NEW YORK STATE OF OPPORTUNITY. Department of Health

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To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

UPDATES ON COVID-19 TREATMENT RECOMMENDATIONS

- **SARS-CoV-2 variants are resistant to the monoclonal antibody (mAb)** Evusheld (authorized for pre-exposure prophylaxis). Due to the prevalence of resistant variants, **Evusheld is no longer authorized** for treatment in the U.S.
- **Paxlovid, Molnupiravir (Lagevrio) and Veklury (remdesivir), are still expected to retain activity against COVID-19**: The NIH COVID-19 treatment Guidelines recommend Paxlovid as the preferred treatment or remdesivir. The antivirals Paxlovid, Remdesivir, and Molnupiravir (Lagevrio) are expected to be active against newer subvariants.
- **Evusheld** is not currently authorized for emergency use in the U.S. Providers; however**, it is a requirement that all providers must continue to report their inventory using HPOP** for all USGA products, including products that have lost their authorization.

Dear Colleagues:

The U.S. Food and Drug Administration (FDA) announced on January 26, 2023, that the Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) has been revised and based on this revision, Evusheld is **not** currently authorized for use in the U.S. Based on CDC data, Evusheld is unlikely to be active against more than 90% of the SARS-CoV-2 variants currently circulating in the U.S. HHS and AstraZeneca have paused distribution of Evusheld until further notice by the Agency.

Individuals for whom COVID-19 vaccination is recommended should consider getting vaccinated with the primary series and an updated vaccine when eligible to increase protection against the most serious consequences of COVID-19.

Please visit the FDA's website and view ASPR's information sheet for additional details. You may also contact ASPR at COVID19Therapeutics@hhs.gov should you have questions.

COVID-19 antivirals are available and effective

Outpatient antiviral treatments for COVID-19, including oral antivirals (OAVs) and IV remdesivir (Veklury), are effective in reducing the risk for hospitalization and death. Nirmatrelvir with ritonavir (Paxlovid) is the preferred treatment for most outpatients or remdesivir if Paxlovid is contraindicated. The oral antiviral molnupiravir (Lagevrio) is authorized as an alternative when Paxlovid and remdesivir are not accessible or clinically appropriate. (NIH COVID-19 Treatment Guidelines for Non-Hospitalized Adults) The antivirals Paxlovid, remdesivir, and molnupiravir are expected to be active against circulating subvariants.

- Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- Lagevrio is authorized for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

- Veklury is approved for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

Evusheld inventory reporting is required

Please continue to report inventory for Evusheld in HPOP once per week by 11:59 PM on Mondays. Providers with a zero-dose available balance of Evusheld do not need to continue reporting "0". However, those that continue to have product on-hand (to include Evusheld) are required to report inventory on a weekly basis.

See the below instructions on how to report inventory in HPOP for each therapeutic type 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." Do not enter a cumulative total here.
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 around midnight EST. Ability to edit Administered / Available: If a person inadvertently enters an incorrect value, or transposes the Administered and Available numbers, they can edit and correct the data entry errors.

Disposing of Evusheld

For licensed provider locations with destruction procedures in place that follow all federal, state, and local regulations, therapeutics can only be destroyed if the product is expired, or unauthorized product can no longer be stored. No unexpired product that is currently authorized for use can be destroyed. All product that is destroyed must be recorded as wastage in HPOP.

Access to COVID-19 therapeutics

People who are immunocompromised, older adults, and people with disabilities continue to face increased risks from COVID-19. HHS has ramped up efforts to get high-risk populations

vaccinated and ensure their timely access to tests and lifesaving treatments. Through these efforts, Paxlovid and Lagevrio are now widely available at pharmacies, Test to Treat sites, long-term care facilities, and other sites; and states have been encouraged to set up infusion clinics for Veklury.

Resources

Accessing COVID-19 Oral Antivirals

- Paxlovid and molnupiravir are widely available in NYS pharmacies listed on the COVID-19 Therapeutics Locator and Test to Treat Locator.