Louisiana Department of Health
Protocol- Monoclonal Antibodies for Treatment of COVID-19
Sotrovimab
Revised 10/01/2021

GENERAL REQUIREMENTS

1. Review and be familiar with the most current revision of the **Fact Sheet for Health Care Providers for the EUA of Sotrovimab**, available at: https://gskpro.com/content/dam/global/hcpportal/en_SG/sotrovimab-fact-sheet-for-healthcare-professionals-hsa.pdf.
2. Verify that the individual meets the FDA EUA criteria for administration of Sotrovimab.
3. Review and be familiar with personal protective equipment (PPE) required for providing Sotrovimab to qualifying patients.
4. Review and follow the "Intravenous Infusion Preparation and Administration Instructions" outlined in this Protocol for qualifying patients receiving intravenous infusion.
5. Review and follow the "Subcutaneous Injection Preparation and Administration Instructions" outlined in this Protocol for qualifying patients receiving subcutaneous injections.
6. Inform each patient, or parent or legal guardian if the patient is under 18 years of age or incapable of consenting, that Sotrovimab is not approved by the FDA but has received emergency use authorization from the FDA for (1) the treatment of mild to moderate COVID-19 in adult 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 and (2) for post-exposure prophylaxis of COVID-19 in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. Provide to the patient, or parent or legal guardian if the patient is under 18 years of age or incapable of consenting, the most current revision of the **Fact Sheet for Patients, Parents and Caregivers for the EUA of Sotrovimab**, available at https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-PATIENT-FACT-SHEET.PDF, prior to administering the drug.
7. Receive informed written consent for use of Sotrovimab for treatment of COVID-19 or post-exposure prophylaxis from the patient, or parent or legal guardian if the patient is under 18 years of age or incapable of consenting.
8. Submit a report on all medication errors and all serious adverse events potentially related to Sotrovimab.
9. Advise all patients, or parents or legal guardians if the patient is under 18 years of age or incapable of consenting, to continue to self-isolate and use infection control measures.

Patient Selection and Treatment Initiation

This section provides essential information on the unapproved product sotrovimab, for the 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 whoare at high risk for progression to severe COVID-19, including hospitalization or death *[see Limitations of Authorized Use]*.

The following medical conditions or other factors may place adults and pediatric patients (12 to17 years of age weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example ≥65 years of age)
- Obesity or being overweight (for example, adults with BMI >25 kg/m^2, or if 12 to 17 years ofage, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- 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 confermedical 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 medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of sotrovimab under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for

progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need- extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider thebenefit-risk for an individual patient.

Dosage

The dosage of sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is 500 mg of sotrovimab. Sotrovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viralItesting and within 10 days of symptom onset. Sotrovimab must be diluted and administered as a single IV infusion over 30 minutes.

Dosage Adjustment in Specific Populations

No dosage adjustment is recommended based on renal impairment, during pregnancy or whilelactating *[see Full EUA Prescribing Information, Use in Specific Populations (11)]*.

Preparation and Administration

Preparation

Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration.

Sotrovimab injection should be prepared by a qualified healthcare professional using aseptictechnique.

- Gather the materials for preparation:
  - Choose from the following:
    - Polyvinyl chloride (PVC) or polyolefin (PO), sterile, prefilled 50-mL or 100-mLinfusion bag containing 0.9% Sodium Chloride Injection, or
    - PVC, sterile, prefilled 50-mL or 100-mL infusion bag containing 5% DextroseInjection, and
  - One vial of sotrovimab (500 mg/8 mL).
- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to roomtemperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the

solution must be discarded and a fresh solutionprepared. Sotrovimab is a clear, colorless or yellow to brown solution.

- Gently swirl the vial several times before use without creating air bubbles. **Do not shake thevial.**
- Withdraw 8 mL of sotrovimab from one vial and inject into the prefilled infusion bag.
- Discard any product remaining in the vial.
- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. **Donot invert the infusion bag.** Avoid forming air bubbles.
- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the dilutedsolution of sotrovimab up to 6 hours at room temperature (up to 25°C [up to 77°F]) or refrigerated up to 24 hours (2°C to 8°C [36°F to 46°F]).

Administration

Sotrovimab infusion solution should be administered by a qualified healthcare professional.

- Gather the materials for infusion:
  - Polyvinyl chloride (PVC) or polyolefin (PO) infusion set, and
  - Use of a 0.2 micron polyethersulfone (PES) filter is strongly recommended.
- Attach the infusion set to the IV bag using standard bore tubing.
- Prime the infusion set.
- Administer the entire infusion solution in the bag over 30 minutes. Due to potential overfillof prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.
- Do not administer as an IV push or bolus.
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of sotrovimab with IV solutions and medications other than0.9% Sodium Chloride Injection and 5% Dextrose Injection is not known.
- Once infusion is complete, **flush the tubing** with 0.9% Sodium Chloride or 5% Dextrose toensure delivery of the required dose.
- If the infusion must be discontinued due to an infusion reaction, discard unused product.

- Clinically monitor patients during infusion and observe patients for at least 1 hour afterinfusion is complete.

Storage

Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in original carton. Do not freeze orshake. Protect from light.

Warnings

There are limited clinical data available for sotrovimab. Serious and unexpected adverse eventsmay occur that have not been previously reported with use of sotrovimab.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of sotrovimab *[see Full EUA Prescribing Information, Overall Safety Summary (6.1)]*. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxisoccur, immediately discontinue administration and initiate appropriate medications and/or supportive care.

Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion,have been observed with administration of sotrovimab. These reactions may be severe or life threatening.

Signs and symptoms of infusion-related reactions may include:

- fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrialfibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vaso-vagal reactions (e.g., pre- syncope, syncope), dizziness, and diaphoresis.

Consider slowing or stopping the infusion and administer appropriate medications and/orsupportive care if an infusion-related reaction occurs.

Hypersensitivity reactions occurring more than 24 hours after the infusion have also beenreported with the use of SARS-CoV-2 monoclonal antibodies under Emergency Use Authorization.

Clinical Worsening After SARS-CoV-2 Monoclonal Antibody Administration

Clinical worsening of COVID-19 after administration of SARS-CoV-2 monoclonal antibody treatment has been reported and may include

signs or symptoms of fever, hypoxia or increasedrespiratory difficulty, arrythmia (e.g., atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to SARS-CoV-2 monoclonal antibody use or were due to progression of COVID-19.

Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19

Benefit of treatment with sotrovimab has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Therefore, sotrovimab is not authorized for use in patients*[see Limitations of Authorized Use]*:

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronicoxygen therapy due to underlying non-COVID-19 related comorbidity).

Side Effects

Adverse events have been reported with sotrovimab *[see Full EUA Prescribing Information,Overall Safety Summary (6.1)]*.

Additional adverse events associated with sotrovimab may become apparent with morewidespread use.