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

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

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

* Within 7 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: High-Risk Criteria (must meet at least 1)**

|  |
| --- |
| Older age (for example, age ≥65 years of age)  Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI  ≥85th percentile for their age and gender based on CDC growth charts)  Pregnancy  Chronic kidney disease  Diabetes  Immunosuppressive disease or immunosuppressive treatment  Cardiovascular disease (including congenital heart disease) or hypertension  Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma  [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary  hypertension)  Sickle cell disease  Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that  confer medical complexity (for example, genetic or metabolic syndromes and severe  congenital anomalies)  Having a medical-related technological dependence (for example, tracheostomy,  gastrostomy, or positive pressure ventilation (not related to COVID 19))  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**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 bebtelovimab 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 bebtelovimab.
* 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 bebtelovimab and have provided a copy of this fact sheet.
* Communication to the patient/caregiver included:
  + FDA has authorized the emergency use of bebtelovimab 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 bebtelovimab.
  + The significant known and potential risks and benefits of bebtelovimab, 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 bebtelovimab 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 healthcare provider and/or the provider’s designee is/are responsible for mandatory reporting of all serious adverse events and medication errors potentially related to bebtelovimab within 7 calendar days from the healthcare provider’s awareness of the event, using FDA Form 3500. The FDA requires that such reports, using FDA Form 3500, include the following: Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, gender, weight, ethnicity, and race); a statement "Bebtelovimab use for COVID-19 under Emergency Use Authorization (EUA)” under the “Describe Event, Problem, or Product Use/Medication Error” heading; information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatments required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes); patient’s preexisting medical conditions and use of concomitant products; and information about the product (e.g., dosage, route of administration, NDC #).

**Order:**

**Bebtelovimab 175 mg administered as a single IV injection over at least 30 seconds.**

**The injection is to be followed by clinical monitoring for infusion reaction2 and 1 hour of observation, 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_