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Donald Kauerauf
Director

Michael L. Parson
Governor

September 14, 2021

Standing Order for
Eli Lilly mAb Cocktail (bamlanivimab/etesevimab) Administration

The Director of the Department of Health and Senior Services, finding it necessary to protect public health and prevent the further spread of COVID-19, pursuant to the authority granted under section 192.020, RSMo, and 19 CSR 20-20.040, hereby orders the following:

Purpose

This Standing Order authorizes eligible healthcare providers who are trained in the administration of Eli Lilly mAb cocktail to administer bamlanivimab/etesevimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult 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 progression to severe COVID-19, including hospitalization or death.
This Standing Order is in accordance with the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) for bamlanivimab/etesevimab, as updated (https://www.fda.gov/media/145802/download#:~:text=The%20U.S.%20Food%20and%20Drug,patients%20(12%20years%20of%20age)

Patient Eligibility

Adults and adolescents 12 years of age and older weighing at least 40 kg with positive results of direct SARS-CoV-2 testing within 10 days of symptom onset who meet any of the criteria below.

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender)
- Pregnancy
- Chronic kidney disease

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER: Services provided on a nondiscriminatory basis.

- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))
- Other medical conditions or factors (such as race and ethnicity) that may place individuals at an increased risk for progression to more severe disease. Authorization of Eli Lilly mAb cocktail under the current EUA is not limited to the medical conditions or factors listed above.

LIMITATIONS OF AUTHORIZED USE

Combined Frequency of Variants Resistant to Bamlanivimab and Etesevimab

• Bamlanivimab and etesevimab are not authorized for use in states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab exceeds 5%.

• A list of states, territories, and US jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized is available on the following FDA website: https://www.fda.gov/media/151719/download

Use in Patients Who Are Hospitalized or Who Require Oxygen Due to COVID-19

• Bamlanivimab and etesevimab are not authorized for use in patients:
who are hospitalized due to COVID-19, OR
who require oxygen therapy due to COVID-19, OR
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.

Procedure

1. Verify that the individual meets the FDA EUA criteria for administration of bamlanivimab/etesevimab
2. Review and follow the "Intravenous Infusion Preparation and Administration Instructions" for qualifying patients receiving infusion (**Attachment A)**
3. Receive informed written consent for use of bamlanivimab/etesevimab for treatment of COVID-19 from the patient, or parent or legal guardian if the patient is under 18 years of age or incapable of consenting.
4. Submit a report on all medication errors and all serious adverse events potentially related to bamlanivimab/etesevimab
5. Advise all patients, or parents or legal guardians if the patient is under 18 years of age or incapable of consenting, to continue to self-isolate and use infection control measures.
6. Provide patient a copy of the Patient Fact Sheet:

• English: http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-patient.pdf

• Spanish: http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf

Duration of Standing Order

This Standing Order shall remain in effect for the duration of the FDA's EUA for treatment of COVID-19 with bamlanivimab/etesevimab, and the duration of the PREP Act immunity provisions as established in the Declaration as effective on February 4, 2020 and all subsequent Declarations. This Standing Order shall automatically be rescinded upon the revocation of the FDA's EUA for treatment of COVID-19 with bamlanivimab/etesevimab, or the expiration of the COVID-19 immunity protections for covered countermeasures under the PREP Act, whichever occurs first.

Donald Kauerauf
Director, Missouri DHSS

George Turabelidze, M.D
Missouri State Epidemiologist

ATTACHMENT “A”

General Guidelines for bamlanivimab/etesevimab Dosing, Dilution, and Administration

4

Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion[a] in Patients Weighing 50 kg or More

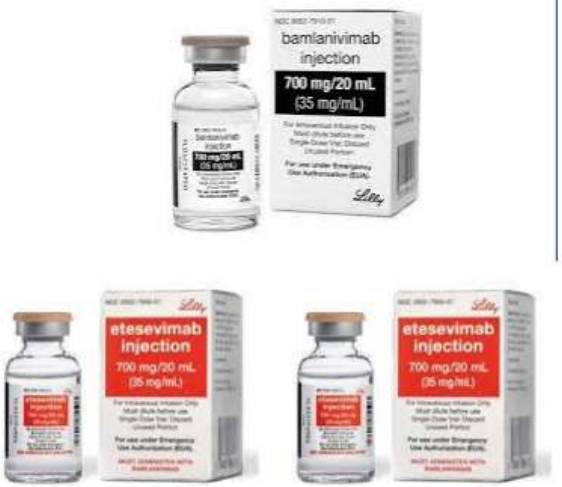
Drug[a]: Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as instructed below		
Size of Prefilled 0.9% Sodium Chloride Infusion Bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL	310 mL/hr	60 minutes

[a] 700 mg of bamlanivimab and 1,400 mg of etesevimab are added to the same infusion bag and administered together as a single intravenous infusion.

Table 2: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion in Patients Weighing Less Than 50 kg

Drug[a]: Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total 60 mL to an infusion bag and administer as instructed below		
Size of Prefilled 0.9% Sodium Chloride Infusion Bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes

1 Patient Course of bamlanivimab/etesevimab



Notes for Eli Lilly: BAMLANIVIMAB MUST BE ADMINISTERED TOGETHER WITH ETESEVIMAB AFTER DILUTION BY INTRAVENOUS (IV) INFUSION ONLY. ***Note: not all 50mL & 100mL saline bags will allow addition of 60mL of bam / ete – ensure bag allows for mixing***

45

http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf

For full dosage and administration information, please see the Fact Sheet for Healthcare Providers at

http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf