

Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic: tixagevimab and cilgavimab injection

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Background

Recent studies show that immunocompromised patients, those with compromised immune system due to a medical condition or due to receipt of a medication that treats inflammation (an immunosuppressive treatment), have a lower response rate to the COVID-19 vaccines. Evusheld™ (tixagevimab co-packaged with cilgavimab) is a combination of two separate monoclonal antibody SARS-CoV-2 spike protein-directed attachment inhibitors given in two separate consecutive intramuscular (IM) injections. Evusheld has demonstrated a significant reduction in incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness (COVID-19) when compared to placebo. Recognizing the decreased immunity to COVID-19 in immunocompromised patients, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Evusheld injection as pre-exposure prophylaxis in patients 12 and older.

While the approved vaccines for COVID-19 remain the most important defense, Evusheld is authorized for patients whose immunity to COVID-19 is likely inadequate due to severe immunocompromise. Importantly, this EUA should not serve as a substitute for the approved vaccines but are to be used for patients who do not have an adequate immunity with the vaccines alone.

Recognizing the importance of ensuring immunocompromised patients are protected against the coronavirus (SARS-CoV-2) while being mindful of the limited supply of these newly authorized treatments, we offer the following recommendations. *Note that evaluation of Evusheld is ongoing and additional guidance will be included in a forthcoming update of COVID-19 guidance from the ACR.*

Recommendations

- All patients, and especially those who are immunocompromised, are strongly encouraged to get vaccinated. Vaccination remains the primary defense mechanism to prevent severe coronavirus symptoms, hospitalization, and death. It is recommended that immunocompromised patients receive the appropriate vaccination schedules and boosters as recommended by the CDC.
- Moderately to severely immunocompromised patients are candidates for Evusheld and should be actively considered for pre-exposure prophylaxis (an

ACR guidance on appropriate use of Evusheld for patients with rheumatic diseases is forthcoming).

- Resource allocation may need to be prioritized to allow the most severely immunocompromised – those on B cell depleting therapies (e.g., rituximab), mycophenolate and high dose corticosteroids – to receive first consideration of treatment.

References

1. Emergency Use Authorization, FDA. Accessed December 13, 2021.
<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure>