Bamlanivimab

FDA issued an Emergency Use Authorization (EUA) for bamlanivimab to be available to treat nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization.

Patient Requirements

- Lab confirmed COVID-19
- Weigh > = 40 kg
- Not being admitted to the hospital
- Doesn't require oxygen or an increase in oxygen flow rate due to COVID-19 for those on oxygen due to underlying comorbidity.
- Have at least 1 risk factor from boxes below

Meets at least one of the following:

- Have a BMI ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressant treatment
- Are ≥65 years of age

OR

Is ≥55 years of age AND has one of the following:

- Cardiovascular disease **OR**
- Hypertension **OR**
- COPD/other chronic respiratory disease

Provider Requirements

- Document patient and caregiver factsheet provided.
- Inform patient/caregiver that bamlanivimab is an unapproved drug authorized for use under the EUA.
  - Experimental drug with limited scientific data.
  - Bamlanivimab may be effective for treatment of COVID-19.
  - The patient may be contacted to provide information to help with assessment of the use of bamlanivimab.
- Provide the patient/caregiver option to refuse or accept treatment.
- Communicate known and potential risks associated with receiving bamlanivimab.
  - May cause nausea, diarrhea, dizziness, headache, itching, and vomiting.
  - May cause mild hypersensitivity reactions including but not limited to flushing, itching, and swelling.
  - Potential serious adverse events are possible including death, a life-threatening event, persistent or significant incapacity, birth defects, or other adverse events that may require medical or surgical intervention.
- Communicate known and potential benefits associated with receiving drug.
  - May decrease potential for hospital admission or return visits to the ER.
- Communicate unknown risks and benefits associated with receiving drug.
  - Safety and effectiveness of this investigational therapy continues to be evaluated and additional side effects are possible that are yet unknown.
- Inform patient/caregiver of alternative to receiving bamlanivimab.
  - No alternative is presently available. However, other similar antibody treatments are likely to be available in near future.
- Ensure patient is aware that they must continue to self-isolate.

Administration

- Administered as a single IV infusion of 700 mg over 1 hour with a 1 hour post infusion observation time.
- Administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset.
- Could be out-of-pocket costs related to administration of the bamlanivimab.

11.23.2020

Additional Information

- *The Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab Authorized use Limitations of Authorized Use* bamlanivimab-eua-factsheet-hcp.pdf (lilly.com)
- *The Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)* bamlanivimab-eua-factsheet-patient.pdf (lilly.com)
- Statement from NIH on Bamlanivimab EUA/COVID-19 Treatment Guidelines Statement on Bamlanivimab EUA | COVID-19 Treatment Guidelines (nih.gov)
- Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 (idsociety.org)
- American College of Emergency Physicians Clinical Summary of Bamlanivimab https://www.acep.org/globalassets/sites/acep/media/covid-19-main/bamlanivimab---acep-clinical-summary.pdf
- Lilly Bamlanivimab Antibody Playbook November 2020 https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf