# KENTUCKY MONOCLONAL ANTIBODY THERAPEUTICS PROGRAM

# EVUSHELD FACT SHEET

Kentucky Public Health
Prevent. Promote. Protect.

## BACKGROUND

In December 2021, the Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab) for pre-exposure prophylaxis against coronavirus disease 2019 (COVID-19) in certain high risk persons age 12 and older.

## ELIGIBILITY

Evusheld is a combination of two long-acting monoclonal antibodies delivered intramuscularly in two injections authorized for COVID-19 pre-exposure prophylaxis use in adults and pediatric individuals (12 years of age **and** older weighing at least 40 kg) 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 (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

## REFERENCES


- AstraZeneca's Evusheld website
- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for EVUSHELD
- Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of EVUSHELD for Coronavirus Disease 2019 (COVID-19)
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States


## LIMITED AVAILABILITY/LOCATIONS

Kentucky will receive allocations of Evusheld from the U.S. Department of Health and Human Services in limited quantities and will distribute to select medical facilities across the state. Please visit KY COVID-19 Regional COVID-19 Monoclonal Antibody Administration Centers website for locations.

Please note, quantities will be extremely scarce for a prolonged time and therefore strictly prioritized to persons with severely immunocompromising conditions such as organ transplant recipients and persons on high-potency immunocompromising medications including, but not limited to chemotherapy. Facilities will determine eligibility based on product availability and guidance provided both in the FDA EUA and by the Kentucky Department for Public Health. When calling an administration site to request Evusheld, a referral letter from the patient's treating physician documenting their severely immunocompromising condition and proof of prior COVID-19 vaccination will assist in efficiently determining patient eligibility for Evusheld in Kentucky.

## LIMITATIONS ON AUTHORIZED USE

Evusheld is not authorized for the following uses in individuals:

- For treatment of COVID-19, or
- For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

Pre-exposure prophylaxis with 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. For individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

EVUSHELD should be administered at least two weeks after COVID-19 vaccination.


QUESTIONS

DPH.SEOC@ky.gov



December 21, 2021