

COVID-19 Therapeutics Provider Weekly News Digest

May 8th, 2023

71st Edition

NEW: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19

Secretary Becerra announced that in the coming weeks, he will issue an amendment to the declaration under the PREP Act for medical countermeasures against COVID-19.

Key changes that Secretary Becerra plans to make under the upcoming amended declaration include:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration
- **Extending coverage through December 2024 for federal agreements.**
- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
 - COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
 - COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations.** PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

For more information please visit, Fact Sheet: [Fact Sheet: HHS Intent to Amend the Declaration Under the PREP Act](#)

NEW: Searchable Database COVID-19 Therapeutic Product Expiration Dates

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

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- May 10

New cadence:

HHS/ASPR Office Hours every 2 weeks on Wednesdays from 2:30 - 3:00 PM CT. Next session- May 17

New cadence:

Health Partner Ordering Portal (HPOP) Office Hour COVID 19 Therapeutics and Mpox combined- every three weeks/Thursday (3:00-4:00PM CT) Next Session: May 11

New cadence:

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.

[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.

[Update: Therapeutics Information Sheets](#)

The following updates have been made on therapeutics information sheets:

[Lagevrio Information Sheet](#)

- Quick reference document for health care providers
- Highlights patient eligibility and effectiveness information

[Paxlovid Information Sheet](#)

Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants Monthly on Tuesdays (11:00 11:30PM CT)
Next Session: May 16

Email 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.

- Quick reference document for health care providers
- Highlights patient eligibility and effectiveness information

[Outpatient Veklury Information Sheet](#)

- Quick reference document for health care providers
- Highlights patient eligibility and effectiveness information

[Sotrovimab Information Sheet \(not authorized\)](#)

Clinical Pharmacology, Microbiology (12.4): updated neutralizing data (March 17)

- Neutralization data added for XBB and XBB.1.5
- >30-fold reduction in neutralization against XBB.1.5 live virus

[Reminder: Shelf-Life Extensions](#)

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 December 21st, FDA authorized an additional extension to the shelf life from 18 months to 24 months for **certain lots of Paxlovid.**

- As required by the emergency use authorization, unopened cartons of Paxlovid (300 mg nirmatrelvir and 100 mg ritonavir, or 150 mg nirmatrelvir and 100 mg ritonavir), must be appropriately held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#).
- 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](#)

- [Shelf-Life Extension for Lagevrio \(molnupiravir\) \(Merck\) from 24 to 30 months](#)
- [Shelf-Life Extension for Paxlovid \(Pfizer\) from 9 to 12 months](#)
- [Shelf-Life Extension for Paxlovid from 12 to 18 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.
