Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update

January 25, 2022

FDA Limits Use of Bamlanivimab/Etesevimab and REGEN-COV

On January 24, 2022***, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use*** to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.[1]

Also, on January 24, 2022, the U.S. Department of Health and Human Services reported that with the arrival of the Omicron variant, a review was conducted of existing monoclonal antibody treatments for COVID-19 and available data on whether they would work against the new variant. Following this review, it was determined that bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) are not effective against Omicron. Subsequently, both Lilly and Regeneron have said their products are not likely to be effective against Omicron, and several independent studies have shown this as well.[2]

Based on Centers for Disease Control and Prevention data[3], the Omicron variant of SARS-CoV-2 is estimated to account for more than 99% of cases in the United States as of January 15, 2022. Therefore, 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.*** This avoids exposing patients to side effects, such as injection site reactions or allergic reactions, which can be potentially serious, from specific treatment agents that are not expected to provide benefit to patients who have been infected with or exposed to the Omicron variant.[1]

The NIH COVID-19 Treatment Guidelines Panel, an independent panel of national experts, 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.[1,4]

Importantly, there are several other therapies – Paxlovid®, sotrovimab, Veklury® (remdesivir), and molnupiravir – that are expected to work against the Omicron variant, and that are authorized or approved to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death. Healthcare providers should consult the NIH panel's COVID-19 treatment guidelines and assess whether these treatments are right for their patients.[1] ***Updated clinical guidance for IHS staff regarding COVID-19 Emerging Treatments may be found in the COVID-19 section of the IHS NPTC website.***[5]

As a result of the extremely high prevalence of omicron and recent guidance from FDA and NIH, ***on January 24, 2022, the U.S. Department of Health and Human Services announced that they will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) in ongoing allocations for COVID-19 therapeutics until further notice.***[2]

References:

1. U.S. Food and Drug Administration. FDA Statement. COVID-19 Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant. Released January 24, 2022.
2. Department of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. Public Health Emergency. Allocation f Bamlanivimab/Etesevimab and REGEN-COV Therapeutics Paused. Published January 24, 2022.
3. Centers for Disease Control and Prevention. COVID Data Tracker: Variant Proportions. Accessed January 24, 2022.
4. U.S. National Institutes of Health. COVID-19 Treatment Guidelines. Accessed January 24, 2022.
5. Indian Health Service. National Pharmacy & Therapeutics Committee, COVID-19 Emerging Treatments Updates. Accessed January 23, 2022.