Health Alert Notice for District of Columbia Health Care Providers

FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

SUMMARY
The U.S. Food and Drug Administration (FDA) has issued updated Emergency Use Authorization (EUA) fact sheets for two COVID-19 monoclonal antibody treatments: bamlanivimab and etesevimab (when administered together) and REGEN-COV (casirivimab and imdevimab administered together). After reviewing the current data, the FDA has made the decision to restrict the use of bamlanivimab/etesevimab and REGEN-COV to treat COVID-19 positive patients at this time. Data indicates that these two treatments are highly unlikely to be active against the Omicron variant which is circulating at a very high frequency throughout the United States.

At this time, bamlanivimab/etesevimab and REGEN-COV are not currently authorized for use anywhere in the U.S. states, territories, and jurisdictions, due to the prevalence of Omicron. The FDA is encouraging healthcare providers to choose authorized treatment options with activity against circulating variants in their jurisdiction. Providers who have these monoclonal antibodies on hand are advised to hold them as they could be effective against subsequent variants in the future.

BACKGROUND
Monoclonal antibodies are proteins made in a laboratory that mimic the body’s natural immune response to neutralize harmful pathogens, like SARS-CoV-2. Just like any other infectious organism, SARS-CoV-2 can mutate over time. These mutations can result in treatments becoming less effective.

Throughout the pandemic, the FDA has used the most up to date science and data to evaluate the latest COVID-19 therapeutic treatments. While not a substitute for staying up to date on COVID-19 vaccines, these treatment options have given healthcare providers additional tools to save lives for those who become infected with SARS-CoV-2. As more up to date data becomes available, the FDA reviews current EUAs to ensure the potential benefits continue to outweigh the known and potential risks. Recent studies and data concerning the efficacy of bamlanivimab/etesevimab and REGEN-COV have triggered the revisions to the EUA indicated in this notice.

OMICRON VARIANT PREVALANCE & TREATMENT EFFICACY
Data released by the Centers for Disease Control and Prevention (CDC) last week confirms that Omicron is the overwhelmingly dominant variant of concern (VOC) in the United States at a prevalence of greater than 97.8% in all regions and nationally greater than 99%. Based on this data, the FDA has determined that it is highly unlikely that COVID-19 patients seeking care in the U.S. at this time are infected with a variant other than Omicron, and these treatments are not authorized to be used at this time.

The NIH COVID-19 Treatment Guidelines Panel, an independent panel of national experts, also recently recommended against the use of bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) because of markedly reduced activity against the Omicron variant and because real-time testing to identify rare, non-Omicron variants is not routinely available. Additionally, the U.S. Department of Health and Human Services (HHS) actively assesses data on a continuous basis to adjust COVID-19 therapeutics allocation guidelines as required. After reviewing recent data on existing monoclonal antibody treatments authorized by the FDA under an EUA for the treatment of COVID-19 positive patients, bamlanivimab/etesevimab and REGEN-COV have been identified to not be effective against the Omicron variant.
ADDITIONAL/APPROVED TREATMENT OPTIONS

Providers and patients should be aware that there are additional treatment options available that work against Omicron for COVID-19 patients who are at high risk for progression to severe disease including oral (Paxlovid, Molnupiravir) and IV antivirals (Remdesivir/Veklury) in addition to the monoclonal antibody sotrovimab. Additionally, the monoclonal antibody Evusheld (cilgavimab and tixagevimab) is an authorized pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric individuals who have certain health conditions including moderate to severely compromised immune systems or for those whom COVID-19 vaccination is not recommended.

POTENTIAL FOR FUTURE USE

The FDA has stated that if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these bamlanivimab/etesevimab and REGEN-COV may be authorized in these regions. DC Health will be monitoring future changes to the authorization of these two monoclonal antibody therapeutics as well as the Omicron prevalence in the District and the region in order to inform providers of any changes in the authorized utilization of these products.

ADDITIONAL RESOURCES


- National Institutes of Health (NIH) COVID-19 Treatment Guidelines recommending against the use of bamlanivimab/etesevimab and REGEN-COV due to reduced activity against the Omicron variant: [covid19treatmentguidelines.nih.gov](covid19treatmentguidelines.nih.gov)

- Updated Patient Fact Sheets
  - Bamlanivimab and etesevimab (administered together):
    - [fda.gov/media/145802/download](fda.gov/media/145802/download)
  - REGEN-COV:
    - [fda.gov/media/145611/download](fda.gov/media/145611/download)

For questions regarding COVID-19 Therapeutics, please contact DC Health at:
Phone: 1-855-363-0333 (M-Sa 9:00am – 5:30pm) | Email: covid.therapeutics@dc.gov