PRIOR AUTHORIZATION POLICY

POLICY: Coronavirus Disease – Evusheld Prior Authorization Policy
- Evusheld™ (tixagevimab intramuscular injection and cilgavimab intramuscular injection – AstraZeneca)

REVIEW DATE: 02/07/2024

OVERVIEW

On December 8, 2021 the FDA issued an Emergency Use Authorization (EUA) for Evusheld for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19). Based on data showing that Evusheld is unlikely to be active against currently circulating variants of COVID-19, the FDA removed the EUA for Evusheld on January 26, 2023.[4]

Evusheld, a combination product containing two severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein-directed attachment inhibitors, received EUA for the **pre-exposure prophylaxis of COVID-19** in patients ≥ 12 years of age and weighing ≥ 40 kg:[1]

- 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 of severe adverse reactions (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Guidelines

The Infectious Disease Society of America (IDSA) and the National Institutes of Health (NIH) have developed treatment guidelines for the management of COVID-19 and each address the use of Evusheld.[2,3] The NIH recommends against the use of Evusheld for the pre-exposure prophylaxis of COVID-19.[2] In addition, the IDSA states that the benefits of prophylaxis with Evusheld no longer outweigh the small but known risks associated with its use.[3]

POLICY STATEMENT

Due to the lack of clinical efficacy, **approval is not** recommended for Evusheld.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

None.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Evusheld is not recommended in the following situations:

1. **Coronavirus Disease 2019 (COVID-19), Pre-Exposure Prophylaxis.** Approval is not recommended. The FDA has removed the EUA for Evusheld due to the high combined frequency of non-susceptible

SARS-CoV-2 variants to Evusheld nationally.[4] According to the Centers for Disease Control and Prevention, the non-susceptible strains of SARS-CoV-2 are expected to account for > 90% of current infections. In addition, the NIH stated on January 30, 2023 that the prevalence of SARS-CoV-2 strains resistant to Evusheld is estimated to be > 97%.[5] The NIH now recommends against the use of Evusheld for pre-exposure prophylaxis of COVID-19.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Evusheld™ intramuscular injections [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
2. COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. December 20, 2023. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on January 29, 2024.
3. Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Disease Society of America Guidelines on the treatment and management of patients with COVID-19. June 26, 2023. Available at: https://www.idsociety.org/COVID19guidelines. Accessed January 29, 2024.
4. Food and Drug Administration. FDA announces Evusheld is not currently authorized for emergency use in the U.S. U.S. Food and Drug Administration Website. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us. Accessed on January 29, 2024.
5. COVID-19 Treatment Guidelines Panel. The COVID-19 Treatment Panel's revised statement on tixagevimab plus cilgavimab (Evusheld) as pre-exposure prophylaxis of COVID-19. National Institutes of Health. January 30, 2023. Available at: https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/revised-statement-on-evusheld-01-30-2023.pdf. Accessed on January 29, 2024.