10.17 Administration of Bamlanivimab	**Revision Dates**
Application Licensed Nurses Providing Infusion Therapy in the LTC Facility	**Original Date** November 2020

THE FACILITY MUST ENSURE THAT ALL NURSES RESPONSIBLE FOR THE CARE AND MANAGEMENT OF PATIENTS RECEIVING MONOCLONAL ANTIBODY INFUSIONS ARE KNOWLEDGEABLE AND COMPETENT IN THE ADMINISTRATION PROCEDURES AND THE POTENTIAL COMPLICATIONS ASSOCIATED WITH THIS THERAPY.

To Be Performed By:

Licensed nurses in accordance with state law and facility policy. The nurse shall be competent in the safe delivery of infusion therapy within his or her scope of practice. Competency validation is documented in accordance with organizational policy.

Considerations:

1. Bamlanivimab is a monoclonal antibody for the treatment of mild to moderate COVID-19.
2. The FDA has issued an Emergency Use Authorization (EUA) to treat mild to moderate COVID-19 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 with high risk for progressing to severe COVID-19 and/or hospitalization.
3. This EUA is for the use of the unapproved product Bamlanivimab for the treatment of mild to moderate COVID-19. Patients categorizing as high risk must have at least one of the following criteria:
    - 3.1 Body mass index (BMI) ≥ 35
    - 3.2 Chronic kidney disease
    - 3.3 Diabetes
    - 3.4 Immunosuppressive disease
    - 3.5 Currently receiving immunosuppressive treatment
    - 3.6 Are ≥ 65 years of age
    - 3.7 Are ≥ 55 years of age AND have
        - 3.7.1 Cardiovascular disease OR
        - 3.7.2 Hypertension OR
        - 3.7.3 Chronic obstructive pulmonary disease/other chronic respiratory disease
    - 3.8 Are 12 – 17 years of age AND have
        - 3.8.1 BMI ≥ 85th percentile for their age and gender based on CDC growth charts (see reference link at the end of this document) OR
        - 3.8.2 Sickle cell disease OR
        - 3.8.3 Congenital or acquired heart disease OR
        - 3.8.4 Neurodevelopmental disorders, for example, cerebral palsy OR
        - 3.8.5 A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19) OR
        - 3.8.6 Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

4. Bamlanivimab is not authorized for use in patients:
   - 4.1 Who are hospitalized due to COVID-19
   - 4.2 Who require oxygen therapy due to COVID-19
   - 4.3 Oxygen dependent patients who require an increase in oxygen flow rate due to COVID-19 complications
5. Benefit of treatment with Bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as Bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
6. Bamlanivimab and COVID-19 Vaccines[1]:
   - 6.1 Currently, there is no data on the safety and efficacy of Pfizer-BioNTech COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
   - 6.2 Based on the estimated half-life of such therapies, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure, until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses
7. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and adverse events (death, serious adverse events) potentially related to Bamlanivimab treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words **"Bamlanivimab under Emergency Use Authorization (EUA)" in the description section of the report.**
   - 7.1 Submit adverse event reports to FDA MedWatch using one of the following methods:
     - 7.1.1 Complete and submit the report online: www.fda.gov/medwatch/report.htm
     - 7.1.2 By using a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-277 800-FDA-0178)
     - 7.1.3 Call 1-800-FDA-1088 to request a reporting form
     - 7.1.4 OTHER REPORTING REQUIREMENTS
       In addition, please provide a copy of all FDA MedWatch forms to:
       Eli Lilly and Company, Global Patient Safety
       Fax: 1-317-277-0853 E-mail: mailindata_gsmtindy@lilly.com
       Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.
   - 7.2 Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" a statement "Bamlanivimab treatment under Emergency Use Authorization (EUA)."
   - 7.3 Serious Adverse Events are defined as:
     - 7.3.1 Death
     - 7.3.2 A life-threatening adverse event
     - 7.3.3 Inpatient hospitalization or prolongation of existing hospitalization
     - 7.3.4 A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
     - 7.3.5 A congenital anomaly/birth defect
     - 7.3.6 A medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly
8. Licensed nurses caring for patients receiving infusion therapies are expected to follow infection prevention procedures.

[1] https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html

Guidance

1. Bamlanivimab is administered as a single intravenous infusion of 700 mg over a minimum of 60 minutes, as soon as possible after a positive COVID-19 test and within 10 days of symptom onset.
    1.1 Consider slower infusion rate for patients with CHF, chronic kidney disease, and Systemic Inflammatory Response Syndrome (SIRS)
2. There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of Bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.
    2.1 Anaphylaxis and infusion-related reaction orders must be obtained prior to infusion
    2.2 Anaphylaxis kit/medications must be readily available
3. The Bamlanivimab infusion must be followed by administration of 25 mL 0.9% Sodium Chloride to clear the medication from the administration set, ensuring the complete dose is administered. A physician/LIP order must be obtained for this solution, at the same rate as the medication.
4. Bamlanivimab reconstituted bag or vial must be removed from the refrigerator approximately 20 minutes prior to administration to bring to room temperature. Do not expose to direct heat.
    4.1 **Prior to removing from refrigerator, confirm the presence of a patent vascular access device**
5. Inspect for particulate matter and discoloration. Solution is slightly opalescent and colorless to slightly yellow to slightly brown. Do not use if particulate matter identified.
6. Do not freeze, shake or expose to direct light.
7. Monitor patient during administration and for at least one hour post infusion. Signs and symptoms of infusion-related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticarial, pruritus, myalgia, and dizziness.
8. Monitor vital signs:
    8.1 Prior to initiating infusion
    8.2 Every 15 minutes during infusion
    8.3 Every 15 minutes for 1 hour post infusion
9. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and supportive care per prescriber's orders. Stop infusion for signs and symptoms of clinically significant hypersensitivity reaction or if anaphylaxis occurs.
10. Administration set with 0.2 or 0.22 micron in-line filter provided by the pharmacy must be used. Use of electronic infusion device for medication administration is preferred.
11. No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, during pregnancy or while lactating, or for disease severity or inflammation.
12. Patients treated with Bamlanivimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
13. Precaution must be taken during administration of this medication as there are no preservatives or any bacteriostatic agents in the products.
14. Patient with known hypersensitivity to any ingredient of Bamlanivimab must not receive Bamlanivimab.
15. As the healthcare provider, communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" prior to the patient receiving Bamlanivimab. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:

15.1 Provided the "Fact Sheet for Patients, Parents and Caregivers"
15.2 Informed of alternatives to receiving authorized Bamlanivimab
15.3 Informed that Bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization

Equipment if facility is admixing medication:

- Medication vial(s)
- 20 mL syringe, or 2-10 mL syringes
- 250 mL minibag of 0.9% sodium chloride
- Medication added label
- Alcohol pads
- Safety engineered needle (20 gauge)
- 50-100 mL minibag of 0.9% sodium chloride for clearing medication from administration set
- Prescribed flushing/locking agent(s) in 10 mL barrel diameter or larger syringe
- Electronic infusion device
- Administration set with 0.2 or 0.22 micron filter
- Clean gloves

Equipment if pharmacy is admixing medication:

- Compounded medication bag
- 50-100 mL minibag of 0.9% sodium chloride for clearing medication from administration set
- Alcohol pads
- Prescribed flushing/locking agent(s) in 10 mL barrel diameter or larger syringe, if appropriate
- Electronic infusion device
- Administration set with 0.2 or 0.22 micron filter
- Clean gloves

Procedure:

1. Verify physician/LIP order.
2. Assemble equipment and supplies on clean work surface.
3. Perform hand hygiene. Don clean gloves.
4. Establish vascular access, if needed. (Refer to procedure 4.1 Short Peripheral Catheter Insertion.)
5. **If pharmacy is admixing medication remove medication bag from refrigerator and allow to reach room temperature. Then proceed to step 8.**
6. **If facility is admixing medication:** Remove Bamlanivimab vial from refrigerator and allow to reach room temperature over approximately 20 minutes. Do not expose to direct heat.
7. Admix Bamlanivimab dose using aseptic technique:
   7.1 Inspect Bamlanivimab vial visually for particulate matter and discoloration
   7.2 Gently invert vial by hand approximately 10 times. Do not shake.
   7.3 Withdraw 20 mL Bamlanivimab from vial using 20 mL syringe
   7.4 Transfer Bamlanivimab into 250 mL 0.9% Sodium Chloride Injection infusion bag
   7.5 Discard any remaining product in the vial
   7.6 Gently invert IV bag by hand approximately 10 times to mix. Do not shake.
   7.7 Complete and affix medication added label to bag
8. Administer using the administration set containing a 0.2 to 0.22 micron filter. Program infusion pump to infuse over a minimum of 60 minutes. Program in BASIC mode when using Sigma Spectrum infusion pump. (Refer to procedure 3.6, Administration of an Intermittent Infusion for administration steps)

9. Monitor patient during administration and for at least one hour post infusion. Signs and symptoms of infusion-related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticarial, pruritus, myalgia, and dizziness.
10. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care. Stop infusion for signs and symptoms of clinically significant hypersensitivity reaction or if anaphylaxis occurs.
11. Upon completion of Bamlanivimab infusion, replace empty medication bag with a 50 – 100 mL 0.9% Sodium Chloride minibag. This will be used to clear administration set of medication ensuring the complete dose has been administered. Administer 0.9% Sodium Chloride at same rate as infusion for a volume of **25 mL** (reset the volume to be infused on the infusion pump at 25 mL). Continue infusion.
12. Upon completion of infusion, perform hand hygiene.
13. Don gloves.
14. Close the clamp and disconnect the administration set from needleless connector.
15. Perform a vigorous mechanical scrub to manually disinfect the needleless connector. Allow to air dry. Follow with prescribed flushing/locking solution, if vascular access device is to remain intact.
16. Dispose of used supplies per facility policy.
17. Remove gloves.
18. Perform hand hygiene.
19. Documentation in the medical record includes, but is not limited to:
    - 19.1 Date and time
    - 19.2 Medication/solution
    - 19.3 Rate and method of infusion
    - 19.4 Prescribed flushing/locking agent(s), if applicable
    - 19.5 Site assessment
    - 19.6 Complications and interventions
    - 19.7 Patient response to procedure and/or medication
    - 19.8 Patient/significant other teaching

References:

1. Lilly. Bamlanivimab. Lilly website. http://pi.lilly.com/eua/Bamlanivimab-eua-factsheet-hcp.pdf. Accessed December 15, 2020.
2. https://www.cdc.gov/growthcharts/clinical_charts.htm
3. Lilly. Bamlanivimab. Lilly website. https://www.covid19.lilly.com/Bamlanivimab/hcp/dosing-administration?gclid=EAIaIQobChMI7ZHDoYCS7QIVB3iGCh0M6gXDEAAYASADEgLRKvD_BwE#dosing-and-administration. Accessed December 15, 2020.