CHI St. Luke's Health
The Woodlands Hospital

Emergency Use Authorization
Bamlanivimab Request Form

Patient Name		Patient DOB	MR#

Ordering Physician: _____ Contact Number:_____

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 symptomatic mild to moderate coronavirus disease 2019 in adults and pediatric patients.

Response	Inclusion Criteria (All must apply)
❑ Yes ❑ No	Authorized for use under an EUA for treatment of symptomatic mild to moderate 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.**
❑ Yes ❑ No	**Symptomatic from SARS-CoV-2 within 7 days** of direct SARS-CoV-2 viral testing.
❑ Yes ❑ No	Are at **high risk** for progressing to severe COVID-19 and/or hospitalization and **meet at least 2 high risk criteria in adult patients and 1 high risk criteria in pediatrics.**

High Risk Criteria – ADULTS	High Risk Criteria – PEDIATRICS (Ages 12 – 17 yrs)
❑ Yes ❑ No Are ≥ 65 years of age ❑ Yes ❑ No Have a body mass index (BMI) ≥ 35 ❑ Yes ❑ No Have chronic kidney disease ❑ Yes ❑ No Have diabetes ❑ Yes ❑ No Have immunosuppressive disease ❑ Yes ❑ No Are currently receiving immunosuppressive treatment Are ≥55 years of age AND have: ❑ Yes ❑ No Cardiovascular disease, OR ❑ Yes ❑ No Hypertension, OR ❑ Yes ❑ No Chronic obstructive pulmonary disease/other chronic respiratory disease	Are 12 – 17 years of age AND have: ❑ Yes ❑ No BMI ≥ 85th percentile for their age and gender based on CDC growth charts, OR ❑ Yes ❑ No Sickle cell disease, OR ❑ Yes ❑ No Congenital or acquired heart disease, OR ❑ Yes ❑ No Neurodevelopmental disorders (e.g. cerebral palsy) OR ❑ Yes ❑ No A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR ❑ Yes ❑ No Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Response	Exclusion Criteria (If any are marked YES, the patient is excluded from receiving bamlanivimab):
❑ Yes ❑ No	Hospitalized due to SARS-CoV-2
❑ Yes ❑ No	Requires new oxygen therapy due to SARS-CoV-2
❑ Yes ❑ No	Requires an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-**SARS-CoV-2** related comorbidity

Bamlanivimab Infusion

☑ Bamlanivimab 700 mg (20 mL) in 200 mL 0.9% Sodium Chloride infused at 200 mL/hr over 60 minutes; **use 0.2 micron filter**

❑ Premedication: acetaminophen 1000 mg PO, diphenhydramine 50 mg IV 1

Stable for 7 H at room temp; 24 H refrigerated.

- **Nurse must don appropriate PPE** as set by hospital policy.
- Bamlanivimab may take at least 60 minutes to prepare by pharmacy (due to reconstitution time).
- Bamlanivimab infusion must be set on an infusion pump or gravity over 60 minutes and use a 0.22 micron in-line filter to administer infusion.
- Once infusion is complete, line must be flushed to ensure the patient receive the full dose.
- **Patient must be directly observed** for **anaphylactic reactions and infusion related reactions** such as (but not limited to) fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, and dizziness.
- **Patient must remain observed for at least 60 minutes post infusion.**

Provider has documented in the Electronic Health Record that the patient or legally authorized representative has received the following:

❑ I spoke with the patient/healthcare proxy to provide information about bamlanivimab for the patient. I offered them the "Fact Sheet for Patients and Parents/Caregivers" for bamlanivimab to read and review. I stated the therapy has been approved by an emergency use authorization (EUA) process and has not been fully reviewed or approved by the FDA. I shared potential risks from the therapy including anaphylaxis and infusion related reactions. Infusion-related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness. I discussed there are other potential treatment options to treat COVID-19. If applicable, I discussed with the patient that pregnancy is not an exclusion for bamlanivimab, but the therapy has not been fully evaluated in pregnant patients. I offered opportunity to ask questions and all questions were answered. The patient/healthcare proxy voiced understanding and agreed to proceed with treatment for the patient.

A Completed Emergency Use Authorization – Bamlanivimab Request Form Sent to Pharmacy
Physician Documentation of Required Attestation Documented on the Request Form AND in EPIC

_____ **Physician Signature**

_____/_____/_____ **Date**

_____ **AM PM** **Time**