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

Last Updated: January 10, 2023

The prevalence of SARS-CoV-2 Omicron subvariants likely to be resistant 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, and XBB.[1] In addition, the XBB.1.5 subvariant is not anticipated to be neutralized by tixagevimab plus cilgavimab.[2,3] As of January 6, 2023, the overall prevalence of these Omicron subvariants is estimated to be more than 91%.

Tixagevimab plus cilgavimab is authorized by the Food and Drug Administration (FDA) for pre-exposure prophylaxis (PrEP) of COVID-19 in people who are not expected to mount an adequate immune response to COVID-19 vaccination or people with contraindications for COVID-19 vaccination.

Due to the high prevalence of resistant Omicron subvariants in the United States, tixagevimab plus cilgavimab is unlikely to be effective at preventing COVID-19 in the vast majority of individuals, although it is still authorized by the FDA for COVID-19 PrEP. However, given the lack of alternative PrEP options, clinicians could still administer tixagevimab plus cilgavimab after considering an individual patient's risks and the regional prevalence of the resistant subvariants.

Regardless of their use of tixagevimab plus cilgavimab, it is crucial that these high-risk patients:

- 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. Fact sheet for healthcare providers: Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab). 2022. Available at: https://www.fda.gov/media/154701/download.
2. Yue C, Song S, Wang L, et al. Enhanced transmissibility of XBB.1.5 is contributed by both strong ACE2 binding and antibody evasion. *bioRxiv*. 2023;Preprint. Available at: https://www.biorxiv.org/content/10.1101/2023.01.03.522427v2.
3. Food and Drug Administration. FDA releases important information about risk of COVID-19 due to certain variants not neutralized by Evusheld. 2023. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-releases-important-information-about-risk-covid-19-due-certain-variants-not-neutralized-evusheld. Accessed January 9, 2023.