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.

**Note:** PAXLOVID is not authorized for use for longer than 5 consecutive days.
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.

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

19 therapeutic, select the links below:
- Bebtelovimab
- 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 at: therapeutics@dshs.texas.gov or by phone at (833) 832-7068, Option 0.
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.

Evusheld Repeat Dosing, Expiration Dates, and HPOP Reporting

Repeat Dosing Schedule released
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. Repeat dosing is calculated from the most recent dose if a patient received the smaller dose of 150 mg of tixagevimab and 150 mg of cilgavimab on separate occasions.

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. The FDA continues to monitor the neutralizing activity of Evusheld against emerging SARS-CoV-2 variants and will provide additional updates as needed.

Expiration dates extended for specific lots
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.

Reporting Evusheld in HPOP
Each EVUSHELD carton contains two vials: 1 vial tixagevimab solution (150 mg/1.5 mL) and 1 vial tixagevimab solution (150 mg/1.5 mL).
For both inventory and administration data, report Evusheld in HPOP by the count of the CARTON – not the vial or patient course. For administration with the recommended doses of 300 mg of tixagevimab and 300 mg cilgavimab, record TWO cartons administered for each patient. This keeps the reporting consistent across the change in dosing for this product.

### 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 retained 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:
- Bebtelovimab
- 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.
Bebtelovimab 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](https://www.paxlovid.com/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](https://www.comforthealth.org/DSHS-therapeutics-treatments) (Providers)
- [DSHS COVID-19 Therapeutics and Treatments Page](https://www.comforthealth.org/DSHS-therapeutics-treatments) (Patients)