## HIC HENRY COUNTY MIC MEDICAL CENTER

#### Outpatient Criteria For Bamlanivimab Use Under FDA Emergency Use Authorization (EUA)

Criteria for Use	Patients with mild to moderate COVID-19 with POSITIVE RESULTS of direct SARS-CoV-2 viral testing who are 18 years of age & older weighing at least 40 kg, & who are at high risk for progressing to severe COVID-19 &/or hospitalization. Patients must be <10 days since symptom onset			
	≥65 years of age	<ul> <li>≥55 years of age &amp; have ONE or more of the following:</li> <li>1. Coronary artery disease</li> <li>2. Congestive heart failure</li> <li>3. Cerebrovascular disease</li> <li>4. Hypertension</li> <li>5. Chronic lung disease such as COPD or Interstitial Lung Disease</li> <li>6. Sickle Cell Disease</li> </ul>	<ul> <li>≥18 years of age &amp; have one of the following:</li> <li>1. Body mass index (BMI) ≥35</li> <li>2. Chronic kidney disease stage IV or V</li> <li>3. Diabetes</li> <li>4. Immunosuppressiv e disease</li> </ul>	Currently receiving immunosuppressive treatment such as one of the following: 1. chemotherapy in the past year 2. immunosuppressant use for autoimmune disease, 3. Equivalent of Prednisone 20 mg a day or more for at least 14 days
	High risk is defined as patients who meet <u>at least one</u> of the following criteria:			
Patients <u>NOT</u> approved for treatment	<ol> <li>Hospitalized due to COVID-19, OR</li> <li>Require oxygen therapy due to COVID-19, OR</li> <li>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.</li> <li>Medical condition that would limit 6 month survival in the absence of COVID-19</li> </ol>			

- Dose: Single intravenous (IV) infusion of 700mg IV over at least 60 minutes
- Monitoring: No laboratory monitoring indicated
- Contraindications: None
- Adverse Effects and Precautions:
  - o Potential for serious hypersensitivity reaction, including anaphylaxis
  - Infusion related reactions
  - Symptoms including nausea, diarrhea, dizziness, headache, pruritus, and vomiting were observed in clinical trials, though at rates comparable to placebo.
- Restrictions, Approvals, and Ordering:
  - The EUA Fact Sheet should be provided to the patient and/or caregiver and documentation that it was reviewed should be placed in the clinical record.
  - Medication errors and/or serious adverse events should be reported to the appropriate Pharmacy, who will assist with submitting the required FDA Medwatch reports within 7 days of event

# Outpatient Providers are responsible for ensuring patients meet the criteria of use prior to scheduling an infusion



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#### **Bamlanivimab Ordering and Infusion Process**

#### Ordering physician

- Fax order and demographic information to 644-8397 or 644-8488
- Order should include the following:
  - Patient name, date of birth, allergies, diagnosis, physician signature
  - Start IV with NS 250ml over 1 hour
  - o Bamlanivimab 700mg IV in 250mL 0.9% Sodium Chloride infused over 1 hour
  - Suggested medications to order as needed in case of reaction symptoms:
    - Tylenol 650mg PO ADPRN
    - Benadryl 50mg IVP ADPRN
    - SoluCortef 100mg IVP ADPRN
    - Famotidine 40mg IV ADPRN
- Review the medication with the patient and provide the FDA's Emergency Use Authorization Fact Sheet for Patients, Caregivers and Parents
- $\circ$   $\;$   $\;$  Provide patient with the infusion instructions handout  $\;$
- $\circ$   $\;$  Outpatient infusion will contact patient with appointment date and time

#### Patient

- Drink water, properly hydrate before infusion.
- o Bring insurance cards, driver's license, list of allergies, and list of current home medications
- On the day of your appointment and when you arrive in the ER parking lot, remain in your car. Please call
   731-644-8523 and let them know you have arrived. They will give you instructions to enter the facility and meet you upon your arrival.
- $\circ~$  A mask is required for entrance into the building and for your appointment.
- The appointment will last at least 3 hours, so please be prepared to stay that long.
- If you have any questions before or after your appointment, please call the Outpatient Infusion Center at Henry County Medical Center at 731-644-8524. We are open Monday through Friday, 8:00am-4:00pm.

### FAX COMPLETED ORDER TO HCMC OUTPATIENT INFUSION

## (Fax # 644-8397 or 644-8488)

