82744>. The link can also be found on HHS Website. AstraZeneca also has a helpline for product info and ordering: 1-833-EVUSHLD (1-833-388-7453).

### Therapeutics Provider Webinar

CDPH is beginning a new webinar series for therapeutics providers. The first webinar was held 1 August. These biweekly webinars will discuss therapeutics equity, education, clinical updates, storage and handling, and other timely and relevant topics related to COVID-19 Treatments. To register for the webinar series, click the following, [Register Here](#)

## Important Information and Resources

### Public Health Emergency Renewal

To help meet the needs of the nation during the ongoing COVID-19 pandemic, U.S. Health and Human Services Secretary Xavier Becerra renewed the COVID-19 public health emergency declaration, effective July 15. The first U.S. public health emergency declaration for COVID-19 was signed in January 2020 as the global pandemic response began and has been renewed every 90 days in adherence to the law.

Renewing the public health emergency declaration ensures health care providers and state and territorial health departments have continued flexibility to respond to the pandemic, helping save lives. These flexibilities support efforts such as rapid patient care during emergencies, including waivers from the Centers for Medicare and Medicaid Services for certain requirements under section 1135 of the Social Security Act. Examples of such requirements include preapproval requirements and temporary reassignment of state, territorial, tribal or local staff who typically are funded by federal grants in order to respond to the emergency.

### Paxlovid Submission for Full FDA Approval

Paxlovid has submitted a new drug application to FDA on June 30. The submission includes longer-term follow-up data. Final results from Pfizer's EPIC-HR study showed an 86% reduction in relative risk of hospitalizations or death from any cause; no deaths were observed in patients treated with PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) through Week 24, compared to 15 deaths observed with placebo. You can see the press announcement from Pfizer at the link on their website.

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### Reporting Requirements

Providers administering/dispensing U.S. Government purchased COVID-19 therapeutics are required to report inventory and utilization. For Evusheld, Paxlovid, Lagevrio, bebtelovmab, providers should report twice weekly, on Monday and Thursday, no later than 2359 hours (11:59pm).

As cases rise and therapeutic demand increases, California has the option to request higher weekly thresholds. To qualify, providers must enter inventory twice weekly (as referenced above) to show depletion of inventory so that the request for additional product to be approved. Please work with your providers to ensure that they are completing inventory reporting into HPoP. Providers are also at risk of being denied future allocations if they are not compliant with reporting requirements.

### Evusheld Dosing Interval

FDA revised the [Evusheld Fact Sheet for Healthcare Providers](#) to recommend repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. The previous Fact Sheet for Healthcare Providers did not provide a specific recommendation on the dosing interval. FDA continues to monitor the neutralizing activity of Evusheld against emerging SARS-CoV-2 variants and will provide additional updates as needed. For further details, please refer to the FDA's [Frequently Asked Questions for Evusheld](#).

### Requests for Extra Paxlovid

Requests for extra Paxlovid and renal Paxlovid have increased significantly over the past several weeks. We've been balancing requests from all regions to ensure fairness, and when multiple sites in a county request extra, we divide available courses for that county as much as possible across all requesting sites.

**While the state can request a higher Paxlovid threshold, the federal government will not accept our request while CA provider data shows "excess" inventory.** We shared a file this week with the current inventory showing in the federal system. Numerous sites show large numbers of courses available.

We know you have been working to ensure provider reporting. **Until inventory is reflected accurately in the system, we are implementing this process for any additional Paxlovid/renal Paxlovid requests:**

- We will need real-time inventory and utilization rates for each site requesting additional Paxlovid with your weekly ordering sheet. Requests for extra Paxlovid must still be included in the body of your email.
- We will then review inventory entries in HPoP. If they are not within a reasonable degree of similarity, we will not consider the site's request at that time.

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- Once sites update inventory in HPOP, we can consider the request the following week.

Thank you for your help in getting additional Paxlovid allocated to the state!

### California Test to Treat Initiatives

CDPH continues to pursue options to expand test to treat (T2T) sites in the state.

- Expanding Types of Providers
  - CDPH Therapeutics Task Force members continue to explore options with representatives from the California Board of Pharmacy and Department of Consumer affairs to expand the types of providers that can serve as test-to-treat sites. More to come as all parties review statutory and regulatory issues surrounding this issue.
- My Turn
  - My Turn, California's COVID-19 vaccine scheduling site has added a link to the HHS/ASPR test-to-treat locator webpage. The link is up top on the My Turn landing page.
- Test-to-Treat Playbook
  - The Test-to-Treat playbook has been published and is now on the CDPH website! The 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 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. The playbook can be found here: [COVID-19 Test-to-Treat Playbook \(ca.gov\)](#).
- Optum Serve Test-to-Treat Sites
  - The waiver that allows the Optum Serve T2T sites to dispense oral antivirals has been extended through December 2022. All 146 Optum Serve T2T sites have received therapeutics and are operational. The sites can be located through the [Test-to-Treat ASPR website](#).

### Finding Providers and Test-to-Treat Sites

- [COVID-19 Therapeutics Locator \(arcgis.com\)](#)
- [Test To Treat \(hhs.gov\)](#)

## **Subj: COVID-19 Therapeutics Program Updates, 29 08/05/2022**

### Therapeutics Utilization, Shipping, and Ordering Data Now Available in Snowflake

LHDs can now access utilization, shipping, and ordering data in Snowflake using their preexisting accounts for accessing vaccination data.

### CDPH Snowflake Webinar Recording

The recording and slides for the Snowflake webinar, held on 06/24, can be found in the LHD SharePoint. [Local Health Jurisdiction - Therapeutics - All Documents \(sharepoint.com\)](#). Please email [jeocuser54@cdph.ca.gov](mailto:jeocuser54@cdph.ca.gov) if you have difficulty accessing the SharePoint.

### Shipment Refusals

We have received reports of refused shipments of product. Please advise providers that they should not refuse shipments for any reason. If they are unable to use the product, it is best to accept the shipment and then work with the LHJ and/or region to move the inventory to another site. Refusals result in operational complications, as well as reduced inventory for the county/region, and comes at wasted costs. Returned product is also noted by HHS, which will ultimately lead to a threshold reduction for the state.

### HRSA Uninsured Program

The Uninsured Program has stopped accepting claims for testing and treatment due to lack of sufficient funds. Receipt of an email confirming your submission does not mean a claim will be paid. Claims submitted after March 22, 2022, at 11:59 pm EDT for testing or treatment will not be processed or paid. On April 5, 2022, at 11:59 pm ET, the Uninsured Program also stopped accepting vaccination claims due to lack of sufficient funds. Submitted claims will be paid subject to the availability of funds.

For more information:

- Uninsured Program webpage (hrsa.gov) - <https://www.hrsa.gov/CovidUninsuredClaim>
- FAQs about the submission deadline - <https://www.hrsa.gov/coviduninsuredclaim/submission-deadline>

California's Department of Health Care Services (DHCS) will still accept claims for individuals enrolled in the COVID-19 Uninsured Group Program. Individuals must apply for the COVID-19 Uninsured Group Program through a Medi-Cal Qualified Provider (QP). QPs are providers of the following programs: Presumptive Eligibility for Pregnant Women, Breast and Cervical Cancer Treatment Program, Hospital Presumptive Eligibility, and Child Health and Disability Prevention. Providers must submit applications via the COVID-19 Uninsured Group Application Portal. Providers can submit their COVID-19 testing, testing-related, and treatment claims to DHCS for claims processing.

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As a reminder, the COVID-19 Uninsured Group Program is authorized under the Families First Coronavirus Response Act enacted in March 2020. The COVID-19 Uninsured Group Program will end the last day of the calendar month in which the federal COVID-19 public health emergency ends. For questions or concerns, please email [COVID19Apps@dhcs.ca.gov](mailto:COVID19Apps@dhcs.ca.gov).

### Therapeutics Shelf-Life Extensions

#### **Evusheld**

Evusheld has received a shelf-life extension. The shelf life has been extended from 18 months to 24 months for specific lots. The extension applies to all unopened vials of these lots of Evusheld that have been held in accordance with storage conditions detailed in the Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 104 for Evusheld.

See more information, including the lot numbers and new expiration dates on the [ASPR website](#).

#### **Paxlovid**

Paxlovid received a shelf-life extension in April. The expiration dates were extended 3 additional months. See [this letter from Pfizer](#) for more details, including the lot numbers that received the extension and the new expiry dates.

### CDPH Weekly Therapeutics Update Webinar – Tuesdays

CDPH has begun facilitating weekly Therapeutic Update Webinars on Tuesdays. It will be held each Tuesday to provide therapeutic updates and have an opportunity for questions and answers regarding the distribution and administration of COVID-19 Therapeutics. These meetings will be recorded and uploaded to the CDPH COVID-19 Response LHJ SharePoint. You can access the meeting this week here on Tuesdays at 1100 hours PST: [CDPH Weekly Therapeutics Update](#)