

Prescriber Checklist Tool

Evusheld™

Patient eligibility

The FDA has issued an emergency use authorization (EUA) for tixagevimab co-packaged with cilgavimab (Evusheld) for **pre-exposure prophylaxis** of COVID-19 in the following individuals:

- Aged ≥ 12 years and weighing at least 40 kg, and
- Who are not currently infected with SARS-CoV-2 and 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).
- For whom Evusheld is not being used for treatment or post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

Requirements

Requirements prior to administration of Evusheld under EUA

- Healthcare facilities and healthcare providers will ensure that they are aware of the [Letter of Authorization](#), and the terms therein, and that the authorized Fact Sheets are made available to [healthcare providers and to patients, parents, and caregivers](#), respectively, through appropriate means, prior to administration of Evusheld.
- Consider the risks and benefits prior to initiating Evusheld in individuals at high risk for cardiovascular events (see section 6.1 of the Evusheld [Fact Sheet for Healthcare Providers](#)).

Administration

Important information regarding the administration of Evusheld

- Evusheld is available as an individual single-dose vial of tixagevimab co-packaged with a single-dose vial of cilgavimab for intramuscular (IM) administration.
- The two components of Evusheld are administered consecutively, preferably one in each of the gluteal muscles. Evusheld may be redosed every 6 months.
- If an individual has been vaccinated with the COVID-19 vaccine, administer Evusheld at least two weeks after vaccination.
- Given its IM route of administration, Evusheld should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- Clinically monitor individuals after injections for at least 1 hour due to a risk of hypersensitivity with Evusheld.



Important notice

The prescribing healthcare provider and/or designee must report all medication errors and serious adverse events potentially related to Evusheld within 7 calendar days from the healthcare provider's awareness of the event to [FDA MedWatch](#).

*Per the EUA, medical conditions or treatments that may result in moderate to severe immune compromise and inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic conditions.
- Receipt of solid-organ transplant and taking immunosuppressive therapy.
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts $<200/\text{mm}^3$, history of an AIDS-defining illness without immune reconstitution, or clinical manifestation of symptomatic HIV).
- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day when administered for ≥ 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutics agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents).

