Evusheld Update on Repeat Dosing and Expiration Dates

On June 28, 2022, the FDA revised the Evusheld Fact Sheet for Healthcare Providers to recommend repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. Nonclinical data and pharmacokinetic modeling suggest that activity against the currently circulating SARS-CoV-2 variants and subvariants may be retained for six months at drug concentrations achieved following an Evusheld dose of 300 mg of tixagevimab and 300 mg cilgavimab. We continue to monitor the neutralizing activity of Evusheld against emerging SARS-CoV-2 variants and will provide additional updates as needed.

The FDA and HHS/ASPR also announced the authorization of an extension to the shelf-life for specific lots of the refrigerated AstraZeneca monoclonal antibody, Evusheld (tixagevimab co-packaged with cilgavimab), from 18 months to 24 months.

The agency granted this extension following a thorough review of data submitted by AstraZeneca. As a result of this extension, some batches may be stored for an additional 6 months from the labeled date of expiry (see Table 1 here).

This extension applies to unopened vials of Evusheld that have been held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the EUA Letter of Authorization for Evusheld.

Evusheld lot #AZ2200491 will NOT have an updated expiration date. The expiration date for this lot will remain August 31, 2022.

REGEN-COV Shelf-life Extension

On Monday, June 27th, the FDA authorized an extension to the shelf-life for specific lots of the refrigerated REGEN-COV (Regeneron monoclonal antibodies, casirivimab and imdevimab, administered together) from 24 months to 30 months.

REGEN-COV is not currently authorized for treatment or post-exposure prevention of COVID-19 in any U.S. region. However, it is the recommendation of the U.S. Government that product be

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.

Federal Resources

HHS/ASPR leads two webinars for clinicians on alternating Fridays from 11:00am -12:00pm CT

- COVID-19 Therapeutics Clinical Webinar
- Medical Professionals COVID-19 Roundtable

Weekly HHS/ASPR Conference Call for the Distribution and Administration of COVID-19 Therapeutics on Wednesdays at 2:15-3:15PM CT. There will be no meeting on July 6, the meeting will resume July 13, 2022.

Please email COVID19Therapeutics@HHS.gov for zoom links to any of these meetings.
revisited if future SARS-CoV-2 variants, which may be susceptible to REGEN-COV, emerge and become prevalent in the U.S.

NIH Treatment Guidelines for Therapeutics

Paxlovid (ritonavir-boosted nirmatrelvir) is the preferred treatment recommended by the NIH Treatment Guidelines for high-risk patients with mild to moderate COVID-19.

Additional clinical considerations for Paxlovid can be found at the NIH Treatment Guidelines section on Paxlovid and prescribing tools and resources can be found at the DSHS webpage. The US has sufficient supply of both oral antivirals, and any licensed pharmacy may enroll with Texas DSHS to receive the oral antiviral medication.

Per the NIH Guidelines for Therapeutic Management of Non-Hospitalized Adults update on April 8, 2022, the preferred therapies are listed in order of preference:

- Paxlovid
- Veklury (remdesivir)

Alternative therapies for use only when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:

- Bebtelemab
- Lagevrio (molnupiravir)

Providers should use best clinical judgement in working through the NIH Treatment Guidelines and consider prescribing the oral antiviral medication, Paxlovid, to all patients who are eligible. Paxlovid is widely available for high-risk Texans with symptomatic COVID-19. Bebtelemab remains the therapeutic with the most limited supply. Considering Paxlovid first will help preserve the other options for patients who need them. Patients and clinicians can use the US HHS Therapeutics Locator to find the nearest pharmacy with Paxlovid in stock.

Providers and patients can access additional information and resources through the following links:

- DSHS COVID-19 Therapeutics and Treatments Page (Providers)
- DSHS COVID-19 Therapeutics and Treatments Page (Patients)

Reminder: Inventory Reporting Now Required Twice Per Week in HPOP

The Office of the Assistant Secretary for Preparedness and Response (ASPR) has changed the reporting requirement for COVID-19
therapeutics to twice per week. Providers should report the inventory information in HPOP on Mondays and Thursdays.

In addition, please complete your inventory immediately before placing a request so that DSHS has the most complete picture of your usage and on-hand inventory when the requests are reviewed.

For each product, report:
- The count of patient courses administered/dispensed since the last entry and
- The count of patient courses on-hand

You do not need to enter zeros for products that are not in your inventory.

Requests for Bebtelovimab are Reviewed the Following Week

For all requests for monoclonal antibodies placed before 5 pm on Friday, DSHS will allocate and order the following week. For example, a request for Bebtelovimab placed on Thursday, July 7, will be reviewed by DSHS at the beginning of the week of July 11. Please plan your requests accordingly.

At this time, requests for Evusheld and oral antivirals will be reviewed and approved throughout the week. See 5/17 DSHS communication. Federal allocations to DSHS, and therefore DSHS reviews of the request, are delayed if a federal holiday falls on a Monday.

Check Short Dated Products for Expiration Date Extension

Many COVID-19 therapeutics, including Bebtelovimab, Sotrovimab, Paxlovid, have received expiration date extensions. Check the Product Information page or with the manufacturer for the expiration date for the specific lots of any product that is short dated.