FDA Warns Evusheld May Not Protect Against Certain COVID-19 Variants

The monoclonal antibody combination is used as pre-exposure prophylaxis for immunocompromised people who may not respond to COVID-19 vaccines.

October 6, 2022 By Food and Drug Administration (FDA)

FDA releases important information about risk of COVID-19 due to certain variants not neutralized by Evusheld

FDA added important information to the authorized Fact Sheets for Evusheld (tixagevimab co-packaged with cilgavimab) to inform health care providers and individuals receiving Evusheld of the increased risk for developing COVID-19 when exposed to variants of SARS-CoV-2 that are not neutralized by Evusheld.

Detailed neutralization data can be found in the revised authorized Fact Sheet for Healthcare Providers. Health care professionals should inform patients of this risk and advise patients who develop signs or symptoms of COVID-19 to test for SARS-CoV-2 infection and promptly seek medical attention, including starting treatment for COVID-19, as appropriate if they test positive.

Evusheld is currently the only option for pre-exposure prophylaxis (PrEP) of COVID-19 and is authorized under Emergency Use Authorization (EUA) for use in immunocompromised individuals who may not mount an adequate response to COVID-19 vaccination, and for individuals for whom COVID-19 vaccination is not recommended due to a history of a severe adverse reaction. It is authorized to be administered every six months. Use of Evusheld is not a substitute for COVID-19 vaccination, and individuals for whom COVID-19 vaccination is recommended should get vaccinated. Individuals who received Evusheld but who develop COVID-19 remain eligible for use of any of the available treatments for COVID-19 if the criteria for use are met.

FDA continues to recommend Evusheld as an appropriate option for PrEP to prevent COVID-19, in combination with other preventative measures like getting vaccinated and boosted as recommended, as Evusheld still offers protection against many of the currently circulating variants and may offer protection against future variants.

What Patients Should Know:

- Talk with your health care provider about appropriate treatment options in case you develop

COVID-19. There are several approved and authorized treatments for COVID-19 that are expected to retain activity against currently circulating SARS-CoV-2 variants.

- If you develop COVID-19 symptoms, tell your health care provider and test right away. It's not possible to know which variant of SARS-CoV-2 you may have contracted. Timely treatment can reduce your risk of developing severe disease, including decreasing your risk of hospitalization or death.
- If recommended by your health care provider, get vaccinated or boosted with a bivalent booster dose to help your body increase your protection against SARS-CoV-2 infection. Follow CDC's guidelines on additional prevention strategies to protect yourself from getting sick.

What Health Care Providers Should Know:

- Prescribers should monitor CDC regional variant frequency data and refer to the table of variants detailed in the Fact Sheet for Health Care Providers for the latest data on the neutralization activity of Evusheld against SARS-CoV-2 variants in your area. Prescribers should discuss the risk of developing COVID-19 infection with patients receiving Evusheld.
- There are several treatments – Paxlovid, Veklury (remdesivir), bebtelovimab, and Lagevrio (molnupiravir) – that are expected to retain activity against currently circulating variants, and that are authorized or approved to treat certain patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death. Health care providers should assess whether these treatments are right for their patient in the event the patient develops mild-to-moderate COVID-19.
- FDA has also updated the list of medical conditions or treatments that may result in moderate to severe immune compromise. The conditions listed in the Fact Sheet for Health Care Providers are not intended to be an all-inclusive list. Patients with other conditions not listed may also have moderate to severe immune compromise and therefore be eligible for Evusheld therapy, assuming the remaining terms and conditions of the authorization are met.

This announcement was published by the Food and Drug Administration on October 3, 2022.
