

# COVID-19 Therapeutics Provider Weekly News Digest

July 28<sup>th</sup>, 2023

73<sup>rd</sup> Edition

## REMINDER: Please include LOT numbers when wasting therapeutics in HPOP and double check expiration dates BEFORE wasting products

Please double-check expiration dates as **ALL** COVID-19 therapeutics have received extensions for some or all lots. Contact the manufacturer before removing any products from the proper storage conditions or disposing of them.

**Note: More information about shelf-life extensions under UPDATE: Shelf-Life Extensions and Therapeutic Expiration Dates**

**When reporting dispositions (waste) in HPOP, include LOT numbers. If you have any questions on how to report dispositions, please contact HPOP Support at [HPOP.Support@hhs.gov](mailto:HPOP.Support@hhs.gov) or call 833-868-6386**

## REMINDER: HPOP Reporting Cadence

This is a reminder that **reporting is required in HPOP** for each product if your facility has inventory. Reporting is required at least twice a month on the 15<sup>th</sup> and at the end of the month. Please be sure to enter **both administered (even if it is zero) and on-hand count** for all products that are in your inventory.

For sotrovimab, bam/ete,  
REGEN-COV, bebtelovimab, Evusheld



Reporting required  
once a month

by 11:59ET pm the last day of the month

For Paxlovid and Lagevrio



Reporting required  
at least twice a month

by 11:59ET pm on the 15th and last day of the month

- Reporting should also be made when there is a significant change to stock on hand, e.g., if a specific lot of therapeutics expires and is wasted.

## Provider Resources

Access provider resources by visiting the [Information for COVID-19 Therapeutics Providers](#) page.

Review answers to commonly asked provider questions in the [FAQ for Therapeutics Providers](#).

Access the [COVID-19 Outpatient Therapeutics Videos | HHS/ASPR](#) which describes treatment options for your patients as well as ASPR's work to help ensure that these products are distributed equitably across the United States.

## Federal Resources

### New cadence:

HHS/ASPR COVID 19 Therapeutics Stakeholder Meeting State/Territorial Health Officials Nat'l Health Care Med Orgs/Associations  
Every 2 weeks on Wednesdays from 1:00 - 2:00PM CT.  
Next session- July 19

### New cadence:

HHS/ASPR Office Hours every 2 weeks on Wednesdays from 2:30 - 3:00 PM CT.  
Next session- July 19

### New cadence:

Health Partner Ordering Portal (HPOP) Office Hour COVID 19 Therapeutics. July 7 – 28, Tuesdays at 1 p.m. CT and Fridays at 9 a.m. CT. Please note that sites must [register](#) for each session in advance to receive the link to the meeting. Registration will close

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## NEW: HHS Secretary Signs 11th Amendment to PREP Act for COVID-19 Medical Countermeasures

On May 9, 2023, U.S. Secretary of Health and Human Services Xavier Becerra signed the [11th amendment to declaration under the Public Readiness and Emergency Preparedness\(PREP\) Act for medical countermeasures against COVID-19](#)

HHS Secretary issued this amendment:

- To clarify that COVID-19 continues to pose a credible risk of a future public health emergency
- To add two new limitations on distribution of Covered Countermeasures
- To extend the time period of coverage for certain Covered Countermeasures and Covered Persons
- To clarify the time period of coverage for Covered Persons authorized under the Declaration, and extended the duration of the Declaration to December 31, 2024

Read full details of the amendment in the. [Federal Register Notice online](#)

The end of the COVID-19 Public Health Emergency Declaration does not automatically terminate PREP Act coverage. To learn more, view the [COVID-19 PREP Act FAQs online](#).

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## New: COVID-19 Therapeutics ASPR Webpages updates

ASPR webpages for COVID-19 Therapeutics [Paxlovid](#), [Lagevrio](#), and [Veklury](#) have been updated to include:

- Additional and updated FAQs
- Information that maps to the latest EUA/current approval for each product

For more information, please visit [COVID-19 Therapeutics | HHS/ASPR](#)

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for sessions that reached a capacity of 1,000 attendees.

### New cadence:

Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants Monthly on Tuesdays (11:00 11:30PM CT)  
Next Session: July 18

Email [COVID19Therapeutics@HHS.gov](mailto:COVID19Therapeutics@HHS.gov) for zoom links to these meetings.

### EUAs & Fact Sheets for COVID-19 Therapeutics

To view the EUAs, fact sheets, and other resources associated with each COVID-19 therapeutic, select the links below:

- [Paxlovid](#)
- [Lagevrio](#)
- [Veklury](#) **\*not provided by USG**

### Locating Therapeutics

- [U.S. HHS COVID-19 Public Therapeutic Locator](#)
- [U.S. HHS Oral Antiviral Location Finder – including Test to Treat sites](#)

### Contact Us

If you have therapeutics-related questions, or if a member of your facility would like to be added to or removed from this newsletter's mailing list, contact us by email at: [Therapeutics@dshs.texas.gov](mailto:Therapeutics@dshs.texas.gov).

## REMINDER: Therapeutics Locator Tool to Include Outpatient Veklury(remdesivir) Providers

HHS has begun an initiative that will allow visibility of Veklury outpatient infusion sites on the [HHS COVID-19 Therapeutics Locator](#) to assist in matching patients at high risk of severe COVID-19 to the medications that can prevent disease progression.

- HHS requesting healthcare partners who order Veklury (remdesivir) for outpatient use to support improved public awareness and product access
- Any infusion site opting into this initiative will be featured on the COVID-19 Therapeutics Locator as an outpatient Veklury provider
  - Only information provided by the infusion site will be visible on the locator
  - Infusion sites can opt out of being on the locator at any time
  - Minimal engagement from the infusion sites required for their site to be shown on the locator

**If you want to have your site listed on the Outpatient Veklury (remdesivir) Locator, please click [here](#) to provide your information.**

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## **UPDATE: Shelf-Life Extensions and Therapeutic Expiration Dates**

### **REMINDER: No oral antivirals have expired at this time!**

A searchable database of [COVID-19 Therapeutic Product Expiration Dates](#) is now available.

Search two ways:

- Use the search box to find a specific item or
- Select which product you are interested in and sort by lot number, labelled expiry, or extended expiry.

Pfizer is maintaining a [searchable expiry database](#) for Paxlovid (nirmatrelvir co-packaged with ritonavir). ASPR's expiry webpage includes the link to that site.

Learn more about shelf-life extensions and other COVID-19 therapeutic information in the ASPR [Important Updates](#) webpage.

**ALL COVID-19 therapeutics have received extensions for some or all lots. Please check with the manufacturer before removing any products from the proper storage conditions.**

## Additional Shelf-Life Extension for Paxlovid

On January 18<sup>th</sup>, FDA authorized an additional extension to the shelf life from 18 months to 24 months for all lots of Paxlovid.

- FDA granted this extension following a thorough review of data submitted by Pfizer. **To find the expiry date extension on your product, please download the data tables found on [ASPR's website](#).**

**For up to date information on expiration dates, please visit:**

[Important Updates | HHS/ASPR](#) and [Expiration Dating Extension | FDA](#)

- FDA [Shelf-Life Extension for Paxlovid](#) (Jan 18, 2023); from 18 to 24 months\*no lots have reached expiry
- **NEW!** FDA [Shelf-Life Extension for Lagevrio](#) (June 14, 2023); from 30 to 36 months

Maintain all monoclonal antibodies under proper refrigerated temperatures, even if they are not currently authorized for use. It is possible that monoclonal antibodies will be authorized again in the future for use against new strains of SARS-COV2.

- [Shelf-Life Extension for Evusheld \(ASPR\)](#)
- [Shelf-Life Extension for Bebtelovimab \(ASPR\)](#)
- [Shelf-Life Extension for Bamlanivimab \(ASPR\)](#)
- [Shelf-Life Extension for Bamlanivimab and Etesevimab \(ASPR\)](#)
- [Shelf-Life Extension for REGEN-COV \(ASPR\)](#)
- [Shelf-Life Extension for Sotrovimab \(ASPR\)](#)  
**NEW!** FDA authorized a shelf-life extension from 24 months to 30 months for the GlaxoSmithKline monoclonal antibody sotrovimab. [Sotrovimab Fact Sheet for HCP](#)

## Update: No additional shelf-life extension is possible for etesevimab

- Refer to online resources to determine true expiration date for etesevimab and bamlanivimab vials
- Product can be returned for destruction as a bam/ete patient course using expired ete with matching bam vial of earliest expiration date (patient course = 2 vials ete, 1 vial bam)

**NOTE: ASPR continues to work with product manufacturers to maximize shelf-life. We will provide any updates for upcoming expiration dates as soon as we receive.**

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