# COVID-19 Therapeutics Provider Weekly News Digest

***March 20th, 2023***

**68th Edition**

## Update: 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.
- 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

## 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

**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 Distribution and Administration of COVID 19 Therapeutics every 2 weeks on Wednesdays from 1:00 - 2:00PM CT. Next sessions- March 29, April 12

**New cadence:**
HHS/ASPR Office Hours every 2 weeks on Wednesdays from 2:30 - 3:00 PM CT. Next sessions- March 22, April 5

**New cadence:**
Federal COVID 19 Therapeutics Clinical Rounds Ad-hoc basis from 11:00 AM - noon CT Next Session: TBD

Health Partner Ordering Portal (HPOP) Office Hour COVID 19 Therapeutics and Mpox combined- every three weeks/Thursday (3:00-4:00PM CT)
Next Session: March 9

- 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: 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**

- 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

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## Update: Commercialization Information

HHS-hosted COVID-19 Medical Countermeasures Commercialization webinar held February 28, 2023.

For a brief summary of the meeting, see ASPR's blog: Working with partners to transition COVID-19 medical products to the commercial markets

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## 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**

Stakeholder Meeting: State/Territorial Health Officials + Nat'l Heath Care & Med Orgs/Associations Wednesdays (1:00 - 2:00PM CT);

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

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

Registration required for participation in the Federal COVID-19 Therapeutics Clinical Rounds. You may Register Here

**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

**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)

facility would like to be added to or removed from this newsletter's mailing list, contact us by email at: Therapeutics@dshs.texas.gov.

***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.***