American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

ACEP's Clinical Summary of Bamlanivimab

The FDA has issued an EUA for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

- Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.
- Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are ≥12 years of age and weighing ≥40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization (See Table 10.3 below). This includes those who are ≥65 years of age, or who have certain chronic medical conditions.
- 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 at high risk for disease progression within 28 days after treatment when compared to placebo.
- Bamlanivimab is not authorized for use in the following patient populations:
    - Adults or pediatric patients who are hospitalized due to COVID-19, or
    - Adults or pediatric patients who require oxygen therapy due to COVID-19, or
    - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity
    - Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Table 10.3. Bamlanivimab (Eli Lilly) EUA – High-Risk Criteria

All Patients (who meet at least 1 of the following criteria)	Adolescents (Age 12-17 yrs) who meet at least 1 of the following criteria
BMI ≥35 Chronic kidney disease Diabetes Immunosuppressive disease Receiving immunosuppressive treatment Age ≥ 65 yrs Age ≥ 55 yrs AND have any of the following: • Cardiovascular disease • Hypertension • COPD/other chronic respiratory disease	BMI ≥85th percentile for age/gender Sickle cell disease Congenital or acquired heart disease Neurodevelopmental disorders (e.g. cerebral palsy) Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)] Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

Link to BMI Calculator

NIH Summary Recommendations:

- At this time, there are insufficient data to recommend either for or against the use of bamlanivimab for the treatment of outpatients with mild to moderate COVID-19.
- Bamlanivimab should not be considered the standard of care for the treatment of patients with COVID-19.
- An interim analysis of the BLAZE-1 study, a Phase 2, randomized, placebo-controlled trial, suggested a potential clinical benefit of bamlanivimab for outpatients with mild to moderate COVID-19. However, the relatively small number of participants and the low number of hospitalizations or emergency department visits make it difficult to draw definitive conclusions about the clinical benefit of bamlanivimab.
- More data are needed to assess the impact of bamlanivimab on the disease course of COVID-19 and to identify those people who are most likely to benefit from the drug. Health care providers are encouraged to discuss participation in bamlanivimab clinical trials with their patients.
- Given the possibility of a limited supply of bamlanivimab, as well as challenges distributing and administering the drug, patients at highest risk for COVID-19 progression should be prioritized for use of the drug through the EUA. In addition, efforts should be made to ensure that communities most affected by COVID-19 have equitable access to bamlanivimab.
- Bamlanivimab should not be withheld from a pregnant individual who has a condition that poses a high risk of progression to severe COVID-19, and the clinician thinks that the potential benefit of the drug outweighs potential risk (see the criteria for EUA use of bamlanivimab below).
- Patients who are hospitalized for COVID-19 should not receive bamlanivimab outside of a clinical trial.

More information can be found on The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Bamlanivimab for the Treatment of COVID-19.

Bamlanivimab Administration:

EUA authorizes use of Bamlanivimab for treatment of high risk (See Table 10.3.) COVID 19 outpatients (ages ≥12 y/o, weight ≥40 kg) with mild to moderate symptoms at risk for progressing to severe disease/hospitalization.

Key Summary Steps:

- Direct SARS CoV 2 test (e.g., PCR, rapid antigen test) must be positive
- Administered as soon as possible after positive test result and within 10 days of symptom onset
- Provider to review EUA fact sheet
- Patient/caregiver to be provided with EUA fact sheet (English / Spanish)
- Administered in a setting where healthcare providers have direct access to medications to manage severe reactions
- CMS Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction

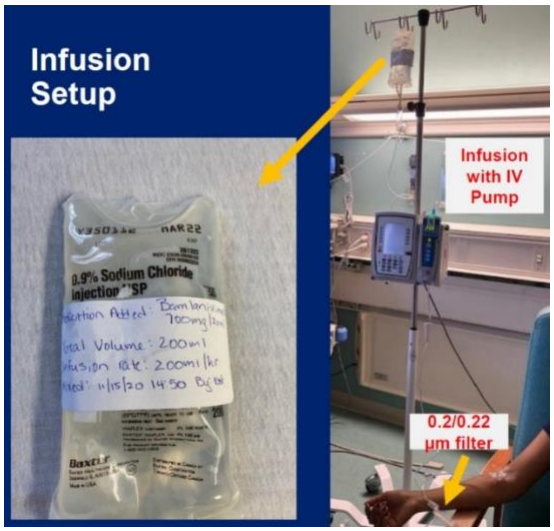
Table 10.4. Dosing and Requirements:

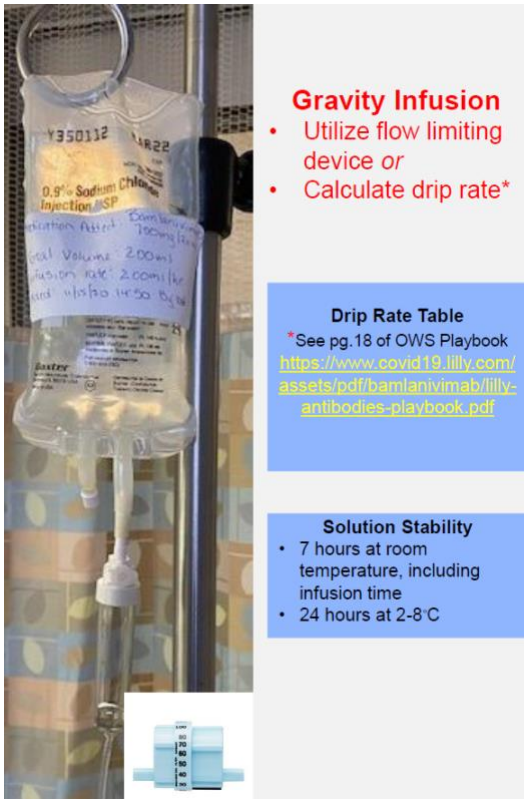
Characteristics	Requirements
Dose	700mg in 200mL 0.9% NaCl IVPB over at least 60 minutes (PVC infusion set with 0.20/0.22 micron filter)
Monitoring	Monitor during infusion (no specified interval) and for 1 hour after completion
Storage Requirements	700mg/20mL vial – store in original carton to protect from light at 2-8℃; do not freeze, shake, or expose to direct light or heat
Stability Once Reconstituted	24 hours at 2-8 ℃ OR up to 7 hours (including infusion time) at room temperature
Required Chart Documentation	• That patient/caregiver has been given fact sheet • Informed patient of treatment alternatives to bamlanivimab • Inform patient that bamlanivimab is an unapproved drug used under the auspices of EUA
Adverse Effects (in <3% of pts)	Hypersensitivity reactions, nausea, diarrhea, dizziness, headache, pruritis, vomiting

Link to [Lilly Bamlanivimab Antibody Playbook]

Infusion Supplies

- 250 ml 0.9% NaCl
- IV Insertion Supplies
- IV Infusion Tubing
- 0.2/0.22 µm Filter
- 20 ml Syringe x2
- 18g Sterile Needle x2
- Alcohol Wipes





Readiness Checklist: Administration of Outpatient mAbs under EUA

- **Allocate dedicated space and develop plan to manage patient flow**
  - Clear process for patients that are coming to clinical site including scheduling requirements
  - Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines'
  - Dedicated room available for treatment
- **Ensure dedicated source of supplies; which may be difficult to procure**
  - Needed infusion components obtained
  - Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications
- **Assign sufficient personnel to meet expected demand**
  - Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist
  - Likely need dedicated team to treat patients
- **Prepare for drug administration process**
  - Pre–visit: Clear treatment and monitoring plan developed for during infusion
  - Treatment: 1-hour treatment and up 1-hour post-treatment observation
  - Emergency protocol defined for addressing potential infusion reactions or complications
  - Post-treatment: Clear process for patient follow-up defined using telemedicine as possible
- **Ensure process for reimbursement in place (non-drug administrative costs)**
- **Prepare for reporting needs for adverse events and record keeping**

A resource for management of anaphylaxis in the ED: https://www.reliasmedia.com/articles/144912-evaluation-and-management-of-anaphylaxis-in-the-emergency-department