

Updated Information on COVID-19 Treatments

Monoclonal Therapeutics & Antiviral Medications

Monoclonal Therapeutics

- 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 emergency use in the U.S. at this time. HHS and AstraZeneca have paused distribution of Evusheld until further notice by the Agency.

- **Evusheld is unlikely to be effective against more than 90% of the SARS- CoV2Variants currently circulating in the U.S. based on CDC data.** The full FDA announcement on Evusheld can be read [here](#).
- Those who are immunocompromised, including older adults and people with disabilities who have used Evusheld still have options to increase their protection against the most serious consequences of COVID-19 through other antiviral medications.
- **There are currently no authorized oral monoclonal therapeutics in any U.S. Region.**
- The U.S. Food and Drug Administration announced on November 11, 2022, the monoclonal **Bebtelovimab is not currently authorized for emergency use in the United States** because it is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1., according to data included in the [Health Care Provider Fact Sheet](#). **Read full FDA announcement regarding Bebtelovimab** [here](#).

Antiviral Medications

Antiviral medications can help your body fight COVID-19 by stopping the virus from multiplying in your cells, which could minimize symptoms and shorten the duration of the illness. This could lower the chances of your illness getting worse and requiring hospitalization.

Two oral antiviral pills are available to treat COVID-19, both available under emergency use authorization from the U.S. Food and Drug Administration (FDA):

• **Paxlovid** (Pfizer) – Eligible individuals must be age 12 or older who weigh at least 88 pounds, test positive for COVID-19, and be at [high risk for progression to severe illness from COVID-19](#).

- o Prescription required. Should be initiated as soon as possible after diagnosis of COVID-19 — no later than five days after symptom onset.

- o Paxlovid is not recommended for those with severe kidney disease or who are on dialysis, or those with severe liver disease. Dose adjustments may be required for patients with mild to moderate kidney disease. Healthcare providers should also monitor for possible drug-to-drug interactions and prescribe alternative treatments as needed or make temporary adjustments to other medications during COVID-19 treatment. *Please review the [Paxlovid FDA EUA Fact Sheet](#) for a list of warnings and precautions.*

• **Molnupiravir** (Lagevrio) – Eligible individuals must be age 18 years or older, test positive for COVID-19, and be at [high risk for progression to severe illness from COVID-19](#).

- Prescription required. Should be initiated as soon as possible after diagnosis of COVID-19 — no later than five days after symptom onset. Molnupiravir is not recommended for individuals who are pregnant. Breastfeeding is not recommended during treatment and for four days after the last dose. *Please review the [Molnupiravir FDA EUA Fact Sheet](#) for a list of warnings and precautions.*

An antiviral treatment administered through intravenous infusion is also available under full FDA approval for adult and pediatric patients (28 days of age and older and weighing at least 6.6 pounds) through hospitals or outpatient treatment locations:

• **Remdesivir** or Veklury (Gilead Sciences) – Eligible adults and children must test positive for COVID-19, and be at [high risk for progression to severe illness from COVID-19](#). Remdesivir was expanded for people who are not hospitalized but are at [high risk for disease progression](#). It was originally approved by the FDA for treating patients hospitalized with COVID-19.

- o Non-hospitalized patients: Can be used for the treatment of mild to moderate COVID-19 in high-risk patients with a three-day course started within seven days of symptom onset.

- o Hospitalized patients: Patients in the hospital with COVID-19 typically receive a five-day course.

- o Prescription required.

- o This is the only available treatment for children younger than age 12 who are at high risk for serious COVID-19 illness.

People who believe they might be eligible for one of these treatments should consult with a qualified provider to discuss medical history and current medications to check for possible drug-to-drug interactions and determine the best course of treatment.

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.

Updated February 9, 2023