**Monoclonal Antibodies (mAb) Emergency Use Authorization (EUA) for COVID-19 – AMITA Health Use Criteria and Dosing**

**Monoclonal Antibodies**
- Sotrovimab (FDA-EUA granted on 5/26/2021)
  - **Suspected** or **proven** serious, active bacterial, fungal, viral, or other infection
  - Requirement of oxygen therapy due to COVID-19
  - Requirement of an increase in baseline oxygen flow rate due to COVID-19 in patients on chronic oxygen due to underlying non-COVID-19-related comorbidity
  - Hospitalized due to COVID-19

- Casirivimab-Imdevimab
  - **Pregnant**
  - **Immunocompromised**
  - Age ≥ 75 years

- Bamlanivimab-Etesevimab
  - **Pregnant**
  - Age ≥ 75 years

**Other agents (casirivimab-imdevimab or bamlanivimab-etesevimab) have been SUSPENDED for use as of 1/8/2021 due to Omicron variant prevalence and susceptibility.**

**References:**

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### Monitoring:
- **Monitor** during infusion and at least one hour after infusion is complete.
- **If an infusion-related reaction occurs,** consider slowing or stopping the infusion and any co-morbidity requiring surgery within 2 (i.e. prophylaxis within 30 days before dosing, convalescent COVID-19 plasma, etc.)
- **Special Considerations:**
  - **Pregnancy:** Anti-SARS-CoV-2 monoclonal antibodies should not be withheld from a pregnant patient with a high-risk condition if the clinician thinks that the potential benefit outweighs the potential risk
  - **Prioritization of patients if logistical or supply constraints exist:** The following patients should be prioritized if logistical or supply constraints occur:
    - Age ≥ 75 years
    - Immunocompromised
    - Pregnant

### Dose & Administration:
- **Sotrovimab 500mg IV infusion given over 30 minutes**
- **After infusion, flush the infusion line to ensure delivery of the required dose**

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### Safety & efficacy of monoclonal antibodies in COVID-19 treatment are being evaluated in multiple ongoing clinical trials.

There are currently three monoclonal antibody (mAb) therapies for COVID-19; casirivimab-imdevimab, sotrovimab, and bamlanivimab-etesevimab were reviewed by the FDA and approved as EUA based on a randomized placebo-controlled trials.

- **NIH:**
  - The Omicron SARS-CoV-2 variant, which includes numerous mutations in the spike protein, is predicted to have markedly reduced susceptibility to several anti-SARS-CoV-2 monoclonal antibodies (mAbs), especially bamlanivimab-etesevimab and casirivimab-imdevimab.
  - **Sotrovimab appears to retain activity against the Omicron variant.**

Under the EUA, anti-SARS-CoV-2 monoclonal antibodies may be used for treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- The data that support the EUA for sotrovimab are from the Phase 3 COMET-ICE trial, which included outpatients with mild to moderate COVID-19 who were at high risk for progression to severe COVID-19 and **within 5 days of symptom onset.**
- The primary endpoint was the proportion of participants who were hospitalized for 24 hours or who died from any cause by Day 29. Endpoint events occurred in 3 of 291 participants (1%) in the sotrovimab arm and 21 of 292 participants (7%) in the placebo arm (P = 0.002), resulting in a 6% absolute reduction and an 85% relative reduction (95% CI, 44-96) in hospitalizations or death associated with sotrovimab.

For complete EUA information for sotrovimab, please see below:
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients and Caregivers (English)
- Fact Sheet for Patients and Caregivers (Spanish)

Risk vs. benefit should be assessed for overall outcome of the patient. As part of the EUA, patient/caregiver communication must take place prior to requesting these products – this communication must be documented in the medical record.

At AMITA Health, anti-SARS-CoV-2 monoclonal antibodies can be considered for treatment of mild-to-moderate COVID-19 in patients with positive SARS-CoV-2 viral testing who are at least 12 years and 40 kg or more, and who are at high risk for progressing to severe COVID-19, including hospitalization or death (**See CDC website for complete list of high risk criteria:** [https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html))

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of sotrovimab, ALL of the following must be met:

1. Patient/Caregiver Communication – Patient/caregiver communication on ALL the following items:
   - Fact Sheet for Patients and Caregivers has been reviewed and given to the patient/caregiver, AND
   - Informed of alternatives to receiving anti-SARS-CoV-2 monoclonal antibodies, AND
   - Informed that anti-SARS-CoV-2 monoclonal antibodies are unapproved therapies authorized for use under EUA
   - Documentation of the above Patient/Caregiver Communication in the medical record

2. INCLUSION CRITERIA: ALL of the following must be met:
   - Age ≥12 years old and weight of 40 kg or more
   - Has one or more mild-moderate COVID-19 symptoms (fever, cough, sore throat, malaise, headache, muscle pain, GI symptoms, or SOB with exertion)
   - Within 10 days of symptom onset
   - Has a positive SARS-CoV-2 viral test within the last 10 days
   - [NOTE: Anti-SARS-CoV-2 monoclonal antibodies should be administered as soon as possible after positive results of direct SARS-CoV-2 viral (either PCR or antigen) testing. Please note that antibody testing will NOT be accepted.]

3. EXCLUSION criteria – Patient does NOT have ANY of the following:
   - Hospitalized due to COVID-19
   - Requirement of oxygen therapy due to COVID-19
   - Requirement of an increase in baseline oxygen flow rate due to COVID-19 in patients on chronic oxygen due to underlying non-COVID-19-related comorbidity
   - Suspected or proven serious, active bacterial, fungal, viral, or other infection (besides COVID-19)
   - Any co-morbidity requiring surgery within 7 days, or that is considered life threatening within 29 days
   - Receipt of an investigational intervention for SARS-CoV-2 (i.e. prophylaxis within 30 days before dosing, convalescent COVID-19 plasma, etc.)

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### References: