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Health Alert
Update on Distribution and Patient Prioritization for Tixagevimab/Cilgavimab (Evusheld)

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Product Information

AstraZeneca's tixagevimab/cilgavimab (Evusheld) received an emergency use authorization (EUA) for pre-exposure prophylaxis (PrEP) against COVID-19 on December 8, 2021. A combination of two long-acting anti-SARS-CoV-2 monoclonal antibodies administered via intramuscular injection, Evusheld is intended to protect individuals who are unable to mount an adequate immune response to COVID-19 vaccination or are unable to receive a COVID-19 vaccine due to a history of a severe adverse reaction. Evusheld is not meant to be a replacement for vaccination in individuals who would otherwise be expected respond to the COVID-19 vaccine.

Evusheld is authorized for adults and children (12 years of age and older weighing at least 40 kg):

Who are 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 COVID19 vaccine component(s).

Clinical Trial Data

In a clinical trial, RT-PCR-confirmed symptomatic SARS-CoV-2 infection was reported for 8 participants (0.2%) in the Evusheld arm and 17 participants (1.0%) in the placebo arm, representing a 77% reduction in the incidence of infection in the Evusheld arm. A post hoc analysis after a median follow-up period of 6.5 months showed a similar relative risk reduction for symptomatic infection in the Evusheld arm. Adverse events were similar in both study arms, although there was a slightly higher risk of cardiac events in the Evusheld arm.

Changes in Distribution to California Jurisdictions

Initial distribution of Evusheld by the California Department of Public Health (CDPH) was to

Mutual Aid Regions with instructions to send treatment courses to transplant and cancer centers and other identified priority locations across their region. This was owing to extremely short supply of the product in the first few weeks of distribution.

Starting February 14, 2022, this process changed and Evusheld will be directly allocated to local health jurisdictions similar to the other federally allocated COVID-19 therapeutics. Local health jurisdictions and Medical Health and Operations Area Coordinator (MHOAC) will be responsible for identifying facilities best placed to provide the product in an equitable fashion to their populations.

The methodology of determining quantity of product supplied to each jurisdiction will remain unchanged, considering the following:

- Total number of Evusheld allocated to each jurisdiction will be tied to the overall population in each quartile of the Healthy Places Index (HPI) equity measure.
- All jurisdictions accepting orders will receive a minimum allocation size of 24 courses.

Healthcare facilities that would like to acquire product should contact their local MHOAC.

Prioritization of Patients to Receive Evusheld

Overall weekly supplies of Evusheld distributed from HHS have remained relatively consistent. However, product scarcity is still possible, especially as the number of sites administering this treatment increases. In cases where supply is limited by supply or logistical constraints, providers should follow the NIH treatment guidelines. In summary, patients eligible for receiving Evusheld can be prioritized into three groups:

Priority 1: People who are severely immunocompromised should be prioritized for Evusheld. According to the NIH treatment guidelines, individuals with the below, or equivalent medical conditions, can be classified as having a severe immunocompromising condition:

- Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
- Patients receiving Bruton tyrosine kinase inhibitors
- Chimeric antigen receptor T cell recipients
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients
- Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)
- Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents
- Patients with severe combined immunodeficiencies

- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3

Priority 2: If adequate supply exists to treat current demand in people meeting the Priority 1 group criteria, those who are moderately immunocompromised (see FDA Fact Sheet for additional medical conditions) and are not expected to mount an appropriate response to COVID-19 vaccination can receive Evusheld if clinically appropriate.

Priority 3: Finally, if adequate product exists to meet the above demands, healthy people with no immunocompromising conditions but history of severe adverse reactions to the COVID-19 vaccine as outlined in the product EUA can be offered Evusheld.

Individuals who continue to meet the criteria for use of Evusheld as PrEP and who remain in a setting with ongoing SARS-CoV-2 circulation can receive repeat dosing every 6 months. Evusheld has only been studied in clinical trials as a first-time dose of the combination therapy and no safety or efficacy data exist for repeat dosing.

Evusheld and COVID-19 Vaccination

Evusheld is not a substitute for COVID-19 vaccination and should not be used in unvaccinated individuals for whom COVID-19 vaccination is recommended and who are anticipated to have an adequate response. If a person has received a COVID-19 vaccine, Evusheld should be administered at least 2 weeks after vaccination. No deferral period is necessary when administering a COVID-19 vaccine after Evusheld administration.

Resources

Providers should review the Evusheld FDA Fact Sheet before use. The HHS Therapeutics Locator can be used to locate facilities with currently supply of Evusheld, although this site does not represent a guarantee of availability. Please refer to the CDPH Therapeutics webpage for information on outpatient products and distribution in California.