|  |  |  |  |
| --- | --- | --- | --- |
| Date of symptom onset: |  | Date of positive SARS-CoV-2 test: |  |
| □ NO CHANGE IN BASELINE OXYGEN REQUIREMENTS | | □ CHANGE IN BASELINE OXYGEN REQUIREMENTS (EXPLAIN): | |

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bamlanivimab-Etesevimab is available for the treatment of **mild to moderate** symptomatic COVID-19 (See Figure 2) in adults and pediatric patients:

* Within 10 days of symptom onset and preferably within 3 days of positive test result
* Who are at high risk for progressing to severe COVID-19 and/or hospitalization (Figure 1)

**Figure 1**

|  |  |
| --- | --- |
| **Age Group** | **High risk criteria – Must meet 1. Check all that apply.** |
| ≥ 65 | All patients in this age group considered high risk |
| 55 – 64 | Cardiovascular disease  Hypertension  Chronic obstructive pulmonary disease/other chronic respiratory disease  Body mass index (BMI) ≥35  Chronic kidney disease  Diabetes  Immunosuppressive disease  Currently receiving immunosuppressive treatment |
| 18 – 54 | Body mass index (BMI) ≥35  Chronic kidney disease  Diabetes  Immunosuppressive disease  Currently receiving immunosuppressive treatment |

**Figure 2**

|  |  |
| --- | --- |
| **Severity of Illness** | **Criteria** |
| Asymptomatic or Presymptomatic Infection | Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test or an antigen test), but who have no symptoms that are consistent with COVID-19. |
| **Mild Illness** | Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging. |
| **Moderate Illness** | Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2) ≥94% on room air at sea level. |
| Severe Illness | Individuals who have SpO2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates >50% |

Source: COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed 18 Nov 2020.

**As the healthcare provider, you MUST communicate to your patient or parent/caregiver information consistent with the “Fact Sheet for Patients and Parents/Caregivers” prior to the patient receiving bamlanivimab-etesevimab AND MUST document in the patient’s medical record. This order form certifies that:**

* I have confirmed that this patient meets criteria for emergency use of bamlanivimab-etesevimab.
* I have reviewed with the patient/current medical decision maker information consistent with that provided by the FDA’s Emergency Use Authorization (EUA) *“Fact Sheet for Patients and Parents/Caregivers”* for bamlanivimab-etesevimab and have provided a copy of this fact sheet.
* Communication to the patient/caregiver included:
  + FDA has authorized the emergency use of bamlanivimab-etesevimab for the treatment of mild to moderate confirmed COVID-19 who are at high risk of progressing to severe COVID-19 and/or hospitalization.
  + The patient or parent/caregiver has the option to accept or refuse bamlanivimab-etesevimab.
  + The significant known and potential risks and benefits of bamlanivimab-etesevimab, and the extent to which such risks and benefits are unknown.
  + Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
  + Patients treated with bamlanivimab-etesevimab should continue to self-isolate and use infection control measures according to CDC guidelines.
* I have discussed that this medication is an FDA unapproved drug authorized for emergency use only for patients with laboratory confirmed COVID-19.  I have communicated the risks, benefits, and alternatives to use as outlined in the fact sheet and have offered the opportunity for questions.
* The patient/current medical decision maker elected to proceed with treatment and has been Informed to report all adverse reactions to a healthcare provider1

1The 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-etesevimab treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words “bamlanivimab and etesevimab treatment under Emergency Use Authorization (EUA)” in the description section of the report. Complete and submit the report here: www.fda.gov/medwatch/report.htm

**Order:**

**Bamlanivimab 700 mg and etesevimab 1400 mg administered together as a single IV infusion given once peripherally over 30 minutes with a 0.2/0.22 micron in-line filter. This infusion is to be followed by 1 hour of patient monitoring for infusion reaction2, including vital sign checking every 15 minutes for that 1 hour.**

2Signs and symptoms of infusion reaction can include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness

Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Prescriber name (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_