Consideration for the Initiation of Bamlanivimab in COVID-19

For non-hospitalized adult patients (≥18 years old) with symptomatic mild-to-moderate COVID-19, **bamlanivimab** may be considered, as authorized by Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA). Due to limited medication supply, patients being considered for banlanivimab should meet all of the following criteria:

I. **Authorized use criteria** *(Patients must meet all of the following criteria)*
   a. Non-hospitalized
   b. Confirmed SARS-CoV-2 positive (must be first positive test)
   c. ≤7 days from initial symptom onset
   d. Age ≥18 years
   e. Weight ≥40kg
   f. Pneumonia Severity Index Score (PSI) < 80
   g. High risk for progressing to severe COVID-19 and/or hospitalization (Must meet ≥1 criteria below)

General risk factors:	Immunosuppressive/high risk disease:
• BMI ≥35 *OR* • Chronic kidney disease *OR* • Diabetes *OR* • Age ≥65 *OR*	• HIV infection with CD4 count ≤200 *OR* • Solid organ or stem cell transplant *OR* • Sickle cell disease
Age ≥55 AND one of the following:	**Receiving immunosuppressive treatment:**
• Cardiovascular disease *OR* • Hypertension *OR* • COPD *OR* • Other chronic respiratory illness	• Chemotherapy in the past year *OR* • Immunosuppressant use for autoimmune disease *OR* • Prednisone ≥20 mg/day (or equivalent) for ≥14 days

II. **Limitations of Authorized Use**
   a. Bamlanivimab is not authorized for use in patients:
      i. Who are hospitalized due to COVID-19, OR
      ii. Who require oxygen therapy due to COVID-19, OR
      iii. Who 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.
   b. Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

III. **Dose:** Single intravenous (IV) infusion of 700 mg over at least 60 minutes

IV. **Contraindications:** None

V. **Monitoring:**
   a. No laboratory monitoring indicated
   b. Clinical monitoring for 60 minutes post infusion

VI. **Adverse Effects and Precautions:**
   a. Potential for serious hypersensitivity reaction, including anaphylaxis or infusion related reactions
   b. Symptoms including nausea, diarrhea, dizziness, headache, pruritus, and vomiting were observed in clinical trials, though at rates comparable to placebo.

VII. **Restrictions, Approvals, and Ordering:**
   a. 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.
   b. Medication errors and/or serious adverse events should be reported to the OLOL Main Pharmacy. They will assist with submitting the required FDA Medwatch reports within 7 days of event.

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