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RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Donald Kauerauf
Director

Michael L. Parson
Governor

October 12, 2021

Standing Order for Sotrovimab Administration

The Director of the Department of Health and Senior Services, finding it necessary to protect public health and prevent the further spread of COVID-19, pursuant to the authority granted under section 192.020, RSMo, and 19 CSR 20-20.040, hereby orders the following:

Purpose

This Standing Order authorizes eligible healthcare providers who are trained in the administration of sotrovimab to use this drug to treat 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 who are at high risk for progression to severe COVID-19, including hospitalization or death.
This Standing Order is in accordance with the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) for sotrovimab (https://www.fda.gov/media/149532/download).

Patient Eligibility

Adults and adolescents 12 years of age and older weighing at least 40 kg with positive results of direct SARS-CoV-2 testing within 10 days of symptom onset who meet any of the criteria below.

- 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)
- 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, 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 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. Healthcare providers should consider the benefit-risk for an individual patient.

LIMITATIONS OF AUTHORIZED USE

Sotrovimab is not authorized for use in the following patient populations:

• Adults or pediatric patients who are hospitalized due to COVID-19, or

• Adults or pediatric patients who require oxygen therapy due to COVID19, or

• Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.

• Sotrovimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

• The use of sotrovimab covered by this authorization must be in accordance with the authorized Fact Sheets (https://www.fda.gov/media/149534/download).

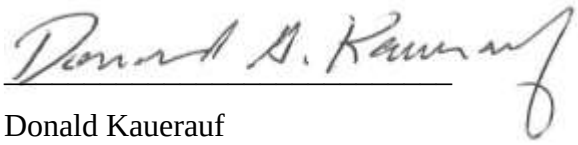
Procedure

1. Verify that the individual meets the FDA EUA criteria for administration of sotrovimab
2. Patients with known hypersensitivity to any ingredient of sotrovimab must not receive sotrovimab.

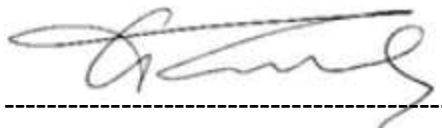
3. Receive informed written consent for use of sotrovimab for treatment of COVID-19 from the patient, or parent or legal guardian if the patient is under 18 years of age or incapable of consenting.
4. Review and follow the intravenous infusion preparation and administration instructions for qualifying patients receiving infusion (**Attachment A**)
5. Submit a report on all medication errors and all serious adverse events potentially related to sotrovimab
6. 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.
7. Provide patient a copy of the Patient Fact Sheet:
• English: https://www.fda.gov/media/149533/download
• Spanish: http://infusioncenter.org/wp-content/uploads/2021/06/sotrovimab-eua-fact-sheet-for-patients-in-spanish.pdf

Duration of Standing Order

This Standing Order shall remain in effect for the duration of the FDA's EUA for treatment of COVID-19 with sotrovimab, and the duration of the PREP Act immunity provisions as established in the Declaration as effective on February 4, 2020 and all subsequent Declarations. This Standing Order shall automatically be rescinded upon the revocation of the FDA's EUA for treatment of COVID-19 with sotrovimab, or the expiration of the COVID-19 immunity protections for covered countermeasures under the PREP Act, whichever occurs first.



Donald Kauerauf
Director, Missouri DHSS



George Turabelidze, M.D
Missouri State Epidemiologist

Attachment A

Sotrovimab Dosing and Administration

Dosage

The dosage of sotrovimab in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is a single IV infusion of 500 mg. Sotrovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.

Sotrovimab must be diluted and administered as a single intravenous infusion over 30 minutes.

Dosage Adjustment in Specific Populations

Pregnancy or Lactation

No dosage adjustment is recommended in pregnant or lactating women.

Pediatric Use

No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg and are 12 years of age and older. Sotrovimab is not authorized for patients under 12 years of age or pediatric patients weighing less than 40 kg.

Geriatric Use

No dosage adjustment is recommended in geriatric patients.

Renal Impairment

No dosage adjustment is recommended in patients with renal impairment.

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 aseptic technique:

- Gather the materials for preparation:

  - Polyvinyl chloride (PVC) or polyolefin (PO), sterile prefilled infusion bag. Choose one of the following sizes: prefilled 50-mL or 100-mL infusion bag containing 0.9% Sodium Chloride Injection, and

  - One vial of sotrovimab (500 mg/8 mL).

- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, 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 fresh solution prepared. 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 the vial**.
- Withdraw 8 mL of sotrovimab from one vial and inject into the prefilled infusion bag containing 0.9% Sodium Chloride Injection.
- 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. **Do not 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 diluted solution of sotrovimab up to 4 hours at room temperature (20°C to 25°C [68°F 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 with 0.9% Sodium Chloride Injection.
- Administer the entire infusion solution in the bag over 30 minutes. Due to potential overfill of 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 than 0.9% Sodium Chloride Injection is not known.
- Once infusion is complete, **flush the tubing** with 0.9% Sodium Chloride to ensure 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 after infusion is complete.

Storage

This product is preservative-free; therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) including transportation and infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 15 minutes prior to administration.

MANDATORY REQUIREMENTS FOR ADMINISTRATION OF SOTROVIMAB UNDER EMERGENCY USE AUTHORIZATION

1. The prescribing healthcare provider and/or the provider's designee is/are also responsible for mandatory reporting of all medication errors and serious adverse events* potentially related to sotrovimab within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "Sotrovimab use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report.

- Submit adverse event reports to FDA MedWatch using one of the following methods:
- Complete and submit the report online at www.fda.gov/medwatch/report.htm, or
- Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
- Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
- Fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form.
- Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement **"Sotrovimab use for COVID-19 under Emergency Use Authorization (EUA)."**

*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;

- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

2. The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of sotrovimab.