

September 7, 2022

COVID-19 Therapeutics Information Brief

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be September 21, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- **Expiration Dating Extension Reminder**
- **Bebtelovimab News**
- Evusheld Update
- Information for Iowa-Licensed Pharmacists on Revised EUA for Paxlovid
- REGEN-COV Shelf Life Extension
- Therapeutic Reporting Cadence
- **Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals**
- COVID-19 Therapeutics Information Resources

Expiration Dating Extension Reminder

Before wasting any product be sure to check for expiration date extensions by using one or more of the following resources:

- [FDA COVID-19 Therapeutics Extensions](#)
- Call: 515-281-7317
- Email: C19Therapeutics@idph.iowa.gov

Select lots of Paxlovid will soon have expiration dates extended from 12 to 18 months. An official announcement is forthcoming.

Bebtelovimab Updates

Lilly and the United States Government (USG) are working together to support the availability of Bebtelovimab without disruption as USG supply ends. Bebtelovimab is now commercially available for purchase. The week of September 6, 2022 will be the final week for USG orders of Bebtelovimab.

Bebtelovimab Commercial Access

Existing AmerisourceBergen Accounts:

- Immediate access to Bebtelovimab will be granted to all existing AmerisourceBergen accounts

Sites Without an AmerisourceBergen Account

- Sites will need to register for an AmerisourceBergen account
- Contact asdaccountsetup@amerisourcebergen.com
- AmerisourceBergen will sell to licensed and approved customers regardless of current HPOP participation

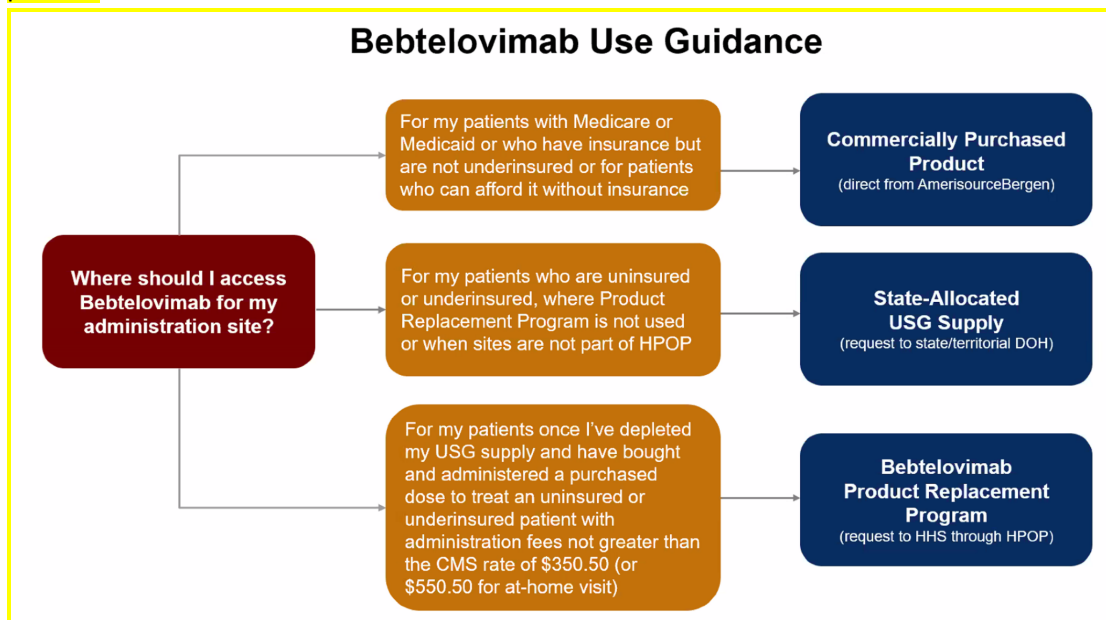
Additional Support

- For any questions regarding access to Bebtelovimab contact:
c19therapies@amerisourcebergen.com

Bebtelovimab Commercial Replacement Requests for Uninsured

Expected to begin the week of September 6, 2022 the US Government will begin supplying replacement doses of Bebtelovimab when a provider meets the following criteria:

- Provider has no inventory of US Government supplied Bebtelovimab
- Provider utilized a commercially purchased dose for treatment of an uninsured or underinsured patient.



The process for requesting a replacement dose in HPOP is as follows:

- In the Replacements tab under Therapeutic Inventory, users will need to input the Replacement Date, Replacement Reason, Therapeutic, Courses, Lot Number, and Lot Expiration Date.
- A replacement order for the courses entered will be created, listed with therapeutic orders, demarcated as a replacement and sent to the distributor.

Therapeutic Replacement

Provider
RASULI PHARM

By requesting a replacement dose through the Commercial Bebtelovimab Replacement Program, the provider affirms:

- The bebtelovimab dose being replaced was commercially-purchased, with cost associated with the procurement of that dose.
- The patient treated with the bebtelovimab dose to be replaced was uninsured, meaning the patient did not have private insurance and is not eligible for Medicaid or Medicare and cannot afford the cost of care, OR the patient is under-insured, meaning the patient has private health insurance but their copays and cost share make up a significant portion (>10%) of their take home pay.
- The infusion fee charged to the patient was waived or reduced.

I agree to the Above

Replacement Date: 09/01/2022

Replacement Reason

Therapeutic: Bebtelovimab (0002-7589-01)

Courses

Lot Number

Lot Expiry Date

Cancel Create

External Partners

Evusheld Update

An additional pathway has been established for small volume ordering:

- For individual providers seeking small quantities of Evusheld (1-3 patient courses)
- May request by going to OrderEvusheld.com or calling 1-833-EVUSHLD (833-388-7453)

On June 29, 2022 the 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](#).

On June 28, 2022 the FDA [authorized the shelf-life extension of Evusheld](#) from 18 months to 24 months for specific lots of refrigerated Evusheld. Please visit the [ASPR website](#) to learn more about this authorization, view an updated table of the affected co-pack lot numbers, labeled co-pack expiration dates, and extended co-pack expiration dates.

The AstraZeneca Call Center is available for questions regarding the updated dosing guidance and/or the shelf-life extension for Evusheld. The AstraZeneca Call Center can be reached at 1-800-236-9933.

Information For Iowa-Licensed Pharmacists on Revised EUA for Paxlovid

The FDA has updated the Emergency Use Authorization and Fact Sheet for Providers for Paxlovid to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid.

Before an Iowa-licensed pharmacist is authorized to prescribe Paxlovid to an eligible patient,

- ***The pharmacist must have access to sufficient patient records to assess the patient's renal and hepatic function as well as to assess potential drug interactions*** Such patient records can be provided by the patient (electronic or printed health records less than 12 months old) or via consultation with the patient's health care provider.

When testing positive for COVID-19, patients should first consider seeking care from their regular health care provider or locating a [Test-to-Treat site](#) in their area. While this action allows state-licensed pharmacists to prescribe Paxlovid with certain limitations as described below, community pharmacies not already participating as a Test-to-Treat site can decide if or how they will offer this service to patients.

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the current [Fact Sheet for Healthcare Providers](#) or due to potential drug interactions for which recommended monitoring would not be feasible.

Resources

- [Coronavirus Treatment Acceleration Program \(CTAP\)](#)
- [Test to Treat Locator](#)
- [COVID-19 Therapeutics Locator](#)
- [Paxlovid EUA Letter of Authorization](#)
- [Frequently Asked Questions on the Emergency Use Authorization for Paxlovid](#)
- [FDA Updates on Paxlovid for Health Care Providers](#)
- [Emergency Use Authorization: Drugs and Non-Vaccine Biological Products](#)
- [Coronavirus Disease \(COVID-19\)](#)

More information can be found on the [FDA's Press Release](#) issued July 6, 2022.

REGEN-COV Shelf Life Extension

The FDA authorized an extension to the shelf-life from 24 months to 30 months for specific lots of the refrigerated Regeneron monoclonal antibodies, casirivimab and imdevimab, administered together or REGEN-COV. Extended expiry dates can be found [here](#).

Due to the high frequency of the Omicron variant and its subvariants, REGEN-COV is not currently authorized in any U.S. region. Therefore, REGEN-COV may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency. However, it is the recommendation of the U.S. Government that the product be retained in the event that future SARS-CoV-2 variants, which may be susceptible to REGEN-COV, emerge and become prevalent in the United States. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#) and the [Letter of Authorization for Emergency Use Authorization \(EUA\) 091](#). These recommendations apply to all unopened vials of casirivimab, imdevimab, and REGEN-COV that have been held in accordance with storage conditions (refrigerated temperature at 2°C to 8°C [36°F to 46°F]) detailed in the authorized Fact Sheet for Health Care Providers for EUA 091 for casirivimab and imdevimab, administered together.

Therapeutic Reporting Cadence

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals **MUST** comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **twice per week** in HPOp.
 - **Reporting should be completed by 11:59 pm on MONDAY and THURSDAY**
 - **Internet Explorer is NOT supported, please use Chrome, Firefox, Edge or Safari**
- Reporting should include product doses utilized since the last report date
- Reporting **IS NOT** a cumulative total of all doses utilized to date
- Please contact C19therapeutics@idph.iowa.gov for assistance with HPOp

Healthcare providers should ensure reporting of the correct Paxlovid or Renal Paxlovid product. Paxlovid (renal) was renamed as Renal Paxlovid and the display order was changed to separate the Paxlovid products.

Allocations Thresholds for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

| Iowa Statewide Allocations Threshold Remaining for the week Monday, September 5th,, 2022 - Sunday September 11th, 2022 | | | | |
|---|----------------------------|--------------------|-------------------|---|
| mAbs | Oral AVs | | | PrEP |
| Bebtelovimab | Molnupiravir (Lagevrio) | Paxlovid | Renal Paxlovid | EVUSHELD |
| 185 courses | 312 courses | 880 courses | 80 courses | 1728 doses (monthly allocation) |

- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a [COVID-19 Therapeutics locator](#).

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center: 515-281-7317.**
- **COVID-19 Therapeutics Email:** Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
- [COVID-19 Therapeutics Table](#): IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- [Outpatient Therapeutics Decision Aid](#)
- [Side-by-Side Overview Outpatient Therapeutics](#)
- [NIH COVID-19 Treatment Guidelines](#)