Public Health
IOWA HHS

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COVID-19 Therapeutics Information Brief

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

The next Therapeutics Information Brief will be November 30, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

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

Allocations Thresholds for Pre-Exposure Prophylaxis Treatment and Antivirals

There will be no allocation of Therapeutics this week

Effective 10/31/2022 Therapeutic Ordering will no longer take place weekly and will move to every other week. The planned schedule for orders will be as follows:

Survey Sent	Survey Closed	Order Placed
10/31/2022	11/1/2022	11/2/2022
11/14/2022	11/15/2022	11/16/2022
11/28/2022	11/29/2022	11/30/2022
12/12/2022	12/13/2022	12/14/2022
12/27/2022	12/28/2022	12/29/2022

- **Iowa HHS 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.

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 have had expiration dates extended from 12 to 18 months. Details may be found HERE.

Bebtelovimab Updates

Bebtelovimab is now commercially available for purchase. The week of September 6, 2022 was the final USG order of Bebtelovimab. Bebtelovimab obtained commercially should **NOT** be reported in HPOP.

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

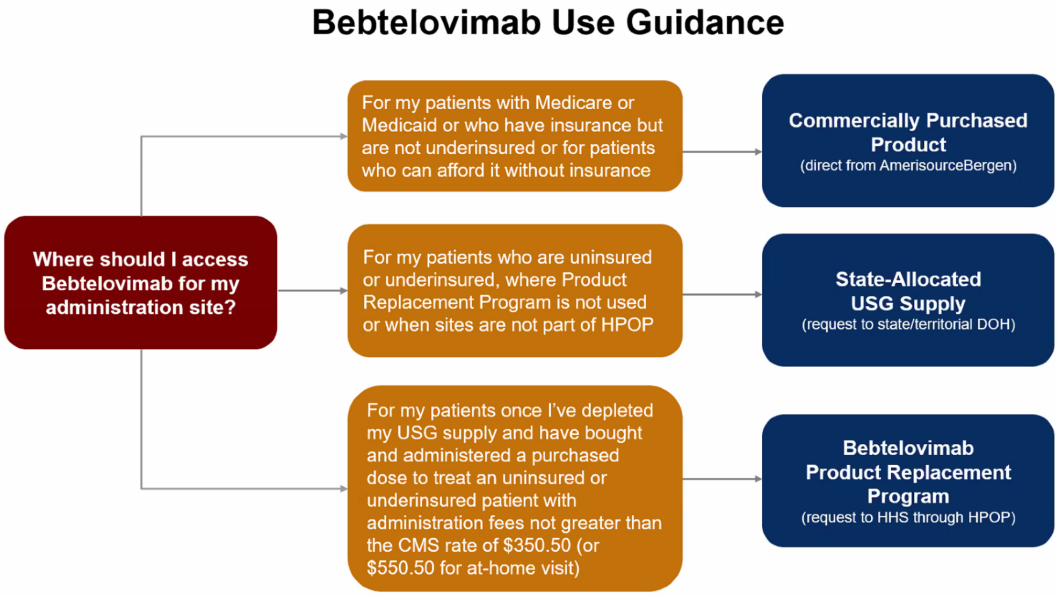
- For any questions regarding access to Bebtelovimab contact: c19therapies@amerisourcebergen.com

Bebtelovimab Commercial Replacement Requests for Uninsured

The US Government is now 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.

Please Note: Providers can use their own established methods for determining uninsured or underinsured status, such as eligibility criteria for existing initiatives for which a patient may already be eligible (examples may include eligibility criteria used for the Advanced Premium Tax Credit (APTC) or for the State/Territory's AIDS Drug Assistance Program (ADAP). Patients can visit healthcare.gov for information regarding possible options for enrolling in or changing healthcare insurance plans.

By requesting a replacement dose through the Commercial Bebtelovimab Replacement Initiative, 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 currently enrolled in a Medicaid or Medicare plan and cannot afford the cost of care, OR the patient is underinsured.
- No cost of drug payment is being pursued from the patient or through other means (e.g, insurance payment).
- The infusion fee charged was taken into consideration to be reasonable for the patient.

Evusheld Update

On October 3, 2022 the FDA added important information to the authorized Fact Sheets for Evusheld (tixagevimab co-packaged with cilgavimab) to inform healthcare providers and individuals receiving Evusheld of the increased risk for developing COVID-19 when exposed to variants of SARS-CoV-2 that are not neutralized by Evusheld. Detailed neutralization data can be found in the revised authorized Fact Sheet for Healthcare Providers. Healthcare professionals should inform patients of this risk and advise patients who develop signs or symptoms of COVID-19 to test for SARS-CoV-2 infection and promptly seek medical attention, including starting treatment for COVID-19, as appropriate if they test positive. For further details, please refer to the FDA's Important Information about Evusheld.

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 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 healthcare provider.
- A Patient Eligibility Screening Checklist Tool may be accessed HERE.

When testing positive for COVID-19, patients should first consider seeking care from their regular healthcare 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 HealthCare Providers for EUA 091 for casirivimab and imdevimab, administered together.

Therapeutic Orders & Reporting Cadence

Effective 10/3/2022 the minimum order quantity for the following products has changed:

- **Evusheld** reduced from 24 doses to 12 doses
- **Lagevrio** reduced from 24 doses to 15 doses

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:**

- For legacy mAbs (Regeneron, Bam/ete, Sotrovimab): Report on-hand data **once per week** in HPoP.
    - **Reporting should be completed by 11:59 pm on Thursday**
- (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.

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