COMMUNITY PHARMACY
Trusted. Dedicated. Innovative.

FAQ Bamlanivimab
Monoclonal Antibody Therapy

As your trusted pharmacy partner, we want to address some questions you may have following the FDA announcement on November 9th regarding the Emergency Use Authorization (EUA) issued for the investigational monoclonal antibody (mAb) therapy, bamlanivimab. We are optimistic about the vaccines and therapeutics being developed in response to the COVID-19 crisis and we will continue to update you as we move through this dynamic time together.

Q: What is bamlanivimab?

A: It is the name of Lilly's investigational monoclonal antibody (mAb) therapy for the treatment of mild-to-moderate COVID-19 in adults with positive test results who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Q: What are monoclonal antibodies?
A: Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. MAbs directly neutralize the COVID-19 virus and are intended to prevent progression of disease. Bamlanivimab is a mAb that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

Q: What is the benefit of mAb therapy?

A: While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients if administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.

Q: Will bamlanivimab be available through the pharmacy?

A: The federal government in conjunction with state health departments will allocate supply of bamlanivimab based on confirmed COVID-19 cases for each distribution week. To access this product, it must be allocated from the state health department directly. Community Pharmacy is working to have medication/treatment available for our skilled nursing customers. Please contact the pharmacy regarding availability and allocation if you anticipate needs.

Q: Which healthcare facilities are eligible to receive bamlanivimab?

A: Eligible facilities must have appropriate healthcare staffing, supplies, and equipment to administer IV infusion therapies. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. We recommend the medical director is engaged to provide physician oversight and careful supervision of the medication administration, to ensure that adverse reactions can be minimized, and residents kept safe.

Q: How is bamlanivimab administered?

A: Medication should be given as soon as possible after positive results of PCR or antigen test and within 10 days of symptom onset. Bamlanivimab solution for infusion should be prepared by a pharmacist using aseptic technique. High level guidance is needed on product shipping and storage under refrigerated conditions to ensure preparation, delivery, receipt and administration occur within a 24- hour window. Administration should be by a qualified nurse as an IV infusion over 1 hour with clinical monitoring during administration and at least 1 hour after infusion is complete.

Q: What are the possible side effects of bamlanivimab?

A: Allergic reactions, fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of lips, face, or throat, rash including hives, itching, muscle aches, and dizziness and brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time. We will monitor as new data on safety and efficacy become available.

Q: What are the limitations of the approved authorized use?

A: Bamlanivimab is NOT authorized for use in patients:

- who are hospitalized due to COVID-19, or
- who require oxygen therapy due to COVID-19, or
- who require an increase in baseline oxygen flow rate due to COVID-19 if on chronic oxygen

It IS authorized for high risk patients defined as patients who meet at least one of the following criteria:

- chronic kidney disease
- diabetes
- Immunosuppressive disease or receiving immunosuppressive treatment
- Body mass index (BMI) ≥35
- Are ≥65 years of age
- Are ≥55 years of age AND have cardiovascular disease, OR hypertension, OR COPD/ other chronic respiratory disease.

See Lilly fact sheet for details: http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf

Q: What other monoclonal antibodies are being tested against COVID-19?

A: AstraZeneca (AZD7442), Eli Lilly (bamlanivimab, etesevimab), GlaxoSmithKline (VIR-7831; COMET-Ice Study), Regeneron (REGN-COV2), and others are testing monoclonal antibodies against COVID-19.

Bamlanivimab is also being studied for COVID-19 prevention in residents and staff of long-term care facilities (BLAZE-2), and other studies are also ongoing. More information on Eli Lilly COVID-19 clinical trials and others can be found at: www.clinicaltrials.gov