DEPARTAMENTO DE SALUD DE PUERTO RICO

**BAMLANIVIMAB ORDER SET**

| | | | | | |
|---|---|---|---|---|---|
| Date: | | Date of COVID PCR Test Positive: | | | |
| Patient Name: | | DOB: | | Age: | |
| Weight (Kg): | | Height: | | BMI: | |
| Phone Num: | | Email: | | | |
| Address: | | | | | |
| Medical Insurance: | | Contract: | | Group: | |
| Physician Name: | | | | | |
| Specialty: | | Lic. num: | | NPI: | |
| Address | | | | | |
| Phone Num: | | Email: | | | |
| Signature: | | | | | |
| Bamlanivimab Order: | **700 mg IV infusion in NSS over 60 minutes** | **Before this date:** | | | |

## PHYSICIAN GUIDANCE AND DRUG USE CRITERIA

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product **BAMLANIVIMAB** for the **treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 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.** Treatment with bamlanivimab should start as soon as possible after positive viral test for SARS-CoV- 2 and within 10 days of symptom onset.

- Providers are required to review **The Fact Sheet for Health Care Providers**: Emergency Use Authorization (EUA) of Bamlanivimab.
- As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the "Fact Sheet for Patients and Parents/Caregivers" (and provide a copy of the Fact Sheet) prior to prescribing Bamlanivimab.
- Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:
  - ✓ Given the "**Fact Sheet for Patients, Parents and Caregivers**" (https://www.fda.gov/media/143604/download),
  - ✓ Informed of alternatives to receiving authorized bamlanivimab, AND
  - ✓ Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

***THIS GUIDANCE FOR USE IS BASED ON THE EMERGENCY USE AUTHORIZATION CLINICAL TRIALS DATA. THIS INFORMATION CAN CHANGE ON A DAILY BASE DURING THIS PANDEMIC AND SHOULD BE REVISED AS NEW INFORMATION BECOMES AVAILABLE.***

## EXCLUSION CRITERIA

- Bamlanivimab is **NOT AUTHORIZED** for use in patients:
  - ✓ who are hospitalized due to COVID-19, OR
  - ✓ who require oxygen therapy (SpO2 sat < 94%) due to COVID-19, OR
  - ✓ who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
- Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. 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**.

## INCLUSION CRITERIA

**Must meet all the following criteria:**

- ☐ Positive result of direct SARS-CoV-2 viral testing
- ☐ 12 years of age and older
- ☐ Weight ≥40 kg
- ☐ Within 10 days of symptom onset
- ☐ High risk for progressing to severe COVID-19 and/or hospitalization (defined as patients **who meet at least one of the following criteria**:)
  - Have a body mass index (BMI) ≥35
  - Have chronic kidney disease
  - Have diabetes
  - Have immunosuppressive disease
  - Are currently receiving immunosuppressive treatment
  - Are ≥65 years of age
  - Are ≥55 years of age AND have
    - cardiovascular disease, OR
    - hypertension, OR
    - chronic obstructive pulmonary disease/other chronic respiratory disease.
  - Are 12 – 17 years of age AND have
    - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
    - sickle cell disease, OR
    - congenital or acquired heart disease, OR
    - neurodevelopmental disorders, for example, cerebral palsy, OR
    - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
    - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- ☐ 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.

## DOSING, PREPARATION, ADMINISTRATION, STORAGE, AND MONITORING

- **Dosage**: Single intravenous (IV) infusion of **700 mg IV administered over at least 60 minutes.** Should be administered as soon as possible after positive viral test for SARS-CoV- 2 and within 10 days of symptom onset.
- **Preparation**
  - Remove bamlanivimab vial from refrigerator and allow the medication to reach room temperature (approximately 20 minutes before preparation). **Do not expose to direct heat.**
  - Inspect bamlanivimab visually for particulate matter and discoloration. Bamlanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution.
  - Gently invert vial by hand approximately 10 times. **Do not shake.**
  - Dilute using a 250 mL prefilled 0.9% Sodium Chloride Injection bag for intravenous infusion following table instructions:

| Treatment | Dose/Volume of Bamlanivimab (# of vials) | Vol of 0.9% NSS to discard from a 250 mL IV bag | Total Volume for Infusion | Minimum Infusion Rate | Minimum Infusion Time |
|---|---|---|---|---|---|
| Bamlanivimab | 700 mg/20 mL (1 vial) | 70 mL | 200 mL | 200 mL/hr | 60 minutes |

  - Gently invert IV bag by hand approximately 10 times to mix. **Do not shake.**
  - This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time.
- **Administration:** Bamlanivimab solution should be administered by a qualified healthcare professional.

- Gather the recommended materials for infusion: Polyvinylchloride (PVC) infusion set containing a **0.20/0.22 micron in-line polyethersulfone (PES) filter.**
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer infusion bag over at least 60 minutes via pump or gravity.
- Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
- Discard unused product.
- Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.

- **Storage**
  - This product is preservative-free and therefore, the diluted infusion solution should be administered immediately.
  - If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time.
- **Monitoring**
  - **Before infusion**: Document vital signs (blood pressure, temperature, heart rate, respiration rate) and oximetry (SpO2). **If SpO2 ≤ 94% do not** administer bamlanivimab and refer patient to the Emergency Room for evaluation due to hypoxemia.
  - **During infusion**: Document vital signs, oximetry and infusion site evaluation every 20 minutes
  - **After infusion**: Document vital signs, oximetry, and infusion site evaluation for at least 1 hour after infusion is complete.
  - **The infusion center personnel are the designated health care providers to manage and document any adverse reaction.**
  - If the patient presents any adverse reaction, the infusion center personnel must provide immediate access to treatment for management and fill out the corresponding documentation in the adverse event section provided by the FDA (see link below) and notify physician after the event.
  - Instructions for self-isolation and infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) must be provided to the patient according to CDC guidelines.
- **Specific Populations**
  - No dosage adjustment is recommended in pregnant or lactating women. There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.
  - No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, or for disease severity or inflammation.
  - **Patients with asthma** should have their inhaled medications readily available for use during and after infusion if deemed necessary. Also, the patient's physician should provide a written order with premedication drugs to use in case of an infusion related reaction.

## STORAGE AND STABILITY

- Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
- Do not freeze, shake, or expose to direct light.
- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.

## CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

- There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

**Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions**

- There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care.
- Infusion-related reactions have been observed with administration of bamlanivimab. Signs and symptoms of infusion related reactions may include:

- fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.

- **If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.**

## ADVERSE DRUG EVENTS

The prescribing health care provider and/or **the provider's designee** are/is responsible for mandatory reporting of all medication errors and serious adverse events* potentially related to bamlanivimab treatment **within 7 calendar days** from the onset of the event. The reports should include unique identifiers and the words "Bamlanivimab treatment under Emergency Use Authorization (EUA)" in the description section of the report.

- Submit adverse event reports to FDA MedWatch using one of the following methods:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
  - By using a postage-paid Form FDA 3500 (available at https://www.fda.gov/media/76299/download and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
  - Call 1-800-FDA-1088 to request a reporting form
  - Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement "Bamlanivimab treatment under Emergency Use Authorization (EUA)"

***Serious Adverse Events are defined as:**

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The prescribing health care provider and/or the provider's designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of Bamlanivimab.

OTHER REPORTING REQUIREMENTS

- In addition, please provide a copy of all FDA MedWatch forms to: Eli Lilly and Company, Global Patient Safety
  Fax: 1-317-277-0853
  E-mail: mailindata_gsmtindy@lilly.com
  Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.

## REFERENCES


Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment. Available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19

Provider Fact Sheet. Available at http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf ; Accessed 11/17/2020

Patient Fact Sheet. Available at http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-patient.pdf ; Accessed 11/17/2020

Spanish Patient Fact Sheet. Available at http://pi.lilly.com/eua/span/bamlanivimab-eua-factsheet-patient-span.pdf ; Accessed 11/17/2020

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