HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI PALI MOMI STRAUB WILCOX

CREATING A HEALTHIER HAWAIʻI

HPH Summary - FDA EUA of Bamlanivimab

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Indications and Usage	The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are ≥12yo and ≥40kg, and who are at high risk* for progressing to severe COVID-19 and/or hospitalization. *High risk is defined as patients who meet at least one of the following criteria: 1. BMI ≥35 2. CKD 3. DM 4. Immunosuppressive disease or currently receiving immunosuppressive treatment 5. ≥65 years of age 6. Are ≥55 years of age and have: - CV disease, - Hypertension, or - COPD or other chronic respiratory disease. 7. Are 12-17 years of age and have: - BMI ≥85th percentile for their age and gender based on CDC growth charts (https://www.cdc.gov/growthcharts/clinical_charts.htm), - Sickle cell disease, - Congenital or acquired heart disease, - Neurodevelopmental disorders (i.e., cerebral palsy), - A medical-related technological dependence (i.e., tracheostomy, gastrostomy, or PPV not related to COVID-19), or - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control. Bamlanivimab is 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.
Dosage, Administration, Monitoring	May only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate EMS as necessary. 700mg IV x 1 over at least 60 minutes. Administer as soon as possible after positive SARS-CoV-2 viral test and within 10 days of symptom onset. Use PVC infusion set containing 0.20/0.22 micron in-line PES filter. Once infusion is complete, flush line to ensure delivery of entire dose.

	Clinically monitor patients during infusion and for at least 1 hour after infusion is complete.
Special Populations	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. Renal Impairment. Not eliminated in urine, thus renal impairment not expected to affect exposure of bamlanivimab. Hepatic Impairment. Patients with mild hepatic impairment had 20% higher clearance than patients with normal hepatic function (not expected to be clinically meaningful). Not studied in patients with moderate to severe hepatic impairment. Geriatric Use. No difference in pharmacokinetics (PK) in geriatric patients compared to younger patients. Pediatric Use. Safety and efficacy not studied in pediatric patients. Dosing for patients ≥12yo and ≥40kg is based on PK modeling. Pregnancy. There is 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 potential benefit > potential risk for the mother and fetus. Lactation. No available data on presence of bamlanivimab in human or animal milk, effects on breastfed infant, or effects on milk production. Maternal IgG is known to be present in human milk. Consider benefits of breastfeeding along with mother's clinical need for bamlanivimab and potential adverse effects on the breastfed child from bamlanivimab or underlying maternal condition.
Contraindications	None
Warnings/ Precautions, Adverse Reactions	There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported. Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions There is potential for serious hypersensitivity reaction, including anaphylaxis, with administration of bamlanivimab. If s/sx of a clinically significant hypersensitivity reaction or anaphylaxis occurs, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. S/Sx of infusion-related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritis, myalgia, dizziness. If an infusion-related reactions occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.

Drug Interactions	Bamlanivimab is not renally excreted or metabolized by CYP P450 enzymes. Therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP P450 enzymes are unlikely.
Dosage Form, Storage, Preparation	700mg/20ml preservative free, single dose vial. Store unopened vials in refrigerator (2-8C) in original carton. Do not freeze, shake, or expose to direct light. Do not expose to direct heat. Dilute bamlanivimb 700mg in total volume 200ml NS. Administer immediately after mixing. If immediate administration is not possible, store diluted solution for up to 7h at room temp (including infusion time) or 24h in the refrigerator. If refrigerated, allow 20 min to equilibrate to room temp prior to administration.

Mandatory EUA Requirements for Bamlanivimab Administration:

1. Treatment of 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, and who are at high risk for progressing to severe COVID-19 and/or hospitalization *[see Limitations of Authorized Use]*.

2. 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:
   a. Given the "Fact Sheet for Patients, Parents and Caregivers",
   b. Informed of alternatives to receiving authorized bamlanivimab, and
   c. Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

3. Patients with known hypersensitivity to any ingredient of bamlanivimab must not receive bamlanivimab.

4. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and 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 treatment under Emergency Use Authorization (EUA)" in the description section of the report.

Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- 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 (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form

- Submitted reports should include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the statement “Bamlanivimab treatment under Emergency Use Authorization (EUA)”

*Serious Adverse Events are defined as:
• death;
• a life-threatening adverse event;
• inpatient hospitalization or prolongation of existing hospitalization;
• a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
• a congenital anomaly/birth defect;
• a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

5. The prescribing health care provider and/or the provider’s designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of bamlanivimab.

6. 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
Phone: 1-855-LillyC19 (1-855-545-5921) to report adverse events.

The full FDA EUA Fact Sheet for Healthcare Providers may be accessed at:
https://www.fda.gov/media/143603/download.

Reference:
1. FDA EUA Bamlanivimab Fact Sheet for Health Care Providers. Available at: https://www.fda.gov/media/143603/download. Accessed November 11, 2020.