COVID-19 Therapeutics Provider Weekly News Digest

July 18th, 2022
39th Edition

Spotlight on EVUSHELD

EVUSHELD is intended for patients who are not expected to have an effective response to vaccination because of moderate to severe immunosuppression. EVUSHELD is indicated for pre-exposure prophylaxis only and not for treatment of patients with COVID-19.

Many major hospital systems have EVUSHELD in their pharmacy inventory. Specialty practices such as rheumatology, immunology, and oncology are encouraged to enroll with DSHS for Evusheld. Any provider that serves a population of immunocompromised patients or can take referrals from other providers may enroll. EVUSHELD supply is not currently limited. Providers can find sites that have Evusheld on the US HHS Therapeutics Locator.

People are considered to be moderately or severely immunocompromised (have a weakened immune system) due to several types of conditions and treatments. Examples include:

- Have been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received chimeric antigen receptor (CAR)-T-cell therapy (a treatment to help your immune system attach to and kill cancer cells) or received a stem cell transplant (within the last 2 years)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress their immune response

EVUSHELD (tixagevimab co-packaged with cilgavimab) is authorized for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction

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

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

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

EUAs & Fact Sheets for COVID-19 Therapeutics

To view the EUAs, fact sheets, and other resources associated with each COVID-
to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s)

EVUSHELD is **not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended**. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.

EVUSHELD **may only be prescribed for an individual patient** by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which EVUSHELD belongs (i.e., anti-infectives). Evusheld is administered as two separate consecutive intramuscular (IM) injections at a doctor’s office or healthcare facility and requires a monitoring period after administration.

The initial dosage is 300 mg of tixagevimab and 300 mg of cilgavimab. The repeat dosage is 300 mg of tixagevimab and 300 mg of cilgavimab every 6 months. Repeat dosing should be timed from the date of the most recent EVUSHELD dose.

**EVUSHELD Resources:**
- Evusheld Fact Sheet for Healthcare Providers
- NIH Guidelines on the Prevention of SARS-CoV-2 Infection
- Shelf-Life Extension for Evusheld (ASPR) - Contact AstraZeneca call center at 1-800-236-9933 with questions on expiration extensions
- AstraZeneca Medical Information

**Shelf-Life Extensions**

Many COVID-19 therapeutics have received expiration date 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 Bebtelovimab (ASPR)
- Shelf-Life Extension for Evusheld (ASPR)

Also see the FDA’s approach to COVID-19 Therapeutics shelf-life extensions [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)

**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.
Reminder! FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations

On July 6, 2022, the U.S. Food and Drug Administration revised the Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir and ritonavir), to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations.

Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid:

- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient’s health care provider.
- A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function. Self-attestation from the patient is not sufficient.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

Prescribers can check with their medical boards or the medical team for the manufacturer if they have questions about prescribing PAXLOVID. In addition, there are two weekly opportunities to ask questions of the HHS/ASPR team about therapeutics. See sidebar for details.
Note: PAXLOVID is not authorized for use for longer than 5 consecutive days.

**PAXLOVID Drug-Drug Interaction Resources**

- NIH Statement on Paxlovid Drug-Drug Interactions
- Healthcare Provider Letter: PAXLOVID EUA dosing and dispensing in moderate renal impairment, and risk of serious adverse reactions due to drug interactions
- COVID-19 Drug Interactions Checker (University of Liverpool) – (app available)
- Paxlovid Drug Interaction Checker
- Management of Drug Interactions with Paxlovid: Resource for Clinicians (The Infectious Diseases Society of America)

**HPOP Tip: Inventory Reporting**

For each therapeutic type that you have received or dispensed:

1. Double-click in the row under Courses Administered and Courses Available.
2. Enter **total number administered** since the last report, click “Save Therapeutic Courses.”
3. After clicking “Save” you will see a short pop up indicating that the save operation completed successfully.

**Note:** After clicking “Save Therapeutic Courses,” the columns will still show the data that you entered. These values will remain until the system moves them to the History column, which happens once a day at around midnight ET.

If a person inadvertently enters an incorrect value, or transposes the Administered and Available numbers, **they can edit and correct the data entry errors** by using the **Edit History** button.

Reporting is required on Mondays and Thursdays. Sites that do not report consistently will not have requests filled.
Veklury: Recommended Alternative to Paxlovid

Paxlovid, an oral antiviral, is the therapeutic recommended first by NIH and CDC for treatment of high-risk patients with symptomatic COVID-19. **For patients for whom Paxlovid is not appropriate, the next recommended therapeutic is Veklury (remdesivir).** Veklury is an intravenous (IV) infusion administered on three consecutive days and must be started within seven days of symptom onset. **It is the only therapeutic currently authorized for treatment of children under twelve years of age.**

Facilities may wish to purchase Veklury (remdesivir) for patients who are unable to take one of the oral antiviral medications. Hospitals can purchase Veklury through multiple distributors through the facility’s normal procurement processes (Gilead Resource Call Center at 1-800-226-2056). Non-hospitals can purchase from AmerisourceBergen (Outpatient Product Information Guide including ordering).

**VEKLURY** is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg) with positive results of SARS-CoV-2 viral testing, who are:

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