NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Intravenous Administration of Sotrovimab Monoclonal Antibodies
October 29, 2021

Purpose: To meet the goal of administering FDA-Emergency Use Authorization Sotrovimab to treat mild to moderate coronavirus disease in patients who are high risk for progression to severe COVID-19 and who meet the criteria set-forth by the Emergency Use Authorization of the Food and Drug Administration.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure and/or scope of practice to include intravenous infusions, or pursuant to orders issued under North Carolina Executive Order 236, or as a covered person under the federal PREP Act functioning as monoclonal antibody providers to administer Sotrovimab authorized by the FDA through an Emergency Use Authorization (EUA) and per conditions of this order.

Sotrovimab Administration	
Condition or Situation	Patients aged 12 years and older, weighing at least 40 kg (88.2 lb.), who present requesting and consent to treatment with monoclonal antibodies Sotrovimab for treatment of mild to moderate COVID-19 and who self-attest to being at high risk for progression to severe COVID-19 disease. Patients should have legal and decisional capacity to consent to treatment with monoclonal antibodies Sotrovimab, in accordance with NC GS § 91-21.13 and NC GS § 90-21.5. Sotrovimab can only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion or hypersensitivity reactions (such as anaphylaxis), and the ability to activate EMS, as necessary and according to local protocol.
Assessment Criteria	
Subjective	**Treatment of Mild to Moderate COVID-19** 1. Patient self-attests to positive results of SARS-CoV-2 viral testing **AND** 2. The patient presents within 10 days of symptom onset of COVID-19.
	In addition to meeting one of the above criteria, the patient self-attests to having a condition that would put them at high-risk for progression to severe COVID-19. Refer to the CDC's review of People with Certain Medical Conditions for the most recent guidance on medical conditions that place a person at higher risk for severe illness with COVID-19. High risk conditions may include, but not be limited to: 1. Older age (for example, over the age of 65) 2. Obesity or being overweight (for example, BMI > 25; or if age 12-17, have BMI ≥ 85th percentile for their age and gender based on CDC growth charts) 3. Pregnancy 4. Chronic kidney disease 5. Diabetes 6. Immunosuppressive disease or immunosuppressive treatment 7. Cardiovascular disease (including congenital heart disease) or hypertension 8. Chronic lung diseases (for example, chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension) 9. Sickle cell disease

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	10. Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies) 11. Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation unrelated to COVID-19) Patients may self-attest they have another condition or factor that may put them at high risk for progression to severe COVID-19 disease that is not listed above. If the patient presents with another condition or factor that is not listed above and the patient is uncertain if it may put them at high risk for progression to severe COVID-19 disease and therefore cannot self-attest to high risk, consult with the physician or advanced practice provider (APP; nurse practitioner, certified nurse-midwife, or physician assistant) providing clinical supervision of the treatment facility/agency/service.
Objective	1. The patient is at least 12 years of age or older. 2. The patient weighs at least 40 kg, or 88.2 lb.
Plan of Care	
Actions	1. Review Fact Sheet for Health Care Providers 2. Review agency protocol for assessment and management of anaphylaxis **before** initiating treatment. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration reaction according to agency protocol. 3. Prior to patients receiving Sotrovimab, provide and review the Fact Sheet for Patients, Parents and Caregivers EUA of Sotrovimab for COVID-19. 4. Before administering Sotrovimab or participating in any patient care activities, don appropriate personal protective equipment (PPE) per CDC guidelines to protect against the transmission of COVID-19.
Precautions: Patient Monitoring	The patient should be clinically monitored during and after administration of Sotrovimab. After administration is complete, the patient should be monitored for a minimum of 1 hour. During this time, the nurse, EMS personnel, or other individuals who are trained and supervised by clinical staff shall observe for signs and symptoms of a hypersensitivity reaction (anaphylaxis) or infusion related reaction. These may include: 1. Fever 2. Difficulty breathing 3. Reduced oxygen saturation 4. Chills 5. Nausea 6. Arrhythmia (such as atrial fibrillation, tachycardia, or bradycardia) 7. Chest pain or discomfort 8. Weakness 9. Altered mental status

	10. Headache 11. Bronchospasm 12. Hypotension 13. Hypertension 14. Angioedema 15. Throat irritation 16. Rash (urticaria) 17. Pruritus 18. Myalgia 19. Vasovagal reaction 20. Dizziness 21. Fatigue 22. Diaphoresis If the patient is showing signs of anaphylaxis or an infusion related reaction during or after administration; stop treatment, implement medical emergency protocols and immediately notify the physician or APP providing clinical supervision of the treatment facility/agency/service.
Treatment	**Sotrovimab must be <u>diluted</u> prior to administration; <u>IV infusion</u> ONLY.** 1. Prepare 500mg Sotrovimab according to manufacturer instructions using aseptic technique. Sotrovimab is available as a concentrated solution and must be diluted prior to administration. Use the RXWorkflow for Sotrovimab 500 mG. 2. Gather the recommended materials for preparation: a. Polyvinyl chloride (PVC) or polyolefin (PO), sterile, prefilled 50-mL or 100mL infusion bag containing 0.9% Sodium Chloride Injection, OR PVC, sterile, prefilled 50-mL or 100mL infusion bag containing 5% Dextrose Injection AND b. One vial of Sotrovimab (500mg/8 ml) 3. Remove one vial of Sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes. 4. 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 solution prepared. Sotrovimab is a clear, colorless or yellow to brown solution. 5. Gently swirl the vial several times before use without creating air bubbles. Do not shake the vial. 6. Withdraw 8 mL of Sotrovimab from one vial and inject into the prefilled infusion bag. Discard any product remaining in the vial. 7. 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

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	the diluted solution 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]). 8. Gather the materials for infusion: a. Polyvinyl chloride (PVC) or Polyolefin (PO) infusion set AND b. Use of a 0.2-micron polyethersulfone (PES) filter is strongly recommended 9. Attach the infusion set to the intravenous bag using bore tubing. 10. Prime the infusion set. 11. 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. 12. Do NOT: a. Administer as an IV push or bolus b. Administer simultaneously with any other medication. The compatibility of Sotrovimab with IV solutions and medications other than 0.9% Sodium Chloride Injection and 5% Dextrose Injection is not known. 13. Flush tubing once infusion is complete, with 0.9% Sodium Chloride or 5% Dextrose to ensure deliver of the required dose. 14. If the infusion must be discontinued due to an infusion reaction, discard unused product. 15. Clinically monitor patients during infusion and observe for at least 1 hour after infusion is complete. (See Precautions/Patient Monitoring Section above)
Follow-up	1. Provide the patient with COVID-19 Antibody Therapy Discharge Instructions and review it with them. 2. Patients treated with Sotrovimab should continue to use infection precautions and isolate or quarantine according to CDC Criteria for Quarantine and Isolation. 3. Administrators of Sotrovimab should report all medication errors and serious adverse events within 7 days from the onset of the event. This can be found here: http://www.fda.gov/medwatch/report.htm. Please note, all fields should be completed with as much detailed information as possible.
Contraindications for Use of this Order	Do not administer monoclonal antibody treatment to patients that: 1. Have previous severe hypersensitivity reaction, such as anaphylaxis, to Sotrovimab or to any ingredient of Sotrovimab. 2. Are hospitalized due to COVID-19. 3. Require oxygen therapy due to COVID-19. 4. Require an increase in baseline oxygen flow rate due to COVID-19 for patients on chronic oxygen therapy due to underlying non-COVID-19 related morbidity.
Criteria or Circumstances for Notifying the Physician or Advanced Practice Provider (APP)	Notify the physician/advanced practice provider (APP) if: 1. The patient desires treatment with Sotrovimab but is uncertain if they meet the assessment criteria for use. 2. The patient exhibits signs of a hypersensitivity reaction (anaphylaxis) or an infusion/injection-related reaction. In this instance, stop treatment; initiate

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	emergency medical protocols and notify the physician/ APP providing clinical supervision of the treatment facility/agency/service. 3. Notify the physician/APP from the organization providing clinical supervision of the treatment facility/agency/service at any time there are questions or problems with carrying out this standing order.

Approved by: _____ _____ Date approved: _10-29-21_____
Elizabeth Cuervo Tilson, MD, MPH
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This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. Legal Authority Executive Order 236