COVID-19 Therapeutics Provider Weekly News Digest

January 9th, 2023

63rd Edition

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 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: FDA Labeling Supplement for Veklury

On December 16th, FDA approved a labeling supplement modifying the indication for Veklury as shown below; a positive result of a COVID test is no longer required.

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 11

Federal COVID 19 Therapeutics Clinical Rounds every other Friday from 11:00 AM - noon CT
Next Session: January 20
Topic: COVID-19 Call and Resource Centers: best practices/lessons learned

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 +

VEKLURY is a severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID 19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) ~~with positive results of direct SARS CoV 2 viral testing,~~ who are:

- Hospitalized, or
- Not hospitalized and have mild to moderate COVID 19 and are at high risk for progression to severe COVID 19, including hospitalization or death

How to order Velkury:

Hospitals can place orders with any of the following distributors by calling directly:

- AmerisourceBergen Specialty Distribution: 800-746-6273
- Cardinal Specialty: 855-855-0708
- McKesson Plasma and Specialty: 877-625-2566

Non-hospitals can contact these two distributors:

- AmerisourceBergen Specialty: 800-746-6273; C19therapies@AmerisourceBergen.com
- Cardinal Specialty: 855-855-0708; GMB-SPD-CSORDERENTRY@cardinalhealth.com

Eligible non-hospitals include:

- Infusion centers
- Long term care
- Skilled nursing facilities
- Dialysis care
- Clinics
- Acute/urgent care
- Retail and Specialty pharmacies that serve Long-term care or skilled nursing facilities

---

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

Nat'l Heath Care & Med Orgs/Associations
Wednesdays (1:00 2:00PM CT);
Next Meeting January 11

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

factor for severe COVID-19 outcomes.

at: Therapeutics@dshs.texas.gov.

Reminder: Evusheld and Omicron Variants

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

- Over **90**% of circulating variants are projected to be resistant to Evusheld.
- Breakthrough infections are possible**. Advise patients to have a treatment plan in place and to seek timely medical attention if symptoms occur**
    - This is important messaging to both patients that received Evusheld previously and patients getting first dose

NIH Guidelines update (Dec 1) notes the prevalence of Omicron subvariants that are resistant to Evusheld is rapidly increasing. However, Evusheld is the only agent FDA authorized for SARS-CoV-2 PrEP in people who are not expected to mount an adequate immune response to COVID-19 vaccination or those with contraindications for COVID-19 vaccines. Therefore, the **Panel continues to recommend the use of tixagevimab plus cilgavimab** as PrEP for eligible individuals. This recommendation may change if the prevalence of resistant subvariants increases.

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

-

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 Evusheld

On December 5th, FDA authorized an additional extension to the shelf life from 18 months to 30 months for all lots of Evusheld (tixagevimab co packaged with cilgavimab).

- As a result of this extension to all Evusheld product, there are currently **no expired Evusheld lots** and therefore no returns or on-site destruction of uncompromised product is allowable.

- Lot AZ220049 that was previously noted as expired has received an extension; this lot may be administered if it is in your inventory and has been kept under proper temperatures.
- This extension applies to all unopened vials of Evusheld that have been held in accordance with storage conditions detailed in the authorized Fact Sheet For Healthcare Providers and the Evusheld Letter of Authorization
- Visit ASPR's website to learn more and review the table with co-pack lot numbers, labeled co-pack expiration dates, and the extended co-pack expiration 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.
