Patient ID Sticker

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Allergy: |  | Height: |  | (cm) | Weight: |  | (kg) | BSA: |  |

1. ***Inclusion Criteria***

The FDA granted emergency use authorization (EUA) to bamlanivimab based on trial data showing that a one-time infusion of the treatment reduced the need for hospitalization or emergency room visits in high-risk COVID-19 patients. It was not authorized for hospitalized patients nor for those who require oxygen therapy due to COVID-19 as it could worsen clinical outcomes for such patients.

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|  | Positive SARS-CoV-2 viral confirmatory laboratory test who are 18 years of age and older weighing at least 40 kg and who are at high risk for progressing to severe COVID-19 and/or hospitalization who meet following criteria. **Recommended Patient is within 7 days of symptom** onset (EUA requirement is 10 day) and within 3 days of specimen collection: **Date of positive Test Result\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Meet **at least 1 of the criteria below in addition to above based on federal allocation supply**: (CDPH recommends use in pts ≥ 65 Years of Age OR Body Mass Index (BMI) ≥ 35 if supply is limited due to Blaze-1 Trial: pt. ≥65 years or having a BMI ≥35 the percentage of hospitalization was 4 % in the Bamlanivimab group vs 15 % in the placebo group. |
|  | ≥ 65 Years of Age |
|  | Body Mass Index (BMI) ≥ 35 |
|  | Diabetes |
|  | Chronic Kidney Disease |
|  | Are ≥ 55 Years of Age AND have **TWO of the Following:**  Body Mass Index (BMI) ≥ 35  Diabetes  Cardiovascular Disease  Hypertension  Chronic Obstructive Pulmonary Disease |

***2.*** ***Exclusion Criteria: (if any box checked, unable to administer drug)***

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|  | Hospitalized for worsening COVID-19 symptoms |
|  | Patient requires oxygen therapy due to COVID-19 symptoms |
|  | Known hypersensitivity to any ingredient of bamlanivimab |
|  | **PATIENT DOES NOT MEET ANY OF THE EXCLUSION CRITERIA LISTED ABOVE** |

***3.*** ***The Undersigned Confirms Adherence to the Following Requirements for Bamlanivimab Prescribing***

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| c. | Healthcare provider must document in the patient’s medical record that the patient/caregiver has been:   1. Given the Fact Sheet for Patients, Parents and Caregivers 2. Informed of alternatives to receiving authorized bamlanivimab, and consents to receive the medication   Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization. |

I have confirmed the INCLUSION Criteria and EXCLUSION Criteria of Bamlanivimab screening for High-Risk COVID-19 Patients

Signature/Printed name of Authorized Prescriber: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_Time: \_\_\_\_\_\_\_\_\_\_

**1. Admit Outpatient Account (ED) for Bamlanivimab. ED Provider places order in Cerner for qualified patients whom consent to treatment.**

**2. Diagnosis: COVID-19 +**

**3. Obtain peripheral IV access. Start IV per hospital policy.**

**4. Bamlanivimab 700 mg in 250 mL normal saline IV infusion administered over 1 hour x 1 dose.**

**5. Flush line with 30 mL normal saline to ensure delivery of required dose.**

**6. Check vital signs prior to, every 30 minutes during, and up to 1 hour after infusion is complete.**

**7. If patient experiences an adverse drug reaction such as but not limited to, severe hypersensitivity, anaphylaxis, angioedema, fever, chills, rigors, pruritus, rash, stop infusion and call physician.**

**Additional Information: Counsel Patient: Covid-19 Vaccination should be deferred for at least 90 days after receiving monoclonal antibodies (Bamlanivimab) to avoid inference with the Covid-19 vaccine induced immune response.**

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| c. | Healthcare provider must document in the patient’s medical record that the patient/caregiver has been:  Given the Fact Sheet for Patients, Parents and Caregivers **To access Fact Sheet for Patients and Parents/Caregivers**  **English:** <http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-patient.pdf>  **Spanish:** <http://pi.lilly.com/eua/span/bamlanivimab-eua-factsheet-patient-span.pdf>  Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.   * Informed of alternatives to receiving authorized bamlanivimab, and Emergency Use Authorization Bamlanivimab. Fact sheet for health care providers. Eli Lilly and Company. Accessed online 11/16/20. <http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf> |

5.  ***Hypersensitivity Reaction:***

1. Stop the drug administration immediately when any sign of an allergic reaction is observed.
2. Notify physician immediately.
3. Maintain IV access with normal saline at TKO.
4. Summon help. Stay with patient.
5. Obtain vital signs and monitor at least every 5 minutes until stable. Observe for acute respiratory distress.
6. Begin O2 at 2 liters per nasal cannula in presence of respiratory distress. Maintain open airway. Assess for sign of increasing edema.
7. Administer emergency medications as ordered by a physician.
8. Call an RRT or “Code Blue” if condition worsens.

**Mandatory** reporting of all medication errors and serious adverse events potentially related to balmanivimab treatment within 7 calendar days from the onset of the event is required at www.fda.gov/medwatch/report.htm

**References**

* Chen P et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with COVID-19. NEJM 2020. PMID: 33113295 <https://www.nejm.org/doi/full/10.1056/NEJMoa2029849>
* COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 11/16/20.
* Emergency Use Authorization Bamlanivimab. Fact sheet for health care providers. Eli Lilly and Company. Accessed online 11/16/20. <http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf>