NEW MEXICO Department of Health

MICHELLE LUJAN GRISHAM
Governor

DAVID R. SCRASE, M.D.
Acting Cabinet Secretary

NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

Latest Guidance from FDA on AstraZeneca COVID-19 monoclonal antibody Evusheld

DATE

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Background

On December 08 , 2021, the Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) to AstraZeneca's COVID19 monoclonal antibody Evusheld (tixagevimab co-packaged with cilgavimab).

The New Mexico Medical Advisory Team reviewed and concurred with the FDA's recommendations for use of Evusheld as a pre-exposure prophylaxis of COVID-19.

Prescribing Information for Clinicians

- Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended, including those with moderate to severe immunocompromise.

- One dose of Evusheld, administered as two separate consecutive intramuscular injections may be effective for pre-exposure prevention for six months.

- A dose of Evusheld for adults and pediatric individuals (12 years of age and older weighting at least 40 kg [about 88 pounds]) is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections.

- Evusheld may only be used in adults and pediatric individuals (12 years of age and older weighing at least 40 kg [about 88 pounds]):
    - Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infect with SARS-CoV-2

  In addition, the authorization requires that individuals either 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 (see Frequently Asked Questions on the Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab) for Pre-exposure Prophylaxis (PrEP) of COVID-19 (fda.gov) for examples) **or**
    - A history of severe adverse reactions to a COVID-19 vaccine and/or component(s) where administration of the vaccine is not recommended.

Safety Considerations:

- Tixagevimab and cilgavimab are not eliminated intact in the urine. Renal impairment is not expected to impact the pharmacokinetics of tixagevimab and cilgavimab, since monoclonal antibodies with molecular weight >69 kDa are known not to undergo renal elimination. Similarly, dialysis is not expected to impact the pharmacokinetics of tixagevimab and cilgavimab.
- Evusheld should only be used during pregnancy if the potential benefits outweigh the potential risk for the mother and the fetus.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Evusheld and any potential adverse effect on the breastfed infant from Evusheld.
- In the PROVENT trial, serious cardiac adverse events were infrequent, but more trial participants had serious cardiac adverse events after receiving Evusheld compared to placebo. These participants all had risk factors for cardiac disease or a history of cardiovascular disease.
- Evusheld is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of Evusheld.

Additional Provider Information:

- Evusheld is not authorized for individuals for the treatment of COVID-19 or for post-exposure prevention of COVID-19.
- For individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination.
- No dosage adjustment is recommended in pregnant or lactating individuals, in geriatrics, and in individuals with renal impairment.

Access to Evulsheld in New Mexico

- New Mexico COVID-19 Evusheld providers can start providing Evusheld injections immediately. However, providers have not yet received their supply. Direct shipments to the providers are anticipated to arrive in the next week. If you have questions on Evusheld access in New Mexico, please contact the New Mexico Department of Health COVID19 Therapeutics Team at COVID.Therapeutics@state.nm.us .
- Evusheld will be made available to the following specialty clinics: HIV/AIDS care, transplant services, oncology, hematology, rheumatology, neurology, gastroenterology, and allergy/immunology.
- Allocations from Federal Government are based on available manufactured supply and state population.
- New Mexico will follow all recommendations in the EUA
  EUA for Evusheld Providers (https://www.fda.goc/media/154701/download)
  EUA for Recipients and Caregivers (https://www.fda.gov/media/154702/download)

EPIDEMIOLOGY AND RESPONSE

1190 St. Francis Drive, N1320 • Santa Fe, New Mexico • 87502-6110

(505) 827-0006 • FAX: (505) 827-2110 • www.nmhealth.org

Additional Resources:

1. Evusheld Fact Sheet for Healthcare Providers https://www.fda.gov/media/154701/download
2. AstraZeneca's website www.EVUSHELD.com
3. FDA News Release for Evusheld
4. For clinicians who have other access questions please contact the New Mexico Department of Health COVID19 Therapeutics Team at **COVID.Therapeutics@state.nm.us** .

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page https://nm.readyop.com/fs/4cjZ/10b2 Please provide all information requested to begin receiving important health alerts and advisories.