PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/08/2023

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.

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

Dosing Information

The initial dose of Evusheld is 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.[1] Individuals who received 150 mg of tixagevimab and 150 mg of cilgavimab ≤ 3 months ago should receive a second dose of Evusheld (150 mg of tixagevimab and 150 mg of cilgavimab). Individuals who received 150 mg of tixagevimab and 150 mg of cilgavimab > 3 months ago should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab. Repeat doses of Evushield (300 mg of tixagevimab and 300 mg of cilgavimab) should be administered once every 6 months.

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

Prior Authorization is recommended for prescription benefit coverage of Evusheld. All approvals are provided for 30 days, which is an adequate duration for the patient to receive one dose, which is a 6 month supply of Evusheld. All reviews will be forwarded to the Medical Director for evaluation.

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Evusheld is recommended in those who meet the following criteria:

Emergency Use Authorization

1. **Coronavirus Disease 2019 (COVID-19), Pre-Exposure Prophylaxis.** Approve a single dose if the patient meets ALL of the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient weighs ≥ 40 kilograms; AND
   - **C)** Patient is NOT currently infected with COVID-19; AND
   - **D)** Patient does NOT have a known recent exposure to someone infected with COVID-19; AND
   - **E)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient meets both of the following criteria (a and b):
       - **a)** Patient is moderately to severely immunocompromised; AND
         Note: This can include medical conditions and/or treatment with immunosuppressive medications.
       - **b)** According to the prescriber, patient may not mount an adequate immune response to COVID-19 vaccination; OR
     - **ii.** Vaccination with any COVID-19 vaccine is not recommended due to a of severe adverse reaction to a COVID-19 vaccine.
       Note: For example a severe allergic reaction to a COVID-19 vaccine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Evusheld is not recommended in the following situations:

1. 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. Available at: https://www.covid19treatmentguidelines.nih.gov/. Accessed on February 3, 2023.
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. January 20, 2023. Available at: https://www.idsociety.org/COVID19guidelines. Accessed February 3, 2023.

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