NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Intravenous Administration of Bebtelovimab Monoclonal Antibodies
February 15, 2022

Purpose: To meet the goal of administering FDA-Emergency Use Authorization Bebtelovimab 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.

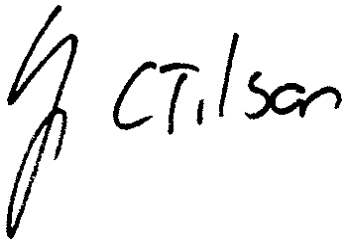
Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure and/or scope of practice to include intravenous infusions, or pursuant to orders issued under North Carolina Executive Order 245, or as a covered person under the federal PREP Act functioning as monoclonal antibody providers to administer Bebtelovimab authorized by the FDA through an Emergency Use Authorization (EUA) and per conditions of this order.

Title	
Situation	Patients aged 12 years and older, weighing at least 40 kg (88.2 lb.), who request and consent (or parent/legal guardian on their behalf) to treatment with monoclonal antibody product Bebtelovimab for treatment of mild to moderate COVID-19.
Condition	1. Patients self-attest to being at high risk for progression to severe COVID-19 disease. 2. Patients should have legal and decisional capacity to consent to treatment with monoclonal antibodies Bebtelovimab, in accordance with NC GS § 91-21.13 and NC GS § 90-21.5. 3. Bebtelovimab 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 Findings	**Treatment of Mild to Moderate COVID-19** 1. Patient self-attests to positive results of SARS-CoV-2 testing **and** 2. Patient self-attests to being at high risk for progression to severe COVID-19 disease **and** 3. Patient presents within 7 days of symptom onset of COVID-19.
Objective Findings	1. The patient is at least 12 years of age or older. 2. The patient weighs at least 40 kg, or 88.2 lb. 3. Patient for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate.
Plan of Care	

Actions	**Patient Education** 1. 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. 2. Prior to patients receiving Bebtelovimab, provide and review the Fact Sheet for Patients, Parents and Caregivers: EUA of Bebtelovimab for COVID-19. 3. Don appropriate personal protective equipment (PPE) per CDC guidelines to protect against the transmission of COVID-19.
Contraindications	Do not administer monoclonal antibody treatment to patients that: 1. Have previous severe hypersensitivity reaction, such as anaphylaxis, to Bebtelovimab, or to any ingredient of Bebtelovimab. 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.
Precautions/Patient Monitoring	The patient should be clinically monitored during and after administration of Bebtelovimab. 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 (i.e., 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	**Bebtelovimab Dose is 175 mg/2 mL (IV injection in single dose vials) for adults and pediatric patients 12 and older (weighing at least 40 kg).** 1. Review Fact Sheet for Health Care Providers. 2. Bebtelovimab may only be administered in settings in which healthcare 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. 3. Bebtelovimab should be prepared by a qualified healthcare professional using aseptic technique. 4. Gather recommended materials for injection: • 2 ml dosing syringe (polypropylene), • Syringe extension set [polycarbonate and polyvinylchloride without di-ethylhexylphthalate (DEHP)] • 0.9% Sodium Chloride Injection for flushing • 1 vial of Bebtelovimab (175 mg/2 mL) 5. Remove one vial of Bebtelovimab from refrigerated storage and allow to equilibrate to room temperature, protected from heat, for approximately 20 minutes. Do not shake. 6. Inspect vial for particulate matter and discoloration. Bebtelovimab is clear to opalescent and colorless to slightly yellow to slightly brown solution. Discard the vial if the solution is cloudy, discolored, or visible particles are observed. 7. This product is preservative-free and therefore, should be administered immediately. 8. Attach the syringe extension set. 9. Prime the extension set.

	10. Administer the entire contents of the syringe via IV injection over at least 30 seconds. 11. After the entire contents of the syringe have been administered, flush the extension set with 0.9% Sodium Chloride to ensure delivery of the required dose. 12. If the injection must be discontinued due to an infusion reaction, discard unused product. 13. Clinically monitor patients during injection and observe for at least 1 hour after infusion is complete. (See Precautions/Patient Monitoring Section above)
Follow-up/ Monitoring requirements	1. Advise patients to consult medical provider for any worsening symptoms or concerns after treatment. 2. Patients treated with Bebtelovimab may experience infusion relations reactions up to 24 hours after injection. See Fact Sheet for Patients, Parents and Caregivers EUA of Bebtelovimab for COVID-19 3. Patients treated with Bebtelovimab should continue to use infection precautions and isolate or quarantine according to CDC Criteria for Quarantine and Isolation. 4. It is NOT necessary for patients receiving Bebtelovimab to delay COVID-19 vaccination following treatment. See CDC Interim Clincal Considerations for COVID-19 Vaccines. 5. Administrators of Bebtelovimab 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.
Criteria for Notifying Provider	Notify the physician/advanced practice provider (APP) if: 1. The patient desires treatment with Bebtelovimab 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 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.



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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 245