COVID-19 Therapeutics Provider Weekly News Digest

January 16th, 2023

64th Edition

NEW: Variants and Evusheld Resistance Updates

On Friday, January 6th, FDA released important information about risk of COVID-19 due to certain variants not neutralized by Evusheld

- FDA is closely monitoring the emergence of the XBB.1.5 subvariant, a SARS-CoV-2 Omicron variant that is currently estimated to account for 28% [as of Jan. 6, 2023] of circulating variants in the U.S.[Total resistance including XBB.1.5 is estimated at ~92%]
- Because of its similarity to variants that are not neutralized by Evusheld(e.g., XBB), **FDA does not anticipate that Evusheld will neutralize XBB.1.5.**
- This means that Evusheld may not provide protection against developing COVID-19 for individuals who have received Evusheld and are later exposed to XBB.1.5. However**, FDA is awaiting additional data to verify that Evusheld is not active against XBB.1.5.**
- **Further updates will be provided as new information becomes available.**
- **Health care providers should inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 variants not neutralized by Evusheld.**

On Tuesday, January 10th, NIH updated their statement regarding Evusheld here: Statement on Evusheld | COVID-19 Treatment Guidelines (nih.gov)

- In the US, the prevalence of subvariants likely to be resistant to tixagevimab plus cilgavimab (Evusheld) is more than 91%. Although tixagevimab plus cilgavimab is still authorized by the FDA for COVID 19 pre-exposure prophylaxis (PrEP), it is unlikely to be effective at preventing COVID 19 in the vast majority of individuals. However, no alternative options for PrEP are available, and clinicians could still administer tixagevimab plus cilgavimab after considering an individual patient's risks and the regional prevalence of the resistant subvariants

The Evusheld Fact Sheet has been updated to reflect in-vitro neutralizing data for several Omicron subvariants

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); Next Session January 18

Federal COVID 19 Therapeutics Clinical Rounds every other Friday from 11:00 AM - noon CT
Next Session: January 27

Office Call Session: Health Partner Ordering Portal (HPOP) every three weeks/Thursday (3:00-4:00PM CT)
Next Session: January 26

Stakeholder Meeting: State/Territorial Health Officials + Nat'l Heath Care & Med Orgs/Associations
Wednesdays (1:00 - 2:00PM CT); Next Meeting January 18

Refer to FDA releases important information about risk of COVID-19 due to certain variants not neutralized by EVUSHELD

NEW: Therapeutics Information Sheets

New Lagevrio Information Sheet

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

Updated as of January 2023: Paxlovid Information Sheet

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

Coming soon: Outpatient Veklury Information Sheet

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

NEW: Walgreens Expands Home Delivery to include Lagevrio

On Dec. 27, 2022, Walgreens expanded the oral antiviral free prescription delivery service to include Lagevrio which delivers COVID-19 medications directly to the doorsteps of Americans. Previously, this program was only for Paxlovid.

Patients with a prescription for Lagevrio or Paxlovid that is filled at Walgreens in a socially vulnerable community, based on the Centers for Disease Control and Prevention (CDC) Social Vulnerability Index, will be able to have their Lagevrio or Paxlovid prescription delivered to their home at no cost via Walgreens.com and the Walgreens app.

NEW: Legislative Provision to Allow Part D payment of EUA oral antivirals ***if commercialized*** while under EUA

H.R. 2617 enacted to include EUA oral antivirals as covered Part D drugs. HR2617 Bill has the following impact:

- NO CHANGE to the current payment structure
- Allows coverage of COVID-19 oral antivirals (Paxlovid, Lagevrio) by Medicare Part D *plans* ***if a product is commercialized while under EUA*** (prior to change, a

Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants
Monthly on Tuesdays (11:00 11:30PM CT)
Next Session January 17

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
- Evusheld

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.

product available only under EUA would not have met statutory definition of a covered Part D drug)

- **COVID-19 oral antivirals continue to be provided by HHS free of charge; no payment can be sought for USG procured medications**
- CMS is already able to cover fully approved oral antivirals under Part D
- There remains ample supply of USG procured product to facilitate continued distribution of free product

---

New and Updated Resources: Lagevrio Information Sheet, Digital Toolkit, and CDC Webpages

ASPR has added a new Lagevrio Information Sheet and updated their Digital Toolkit with Test to Treat social media content.

CDC has also updated the Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19 for Healthcare Professionals. This update highlights Age being the strongest risk factor for severe COVID-19 outcomes.

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. FDA is working on updating webpages to reflect extended dates.

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
- Shelf-Life Extension for Evusheld (ASPR)

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 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)

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.
