Bamlanivimab Home Infusion Standard Operating Procedure

Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Patient Screening for Eligibility for Home Administration

Factors to consider before administration

1. Availability of resources to be considered*:
    - Emergency transport services are available/accessible
    - Telephone availability present to reach 911
    - Proximity of the patient to emergency services (distance to hospital with emergency department, etc.) within 30 minutes
        - *If any of the criteria are not met, the first dose should not be administered in the home

2. The patient must be evaluated for any history of drug allergies or adverse reactions to the prescribed medication or a medication in the same drug classification; if these criteria are present, the medication should not be administered in the home

Referral and Medication Order Pathway

1) Screen Patient

UNC Health Criteria for Use

Inclusion Criteria

Exclusion Criteria

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2) Place Home Infusion Referral

1) Place order for "Referral to Home Infusion (REF344)"
2) Use the example referral below to enter the needed information:

Agency Details:
Infusion Agency: UNC Fax:
Infusion Start of Care Date:

Nursing Agency: UNC Home Care Phone: Fax:
Home Health Start of Care Date:

HH Skilled Nurse to teach patient/caregiver the administration of home infusion therapy as ordered. Please teach/review the following, as applicable: how to flush and maintain IV line, medication bag change, storage/disposal of medication/supplies, and inventory control.
Monitor for signs and symptoms of infection, phlebitis, dislodgement/catheter migration, and occlusion of IV line. Instruct to keep IV site clean, dry and intact.
Review medication side effects.
Teach how to troubleshoot device/IV line function and who to call if dressing gets dirty, wet, or lifts off.
Review and provide the patient/caregiver with contact information regarding who to contact within your agency for questions, concerns or issues.

IV Access:
Line Type: peripheral Lumens: single
Diameter/Gauge: 24 or larger.
Length Total: NA.
Site: any available peripheral (Example: Basilic or IJ Vein, etc.)
Arm Circumference: NA (PICC line only)
Placement Date:

Special Instructions:

Flush Orders:

Flush with 5mL Sodium Chloride 0.9% per SASH technique or as directed
Flush with 3mL Heparin 10units/ml per SASH technique or as directed
PIV to stay in place for duration of treatment.

LABS:
Follow-up Labs: NONE

Physician to Follow Patient's Care (the person listed here will be responsible for signing ongoing orders):
Name:
Phone: *(Make sure the number provided can also be used for after-hours contact)*
Fax: NA

3) Order Medications (7 total)

1) Place the medication orders using "Bamlanivimab external prescriptions order panel" on the "Discharge Order" tab in EPIC (use screenshot below):

    a. There at 7 total prescriptions – make sure all 7 are checked:
        i. Acetaminophen (pre-med)
        ii. Diphenhydramine (pre-med)
        iii. Bamlanivimab
        iv. Methylprednisolone (PRN anaphylaxis)
        v. Famotidine (PRN anaphylaxis)
        vi. Epinephrine (PRN anaphylaxis)
        vii. Diphenhydramine (PRN anaphylaxis)
    b. Once order panel is signed, all seven prescriptions will print to local printer. Confirm that each prescription is signed (either electronically or manually).

2) **Fax the hardcopy prescriptions to UNC HCS Pharmacy:**
    a. (traditional fax machine)
    b. (email fax option)

4) Send email notification to UNC HCS Central Intake department

- To:
- CC:
- Subject: *leave blank*
- Body of email:
    - BAMLANIVIMAB – STAT
    - Patient Name
    - MRN
    - Date of Birth

Administration

COVID-19 Personal Protective Equipment Requirements for Home Administration on Bamlanivimab

All UNC staff and contract personnel must follow the UNC COVID PPE Reference Guide when entering the home of a patient who is laboratory confirmed COVID +.

- For laboratory confirmed COVID + patients, Special Airborne Contact precautions should be utilized
    - Take in the least amount of equipment needed to provide care
    - Don and Doff PPE for COVID 19 directly outside of the patient home (Preferable in a private area such as a car port or back porch to give patient privacy).
    - PPE should include:
        - N95 Respirator
        - Gown
        - Eye protection
        - Gloves
        - Shoe covers
    - Doffing of all PPE upon exiting the patient home should follow UNC Doffing Protocol
    - Dispose of all PPE in the trash directly outside of the patient's home
    - Sanitize all touched surfaces such as doorknobs and latches
    - Perform hand hygiene
    - When possible use disposable equipment and thoroughly clean with approved disinfectant

Prior to Administration

- Adhere to COVID 19 in home infection control precautions.
- Identify patient using at least two patient identifiers.
- Educate the patient/caregiver using the provided EUA Fact Sheet for Patients, Parents, and Caregivers including of the potential risk of a medication reaction and signs and symptoms to report.
- Explain procedure to patient/caregiver.
- Administer pre-medications 30 minutes prior to bamlanivimab infusion.
- Measure vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation, and temperature. Contact provider prior to administration of bamlanivimab if the oxygen saturation (SpO2; Pulse Ox) is less than 95%, OR if the resting respiratory rate (RR) is greater than 20 breaths per minute. Infusion may proceed if provider has reviewed patient presentation and deems therapy as appropriate.

Drug Preparation – Home Mix

1. Remove the bamlanivimab vial from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat.
2. Inspect bamlanivimab visually for particulate matter and discoloration.
    a. Bamlanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution.
3. START peripheral IV.
    a. If IV access cannot be obtained, return medication to the refrigerator.
4. Remove 250mL 0.9% Sodium Chloride infusion bag from outer wrapping.
5. Spike and prime bag with tubing PRIOR TO injecting medication.
    a. Tubing provided: CADD High Volume tubing with 0.2 micron filter
6. After vial has sat at room temperature for 20 minutes, gently invert vial by hand 10 times. Do not shake.
7. Withdraw 20 mL of bamlanivimab from the vial using an appropriately sized syringe and needle.
8. Transfer bamlanivimab to the 250mL 0.9% Sodium Chloride Injection infusion bag.
9. Discard any product remaining in the vial.
10. Gently invert IV bag by hand approximately 10 times to mix. Do not shake.

Drug Administration

- Bamlanivimab infusion solution should be administered by a qualified healthcare professional.
- Check WarmMark temperature indicator to verify temperature maintained within 36°F to 46°F. If temperature is out of specified range, contact UNC HCS pharmacist.
- Gather the recommended materials for infusion.
- Administer the infusion solution via CADD Prizm Pump over 60 minutes.
- Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
- Discard unused product.
- Clinically monitor patients during administration and observe patients for at least 60 minutes after infusion is complete.
- Observe patient for signs and symptoms of allergic/anaphylactic reaction
    - Appearance of hives on face and upper chest
    - Diffuse erythema and the feeling of warmth with or without itching
    - Swelling of eyes, face, lips, tongue, throat, hands or feet
    - Respiratory difficulty and wheezing
    - Severe abdominal cramping with associated gastrointestinal or genital-ureteral symptoms
    - Vascular collapse with circulatory failure
- In the event of signs/symptoms of infusion reaction/anaphylaxis
    - Discontinue medication administration
    - Call 911 to activate Emergency Management Services
    - Take vital signs, and 0_2 sat using pulse oximeter
    - Provide basic life support as needed

- Administer infusion reaction medications as ordered (see Appendix for Grading System)
  - Diphenhydramine injection 25mg intravenously
    - Once as needed, for grade 1 – mild symptoms, grade 2 – moderate symptoms, or grade 3 – severe/anaphylaxis symptoms
  - Famotidine injection 20mg intravenously
    - Once as needed, for grade 1 – mild symptoms, grade 2 – moderate symptoms, or grade 3 – severe/anaphylaxis symptoms
  - Methylprednisolone injection 125mg intravenously
    - Once as needed, for grade 2 – moderate symptoms, or grade 3 – severe/anaphylaxis symptoms
  - Epinephrine injection 0.3mg Intramuscular
    - Once as needed, for grade 3 – severe/anaphylaxis symptoms. May repeat epinephrine 0.3 mg once every 3-5 minutes if needed (up to 3 doses).
    - Epinephrine is administered cautiously to the elderly, pregnant, those with cardiovascular disease, hypertension, diabetes, hyperthyroidism and psychoneurosis. Epinephrine is contraindicated in narrow angle glaucoma, organic brain syndrome and cardiac insufficiency.

Equipment in the event of an anaphylactic/adverse drug reaction

- Anaphylaxis Kits as dispensed from pharmacy.
  - 20 – Alcohol Prep Pads
  - 1 – Anaphylaxis kit instructions
  - 2 – Epinephrine injection 1mg/mL vials
  - 1 – Diphenhydramine injection 50mg vial
  - 1 – Methylprednisolone injection 125mg vial
  - 1 – Famotidine injection 20mg vial
  - 4 – Sodium Chloride 0.9% 10 mL flushes
  - 4 – 1 mL syringes
  - 4 – 3 mL syringes
  - 10 - 20G 1” needles

Proper care after anaphylaxis/adverse drug reaction

- Document the following items in the patient’s record after administration
  - Medication administered– dose, time, rate and route
  - Patient's response to treatment
  - Identity and location of emergency facility, if indicated
  - Condition of patient at time of transportation, if indicated
  - Instructions given to patient/caregiver
  - Communication with physician
  - Complete occurrence report per organizational policy
  - Complete FDA MedWatch and submit to Pharmacy

After Administration

- The nurse will sanitize pump, pump clamp, and IV pole and place outside on patient's front porch. The pump should be placed in a bag or empty box.
- The nurse will dispose of all PPE in the outside garbage can.
- The home infusion pharmacist will submit a pump-pickup ticket, indicating on the ticket and calendar that patient is COVID-positive.
- Dispatch technician will pick-up items, following standard COVID precautions.
- All returned pumps, clamps, and IV poles will be sanitized again upon return to UNC Homecare facilities.

Storage

- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.

Transport

- Bamlanivimab will be packaged in a Styrofoam cooler with ice packs to maintain a temperature of 36°F to 46°F during transport and until administration
- A WarmMark temperature indicator will be included in each delivery to be checked by the receiving nurse to verify cold chain maintained
- If any excursion in temperature then nurse to notify home infusion pharmacy

Bamlanivimab Infusion Nurse Checklist

1. **Patient Screening for Eligibility for Home Administration**
   - ☐ Emergency transport services are available/accessible
   - ☐ Telephone availability present to reach 911
   - ☐ Specific physician order for the first dose and willingness of the physician to prescribe medications to treat a potential anaphylactic drug reaction
   - ☐ Proximity of the patient to emergency services (distance to hospital with emergency department, etc.) within 30 minutes
2. **Prior to Administration**
   - ☐ Identify patient using at least two patient identifiers.
   - ☐ Educate the patient/caregiver using the provided EUA Fact Sheet including of the potential risk of a medication reaction and signs and symptoms to report.
   - ☐ Explain procedure to patient/caregiver.
   - ☐ Administer pre-medications 30 minutes prior to infusion.
   - ☐ Assess vitals: temperature, blood pressure, heart rate, respiratory rate, and oxygen saturation.*
     - *Contact provider if the oxygen saturation (SpO2; Pulse Ox) is less than 95%, OR if the resting respiratory rate (RR) is greater than 20 breaths per minute. Infusion may proceed if provider has reviewed patient presentation and deems therapy as appropriate.
3. **Drug Prep/Administration**
   - ☐ Establish peripheral IV access <u>before</u> preparing medication.
   - ☐ Gather the recommended materials for infusion and prepare medication according to preparation instructions.
   - ☐ Administer the infusion solution via CADD Prizm Pump.
   - ☐ Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
   - ☐ Discard unused product.
   - ☐ Clinically monitor patients during administration and observe patients for at least 60 minutes after infusion is complete.
   - ☐ Observe patient for signs and symptoms of allergic/anaphylactic reaction
     - Appearance of hives on face and upper chest
     - Diffuse erythema and the feeling of warmth with or without itching
     - Swelling of eyes, face, lips, tongue, throat, hands or feet
     - Respiratory difficulty and wheezing
     - Severe abdominal cramping with associated gastrointestinal or genital-ureteral symptoms
     - Vascular collapse with circulatory failure
   - ☐ In the event of signs/symptoms of anaphylaxis
     - Discontinue medication administration
     - Call 911
     - Provide basic life support as needed Administer infusion reaction/anaphylaxis medications as ordered

Appendix

Table 1. Modified WAO Grading System for Severe Allergic Reactions

Table 1. Modified WAO Grading System for severe allergic reactions

Grades			Anaphylaxis	
Grade 1	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Symptom(s)/sign(s) from one organ system Cutaneous -Urticaria and/or erythema-warmth and/or pruritus other than localized at injection site and/or -Lip tingling or itching or -Angioedema (not laryngeal) or Upper respiratory -Nasal: sneezing, rhinorrhea, pruritus and/or congestion and/or -Throat clearing (itchy throat) and/or -Cough not related to bronchospasm or Conjunctival -Erythema, pruritus, tearing or Other -Nausea -Metallic taste	Symptom(s)/sign(s) From ≥ 2 organ symptoms listed in grade 1	Lower airway -Mild bronchospasm (cough, wheezing, shortness of breath) which responds to treatment and/or Gastrointestinal -Abdominal cramps and/or vomiting/ diarrhea Other -Uterine cramps -Any symptom(s)/ sign(s) from grade 1 would be included	Lower airway -Severe bronchospasm not responding or worsening in spite of treatment and/or Upper airway -Laryngeal edema with stridor -Any symptom(s)/ sign(s) from grades 1 or 3 would be included	Lower or upper airway -Respiratory failure and/or Cardiovascular -Collapse/hypotension and/or -Loss of consciousness (vasovagal excluded) -Any symptom(s)/ sign(s) from grades 1,3, or 4 would be included

The final grade of the reaction is not determined until the event is over, regardless of the medication administered to treat the reaction. The final report should include the first symptom(s)/sign(s) and the time of onset after the causative agent exposure and a suffix reflecting if and when epinephrine was or was not administered: *a*, ≤ 5 min; *b*, > 5 min to ≤ 10 min; *c*, > 10 min to ≤ 20 min; *d*, > 20 min; *z*, epinephrine not administered. Final report: grades 1–5; *a–d*, or *z*; first symptom(s)/sign(s); time of onset of first symptom(s)/sign(s)

Modified from: Cox L, Sánchez-Borges M, Lockey RF. World Allergy Organization systemic allergic reaction grading system: Is a modification needed? *J Allergy Clin Immunol Pract* 2017; 5: 58–62