NIH COVID-19 Guidelines Update for Evusheld

The Panel recommends using tixagevimab plus cilgavimab (Evusheld) as SARS-CoV-2 pre-exposure prophylaxis (PrEP) for adults and adolescents who do not have SARS-CoV-2 infection or recent exposure to an individual with SARS-CoV-2 infection and who are moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination.

There is insufficient evidence for the Panel to recommend either for or against the use of SARS-CoV-2 serologic testing to assess for immunity or to guide clinical decisions about using COVID-19 vaccines or anti-SARS-CoV-2 monoclonal antibodies as PrEP in certain people.

For more information, see the NIH Special Considerations in People Who Are Immunocompromised and CDC Updated Evusheld Guidelines.

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 held in appropriate in storage conditions as detailed in the 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.
Reminder: 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

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) 9 to 12 months](#)
- [Shelf-Life Extension for Paxlovid from 12 to 18 months](#)
- [Shelf-Life Extension for Bebtelovimab (ASPR)](#)

EUA & 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](#)
- [Bebtelovimab](#)
- [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 or by phone at (833) 832-7068, Option 0.
• **Shelf-Life Extension for Evusheld (ASPR)**
  - NOTE: Lot #AZ220049 expired on August 31, 2022. Product returns are being accepted for the expired product only ([evusheld.com](http://evusheld.com)).

Please find an addition listing of expiration extensions from the FDA [here](http://www.fda.gov).

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

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**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.