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Clinical Bulletin

November 23, 2020

Subject: FDA authorizes bamlanivimab for early use in COVID-19

The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for the investigational monoclonal antibody, bamlanivimab, for the treatment of mild-to-moderate COVID-19 (C19) illness in adult and pediatric patients.[1] While the safety and effectiveness of this investigational treatment continues to be evaluated, bamlanivimab was shown, in clinical trials (within 28 days compared to placebo), to reduce C19 related emergency room visits and hospitalizations in patients at high risk for disease progression.

The EUA specifically authorizes bamlanivimab use for patients over 12 years old, weighing over 40 kilograms (88 pounds) with a positive, direct test result for SARS-CoV-2 virus and who are at high-risk for progression of their illness. (e.g., over 65 years of age, existing condition of respiratory or immune compromise, and certain other chronic conditions).

This EUA specifically notes that bamlanivimab is not authorized for any hospitalized patient or those requiring oxygen therapy due to C19, since no benefit has been demonstrated for patients whose illness is progressed to later stages, when the body's immune defenses may be overactive. The FDA noted that administering the drug in later stages of C19 illness could be associated with negative outcomes.

Bamlanivimab was modeled from an antibody that Eli Lilly researchers found in a recovered C19 patient. It works by binding to a spike protein on the surface of C19 viruses and interferes with its ability to invade human host cells. Its availability through the issuance of an EUA allows for it to be distributed before formal approval and administered as a single, intravenous dose by health care providers. There are no adequate, approved and available alternative treatments for the authorized population. Based on FDA review of the available evidence, the agency determined that it is reasonable to believe that bamlanivimab may be effective and, for the authorized population, that the known and potential benefits outweigh the potential risks of its use. Possible side effects of bamlanivimab include anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching, and vomiting.

First Script® Smart Prior Authorization (PA) messaging to claims examiners will continue to suggest establishing the relationship of the drug to the compensable injury before approving this medication. This drug is only authorized for use in non-hospitalized patients at high risk for disease progression.

If you have any questions or concerns about why this drug is being prescribed for your injured worker and whether it is related to a work injury, please contact us at Ask The Pharmacist (askthepharmacist@cvty.us.com) or seek another available clinical resource for further research.

For more information, please contact your Account Manager or Account Pharmacist.

Reference:
U.S. Food and Drug Administration (FDA). FDA News and Events. Press Announcements. Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19. November 9, 2020. Accessed at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19?utm_medium=email&utm_source=govdelivery