Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update

January 27, 2023

FDA announces Evusheld™ is not currently authorized for emergency use in the U.S.

On January 26, 2023, the U.S. Food and Drug Administration revised the Emergency Use Authorization (EUA) for Evusheld™ (tixagevimab co-packaged with cilgavimab) to limit its use to when the combined frequency of non-susceptible SARS-CoV-2 variants nationally is less than or equal to 90%. Based on this revision, Evusheld™ is not currently authorized for use in the U.S. until further notice by the Agency, as recent data show it is unlikely to be active against certain SARS-CoV-2 variants.

The most recent Nowcast data from the Centers for Disease Control and Prevention shows that these variants are projected to be responsible for more than 90% of current infections in the U.S. This means that Evusheld™ is not expected to provide protection against developing COVID-19 if exposed to those variants. ***Given that a COVID-19 infection is likely to be caused by a non-susceptible SARS-CoV-2 variant, and consistent with the terms and conditions of the Letter of Authorization, Evusheld™ is not currently authorized for emergency use in any U.S. region at this time.***

This action to limit the use of Evusheld™ prevents exposing patients to possible side effects of Evusheld™ such as allergic reactions, which can be potentially serious, at a time when fewer than 10% of circulating variants in the U.S. causing infection are susceptible to the product.

The U.S. Government recommends that facilities and providers with Evusheld™ retain all product in the event that SARS-CoV-2 variants which are neutralized by Evusheld™ become more prevalent in the U.S. in the future. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization.

Health care providers should use other approved or authorized products that are expected to retain activity against currently circulating variants as they choose appropriate treatment options for patients, which include the following:

- Paxlovid™ (nirmatrelvir and ritonavir) is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
- Veklury® (remdesivir) is approved for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. Note: remdesivir is also indicated in hospitalized patients for treatment of laboratory-confirmed COVID-19.
- Lagevrio™ (molnupiravir) is authorized for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Individuals for whom COVID-19 vaccination is recommended should consider getting vaccinated with the primary series or, if vaccinated with the primary series, boosted with an updated bivalent vaccine when eligible to increase protection against the most serious consequences of COVID-19, including hospitalization and death.

For more information related to the therapeutic management of non-hospitalized patients with mild-to-moderate COVID-19, refer to the NIH COVID-19 Treatment Guidelines.

Reference(s):
1. U.S. Food & Drug Administration. FDA announces Evusheld is not currently authorized for emergency use in the U.S.. Published online January 26, 2023.