The Delaware Division of Public Health, Office of Emergency Medical Services and Hospital Preparedness is issuing this information guide on the emergency use authorization administration of the newest monoclonal antibody bebtelovimab.

Summary

On February 10, 2022, The US Food and Drug Administration issued an Emergency Use Authorization for the human immunoglobulin G-1 (IgG1 variant) monoclonal antibody bebtelovimab.

Background

Based on the totality of scientific evidence available, it is reasonable to believe that bebtelovimab may be effective for the treatment of patients with mild-to-moderate COVID-19 to reduce the risk of progression to hospitalization or death. In addition, the mechanism of action for bebtelovimab is like other neutralizing SARS-CoV-2 monoclonal antibodies, including bamlanivimab and etesevimab, that have data from Phase 3 clinical trials showing a reduction in disease progression in high-risk patients infected with other SARS-CoV-2 variants.

Recommendations

Providers caring for pediatric and adult patients who are 12 years of age or older, and weigh at least 40kg, may consider the administration of bebtelovimab if the following criteria has been met:

- Positive results of direct SARS-CoV-2 testing and within seven days of start of symptoms
- Patient is at high risk for progression to severe COVID-19, including hospitalization and death
- Alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically inappropriate

Dose and Administration:

Bebtelovimab is packaged as a single dose vial containing 175mg/2mls (87.5mg/ml)

The dose in adults (18 years of age and older) and pediatric patients (greater than 12 years of age and weighing at least 40kg) is 175 mg administered as a single intravenous injection over at least 30 seconds.

Administer bebtelovimab as soon as possible after positive results of a direct SARS-CoV-2 viral testing and within seven days of symptom onset.

Clinically monitor the patient for possible infusion-related reactions during administration and observe patients for at least one hour after the injection is complete.

Bebtelovimab may only be administered in settings in which health care providers have immediate access to medications to treat severe infusion reactions such as anaphylaxis, and the ability to activate the emergency medical services system (911) if needed.

Adverse Reactions:

Most common adverse reactions are infusion related reactions, pruritus, and rash.

Warnings and Precautions:

Providers must familiarize themselves with the clinical information regarding the administration of bebtelovimab by reading the full fact sheet for health care providers. More resources are available at the end of this document.

Hypersensitivity including anaphylaxis and infusion-related reactions have been observed with administration of other SARS-CoV-2 monoclonal antibodies and could occur with administration of bebtelovimab. Infusion-related reactions, which may occur up to 24 hours after injection, have been observed in clinical trials of bebtelovimab when administered with other monoclonal antibodies and may occur when used alone.

Additional Information

Clinical worsening of COVID-19 after administration of monoclonal antibody treatment has been reported and may include fever, hypoxia, increased respiratory difficulty, cardiac arrythmias (a-fib, sinus tach, bradycardia) fatigue, and altered mental status. It is not known if these events were related to the treatment or progression of the COVID-19.

There are insufficient data to evaluate drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes in pregnant patients. Bebtelovimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and fetus. Also, there are no available data on the presence of bebtelovimab in human or animal milk, the effects of the breastfed infant, or the effects on milk production. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Obtaining doses:

Providers wishing to obtain bebtelovimab may do so by submitting an email request to OEMS@delaware.gov. Once your email has been reviewed, you will receive further instructions so that your request can be processed.

Resources

http://www.lillyantibody.com/bebtelovimab

http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-hcp.pdf

http://pi.lilly.com/eua/bebtelovimab-eua-factsheet-patient.pdf

Lilly COVID Hotline: 855-LillyC19 (855-545-5921)