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

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

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.


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:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td>700mg in 200mL 0.9% NaCl IVPB over at least 60 minutes (PVC infusion set with 0.20/0.22 micron filter)</td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td>Monitor during infusion (no specified interval) and for 1 hour after completion</td>
</tr>
<tr>
<td><strong>Storage Requirements</strong></td>
<td>700mg/20mL vial – store in original carton to protect from light at 2-8°C; do not freeze, shake, or expose to direct light or heat</td>
</tr>
<tr>
<td><strong>Stability Once Reconstituted</strong></td>
<td>24 hours at 2-8 °C OR up to 7 hours (including infusion time) at room temperature</td>
</tr>
</tbody>
</table>
| **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**