Provider Bulletin





April 6, 2021

Monoclonal Antibody Treatments for COVID-19

The Food and Drug Administration (FDA) has authorized Emergency Use Authorization (EUA) and approved multiple monoclonal antibody therapies for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients who are at high risk for progressing to severe COVID-19 and/or hospitalization. These agents include the combination of casirivimab and imdevimab, bamlanivimab alone, and the combination of bamlanivimab and etesevimab. An overview of these <u>therapeutic options for COVID-19 patients</u> can be found on the Minnesota Department of Health (MDH) website.

Updates to the EUA for bamlanivimab with/without estesevimab

The FDA recently updated the <u>fact sheet for bamlanivimab</u> and the <u>fact sheet for bamlanivimab and etesevimab</u>. Recent data has shown that the use of bamlanivimab alone or in combination with etesevimab may only be effective against the B.1.1.7 (UK origin) variant of COVID-19. In other words, it's unlikely that these specific monoclonal antibody treatments will be effective against several variants such as the B.1.351 (South Africa origin), P.1 (Brazil origin), B.1.427/B.1.429 (California origin) or the B.1.526 (New York origin). As of March 24, 2021, the government has halted distribution of bamlanivimab alone due to the increase of resistance of variants. The EUA was updated to encourage providers to consider the local variant trends before using monoclonal antibody therapy.

How do I learn more about COVID-19 variants in my area?

Health professionals can use the <u>Variants of the Virus that Causes COVID-19</u> page on the Centers for Disease Control and Prevention (CDC) website to obtain updated information about which variants have been reported in the United States. The website contains an up-to-date, <u>interactive map</u> of variant activity and a breakdown of <u>variant proportions</u>.

What important safety information should I consider?

All monoclonal antibody therapies have been authorized for EUA only. Monoclonal antibody infusion treatments should only be administered in settings in which health care providers have immediate access to medications to treat severe infusion reactions, including anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Product-specific dosing, warnings, adverse effects and storage requirements can be found on the FDA-approved fact sheets for <u>bamlanivimab and etesevimab</u> and <u>casirivimab and imdevimab</u>.

How can I obtain access for use?

The U.S. Department of Health & Human Services has resources on their website to find <u>potential treatment</u> <u>locations</u>. Regeneron and Lilly sponsored the <u>National Infusion Center Association's tool</u> for locating COVID-19 monoclonal antibody infusion centers. Lilly is also directing providers to use their <u>direct order form</u> to obtain bamlanivimab and etesevimab. The Centers for Medicare & Medicaid Services (CMS) have information regarding current therapies and reimbursement that can be found on their <u>Monoclonal Antibody COVID-19 Infusion</u> page.



Questions

If you have further questions, please call UCare's Provider Assistance Center at 612-676-3300 or 1-888-531-1493 (toll free) or visit <u>ucare.org/providers</u>.

