COVID-19 Monoclonal Antibodies: Bamlanivimab Information for Providers

What is Bamlanivimab?

Bamlanivumab (formerly LY-CoV555) is a neutralizing human IgG-1 monoclonal antibody to SARS-CoV-2 spike protein which binds and blocks spike protein interaction with human ACE2 receptor thus preventing cellular entry of virus.

Evidence for Effectiveness and Safety

Data supporting emergency use authorization (EUA) approval for Bamlanivimab were based on the BLAZE-1 phase 2 clinical trial (Chen et al., *NEJM* Oct 2020). Non-hospitalized patients with mild-moderate COVID-19 were randomized to one of three ascending doses of bamlanivimab or placebo.

The primary endpoint was change in SARS-CoV-2 viral load from baseline to day 11, and showed that the intermediate bamlanivimab dose achieved statistically superior viral load decline vs. placebo. No difference was observed for the low and high doses of bamlanivimab vs. placebo.

A secondary endpoint was hospitalization or ER visit at day 28; these were lower for all bamlanivimab recipients (2%, n=5/309) vs. placebo (6%, n=9/156), though no formal statistical analysis was performed for this endpoint. Among high-risk individuals, the incidence of hospitalization or ER visits was 4% (n=4/95) for bamlanivimab and 15% (n=7/48) among placebo recipients.

There were no serious safety events observed among bamlanivumab recipients. The most common adverse effects were nausea, diarrhea, and dizziness. Overall, treatment was well tolerated.

Note: EUA status may be granted to investigational agents that are "possibly effective" and for settings in which no alternatives exist. EUA is not equivalent to FDA-approval and bamlanivumab is currently not considered standard of care. Clinical judgment should be exercised when deciding if bamlanivumab might be appropriate for a patient.

Dosing and Administration

- 700 mg IV infusion for one dose given over 1 hour, with at least 1 hour observation post-infusion.
- No dosage adjustments are indicated for renal or hepatic impairment.
- Note: currently the medication is provided at no cost; however, infusion facility fees may apply.

Criteria for Use

The FDA granted EUA for Bamlanivimab on November 9, 2020 for adults and children 12 years and older weighing at least 40kg with mild-moderate COVID-19 infection who are at high-risk for complications, and in whom treatment can be given within 10 days from the date of symptom onset. Please review the FDA Provider Fact sheet available at: https://www.fda.gov/media/143603/download

EUA high-risk criteria:

- BMI ≥ 35
- Chronic kidney disease
- Diabetes mellitus
- Immunocompromised state
- Age ≥ 65 years
- Age ≥ 55 years AND have cardiovascular disease, hypertension, or COPD/other chronic respiratory disease
- Age 12-17 years AND have BMI ≥ 85th percentile, sickle cell disease, congenital or acquired heart disease, neurodevelopmental disorders, medical-related technological dependence (e.g. tracheostomy), or asthma, reactive airway disease, or other chronic respiratory disease that requires daily medication for control

Bamlanivimab is NOT indicated for patients who:

- Are hospitalized due to COVID-19
- Require new oxygen therapy or an increase in baseline oxygen flow rate due to COVID-19 (SpO2 <90%)

How to Order

- Due to limited supply, a statewide random allocation process will be used to ensure equitable medication access. Please see schematic of the process on page 3.
- If considering bamlanivimab for a patient, please provide and review the FDA Fact Sheet for Patients, Parents, and Caregivers:
  - English: https://www.fda.gov/media/143604/download
  - Spanish:https://www.fda.gov/media/143645/download
  - Obtain verbal consent and ensure patient is capable and available to be infused within 10 days of symptom onset at a designated infusion site.
- Providers can request banlamivumab for their patient by submitting their information to the statewide random allocation system using this link: https://cdphe.redcap.state.co.us/surveys/?s=PX9LW9CEET
- Providers will be notified in real-time if their patient has been selected. The provider will then choose an infusion center where the patient would like to be scheduled.

uchealth

- If patient is selected, provide patient with the UCHealth Bamlanivumab Patient Instruction sheet.
- Providers must order the medication (in Epic, enter a Therapy Plan for banlamivumab infusion; see attached instructions).
- Providers outside of UCHealth or who do not use Epic may send infusion orders using the paper Bamlanivimab Order Form (see attached form), faxed to the appropriate infusion location.
- After the infusion site receives the medication order, the patient will be contacted for scheduling.
- *Note: UCHealth Anschutz Medical Campus cannot receive external orders at this time.*

UCHealth Locations for Bamlanivimab

University of Colorado Hospital
12605 E. 16th Avenue Aurora, CO 80045.
Phone: (720) 848-0000
Fax: infusionAMC@uchealth.org

Memorial Central Outpatient Infusion
1400 E Boulder St Suite 1370, Colorado Springs, CO 80909
Phone: (719) 365-5650
Fax: (719) 365-6274
Email: infusionMHC@uchealth.org

Poudre Valley Hospital COVID Infusion Clinic
1024 S Lemay Ave 1st floor, Fort Collins, CO 80524
Phone: (970) 495-8388
Fax: (970) 495-7627
Email: infusionPVH@uchealth.org

Yampa Valley Medical Center
1024 Central Park Drive, Steamboat Springs, CO 80487
Phone: (970)-870-1040
Fax: (970)-871-2315
Email: uchealthyvmc-pharmacy@uchealth.org

Important Information for Patients

- Bamlanivumab is an investigational drug that is available for people with COVID-19 who are early in their course of infection, have mild-moderate symptoms, do not require supplemental oxygen, and are at high risk for developing severe disease.
- Bamlanivimab is not FDA-approved and is not considered standard of care, but it may prevent hospitalization in people who are at high risk for severe disease.
- **In order to receive the infusion, eligible patients must 1) be selected in a statewide random allocation process (i.e. lottery), AND 2) be able to be scheduled at a designated infusion site. Due to limited drug supply and locations available for infusion, not all patients who are selected in the random allocation process will actually be able to receive the medication. Please set this expectation with patients.**
- Bamlanivumab is a one-time IV infusion that must be given at a designated infusion. The infusion takes 1 hour, followed by a 1-hour observation period. Patients should anticipate a total appointment time of about 3 hours.
- In preliminary studies, the medication was overall well-tolerated and seemed to be safe. The most common side effects were nausea, diarrhea, and dizziness. More serious adverse events are possible (e.g. anaphylaxis). Provide FDA fact sheet and review with the patient.

Other Helpful Talking Points With Patients

- This medication may or may not improve the symptoms related to COVID-19. The goal of this medication is to prevent the need for hospitalization or going to the ER.
- If selected, bamlanivimab should be given as soon as possible to be effective. After >10 days from symptom onset, it is unlikely to be beneficial.
- If this is a medication you would like to try, we can attempt to obtain the medication through the statewide random allocation process.
  - I will enter you into the state random allocation system and I will let you know if you are selected. If selected, you will be required to schedule the infusion before day 10 of your symptom onset.
- Even if you have been selected, you may not be able to receive the infusion if:
  - Your oxygen saturation is less than 90% when you arrive for your appointment,
  - There is no remaining supply,
  - More than 10 days have passed since your symptoms started.
- Whether or not you are able to get the infusion, you should continue isolation and supportive measures at home – rest, hydrate, etc. and let me know if you have worsening symptoms.
- If you receive the infusion, I would like to schedule a follow-up appointment with you 1-2 weeks afterward to see how you are doing. Please let me know if you experience any adverse events or require hospitalization.

Adverse Event Reporting

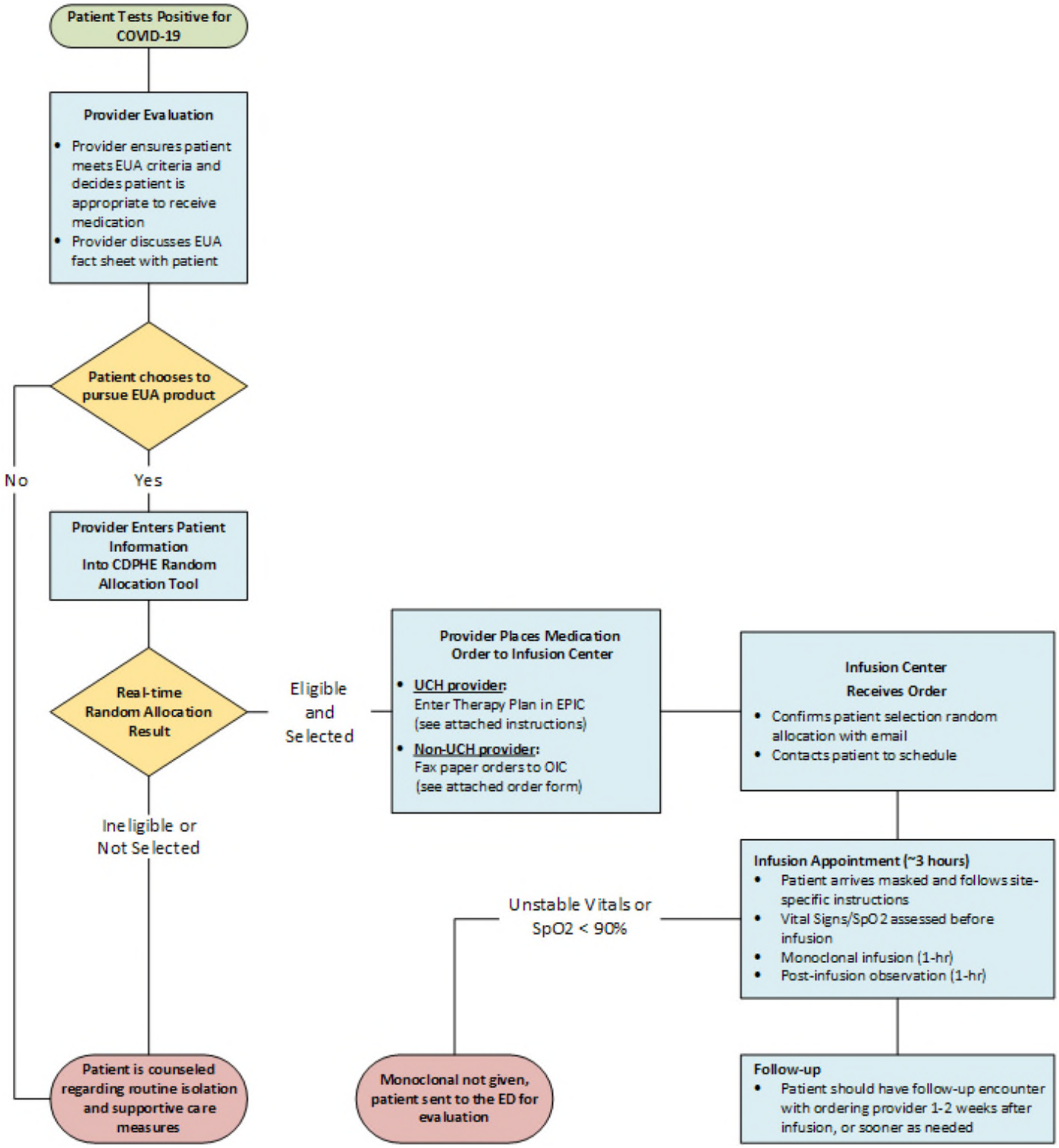
- The prescribing health care provider (and/or the provider's designee) is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event.
- Events may be reported with RL Solutions (In-system provider) or directly to FDA via Medwatch http://www.fda.gov/medwatch/report.htm

Other FAQs

- Can selection by the random allocation system be transferrable to others (e.g. family members)? No, selection is for individual patients only.
- Can bamlanivumab be given in the clinic or ED? No, it must be given at a designated infusion site. Additional sites around the state may become available in the future.
- If my patient cannot be scheduled at their preferred infusion site, can they try to be scheduled at another infusion site? Yes, they can contact another infusion site and inquire about availability.
- Are pregnant patients eligible? Currently, bamlanivumab will not be offered to pregnant patients in Colorado due to lack of safety data.
- Can patients who are hospitalized for another reason but who tested positive for COVID-19 get bamlanivumab? No, bamlanivumab cannot be offered to any hospitalized patients at this time.
- Can patients who are evaluated in the ED receive the medication? Patients seen in the ED who meet criteria and are deemed candidates for the medication can be entered in to the random allocation system, and if selected, the ED provider can place the infusion order to initiate the outpatient scheduling process. The medication will not be administered in the ED.

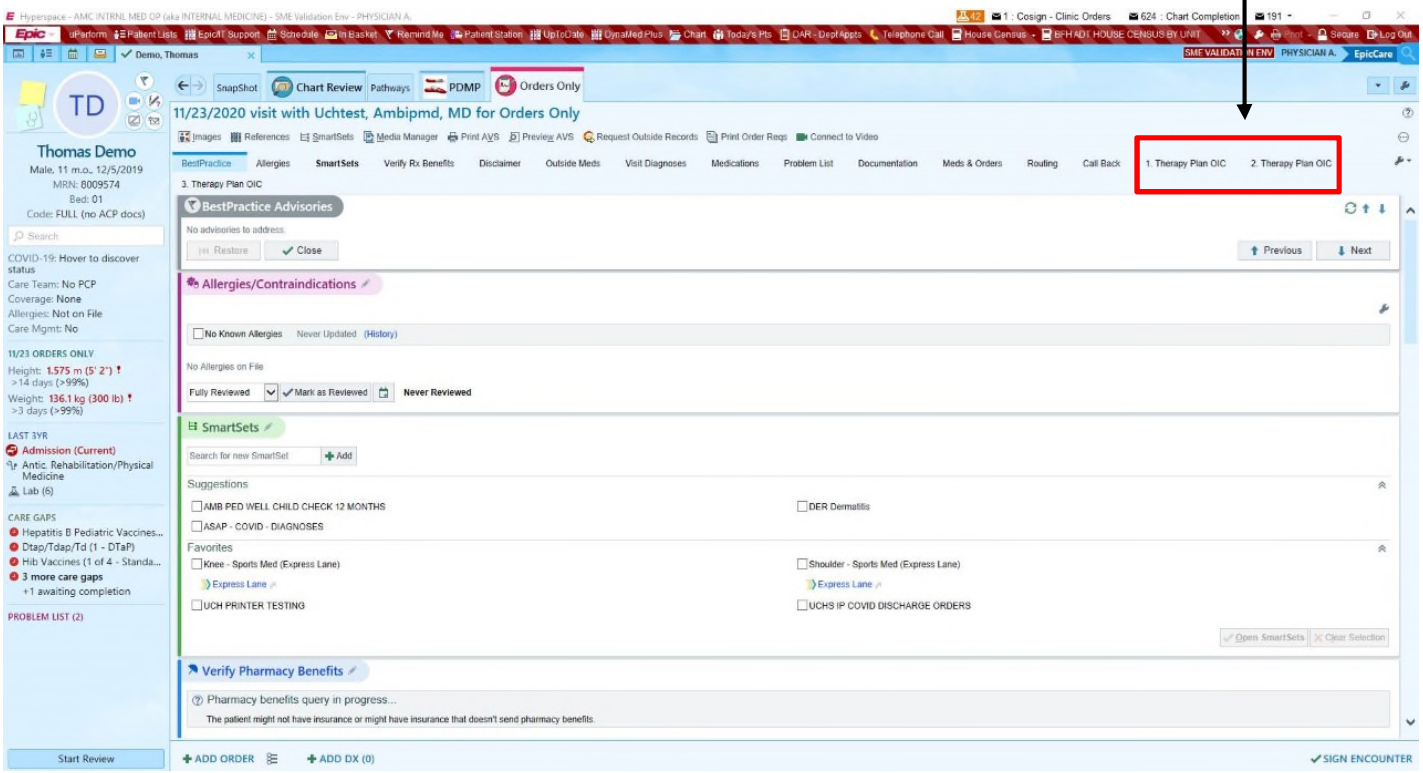
- Other questions? Please contact your regional Antimicrobial Stewardship representative for more information.

UCHealth Monoclonal Antibody Infusion Process



Epic Therapy Plan Infusion Order Instructions

1. Within the patient visit, select Therapy Plan in header (see screen shot below)
2. Search “Bamlanivimab infusion OIC”
3. Associate with correct diagnosis
4. Plan start date is today
5. Select corresponding treatment department
    a. North Region: PVH Infusion OP
    b. South Region: MHC Infusion OP
    c. Denver/Metro Region: AMC CTRC Infusion Unit
6. Select Assign Plan
7. Do not uncheck any orders or change timing
8. Dosing is defaulted, please answer order questions accordingly
9. Accept and Sign-Plan



uchealth

Patient Name: _____

MRN: _____

BAMLANIVIMAB EMERGENCY USE AUTHORIZATION (EUA) CARE ORDERS

Please note: This order is not a guarantee of treatment. Supply is limited and on allocation from the government. To provide a higher level of equity in distribution process, patients will be selected for treatment by random lottery.

Start Date: _____

Weight: _____kg Height: _____cm

Allergies: _____

Provider Communication:

GUIDELINES FOR PRESCRIBING:

1. Send FACE SHEET, copy of insurance card, and H&P or most recent provider progress note.
2. Ensure that patient meets **ALL** EUA criteria – check boxes below:
   - ☐ Positive SARS-CoV-2 viral test Date of positive test:_____
   - ☐ Within 10 days of symptom onset Date of symptom onset:_____
   - ☐ Not requiring supplemental oxygen due to COVID-19 (if on oxygen at baseline, no increase in oxygen flow rate due to COVID-19)
   - ☐ Weight at least 40 kg
3. Use is authorized for adults and children 12 years and older weighing at least 40kg with mild-moderate COVID-19 infection who are at high-risk for complications. High risk is defined as patients who meet AT LEAST ONE of the following criteria:
   - ☐ Have body mass index (BMI) **≥**35
   - ☐ Have chronic kidney disease
   - ☐ Have diabetes
   - ☐ Have immunosuppressive disease
   - ☐ Are currently receiving immunosuppressive treatment
   - ☐ Are **≥** 65 years of age
   - ☐ Are **≥** 55 years of age AND have cardiovascular disease, OR hypertension, OR chronic obstructive pulmonary disease / other chronic respiratory disease.

MEDICATION ORDER:

- Bamlanivimab 700 mg in sodium chloride 0.9 intravenous, 200 mL, ONCE, over 60 minutes

NURSING ORDERS:

1. Place peripheral IV or access existing indwelling venous access. Discontinue peripheral IV or de-access indwelling venous access at conclusion of the visit. If applicable, perform central line care per Hospital Policy and Procedure. If needed for sequential visits, may leave peripheral IV in place; change site every 72-96 hours. Staff may use appropriate Flush SmartSet to add medications. Sign using "Protocol Cosign Required" to send InBasket message to provider.
2. Perform vital signs including baseline SpO2 prior to infusion, at end of infusion, and at end of observation period prior to discharge.
3. After infusion is complete, flush the infusion line to ensure delivery of the required dose.
4. Clinically monitor patients for at least 1 hour after infusion is complete. If infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and supportive care.

HYPERSENSITIVITY MEDICATIONS:

1. I agree to allow infusion center staff to utilize the unit specific hypersensitivity/anaphylaxis protocol in the event of a hypersensitivity reaction.

By signing below, I affirm the following:

- ☐ I have read the FDA fact sheet at the following link for healthcare providers. https://www.fda.gov/media/143603/download
- ☐ The patient is aware of the risks/benefits of EUA bamlanivimab and agrees to treatment.
- ☐ The patient has/will be provided a copy of the FDA patient and family member fact sheet.
  - o English Patient/Caregiver Information - https://www.fda.gov/media/143604/download
  - o Spanish Patient/Cargiver Information - https://www.fda.gov/media/143645/download
- ☐ I acknowledge that any adverse event (AE) or death following initiation of bamlanivimab must be immediately reported pursuant to FDA requirements. UCHealth sites will use RL solutions to report AEs.

Provider Signature:_____ Date/Time:_____

Provider Name (Print):_____ Phone: _____ Fax: _____