COVID-19 Therapeutics Provider Weekly News Digest

September 12th, 2022

47th Edition

New: Paxlovid Shelf-Life Extension from 12 to 18 months

On September 6th, the FDA authorized an extension to the shelf life from 12 months to 18 months for certain lots of Paxlovid. Lots of Paxlovid with dates of expiry from July 2022 to May 2023 may be stored for an additional six months from the labeled date of expiry (see Table).

As required by the emergency use authorization, unopened cartons of Paxlovid must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) for Paxlovid.

For more information, visit the FDA website or contact COVID19Therapeutics@hhs.gov

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<th>Labeled Expiry Date (YYYY-MM)</th>
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Provider Resources

Access provider resources by visiting the Information for COVID-19 Therapeutics Providers page.

Review answers to commonly asked provider questions in the recently updated FAQ for Therapeutics Providers.

Review the COVID-19 Therapeutics Product Guide to see which therapeutics are distributed by DSHS, along with their reporting requirements and resources.

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 Conference Call for the Distribution and Administration of COVID-19 Therapeutics on Wednesdays at 2:15-3:15PM CT.

HHS/ASPR COVID-19 Therapeutics Clinical Webinar on Fridays from 11:00am -12:00pm CT

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

HPOP Reporting Required

Reporting for all products, both administered (even if it is zero) and on-hand count, is required in HPOP. If a facility has inventory, reporting is required on Mondays and Thursdays.
When reporting, please enter:
1. patient courses administered/dispensed and
2. patient courses on-hand

Enter the courses administered/dispensed since last entry AND on hand. DO NOT enter cumulative totals that have already been reported.

If your site would like additional training on reporting, please contact HPOP-Therapeutics@hhs.gov

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**Revised PAXLOVID Fact Sheet for Patients, Parents, and Caregivers**

Pfizer has become aware of reports of wrong-dose medication errors that have occurred with Paxlovid. **These wrong-dose errors have occurred during prescribing, dispensing, and administration.** Many of these errors have occurred during patient self-administration and generally involved patients incorrectly taking the wrong combination of nirmatrelvir tablets and ritonavir tablets from the blister card leading to wrong-dose medication errors.

Pfizer has revised the PAXLOVID Patients, Parents, and Caregivers Fact Sheet to address wrong dose medication errors that occur during patient self-administration. The revised Fact Sheet will show how the medication is labeled and inform the patient on how to correctly take Paxlovid. **Each dispensed prescription for Paxlovid should include a Patients, Parents, and Caregivers Fact Sheet.**

For more information, refer to the revised Fact Sheet for Patients, Parents, and Caregivers, the Fact Sheet for Healthcare Providers, and the DHCP Letter.

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**Reminder: Shelf-Life Extensions**

Several products have initial expiration dates approaching, but many COVID-19 therapeutics have received extensions. Please check with the manufacturer before removing any products from the proper storage conditions.

See links below for detailed expiry information:

- [Shelf-Life Extension for Paxlovid (Pfizer)](Shelf-Life-Extension-for-Paxlovid-Pfizer)
- [Shelf-Life Extension for Bebtelovimab (ASPR)](Shelf-Life-Extension-for-Bebtelovimab-ASPR)
- [Shelf-Life Extension for Evusheld (ASPR)](Shelf-Life-Extension-for-Evusheld-ASPR)
  - **NOTE:** Lot #AZ220049 expires on August 31, 2022 and will not have an extended expiration date. Product returns are being
accepted for the expired product only (evusheld.com).

Please find an addition listing of expiration extensions from the FDA here.

Maintain all monoclonal antibodies under proper refrigerated temperatures, even if they are not currently authorized for use. It is expected that will be authorized again in the future for use against new strains of SARS-COV2.

- 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) – additional extension granted

**Bebtelovimab Available for Purchase**

Bebtelovimab will be available for purchase from the distributor AmerisourceBergen (ABC).

- The purchase cost per patient course of bebtelovimab will be $2,100.
- A commercial ABC account is required to purchase bebtelovimab. Contact asdaccountsetup@amerisourcebergen.com to set up an ABC account.
- For questions about purchasing bebtelovimab, contact c19therapies@amerisourcebergen.com.
- ABC will not take returns of purchased bebtelovimab for refunds.
- CMS reimbursement cost for the medication for Medicaid and Medicare patients is posted here when it is available. See also CMS COVID-19 Monoclonal Antibodies.
- Reimbursement by private insurance companies will vary by plan.

**Existing USG Bebtelovimab**

The United States Government (USG) requests that providers reserve the USG-purchased bebtelovimab for uninsured and underinsured patients that are not able to take or access Paxlovid or Veklury (remdesivir), the two recommended therapeutics.

Facilities must continue to report transfers, wastage, and administration and on-hand inventory of all USG-purchased bebtelovimab in HPOP on Mondays and Thursdays until this supply has been depleted.
Providers MAY NOT seek reimbursement for bebtelovimab that was distributed at no cost from the USG and should keep this stock separated from any product that is purchased. The batch numbers for bebtelovimab will be different for commercial bebtelovimab than the USG supply. Do not report commercially purchased bebtelovimab in HPOP.