COVID-19 Therapeutics Provider Weekly News Digest

January 23rd ,2023

65th Edition

NEW: Information Sheet: Key Messages for Long Term Care Facilities

Effective January 2023, there is a new LTC Facility information sheet. The sheet includes the following information:

- COVID-19 Treatments are safe, effective, and widely available.
- Treatments should be considered for any patient over the age of 50 or with a high-risk health condition.
- Treatments must be started early, even if symptoms are mild.
- The oral antiviral pill Paxlovid (ritonavir-boosted nirmatrelvir) and the IV administered drug Veklury(remdesivir) are the preferred treatments for eligible patients.
- Lagevrio (molnupiravir) is an alternative oral antiviral for patients for whom neither Paxlovid nor Veklury are clinically appropriate or feasible.
- Long-term care facilities should ensure timely access to effective COVID-19 treatments for all eligible patients, including through pre-positioning the medications directly at facilities.

For the entire fact sheet, please visit COVID-19 Treatments: Information for Long Term Care Facilities

Reminder: 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

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: February 3

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 February 21

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

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

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Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants
Monthly on Tuesdays (11:00 11:30PM CT)
Next Session January 25

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**.**

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
- 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.
