GUAM REGIONAL MEDICAL CITY
Where Patients are Partners

November 23, 2020

Dear Medical Provider,

Bamlanivimab is a novel, single-dose, intravenous therapy that has recently been given Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) given **its potential to decrease hospitalizations in COVID-19 patients with mild to moderate symptoms**. A limited number of doses have been made available to Guam through the generous efforts of the U.S. Department of Health and Human Services (HHS). In partnership with HHS and GMH, GRMC has created a dedicated COVID-19 outpatient infusion clinic in order to help streamline the safe administration of this therapy. It is currently located within one of the negative-pressure BLU-MED tents erected outside GRMC's Emergency Department.

Please review the indications and limitations below and the referral sheet on the following page to determine if your patient may be a candidate to receive this medication. Once referral received, your patient will undergo a pre-visit telemedicine evaluation and scheduled. Availability will be made based on drug stock and infusion stations. Inaugural clinical hours will run Monday through Friday, 1PM-5PM with up to seven (7) infusion stations available. Note that priority will be given to those with higher risk factors and moderate symptoms, thus more likely to benefit from bamlanivimab.

AUTHORIZED USE

The FDA has issued an 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. Bamlanivimab **should be given as soon as possible** after positive results of direct SARS-CoV-2 molecular or antigen testing and **within 10 days of symptom onset.**

LIMITATIONS OF AUTHORIZED USE

- Bamlanivimab is NOT authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy 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.**

HIGH RISK IS 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 REFERRAL FORM

Patient Name: _____ **Date of Birth:**_____

Mobile Phone: _____ **Other Phone (Type):** _____

Insurance Provider: _____
Note that the medication is being provided by the federal government without cost. The expenses associated with the infusion will be billed to the appropriate insurance provider. Special assistance/arrangements will be made for those uninsured or underinsured.

IF YOUR PATIENT REQUIRES OXYGEN THERAPY BECAUSE OF COVID-19, THEY ARE NOT A CANDIDATE FOR BAMLANIVIMAB. PLEASE CONSIDER REFERRING THEM TO THE EMERGENCY DEPARTMENT FOR FURTHER EVALUATION AND POSSIBLE HOSPITAL ADMISSION.

Which of the following inclusion criteria(s) does your COVID-19 patient meet for the infusion of bamlanivimab? ***(check all that apply)***

- ❑ Has a body mass index (BMI) ≥35 (specify): _____
- ❑ Has chronic kidney disease
- ❑ Has diabetes
- ❑ Has immunosuppressive disease (specify): _____
- ❑ Is currently receiving immunosuppressive treatment
- ❑ Is ≥65 years of age
- ❑ Is ≥55 years of age AND has
  - ❑ cardiovascular disease, OR
  - ❑ hypertension, OR
  - ❑ chronic obstructive pulmonary disease/other chronic respiratory disease.
- ❑ Is 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
  - ❑ neuro developmental 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.

Notes/Comments:
_____

_____

Referring Provider: _____ **Date:** _____

Referring Clinic/Facility and Phone: _____

This referral is limited to the infusion of bamlanivimab and immediate post-infusion monitoring. Patient will be instructed to isolate, and follow-up as directed with referring provider.

PLEASE SEND REFERRAL VIA:
Fax: 671-969-4929
and/or
Email: COVID.outpatient@GRMC.gu

To speak directly with an infusion provider, please contact:
Felix Cabrera, MD or Greg Woodard, NP via
GRMC Main Line: 671-645-5500