

COVID-19 Therapeutics Provider Weekly News Digest

April 3rd, 2023

69th Edition

NEW: Enhanced HPOP coming April 10, 2023

HPOP will be enhanced to a new interface. Below is a timeline of changes that are expected:

April 7- HPOP users will receive instructions on how to re-authenticate their accounts for the Enhanced HPOP System.

- To make sure the NEW Enhanced HPOP notification system e-mails make it through your spam filter, please add the NEW email address, noreply.HPOP@hhs.gov to your known senders list.
- You will continue to receive some notifications from the current HPOP email system prior to launch.

April 10- All HPOP users will receive a **reauthentication notification** with the necessary links to reauthenticate their account and the new URL to access HPOP

- All notifications will be sent from the enhanced HPOP notification system, noreply.HPOP@hhs.gov (please add this to your known contact list to avoid it being labeled SPAM)
- The new URL will be <https://hpop.hhs.gov/>

There will be no change to COVID 19 vaccine ordering through VTrckS

Reminder: Users will have to Reauthenticate their e-mails for the new Enhanced HPOP- more information is forthcoming

Reminder: NIH COVID-19 Treatment Guidelines March 6

The NIH COVID-19 Treatment Guidelines have been updated to reflect the following changes:

- Updates regarding Evusheld. The Panel now recommends against the use of tixagevimab plus cilgavimab as COVID-19 PrEP.

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- April 12

New cadence:

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

New cadence:

Federal COVID 19 Therapeutics Clinical Rounds Ad-hoc basis from 11:00 AM - noon CT. Next Session: April 14

New cadence:

Health Partner Ordering Portal (HPOP) Office Hour COVID 19 Therapeutics and Mpox combined- every three

- Updates on the [Clinical Spectrum](#) of SARS-CoV-2 Infection. The Panel updated the information on breakthrough infection in this section.
- Updates on [Paxlovid](#). This section has been updated with information from 2 case series that describe clinical experience with ritonavir-boosted nirmatrelvir in pregnant patients with COVID-19.
- Updates on [Ivermectin](#). Three large randomized controlled trials that were published after the last Guidelines update have reported that the use of ivermectin did not provide a clinical benefit for patients with mild to moderate COVID-19.

For more information check out the [NIH COVID-19 Treatment Guideline](#)

weeks/Thursday (3:00-4:00PM CT)
Next Session: May 11
Paused in April during enhanced HPOP training

New cadence:

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

Email COVID19Therapeutics@HHS.gov for zoom links to these meetings.

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.

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](#)

Update: Therapeutics Information Sheets

The following updates have been made on therapeutics information sheets:

[Lagevrio Information Sheet](#)

- Quick reference document for health care providers

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

- Highlights patient eligibility and effectiveness information

at:
Therapeutics@dshs.texas.gov.

[Paxlovid Information Sheet](#)

- 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

***NEW** [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.
