COVID-19 Therapeutics Provider Weekly News Digest

February 20th, 2023

67th Edition

NEW: Clinical Implementation Guide

The Federal Response to COVID-19: Therapeutics Clinical Implementation Guide has been updated February,2023. The new update includes:

- Comprehensive review of available outpatient COVID-19 therapeutics to treat eligible non-hospitalized patients with mild-to-moderate symptoms of COVID-19
- Summarizes key information on COVID-19 therapeutics to assist healthcare providers with prescribing and implementing their administration
- Describes processes for obtaining and reporting COVID-19 therapeutics

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.

Reminder: Evusheld Not Currently Authorized for Use in U.S.

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

HHS/ASPR Distribution and Administration of COVID 19 Therapeutics on Wednesdays from 1:00 - 2:00PM CT.

HHS/ASPR Office Hours on Wednesdays from 2:30 - 3:00PM CT. 4:00PM ET);

Federal COVID 19 Therapeutics Clinical Rounds every other Friday from 11:00 AM - noon CT
Next Session: March 3

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

Stakeholder Meeting: State/Territorial Health Officials + Nat'l Heath Care & Med Orgs/Associations

Effective January 26, 2023 Evusheld **is no longer authorized for use in the United States.** Data show that Evusheld is unlikely to be active against more than 90% SARS-CoV-2 variants that are currently circulating, according to the most recent CDC COVID data tracker: Variant Proportions.

- The U.S. Government recommends that facilities and providers with Evusheld retain all product in the event that SARS-CoV-2 variants which are neutralized by Evusheld become more prevalent in the U.S. in the future.
- Retained product must be appropriately held in accordance with storage conditions detailed in the Fact Sheet authorized for Health Care Providers and the Letter of Authorization.

Please visit the FDA's website and view ASPR's information sheet for additional details. You may also contact ASPR at COVID19Therapeutics@hhs.gov should you have questions.

For provider communication, please see DSHS Therapeutic Communication and DSHS Information for COVID-19 Therapeutics for current information.

Reminder: FDA EUA Revision for Paxlovid and Lagevrio

On February 1st, 2023 the FDA authorized revisions to the Paxlovid and Lagevrio EUA.

Paxlovid revisions:

- Removal of **requirement** of SARS-CoV-2 viral testing
- The FDA recognizes that, in rare instances, individuals with a recent known exposure (e.g., a household contact) who develop signs and symptoms consistent with COVID-19 may be diagnosed by their health care provider as having COVID-19 even if they have a negative direct SARS-CoV-2 viral test result. In such instances, their health care provider may determine that treatment with Paxlovid for COVID-19 is appropriate if the patient reports mild-to-moderate symptoms of COVID-19 and is at high-risk for progression to severe COVID-19, including hospitalization or death, and the terms and conditions of the authorization are met, as detailed in the Fact Sheet for Healthcare Providers. The Agency continues to recommend that providers use direct SARS-CoV-2 viral testing to help diagnose COVID-19
- Also revised to include new information on **drug-drug interactions**, specifically verapamil

Lagevrio revisions:

Wednesdays (1:00 - 2:00PM CT); Next Meeting February 22

Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants Monthly on Tuesdays (11:00 11:30PM CT)
Next Session February 21

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

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.

- Mandatory Requirements Box, Use in Specific Populations (Section 8.1): Updates to pregnancy registry information
- Dosage and Administration (Section 2.3) **Addition of preparation and administration instructions via nasogastric and orogastric tube.**
- Microbiology (Section 12.4): Addition of Omicron subvariants
- Toxicology (Section 13.1): Updated
- Removal of **requirement** of SARS-CoV-2 viral testing
- The FDA recognizes that, in rare instances, individuals with a recent known exposure (e.g., a household contact) who develop signs and symptoms consistent with COVID-19 may be diagnosed by their health care provider as having COVID-19 even if they have a negative direct SARS-CoV-2 viral test result. In such instances, their health care provider may determine that treatment with Lagevrio for COVID-19 is appropriate if the patient reports mild-to-moderate symptoms of COVID-19 and is at high-risk for progression to severe COVID-19, including hospitalization or death, and the terms and conditions of the authorization are met, as detailed in the Fact Sheet for Healthcare Providers. The Agency continues to recommend that providers use direct SARS-CoV-2 viral testing to help diagnose COVID-19
- Also revised to include new information on drug-drug interactions, specifically verapamil

Updates sheets here: Lagevrio EUA; Paxloivd EUA

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.
