Applies To: **UNM Hospital**
Responsible Department:
Effective Date: 1.6.21

Title: **Bamlanivimab Adult Inpatient Infusion**				**Guideline**
Patient Age Group:	( ) N/A	( ) All Ages	( ) Newborns	( ) Pediatric (X) Adult

DESCRIPTION/OVERVIEW

Bamlanivimab is a biotherapy drug, a monoclonal antibody. It is not a chemotherapy medication; therefore, it does not require any type of chemo-competency or chemotherapy certification in order to administer. 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 (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, and who are at high risk for progressing to severe COVID-19 and/or hospitalization (Eli Lilly and Company and FDA, 2020). This UNMH guideline is specific to the adult patient population.

REFERENCES

Eli Lilly and Company. (2020). Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab. http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf.

Eli Lilly and Company. (2020). Lilly Bamlanivimab Antibody Playbook. http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf.

U.S. Food and Drug Administration. (2020). Bamlanivimab EUA Letter of Authorization. https://www.fda.gov/media/143602/download.

AREAS OF RESPONSIBILITY

Adult Inpatient Progressive and Intensive Care Units

GUIDELINE STEPS

1. Criteria for administration
    a. Adult patients with positive results of direct SARS-CoV-2 viral testing who are at high risk of progressing to severe COVID-19. Refer to high risk criteria in the guideline below.
    b. Administer bamlanivimab as soon as possible after positive results of direct SARS-CoV-2 testing and within 10 days of symptom onset.
2. Patient Selection Criteria
    a. High risk is defined as patients who meet at least one of the following criteria:
        i. Have a body mass index (BMI) ≥35
        ii. Have chronic kidney disease

iii. Have diabetes
iv. Have immunosuppressive disease
v. Are currently receiving immunosuppressive treatment
vi. Are ≥ 65 years of age
vii. Are ≥ 55 years of age AND have
    1. Cardiovascular disease, OR
    2. Hypertension, OR
    3. Chronic obstructive pulmonary disease/other chronic respiratory disease

3. Use in Specific Populations (pregnancy, lactation, geriatric, renal impairment, and hepatic impairment)
    a. Pregnancy
        i. There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risks for the mother and the fetus.
        ii. Bamlanivimab should not be withheld from a pregnant individual who has a condition that poses a high risk of progression to severe COVID-19, and the clinician determines that the potential benefit of the drug outweighs potential risk.
        iii. Use of bamlanivimab in pregnancy **requires further discussion with Maternal Fetal Medicine** as a case by case scenario.
    b. Lactation
        i. There are no available data on the presence of bamlanivimab in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.
        ii. Bamlanivimab is a large protein molecule with a molecular weight of 146,000, the amount in milk is likely to be very low. Absorption is unlikely due to it probably being destroyed in the infant's gastrointestinal tract. Until more data becomes available, bamlanivimab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant.
    c. Geriatric
        i. Of the 309 patients receiving bamlanivimab in the clinical study, 11% were 65 years of age and 3% were 75 years of age and older. Based on population analysis, there is no difference in geriatric patients compared to younger patients.
    d. Renal Impairment
        i. Bamlanivimab is not eliminated intact in the urine, thus renal impairment is not expected to affect the exposure of bamlanivimab.
    e. Hepatic Impairment
        i. Based on population analysis, there was no significant difference in the use of bamlanivimab in patients with mild hepatic impairment compared to patients with normal hepatic function. Bamlanivimab has not been studied in patients with moderate or severe hepatic impairment.
    f. Dosage Adjustment in Specific Populations
        i. 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 [see Full EUA Prescribing Information, Use in Specific Populations (11)].

4. Limitations of Authorized Use
    a. Bamlanivimab is **not authorized** for use in patients:
        i. who are hospitalized due to COVID-19, OR
        ii. who require oxygen therapy due to COVID-19, OR
        iii. who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
    b. 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.
5. Provider Process (for licensed independent practitioners)
    a. Patient Identification, Education, and Consent
        i. Determine if patient is eligible for administration (Refer to step 1 in guideline). Complete the "Bamlanivimab Inpatient Screening Form" accessed via the "Adult COVID-19 ED & ICU" or "Adult SAC COVID-19" Powerplans.
        ii. If patient is eligible, the provider will discuss the potential benefits and risks of bamlanivimab with the patient. Providers need to consent the patient to receive bamlanivimab and give the patient the EUA fact sheet (link to this sheet is located inside the "Bamlanivimab EUA Attestation" form).
        iii. If the inpatient is eligible and consented, then primary team will
            1. Complete the "Bamlanivimab EUA Attestation" form.
            2. Order bamlanivimab (synomyms: monoclonal, COVID) and associated medications for managing infusion reactions. (Powerplan: "COVID-19 Monoclonal Ab Infusion").
6. Pharmacy Process
    a. Upon receiving order, pharmacy will review "COVID-19 Bamlanivimab Administration Criteria" form and "Bamlanivimab EUA Attestation" to assess for completion.
        i. If forms are not complete, then pharmacist will send a reminder to providers. It is the providers responsibility to ensure that the appropriate documentation is complete.
    b. Dose preparation:
        i. Medication preparation will occur inside the pharmacy setting by the pharmacist at a standard dosage of 700mg for adults (see Table 1)

Table 1: Recommended Dilution and Administration for Instructions for Bamlanivimab

Drug	Number of Vials	Volume of Bamlanivimab	Volume of 0.9% Sodium Chloride	Total Volume for Infusion	Minimum Infusion Rate	Minimum Infusion Time
bamlanivimab (700mg/20 mL)	1 Vial	20 mL	250 mL	270 mL	270 mL/hr.	60 minutes

7. Nursing Medication Administration and Patient Monitoring Process
    a. Medication Administration

i. Gather the following supplies:
    1. IV pump and pole
    2. Infusomat® Space Pump IV Set (primary tubing)
    3. Secondary IV Set (piggyback tubing)
    4. 0.2/0.22 micron polyethersulfone (PES) filter
    5. Bag of 0.9% Sodium Chloride (NS)
    6. Bamlanivimab solution (pre-mixed in pharmacy by the pharmacist)
        a. The solution should be administered immediately, or as soon as possible, after arrival to the unit. The solution can be stored up to 24 hours in the refrigerator (2°-6°C [36°-46°F]) or up to 7 hours at room temperature. Any stored solution that exceeds these time limits needs to be discarded and a new solution must be prepared.

ii. Attach the 0.2/0.22 micron filter to the end of the primary IV tubing set.
iii. Load the primary IV tubing into the IV pump and prime the line with NS.
iv. Spike the bamlanivimab solution with the piggyback IV tubing set and prime the tubing. Set up the infusion to run as a piggyback infusion with the NS.
v. Program the IV pump according to the medication order in the patient's MAR.
vi. Infuse the bamlanivimab solution at the ordered infusion rate (infused over at least 60 minutes).
vii. After the ordered infusion volume has been delivered, flush the primary IV tubing set with NS.
viii. Discard any unused solution.
ix. Do not administer bamlanivimab as IV push or bolus. Do not infuse with other IV medications.

b. Patient Monitoring Process
    i. Assess patient and measure vital signs at the following times:
        1. Immediately prior to the infusion start
        2. After first 15 minutes of infusion start
        3. Every 30 minutes for the duration of the infusion
        4. Every 30 minutes x2 after infusion is completed

c. Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions
    i. Infusion-related reactions have been observed with administration of bamlanivimab. Signs and symptoms of infusion related reactions may include: fever, chills, nausea, hypotension headache, throat irritation, rash including urticaria, pruritus, myalgia, dizziness. If patient experiences infusion related side effects, **STOP INFUSION, administer appropriate medications and/or supportive care, and notify provider immediately.**
    ii. There is a potential for serious hypersensitivity reaction (bronchospasm, angioedema, etc.), including anaphylaxis, with administration of bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, **STOP INFUSION IMMEDIATELY and initiate emergency procedures for anaphylactic reactions. Call provider immediately and activate Rapid Response team by dialing 333**.

8. Adverse Events reporting
    a. Medication errors and serious adverse events potentially related to bamlanivimab treatment are to be reported by nurse or provider utilizing the hospital PSI system.

b. Pharmacy department will complete the adverse event reporting in accordance with the EUA requirement.

DEFINITIONS

Monoclonal Antibodies (mAbs)-directly neutralize the COVID-19 virus and are intended to prevent progression of disease.

RESOURCES/TRAINING

(Training programs, classes, HSC offices, other University or HSC documentation, telephone numbers, and other sources of help completing forms or carrying out procedures.)

Resource/Dept	Contact Information
Inpatient Pharmacy	2-2033
5-West General Medicine Unit Leadership Team	2-2622
Womens Specialty Unit Based Educator	2-2518

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
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Finance	[Name, Title], [UNMH or HSC]		[N/A]
Official Approver			Y
Official Signature		Date:	
Effective Date		[1/6/2021]	

ATTACHMENTS

The following are the online links to the Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19) as follows:

English Language:
http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-patient.pdf

Spanish Language:
http://pi.lilly.com/eua/span/bamlanivimab-eua-factsheet-patient-span.pdf