

The COVID-19 Treatment Guidelines Panel's Revised Statement on Tixagevimab Plus Cilgavimab (Evusheld) as Pre-Exposure Prophylaxis of COVID-19

Last Updated: January 30, 2023

The prevalence of SARS-CoV-2 Omicron subvariants that are not susceptible to tixagevimab plus cilgavimab (Evusheld) has been rapidly increasing in the United States. These subvariants are BA.2.75.2, BA.4.6, BA.5.2.6, BF.7, BF.11, BQ.1, BQ.1.1, XBB, and XBB.1.5. On January 27, 2023, the [overall prevalence of these Omicron subvariants](#) was estimated to be >97%.

On January 26, 2023, the Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) for tixagevimab plus cilgavimab to limit its use.¹ Tixagevimab plus cilgavimab is authorized for use as pre-exposure prophylaxis (PrEP) of COVID-19 when the combined frequency of nonsusceptible subvariants in the United States is $\leq 90\%$.² Because the overall prevalence of these subvariants is now >97%, tixagevimab plus cilgavimab is not currently authorized for use in the United States. To address the revised EUA, the COVID-19 Treatment Guidelines Panel (the Panel) has changed its recommendation for tixagevimab plus cilgavimab.

The Panel now **recommends against** the use of **tixagevimab plus cilgavimab** as PrEP of COVID-19 **(AIII)**.

Currently, there is no authorized or approved agent for use as PrEP of COVID-19. Previously, the FDA authorized tixagevimab plus cilgavimab as PrEP of COVID-19 in people who were not expected to mount an adequate immune response to COVID-19 vaccination and in people with COVID-19 vaccine contraindications.

It remains critical that these individuals:

- Keep up to date with COVID-19 vaccination and boosters, unless contraindicated.
- Take [precautions](#) to avoid infection.
- Be tested for SARS-CoV-2 if they experience signs and symptoms consistent with COVID-19 and, if infected, promptly seek medical attention.

References

1. Food and Drug Administration. FDA announces Evusheld is not currently authorized for emergency use in the U.S. 2023. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us>. Accessed January 26, 2023.
2. Food and Drug Administration. Fact sheet for healthcare providers: Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab). 2023. Available at: <https://www.fda.gov/media/154701/download>.