# Updated Information on COVID-19 Treatments for COVID-19 Healthcare Providers

As part of Ohio's ongoing work to increase awareness of COVID-19 treatment options, this resource has been updated to provide the most current information for all Ohio healthcare providers to help connect eligible Ohioans with available treatment.

## Evusheld

As of January 26, 2023 The U.S. Food and Drug Administration (FDA) announced that the **Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) has been revised and based on this revision:**

**Evushled is not currently authorized for emergency use in the U.S. at this time. HHS and AstraZeneca have paused the distribution of Evusheld until further notice by the Agency.**

Evusheld in unlikely to be effective against more than 90% of the SARS-CoV-2 Variants currently circulating in the U.S. based on CDC data. The full FDA announcement on Evusheld can be read here.

## Bebtelovimab

**As of November 11, 2022, the U.S. Food and Drug Administration announced that 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.

## Monoclonal Therapeutics

**Currently, there are currently no authorized oral monoclonal therapeutics in any U.S. Region.**

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.

More details about these and other treatment options that are expected to retain activity against COVID-19 can be found here and below:

- **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.

- 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 adjustments to other medications during COVID-19 treatment. Please review the Paxlovid FDA EUA Fact Sheet for a list of contraindications, warnings, and precautions.

- **Dosage:** 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for five days, for a total of 30 tablets. An additional dose pack presentation with appropriate dosing is available for those with mild to moderate kidney disease.

- **Timing of treatment:** Paxlovid should be initiated as soon as possible after diagnosis of COVID-19 — no later than five days after symptom onset.

- **Full prescribing information:** Fact Sheet for Healthcare Providers.

- More information about Paxlovid, including dosing instruction, potential side effects, drug interactions, warnings/precautions, contraindications, specific populations, and information about who is able to prescribe Paxlovid, is available in the FDA's Fact Sheet for Healthcare Providers.

- **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.

- Lagevrio 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 Lagevrio FDA EUA Fact Sheet for a list of contraindications, warnings, and precautions.

- **Dosage:** 800 mg (four 200 mg capsules) taken orally every 12 hours for five days, for a total of 40 capsules.

- **Timing of treatment:** Lagevrio should be initiated as soon as possible after diagnosis of COVID-19 — no later than five days after symptom onset.

- **Full prescribing information:** Fact Sheet for Healthcare Providers.

- More information about Lagevrio, including dosing instructions, potential side effects, drug interactions, warnings/precautions, contraindications, specific populations, and information about who is able to prescribe Lagevrio, is available in the FDA's Fact Sheet for Healthcare Providers.

- **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.

- Veklury was originally approved by the FDA for treating patients hospitalized with COVID-19 and its use was expanded this year for people who are not hospitalized, but are at high risk for disease progression. This is the only available treatment for children younger than age 12 who are at high risk for serious COVID-19 illness.

- **Eligibility:** Eligible individuals must be **28 days of age and older and weighing at least 6.6 pounds**, test positive for COVID- 19, and be at high risk for progression to severe illness from COVID-19.

- **Dosage:** Non-hospitalized patients receive a three-day course by IV. Hospitalized patients typically receive a five-day course by IV.

- **Timing of treatment:** Veklury should be initiated in non-hospitalized patients within seven days of symptom onset.

- **Full prescribing information:** National Institutes of Health COVID-19 Treatment Guidelines.

Ohio has built a strong infrastructure of providers for oral antiviral pills that includes hospitals, federally funded health centers, retail pharmacies and long-term health care facilities across the state.

In addition, the national Test to Treat Initiative gives individuals who may not have healthcare home a way to quickly access testing, consultation with a qualified provider and treatment for COVID-19 if eligible.

## Test to Treat Locations

The national Test to Treat initiative includes sites across Ohio that have healthcare providers available to provide timely and thorough assessment and discuss relevant oral antiviral treatment options.

If a person tests positive at a different location or with an at-home test, that person can also go to these Test to Treat locations to receive a prescription from a qualified healthcare provider and access treatment on the spot if eligible.

Appointments are required at many of these locations, so those seeking care are advised to schedule an appointment online and to call ahead to ensure the treatment is still available. Some Test to Treat sites may have telehealth options available.

**More information:** Test to Treat program | Find a Test to Treat Location

**Resources for Providers**

- COVID-19 Therapeutics Provider Locator (ODH)
- COVID-19 Therapeutics Locator (Office of the Assistant Secretary for Preparedness & Response)
- COVID-19 Treatments and Therapeutics (HHS)
- COVID-19 Test to Treat initiative (ASPR)
- COVID-19 Test to Treat Locations (ASPR)
- Federal Response to COVID-19: Therapeutics Clinical Implementation Guide (HHS)
- Additional Resources for Medical Professionals (HHS)

- Product websites:
- Paxlovid
- Lagevrio
- Veklury

• FDA Emergency Use Authorization Fact Sheets for Healthcare Providers of Paxlovid Paxlovid (including a version for people with severe renal impairment) and Lagevrio

**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***