# APPENDIX 4: BAMLANIVIMAB RESOURCE PACKET

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1.28.2021 Bamlanivimab EUA Update Summary

Please refer to the [Updated EUA](#) for bamlanivimab.

3 Key Updates:

1. Dose Preparation and Administration Instructions (Section 2.4) - provides updated **minimum infusion times** based on size of infusion bag used.
   - Facilities may decrease infusion time by mixing in a smaller saline bag as the administering RN feels comfortable. Gravity poles may be used if the rate is monitored.

   ![Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab](#)

   **Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab**

<table>
<thead>
<tr>
<th>Size of prefilled 0.9% Sodium Chloride infusion bag</th>
<th>Maximum Infusion Rate</th>
<th>Minimum infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL</td>
<td>270 mL/hr</td>
<td>16 minutes</td>
</tr>
<tr>
<td>100 mL</td>
<td>270 mL/hr</td>
<td>27 minutes</td>
</tr>
<tr>
<td>150 mL</td>
<td>270 mL/hr</td>
<td>38 minutes</td>
</tr>
<tr>
<td>250 mL</td>
<td>270 mL/hr</td>
<td>60 minutes</td>
</tr>
</tbody>
</table>

   *700 mg of bamlanivimab (20 mL) is added to an infusion bag and administered as a single intravenous infusion.*

2. **Warning: Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions** (Section 5.1) - addition of new symptoms.
   - Signs and symptoms of infusion-related reactions/anaphylaxis include:
     - Fever, HA, weakness, chills, fatigue, diaphoresis, nausea, myalgia, hypertension, throat irritation, throat closing sensation, angioedema, rash/urticaria, pruritus, SOB, bronchospasm, arrhythmia, chest pain or discomfort, altered mental status, hypotension, and reduced oxygen saturation.
     - Please refer to the [CDC on Early Recognition of Anaphylaxis](#).
     - For suspected anaphylaxis, first line treatment is an Epipen injection or 0.3-0.5 mg (1 mL of 1:1000 which is 1mg/mL) epinephrine IM in the outer thigh Q 10-15 minutes as needed.

3. **Warning: Clinical Worsening After Bamlanivimab** Administration (Section 5.2) - new warning added.
   - Clinical worsening after administration of bamlanivimab has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to bamlanivimab use or were due to progression of COVID-19.
MEMORANDUM

Date: January 4, 2020

To: Chief Medical Executives
Chief Physician and Surgeons
Pharmacists In Charge
Primary Care Providers

From: Renee Kanan, MD, MPH, FACP Originally Signed by
Deputy Director, Medical Services

Subject: BAMLANIVIMAB TREATMENT INFORMATION

The purpose of this memorandum is to provide information regarding monoclonal antibody treatment with Bamlanivimab for COVID-19 infection. Monoclonal antibody treatment can mitigate the severity of COVID-19 illness and avoid emergency department and hospital admissions during a time of critical community hospital bed shortages.

This memorandum reviews the eligibility criteria for treatment, updates the workflows for ordering Bamlanivimab to include on-site administration, and clarifies the requirements for medication storage and administration as well as the reporting of adverse drug events and medication errors.

ELIGIBILITY FOR BAMLANIVIMAB TREATMENT

Patients who are appropriate candidates for monoclonal antibody treatment should have positive results of a direct SARS-CoV-2 viral testing with PCR (preferred). However, a patient with a positive point of care (POC) test result awaiting PCR confirmation may also receive treatment if symptomatic and the pre-test probability of COVID-19 is high.

Patients should manifest mild to moderate symptoms that do not require supplemental oxygen. Also, patients should not have a history of previous infection with COVID-19 nor prior treatment with a monoclonal antibody for COVID-19.

To qualify for treatment, patients should have one of the covered conditions under the Emergency Use Authorization (EUA) that are prioritized in the tiers noted below.

Tier 1 patients are age 65 years or older, and/or have a BMI of 35 and/or require skilled nursing/long-term care.

Tier 2 patients have diabetes mellitus, chronic kidney disease, and/or an Immunosuppressed condition or prescribed an immunosuppressant medication.

Tier 3 patients are age 55 years or older and have cardiovascular disease, hypertension (HTN), and/or chronic obstructive pulmonary disease (COPD)/other chronic respiratory diseases.
Patients with severe disease defined as those who have SpO2 <94% on room air, respiratory rate >30 breaths/min, or lung infiltrates >50% or requiring supplemental oxygen should not receive monoclonal antibody treatment but instead be considered for transfer to higher levels of care.

**HOW TO ORDER THE MONOCLONAL ANTIBODY TREATMENT: WORKFLOW SUMMARY**

The provider should determine eligibility and discuss risks and benefits using effective communication and have the patient sign the consent. [Informed Consent Form 7000-1](#)

The patient should also be given the patient the Lilly Fact Sheet for patients that is language appropriate. [Fact Sheet for Patients - English](#) or [Fact Sheet for Patients - Spanish](#)

The provider should complete the Monoclonal Antibody (MCAB) Treatment Order PowerForm, which is the same PowerForm for on-site (preferred) or off-site administration orders.

**For on-site administration**, a “Consult to” for bamlanivimab order will be automatically placed through the PowerForm. A separate pharmacy order for bamlanivimab must be placed.

If a patient must be sent offsite, choosing the offsite option will generate a “Referral to” order for Immunology.

Please refer to the attached “Updated Instructions on How to Order Monoclonal Antibody Treatment for your Patients” for details.

**BAMLANIVIMAB STORAGE AND ADMINISTRATION**

Bamlanivimab must be refrigerated at 2°C to 8°C (36°F to 46°F) immediately after receipt of the shipment and kept in the original carton to protect from light. It should not be frozen, shaken, or exposed to direct light or heat.

Appropriate space should be identified to prepare and administer the infusions. Emergency medical supplies and medications should be readily available to respond to allergic reactions.

A hood or compounding facility is not needed. Nursing will give the treatment at the bedside in the areas designated for patients in isolation requiring this treatment.

Administration of Bamlanivimab does require a 0.20/0.22 micron polyethersulfone (PES) in-line or add-on filter (not filter needles) but does not require an IV pump.

One vial, which is 20 mL (or 700 mg) of the drug should be drawn up and diluted into a 250 mL bag of normal saline for a total of 270 mL infused over 60 minutes. The bag should be inverted but not shaken.

The medication should be administered immediately after diluting and infused over 60 minutes. If infused without an IV pump, administer via gravity with an in-line flow regulator and visually time/monitor the rate.
After the infusion is completed, the patient should be monitored for an additional 60 minutes for any adverse reactions.

For patients who initially consent but change their minds and decline at the time of the infusion, the refusal should be documented on the Medication Administration Record (MAR) in Cerner.

Refer to the attached “Bamlanivimab Supply Checklist and Administration Instructions Summary” and the most recently updated EUA containing detailed drug product information.

REPORTING ADVERSE EVENTS and ERRORS

Adverse events and errors must be reported. The prescribing healthcare provider and/or the provider’s designee is responsible for mandatory reporting and responding to FDA information requests for all medication errors and serious adverse events potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event.

The adverse event reports are submitted to FDA MedWatch using one of the following methods:

- Complete and submit the report online (for more information, see FDA Medwatch), or
- Use a postage-paid Form FDA 3500 and return it 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 unique identifiers, and in the field name “Describe Event, Problem, or Product Use/Medication Error,” include the statement “Bamlanivimab treatment under Emergency Use Authorization (EUA).”

Also, 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.

QUESTIONS

For pharmacy questions, please contact:
Dr. Tracy Nagao, 916-379-1675, Tracy.Nagao@cdcr.ca.gov

For workflow questions, please contact:
Dr. Amy Krawiec, 916-691-3046, Amy.Krawiec@cdcr.ca.gov

Thank you for your continued commitment to prevent and contain COVID-19 illness among staff and residents.

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1 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.
ATTACHMENTS:
- Monoclonal Antibody Emergency Use Authorization – Review of Clinical Indications and Allocation in California Slides and Bamlanivimab Workflow Slides (Attachment A)
- Updated Instructions on How to Order Monoclonal Antibody Treatment for Your Patients (Attachment B)
- CDCR Form 7000-1 Informed Consent for Monoclonal Antibody Treatment (Attachment C)
- Bamlanivimab Supply Checklist and Administration Instructions Summary (Attachment D)

RESOURCES:
- FDA – EUA of Bamlanivimab for COVID-19 fact sheet for providers
- FDA – EUA of Bamlanivimab for COVID-19 fact sheet for patients, parents, and caregivers
- Lilly Bamlanivimab Antibody Playbook
- Click here for helpful manufacturer training information and training videos.

cc: Joseph Bick, MD, Director, Health Care Services
    Barbara Barney-Knox, Deputy Director, Nursing Services
    Jackie Clark, Deputy Director, Institution Operations
    Regional Health Care Executives
    Regional Deputy Medical Executives
    Regional Chief Nurse Executives
    Headquarters Deputy Medical Executives
    Assistant Deputy Medical Executives
    Chief Executive Officers
    Institution Chief Nurse Executives
    Chief Support Executives
    Greg Doe, Statewide Pharmacy Chief
    Linda Maclachlan, Pharmacy Services Manager
    Tracy Nagao, Pharmacy Services Manager
    Niko Laparan, Pharmacy Services Manager
HOW TO ORDER MONOCLONAL ANTIBODY TREATMENT FOR YOUR PATIENTS

12.31.20

Once the patient is deemed an appropriate candidate for monoclonal antibody (MCAB) treatment:

1. Find the forms on-line or have them printed out and available to providers

**Lifeline location for Provider Forms**

[Image of Lifeline location for Provider Forms]

**COVID-19**

This page is a collection of CDCR/CCHCS produced information as well as external resources designed to provide guidance on the clinical response to the novel coronavirus COVID-19.

- Internal Resources
- CDC/External
- Patient Ed
- Newsletters

- What's New
- Memos
- Clinical Guidance (15)
2. Give the patient a copy of the patient education EUA Fact Sheet for Patients.

3. Discuss the investigational FDA status, risks, benefits and alternatives with the patient and have the patient sign the consent form to agree to or decline the treatment.
   a. If the patient is going off-site for the infusion, print out or email two copies of the consent form; one to send to the infusion center, and one copy for scanning into the EHRS. If receiving the infusion at CDCR, have the patient sign and then have it scanned into the EHRS.

FOR ON-SITE ORDERS:

Fill out the Adhoc Powerform (Prescreening ADHOC FORM)

Access from the Banner Bar- Same form for on-site and off-site orders.

When feature available, choose "On-site". Choosing on-site on the form will automatically generate a "Consult to" order for the treatment.

ALSO a pharmacy order for the bamlanivimab must be placed.
Find “Provider Documentation” and then “MCAB Treatment Prescreening and Order Form” (eRFS and appointment order combination) as below:
Click “CHART and fill out the form:

Note: On and Off site choice feature not live yet
When done sign by clicking the CHECK MARK in the upper left corner

**The appointment order will only fire automatically if all the qualifying conditions are met.**

You can see or modify your form by using form browser (double click on your form):

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**FOR OFF-SITE ORDERS:**

a. Fill out the Infusion Center Referral Form if going off-site for the infusion. Email or print out 2 copies; one to send to the infusion center and one for scanning into the EHRS.

b. Fill out the quick **ADHOC Powerform and APPOINTMENT ORDER form**
   – Access from the Banner Bar. Same form for on-site and off-site orders.

c. When feature live, choose Off-site (automatically generates "Referral To" order)
This is a record of my decision on receiving the medicine bamlanivimab to treat my SARS-CoV-2 (COVID-19) infection.

What is bamlanivimab?

It is an investigational medicine used to treat COVID-19 in non-hospitalized adults with mild to moderate symptoms who are at high risk for developing severe COVID-19 symptoms and/or the need for hospitalization. It is a laboratory man-made antibody against the COVID-19 causing virus. This is not a medication just for California Department of Corrections and Rehabilitation patients; it is being used outside of institutions for the same reasons.

You have the following conditions that lower your immune system (check boxes): □ Age 65 and older, □ Weight (corrected for height as Body Mass Index–BMI) in the obese category, □ Chronic kidney disease, □ Diabetes, □ Other immunocompromising condition or medicine: _________________________. A research study has shown that bamlanivimab may help people with these conditions avoid getting sick enough to be hospitalized if given early in the infection. That is why it is being offered to you. If too much time passes or your medical condition changes, you may not qualify for the drug later on.

Is this medication approved by the Food and Drug Administration (FDA)?

This medication is considered “investigational,” meaning that it has NOT yet been fully tested and is NOT approved by the FDA as effective and safe. However, while that testing and approval process goes on, the FDA has issued an Emergency Use Authorization for this medication, which means it is approved for use in certain patients at risk for severe COVID-19 illness under certain circumstances. Emergency authorization for bamlanivimab was given because the FDA thinks it is reasonable to believe that the drug may prevent you from getting severely sick and that it is unlikely to harm you.

What are the important possible side effects of bamlanivimab?

Possible side effects of bamlanivimab:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your health care provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Very rarely, a person can have a very severe allergic reaction that could lead to death.

- Brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site (these are side effects of getting any medicine by vein).

- It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of the SARS-CoV-2 virus (virus that causes COVID-19). Similarly, bamlanivimab may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your health care provider if you have any questions.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied, so it is possible that all of the risks are not known at this time. Tell your health care provider right away if you have any side effect that bothers you or does not go away.
Do I have to take bamlanivimab?
It is completely your choice to be treated or not with bamlanivimab. There is not enough information to actively recommend this medicine to you, but we do believe it should be offered. If you decide not to receive bamlanivimab or stop it at any time, you will still receive all the current standard care that you need for COVID-19 illness.

If I agree, how will I receive bamlanivimab?
- Bamlanivimab is given to you in one dose, one time, through a vein (intravenous or IV, where a small sterile needle goes into the vein to allow the liquid to drip into the bloodstream) and takes a full hour to go in. After the infusion, the needle is removed, and you will be watched for at least another 1 hour.
- You will need to go out to a hospital or clinic that is offering this treatment.

Signatures

____(Patient’s initials) I have received the manufacturer’s Fact Sheet for Patients, Parents, and Caregivers.

____(Patient’s initials) I understand that I can either consent to or refuse this medication and that if I do not consent to receive it, no one will enforce any penalty or punishment or loss of benefits or withhold future new medicines as a result of not consenting, and I will still receive all other appropriate medical care.

____(Patient’s initials) I understand that this medication is available to me now because I meet the eligibility criteria included in the FDA’s Emergency Use Authorization and that it may not be available to me later if my condition changes. According to the FDA criteria, it is reasonable to believe this medication may help me and is unlikely to harm me. This does not mean that my current health status is considered an “emergency,” and standard medical care for COVID-19 will be given whether or not I agree to take bamlanivimab.

My signature below indicates that I have reviewed the above with my provider and had the chance to have any of my questions answered. **I agree to have bamlanivimab treatment.**

Patient Signature: ___________________________ Date/Time: ___________________________

Provider Signature: ___________________________ Date/Time: ___________________________

Provider Printed Name: ___________________________

My signature below indicates that I reviewed the above with my provider and had the chance to have any of my questions answered. **I do NOT agree to have bamlanivimab treatment.**

Patient Signature: ___________________________ Date/Time: ___________________________

Provider Signature: ___________________________ Date/Time: ___________________________

Provider Printed Name: ___________________________

1. Disability Code:
- TABE score ≤ 4.0
- DPH □ DPV
- LD □ DPS
- DNH □ DDP
- Not Applicable

2. Accommodation:
- □ Additional time
- □ Equipment □ SLI
- □ Louder □ Slower
- □ Basic
- □ Transcribe
- □ Other*

3. Effective Communication:
- □ Patient asked questions
- □ Patient summed information
- Please check one:
- □ Not reached*
- □ Reached

*See chrono/notes

CDCR #: ___________________________

Last Name: ___________________________

First Name: ___________________________

DOB: ___________________________

Comments: ___________________________
Bamlanivimab Supply Checklist and Administration Instructions Summary

ADMINISTRATION LOCATION:
Setting equipped to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS) as necessary, such as the TTA.

SUPPLY CHECKLIST:
- 250 ml 0.9% NaCl IV saline bag
- IV infusion tubing
- 18 gauge sterile needle X 2
- Alcohol wipes
- 0.2-0.22micron polyethersulfone (PES) in-line filter
- IV insertion supplies
- 20 mL syringes X 2
- Bottle of 700mg/20mL bamlanivimab
- Infusion pump or gravity IV fluids hanger
- Anaphylaxis and allergic reaction supplies:
  - Crash cart, IV access, IV fluids, Benadryl or other H1 antihistamine (IV and oral), albuterol, oxygen, epinephrine ampules or vials (pre-filled syringe or auto-injector if possible). See Up to Date on Treatment for anaphylaxis.

PREPARATION:
Bamlanivimab solution for infusion should be prepared by a qualified healthcare professional using the aseptic technique:
- Remove one bamlanivimab vial (700 mg/20 mL) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake the vial.
- Inspect bamlanivimab visually for particulate matter and discoloration.
- Bamlanivimab is a clear to opalescent and colorless to slightly yellow to slightly brown solution.
- Withdraw 20 mL bamlanivimab from one 20 mL vial and inject into an infusion bag containing 250 mL pre-filled 0.9% Sodium Chloride Injection (see Table 1).
- Discard any product remaining in the vial.
- Gently invert IV bag by hand approximately 10 times to mix. Do not shake.
- This product is preservative-free, and therefore, the diluted infusion solution should be administered immediately.

ADMINISTRATION:
Bamlanivimab infusion solution should be administered by a qualified healthcare professional.
- Gather the materials for infusion:
  - Polyvinyl chloride (PVC) or polyethylene (PE)-lined PVC infusion set
  - Use of an in-line or add-on 0.20/0.22 micron polyethersulfone (PES) filter is strongly recommended.
• Attach the infusion set to the IV bag.
• Prime the infusion set.
• Administer the entire infusion solution in the bag via pump or gravity over at least 60 minutes (see Table 1).
• Once the infusion is complete, flush the infusion line to ensure delivery of the required dose.
• Clinically monitor patients during administration and observe patients for at least 1 hour after the infusion is complete.
• If the infusion must be discontinued due to an infusion reaction, discard any unused product.
  o The use of closed system transfer devices (CSTDs), elastomeric pumps, and pneumatic transport with bamlanivimab has not been studied.

TRAINING VIDEO:
Click [here](#) for training information and training videos.
Bamlanivimab Roll Out
Studies – BLAZE-1 RCT trial showed a reduction of **75% in hospitalizations** from 6.3% to 1.6%. However, the overall numbers were quite small (just over 300 patients in the treatment arm).

The Regeneron® (casirivimab/imdevimab) RCT trial showed a **58% reduction in hospitalizations** (4.3% to 1.8%) also had relatively small numbers (~800 patients).

Reassuringly, unpublished data from Mayo Clinic and its associated clinics have looked at ~**3000 patients** and have reportedly seen a **70% reduction in hospitalizations**.
<table>
<thead>
<tr>
<th>Description</th>
<th>Number doses</th>
<th>Number patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses available now</td>
<td>3834 doses available</td>
<td></td>
</tr>
<tr>
<td>Number of doses after this week’s allotment arrives</td>
<td>6184 doses soon available</td>
<td></td>
</tr>
<tr>
<td>Number of Patients who have received Bamlanivimab</td>
<td>166 doses used (4.3% of available)</td>
<td></td>
</tr>
<tr>
<td>Number of Patients who are currently infected &lt; 14 days who have EUA qualifying condition</td>
<td>1096 patients</td>
<td></td>
</tr>
<tr>
<td>Number of deaths with qualifying conditions since Bamlanivimab available 12/31/20</td>
<td>3 patients</td>
<td></td>
</tr>
<tr>
<td>Number of COVID positive patients who were/are hospitalized and have qualifying Bamlanivimab condition</td>
<td>22 patients (19 patients from 1/5-1/11)</td>
<td></td>
</tr>
</tbody>
</table>

We have 3 available doses for every 1 patient who currently qualifies!
FINDING YOUR PATIENTS THAT MAY BENEFIT FROM BAMLANIVIMAB

Sort by: “Active Cases” then “Days from first Positive Test” then MCAB = Qualifying Tier 1, 2, or 3

<table>
<thead>
<tr>
<th>Identification</th>
<th>Release</th>
<th>COVID Status</th>
<th>Days Since First Positive COVID Test</th>
<th>Death Status</th>
<th>MCAB Administration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISP ISP</td>
<td>V66835</td>
<td>Confirmed</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>SIC SIC</td>
<td>1234</td>
<td>Confirmed</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>CMC CMC</td>
<td>T01941</td>
<td>Confirmed</td>
<td>1</td>
<td>0</td>
<td>Tier 2</td>
</tr>
<tr>
<td>ISP ISP</td>
<td>P988386</td>
<td>Confirmed</td>
<td>1</td>
<td>0</td>
<td>Tier 3</td>
</tr>
</tbody>
</table>

MCAB = Qualifying Tier 1, 2, or 3
Finding your patients that may benefit from Bamlanivimab

Coming soon!

Green badge means that the patient qualifies for Bamlanivimab treatment

Report from the EHRS COVID-19 Results Page at the top of Powerchart
Bamlanivimab Roll Out

FILTERS ARE HERE

Flat in-line filters with extension sets were placed yesterday.

Nursing instructions are coming out soon.

Order via usual procurement and swap between facilities as needed.

Designed to eliminate particulate matter, bacteria and fungi. Has been given successfully at CDCR without filter and can be given without filter if aseptic technique can be assured.
Monoclonal Antibody Emergency Use Authorization – Review of Clinical Indications and Allocation in California

Sohrab Sidhu, MD, MPH
Medical Quality Officer
Office of the Medical Director

Many slides adapted from Operation Warp Speed Monoclonal Antibody Playbook
CCHCS Use of Monoclonal Antibodies in COVID-19

Disclosure

None of the faculty, planners, presenters, committee, or staff involved in planning the activity have any relevant financial relationships with commercial interests

December 17, 2020
• To ensure the webinar is free of disruptions, your lines have been MUTED upon entry. Please keep your phones and computer software on MUTE.

• Please utilize the chat function. It will be the primary method of communication. The Q&A session at the end of the presentation will be moderated via the Chat. This will allow everyone to hear the question and answer without disruption. Submit your questions during the talk.

• Please complete sign-in sheet and evaluation and forward to CMEReview@cdcr.ca.gov within the next two (2) business days.
Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to prevent progression of disease.

mAbs likely to be most effective when given early in infection.

Product delivered via single administration (e.g., IV infusion).

Early evidence suggested promise of mAb products in outpatient settings.
Emergency Use Authorizations (EUAs) for bamlilanivimab and casirivimab/imdevimab

1. Positive direct SARS-CoV-2 test (e.g., PCR, rapid antigen test)
2. As soon as possible after positive test, within 10 days of symptom onset
3. In patients at high risk
4. Provider reviews EUA fact sheet; patient/caregiver provided with EUA fact sheet
5. Administered in a setting where HCPs have direct access to medications to manage severe reactions
Emergency Use Authorizations
High-Risk Criteria

• All Patients (who meet at least 1 of the following criteria):
  • BMI ≥35
  • Chronic kidney disease
  • Diabetes
  • Immunosuppressive disease
  • Receiving immunosuppressive treatment
  • Age ≥ 65 years
  • Age ≥ 55 years AND have any of the following
    • Cardiovascular disease
    • Hypertension
    • COPD/other chronic respiratory disease

• Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:
  • BMI ≥85th percentile for age/gender
  • Sickle cell disease
  • Congenital or acquired heart disease
  • Neurodevelopmental disorders (e.g., cerebral palsy)
  • Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
  • Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control
mAb Clinical Indications

- Mild to moderate outpatient treatment
  - Not asymptomatic, not hospitalized and not requiring O2 (or increased baseline O2) due to COVID
  - High risk for severe illness including BMI ≥ 35, chronic kidney disease, diabetes, immunosuppression, or age ≥ 65 years. Additional criteria for ≥ 55 years and for people 12 – 17 years
- Treat early – within 3 days of positive test (median 4 days from symptom onset in clinical trial)
- Administered by intravenous (IV) infusion over 60 minutes
- Mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths

https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx
Bamlanivimab
Clinical Trials to Date

BLAZE-1 clinical trial [1]: 465 non-hospitalized adults
• Secondary analysis of hospitalization or ER visit:
  • Bamlanivimab: 1.6%
    (4.2% age > 65 or BMI > 35)
  • Placebo: 6.3%
    (14.6% age > 65 or BMI > 35)

ACTIV-3 clinical trial [2]: 326 hospitalized participants
• Bamlanivimab was discontinued as not beneficial

Casirivimab / Imdevimab Clinical Trials to Date

- Outpatient 2067 clinical trial - 799 non-hospitalized adults with mild to moderate COVID-19 symptoms
  - The primary study outcome was the change from baseline in viral load and the decline in viral load was significantly larger at day 7 with casirivimab/imdevimab treatment.
- Secondary analysis of hospitalizations or ER visit
  - Casirivimab/imdevimab: 1.8%
    - (2.6% with one risk factor for severe illness)
  - Placebo: 4.3%
    - (9.0% with one risk factor for severe illness)
- Hospitalized patient trial: Based on a potential safety signal and an unfavorable risk/benefit profile, enrollment of hospitalized patients requiring high-flow oxygen or mechanical ventilation was suspended. Hospitalized patients who require no or low-flow oxygen can continue to enroll in the trial.

[1] Fact Sheet for Health Care Providers - Emergency Use Authorization (EUA) of Casirivimab and Imdevimab. Available at: https://www.fda.gov/media/143892/download

Overall Safety Summary

Bamlanivimab

<table>
<thead>
<tr>
<th>Preferred term</th>
<th>Placebo N=156</th>
<th>Bamlanivimab 700 mg N=101</th>
<th>Bamlanivimab 2,800 mg N=107</th>
<th>Bamlanivimab 7,000 mg N=101</th>
<th>Total N=309</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>4%</td>
<td>3%</td>
<td>4%</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5%</td>
<td>1%</td>
<td>2%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Headache</td>
<td>2%</td>
<td>3%</td>
<td>3%</td>
<td>0%</td>
<td>2%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
<td>0%</td>
<td>2%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3%</td>
<td>1%</td>
<td>3%</td>
<td>1%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Casirivimab / Imdevimab

Infusion-related reactions of grade 2 or higher severity were reported in 1.5% of patients and included pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing.

One anaphylactic reaction has been observed with casirivimab/imdevimab. It resolved with treatment including epinephrine.
Bamlanivimab Two Phases of Allocation

• **Phase 1:** states and territories allocate bamlanivimab to hospitals and hospital-affiliated locations only

• **Phase 2:** states and territories allocate to outpatient facilities
  - Skilled Nursing Facilities and the PACE program
  - Urgent care clinics
  - State hospitals
  - State prisons
  - Community sites / temporary tents

Alternate site of care will need same core capabilities and supplies as typical site of administration

Skilled Nursing Facilities Prioritized for Bamlanivimab

SNFs are potentially an optimal non-hospital settings for bamlanivimab treatment as the vast majority of residents are:

• in the age group and medical condition group with the highest potential benefit
• tested frequently, resulting in early diagnoses
• physically residing at a location that can potentially provide an immediate infusion
• Program of All-Inclusive Care for the Elderly (PACE)
Figure. Example Allocation – Numbers of Doses are Included for Illustrative Purposes Only

Step 1: California Allocation
- California weekly allocation: 2,000 bamlanivimab doses
  2,000 casirivimab/imdevimab doses

Step 2: SNF and PACE Allocation
- Specialty Pharmacies that serve SNFs / PACE programs:
  1,000 bamlanivimab doses

Step 3: County Allocations
- MHOAC Allocation:
  1,000 bamlanivimab doses
  2,000 casirivimab/imdevimab doses

Step 4: Facility Allocations
- In-County allocations
  Casirivimab/Imdevimab
  • Acute care hospitals and affiliated settings
  Bamlanivimab
  • Community clinics / FQHCs
  • State hospitals
  • Prisons/Jails
  • Other non-hospital settings

Step 5: Unallocated Product
- Unclaimed doses to California Department of Public Health
mAb Allocations for California

- Week 1: 4,040 vials Bamlanivimab
- Week 2: 2,250 vials Bamlanivimab
- Week 3: 3,230 vials Bamlanivimab
  - And 2,328 doses Casirivimab/Imdevimab
- Week 4: 3,040 vials Bamlanivimab
  - And 2,160 doses Casirivimab/Imdevimab
- Week 5: 4,450 vials Bamlanivimab
  - And 1,240 doses Casirivimab/Imdevimab

- Weekly allocations expected
- 1 vial = 1 dose = 1 treatment course
- California Monoclonal Antibody Allocation (excel) - [Guidance Documents (ca.gov)](ca.gov) – under the “Other” section – updated weekly
Adverse Event Mandatory Reporting

• Clinical trials evaluating the safety of these mAbs are ongoing

• Completion of FDA MedWatch Form to report all medication errors and serious adverse events occurring during use of bamlanivimab and considered to be potentially related to bamlanivimab is mandatory and must be done by the prescribing healthcare provider and/or the provider’s designee. These adverse events must be reported within 7 calendar days from the onset of the event

• 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
Readiness Checklist: Administration of Outpatient mAbs under EUA

Allocate **dedicated space** and develop plan to **manage patient flow**
- Clear process for patients that are coming to clinical site including scheduling requirements
- Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines'
- Dedicated room available for treatment

Ensure **dedicated source of supplies**; which may be difficult to procure
- Needed infusion components obtained
  - Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications

Assign **sufficient personnel** to meet expected demand
- Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist
  - Likely need dedicated team to treat patients

Prepare for **drug administration** process
- Pre–visit: Clear treatment and monitoring plan developed for during infusion
- Treatment: 1-hour treatment and up 1-hour post-treatment observation
  - Emergency protocol defined for addressing potential infusion reactions or complications
- Post-treatment: Clear process for patient follow-up defined using telemedicine as possible

Ensure **process for reimbursement** in place (non-drug administrative costs)

Prepare for **reporting needs** for adverse events and record keeping
# Dosing and Characteristics (bamlanivimab)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>700mg in 200mL 0.9% NaCl IVPB over at least 60 minutes (PVC infusion set with 0.20/0.22 micron filter)</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Monitor during infusion (no specified interval) and for 1 hour after completion</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>700mg/20ml vial – store in original carton to protect from light at 2-8°C; do not freeze, shake, or expose to direct light or heat</td>
</tr>
<tr>
<td>Stability Once Reconstituted</td>
<td>24 hours at 2-8°C OR up to 7 hours (including infusion time) at room temperature</td>
</tr>
</tbody>
</table>
| Required Chart Documentation     | - That patient/caregiver has been given fact sheet  
- Informed patient of treatment alternatives to bamlanivimab  
- Inform patient that bamlanivimab is an unapproved drug used under the auspices of EUA                                                  |
| Adverse Effects (in ≤3% of pts)  | Hypersensitivity reactions, nausea, diarrhea, dizziness, headache, pruritis, vomiting                                                        |
Unique challenges to bamlanivimab administration

- Appropriate healthcare staffing
- Training and equipment to accommodate IV infusion
- Additional prep time
Infusion supplies for bamlanivimab
Infusion setup for bamlanivimab

- Infusion with IV Pump
- OR Gravity IV bag hanger
- 0.2/0.22 µm filter
- Online filter

Gravity Infusion
- Utilize flow limiting device or
- Calculate drip rate*

Drip Rate Table
*See pg.18 of OWS Playbook

Solution Stability
- 7 hours at room temperature, including infusion time
- 24 hours at 2-8°C
Bamlanivimab Administration General

<table>
<thead>
<tr>
<th>Product</th>
<th>Eli Lilly bamlanivimab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>Begin with 250 ml normal saline bag</td>
</tr>
<tr>
<td></td>
<td>Remove 70 ml</td>
</tr>
<tr>
<td>Add</td>
<td>20 ml bamlanivimab</td>
</tr>
<tr>
<td>Final Volume in IV Bag</td>
<td>200 ml</td>
</tr>
</tbody>
</table>

Dilute at bedside immediately before administration.

Do not shake.

Administer over 60 minutes. Watch flowrate if using gravity.

Monitor patient for another 60 minutes after infusion.
# General Guidelines for Regeneron and Lilly mAbs

<table>
<thead>
<tr>
<th>Product</th>
<th>Eli Lilly bamlanivimab</th>
<th>Regeneron casirivimab (Regn 10933) plus imdevimab (Regn 10987)</th>
</tr>
</thead>
</table>
| Start   | - Begin with 250 ml normal saline bag  
- Remove 70 ml | - Begin with 250 ml normal saline bag  
- Remove 20 ml |
| Add     | - 20 ml bamlanivimab | - 10 ml of casirivimab (Regn 10933)  
- 10 ml of imdevimab (Regn 10987) |
| Final Volume in IV Bag | - 200 ml | - 250 ml |

**Notes for Regeneron:**

casirivimab and imdevimab come in two vial sizes, both the same concentration (120 mg/ml):

- 2.5 ml vial
- 11.1 ml vial

CASIRIVIMAB AND IMDEVIMAB MUST BE ADMINISTERED TOGETHER AFTER DILUTION BY INTRAVENOUS (IV) INFUSION ONLY.
Resources (1)

California SARS-CoV-2 Crisis Care Guidelines


California Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19

MedWatch

• Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
• Use 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
Resources (2)

California Monoclonal Antibody Allocation (excel) - [ Guidance Documents (ca.gov) ] – under the “Other” section – updated weekly

Bamlanivimab

- Bamlanivimab EUA Letter of Authorization. U.S. Food and Drug Administration. Available at [https://www.fda.gov/media/143602/download](https://www.fda.gov/media/143602/download)
- Frequently asked Questions on the Emergency Use Authorization for Bamlanivimab. U.S. Food and Drug Administration. Available at [https://www.fda.gov/media/143605/download](https://www.fda.gov/media/143605/download)
- [Fact Sheet for Health Care Providers Emergency use Authorization (EUA) of Bamlanivimab. U.S. Food and Drug Administration](https://www.fda.gov/media/143606/download)

Casirivimab / Imdevimab

- Frequently asked Questions on the Emergency Use Authorization for Casirivimab + Imdevimab. Available at [https://www.fda.gov/media/143894/download](https://www.fda.gov/media/143894/download)
- [Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Casirivimab and Emdevimab (fda.gov)](https://www.fda.gov/media/143896/download)
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• Heidi Bauer (CCHCS)
• John Redd (ASPR)
• Kim McCoy Wade (CDA)
• Karen Mark (DHCS)
Questions?

- Please complete and return evaluations and sign in sheets within 2 days to: CMEReview@cdcr.ca.gov

November 16, 2020
BAMLANIVIMAB WORKFLOWS
CDCR Workflow for Bamlanivimab Infusions

WHERE TO ALLOCATE THE LIMITED SUPPLY:

1. Quality Management (QM) prepares a weekly report that is sent to the CA Dept. of Public Health (CDPH) identifying each institution’s:
   • SARS-CoV-2 Positivity rate
   • # of patients that would have qualified
   • Actual use in the past week 2.

2. ON-SITE NOW AVAILABLE: CDPH allocates to CCHCS directly - Started at certain facilities and expanding quickly. Increases access to the treatment.

3. CDPH allocates to local agreeing hospitals. Currently:
   • Tri-City Medical Center
   • San Joaquin General Hospital
   • Riverside University Hospital System
   • Salinas Valley Memorial Health Care System
   • Palmdale Regional Hospital
CDCR Workflow for Bamlanivimab Infusions

PHASE IN APPROACH IF OFF-SITE AND ON-SITE NOT STARTED YET: If the patient is not near a hospital that is giving infusions, the treating provider may attempt to arrange with Utilization Management (UM).
CDCR Workflow for Bamlanivimab Infusions

WHO TO GIVE IT TO:

For now, the top tier patients qualifying for treatment are:

• Never used MCAB treatment for COVID-19 before, Symptomatic and have their First Infection AND
  o Age >65, OR
  o BMI >35
  o Especially if require skilled nursing/long-term care, and at risk for severe COVID-19

Followed by patients with:

• Diabetes Mellitus (DM)
• Chronic kidney disease (CKD)
• Immunosuppressed condition or on immunosuppressant medications

Followed by patients with:

• Age ≥55 and cardiovascular disease, hypertension (HTN), or chronic obstructive pulmonary disease (COPD)/other chronic respiratory diseases

Note: We will be looking at the COVID risk score. If it correlates strongly with these categories, we will use the COVID registry risk score for convenience.
### COVID-19

This page is a collection of CDC/CHCS produced information as well as external resources designed to provide guidance on the clinical response to the novel coronavirus, COVID-19.

#### What's New
- [Bamlanivimab EUA Manufacturer Fact Sheet for Health Care Providers](#)
- [COVID-19 and Seasonal Influenza: Interim Guidance for Health Care and Public Health Providers](#)
- [Health Net Provider List](#)
- [MSA Advantage 1000 Respirator Cleaning and Disinfecting Instructions for Covid-19](#)
- [Regional Hospital List](#)
- [Sofia2 Start-Up Calibration Configuration Guidance 2020.07.23](#)
CDCR Workflow for Bamlanivimab Infusions

Reminder: Do NOT give to severe disease, oxygen-requiring patients, or those whose chronic oxygen use is increased.

HQ will send the QM analysis of the potential number of qualifying residents out to get an idea of the volume and location of the patients at each institution.

Launching into using these infusion:
As individual providers see COVID positive patients, they can assess patients with mild to moderate COVID-19 illness and check if the patient has qualifying conditions for Bamlanivimab treatment.

If the provider believes the patient is eligible:
- Discuss the risk and benefits with effective communication,
- Give the patient the Lilly Fact Sheet for Patients, and
- Have the patient sign the consent form.
BAMLANIVIMAB WORKFLOWS – CONSENT FORM

Key Topics: Investigational drug, side effects, qualifying condition, administration and trip to the hospital (N95), patient’s choice.

- These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied, so it is possible that all of the risks are not known at this time.
- It is possible that bamlanivimab could interfere with your body’s own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.
- Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Do I have to take bamlanivimab?

- It is completely your choice to be treated or not with bamlanivimab. There is not enough information to actively recommend this medicine to you, but we do believe it should be offered. If you decide not to receive bamlanivimab or stop it at any time, you will still receive all the current standard care that you need for COVID-19 illness.

If I agree, how will I receive bamlanivimab?

- Bamlanivimab is given to you in one dose, one time, through a vein (intravenous or IV), where a small sterile needle goes into the vein to allow the liquid to drip into the bloodstream and takes a full hour to go in. After the infusion, the needle is removed, and you will be watched for at least another 1 hour.
- You will need to go out to a hospital or clinic that is offering this treatment.

Signatures:

(patient’s initials): I have received the manufacturer’s Fact Sheet for Patients, Parents, and Caregivers.

(patient’s initials): I understand that I can either consent to or refuse this medication and that if I do not consent to receive it, no one will enforce any penalty or punishment or loss of benefits or withhold future new medicines as a result of not consenting, and I will still receive all other appropriate medical care.

(patient’s initials): I understand that this medication is available to me now because I meet the eligibility criteria included in the FDA’s Emergency Use Authorization and that it may not be available to me later if my condition changes. According to the FDA criteria, it is reasonable to believe this medication may help me and is unlikely to harm me. This does not mean that my current health status is considered an "emergency." Standard medical care for COVID-19 will be given whether or not I agree to take bamlanivimab.

My signature below indicates that I have reviewed the above with my provider and had the chance to have any of my questions answered. I agree to have the bamlanivimab treatment.

Patient Signature: __________________________ Date/Time: __________________________
Bamlanivimab Workflows: Finding Patient Ed/Consent Form (Coronavirus Webpage)
CDCR Workflow for Bamlanivimab- MCAB Powerform

On-Site Orders

Note: On-site choice on the powerform to generate order is being created now

1. Fill out MCAB TREATMENT Powerform

   On the PowerForm, Providers will choose:

   Onsite generates: “Consult to...” order
   Offsite generates: “Referral to...” order

2. ON-SITE ORDERS WILL ALSO REQUIRE A SEPARATE PHARMACY BAMLAMIVIMAB ORDER.

   (This pharmacy order may be able to be generated from the powerform, but this feature is not active yet)
BAMLANIVIMAB WORKFLOWS: WHERE TO FIND MCAB TREATMENT REQUEST ORDER

Find “Provider Documentation” and then “MCAB Treatment Prescreening and Order Form” (eRFS and appointment order combination) as below:
On-Site or OFF-Site (Choose 1) being created now.
Your patient requires oxygen or needs an increase in flow rate if a chronic user? Yes/No
   If YES: STOP – Monoclonal antibody treatment is CONTRAINDICATED in oxygen-requiring patients/patients with severe COVID.

Your patient has a PCR confirmed COVID-19 infection? Yes/No
   If NO: STOP – Do not refer and first confirm infection with a PCR SARS-CoV-2 test.

Your patient is symptomatic AND within 3 (preferred) to 10 days of symptom onset for COVID-19? Yes/No
   If NO: STOP – Do not refer. Only symptomatic patients will qualify for treatment.

This is your patient’s first COVID-19 infection? Yes/No
   If NO: PAUSE – Priority for the limited dose allocations is for patients with first COVID-19 infection.

Your patient has one of the conditions covered in the emergency use authorization (EUA)?: Yes/No
   If NO: STOP – Do not refer. Investigational drug use should keep with what is authorized by the Food and Drug Administration (FDA) EUA.

Have you discussed the investigational status, risks, benefits, and alternatives with the patient, and the patient has signed the consent form? Yes/No
   If NO: STOP – Discuss and obtain consent before referring.
CDCR Workflow for Bamlanivimab - IF OFF-SITE: NEED INFUSION CENTER REFERRAL FORM

- The off-site choice on the POWERFORM triggers a scheduling order, which tasks UM to assist with confirming available doses, scheduling, and logistics.
- Here’s an example of the referral form the infusion centers will need.

QM & UM will keep up to date on the infusion center dose allocation and utilization.

CCHCS/CDCR Referral for Outpatient Treatment with Monoclonal Antibodies for COVID-19

Please supply the following information to help determine patient eligibility and treatment availability.

BASIC DEMOGRAPHIC INFORMATION

Patient name: ____________________________  CDCR#: __________________
Date of birth: ____________________________  Age: ______________________

Patient’s CDCR institution: ________________  Patient’s preferred language: ________________

Referring provider’s name: __________________  Referring provider’s phone number: __________________

Referring institution leadership phone number: ____________________

Is the patient ambulatory and can the patient walk up four steps?  □ Yes  □ No

Provider has reviewed FDA EUA with patient and consent signed:
  (Bamlanivimab): □ Yes  □ No  (Casirivimab/Imdevimab): □ Yes  □ No

COVID-19 RELATED INFORMATION

Date of symptom onset: __________ Date of positive PCR* test for SARS-CoV-2 (COVID-19): __________

Patient on home oxygen at baseline?  □ Yes  □ No  If yes, baseline oxygen requirement ___ L/min

What is the patient’s current oxygen requirement?  □ None (room air) □ _______ L/min

RELEVANT MEDICAL HISTORY

Patient’s weight (kg): ________  Patient’s height (inches): ________  BMI: ________

Current medications: __________________________

Allergies: __________________________  Is the patient pregnant?  □ Yes  □ No

Past medical history: __________________________

Please check if patient has history of any of the following:

Prior infection with COVID-19?  □ Yes  □ No  If yes, date of prior positive: __________

Patients who showed most benefit in Blaze 1* randomized controlled trial:

□ Age ≥ 65
□ Body Mass Index (BMI) ≥ 35

Groups with the next highest benefit in the Blaze 1* randomized control trial:

□ Chronic kidney disease
□ Diabetes
□ Immunosuppressive disease (not including diabetes)
□ Use of immunosuppressive agents

Other EUA approved conditions:

□ Age ≥ 55 and Cardiovascular Disease
□ Age ≥ 55 and Hypertension
□ Age ≥ 55 and Chronic obstructive pulmonary or other chronic lung disease

*BLAZE-1 Trial

• Facilities- Please provide feedback to QM/Headquarters (HQ) if use allocation needs to be adjusted by CDPH. Each week is re-evaluated.

Questions?

• Please complete and return evaluations and sign in sheets within 2 days to: CMEReview@cdcr.ca.gov
The Secretary of the Department of Health and Human Services has declared a public health emergency that justifies the emergency use of bamlanivimab to treat coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 infection. In response, the US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the unapproved product, bamlanivimab, for the treatment of COVID-19.

- Bamlanivimab has not been approved, but has been authorized for emergency use by FDA, 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, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

- Bamlanivimab is authorized 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 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 only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the bamlanivimab under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

- The FDA issued this EUA, requested by Eli Lilly and Company and based on their submitted data. Find more information in the FDA Letter of Authorization.

- Health care providers should review the Fact Sheet for information on the authorized use of bamlanivimab and mandatory requirements of the EUA.

- Health care providers should review the Fact Sheet for Healthcare Providers for important information on the use of bamlanivimab.
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EXECUTIVE SUMMARY

The world is currently in the midst of a global pandemic. As a global pharmaceutical company, we feel a responsibility to do our part to relieve the burden COVID-19 has placed on countries, communities and families around the world.

Clinical trials have shown that monoclonal antibodies may be effective in treating COVID-19. Lilly in partnership with AbCellara has developed a monoclonal antibody called bamlanivimab. Bamlanivimab is a recombinant neutralizing human IgG1 monoclonal antibody directed against the spike protein of SARS-CoV-2. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus.

This Antibody Playbook provides information for state, territorial and local public health programs to plan and operationalize a bamlanivimab antibody response to COVID-19. The sections of this document cover specific areas of COVID-19 antibody program planning and implementation, as well as links to resources to assist with those efforts. The sections described in this Playbook may also overlap with routine monoclonal antibody treatment and infusion program activities. This playbook represents guidance based on Lilly’s Clinical Trial experience and National Infusion Center Association (NICA) experience in monoclonal antibody treatments and should not supersede local requirements for infusion sites of care. Please defer to local guidelines.

In addition, the Playbook includes information regarding planning and implementation based on varying infusion sites of care, such as:

- Existing hospital or community-based infusion sites of care
- Existing clinical space (e.g., primary care practices affiliated with hospital systems, urgent care locations, emergency departments, surgery centers, dialysis centers, plasma centers, respiratory clinics and other health care delivery entities approved to administer infusion therapies)

We expect most infusion treatments will be administered in one of these aforementioned infusion sites of care, but other infusion sites of care may also be considered. This Playbook provides information that may or may not be applicable to certain spaces depending on existing capabilities.
SECTION 01

POPULATION FOR ANTIBODY TREATMENT AND REGULATORY NOTICES
**POPULATION FOR ANTIBODY TREATMENT**

This EUA is for the use of the unapproved product 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 12 years and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

**Limitations of Benefit in Patients with Severe COVID-19**

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. Therefore, 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.

For more information, reference the Fact Sheet for Healthcare Providers.

**High risk is defined as patients who meet at least one of the following criteria:**

- Have a 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.
- 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](https://www.cdc.gov/growthcharts/clinical_charts.htm), OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
Bamlanivimab must be administered by intravenous (IV) infusion.

Bamlanivimab 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 the emergency medical system (EMS), as necessary.

Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to bamlanivimab. See Sections 8 and 9 of the Fact Sheet for Healthcare Providers for reporting instructions below.

- The authorized dosage for bamlanivimab is a single intravenous (IV) infusion of 700 mg administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset.
- Bamlanivimab is available as concentrated solution and must be diluted prior to administration.
- Administer bamlanivimab 700 mg via IV infusion over at least 60 minutes via pump or gravity.
- Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.
- 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.

The authorized dosage may be updated as additional data from clinical trials becomes available.

For information on clinical trials that are testing the use of bamlanivimab in COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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†Patients with **mild** COVID-19 illness may exhibit a variety of signs and symptoms (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell). They do not have shortness of breath, dyspnea on exertion, or abnormal imaging.

**Moderate** COVID-19 illness is defined as evidence of lower respiratory disease during clinical assessment or imaging, with $\text{SpO}_2 \geq 94\%$ on room air at sea level.

**Source:** National Institutes of Health
Mandatory Requirements for Bamlanivimab Administration Under Emergency Use Authorization

In order to mitigate the risks of using this unapproved product under the EUA and to optimize the potential benefit of bamlanivimab, the following items are required. Use of bamlanivimab under this EUA is limited to the following (all requirements must be met):

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 40kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

2. Healthcare providers must communicate to patients or parents/caregivers, 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* occurring 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
     - Use a postage-paid Form FDA 3500 [available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf] and return it 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)”
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.

*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.
IMPORTANT SAFETY INFORMATION

There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

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.

Infusion-related reactions have been observed with administration of bamlanivimab. Signs and symptoms of infusion related reactions may include:

- fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.

If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.

Limitations of Benefit and Potential Risk in Patients with Severe COVID-19

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. See Limitations of Authorized Use.

Adverse Events

Adverse events reported in at least 1% of BLAZE-1 clinical trial participants on bamlanivimab 700 mg and placebo were Nausea (3% vs 4%), Diarrhea (1% vs 5%), Dizziness (3% vs 2%), Headache (3% vs 2%), Pruritus (2% vs 1%) and Vomiting (1% vs 3%).

Use in Specific Populations

Pregnancy

There are insufficient data on the use of bamlanivimab during pregnancy. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Breastfeeding

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.
SECTION 02

SUPPLY AND SCALE OF EFFORT
SUPPLY AND SCALE OF EFFORT

Product Allocation and Supply
Lilly has committed to manufacturing up to 1,000,000 vials of bamlanivimab in 2020, with 100,000 doses available to ship within days of authorization.

Additionally, Lilly has reached an agreement with the U.S. government to supply 300,000 vials within the first two months after Emergency Use Authorization (EUA) with the option to purchase an additional 650,000 vials through June 2021.

Bamlanivimab will be allocated to each state by the Federal Government. Upon EUA, the Federal Government will begin allocating to states immediately and thereafter on a weekly basis. Weekly allocations to state and territorial health departments will be proportionally based on confirmed hospitalizations and COVID-19 cases in each state and territory over the previous seven days, based on data hospitals and state health departments enter into the HHS Protect data collection platform. State Health Authorities will then allocate to individual sites of care within their jurisdiction. If you would like more information about the allocation process or would like to be considered for product allocation, please contact your state health department directly.

Scaling Operations
The time duration to administer a 700mg/20mL dose of bamlanivimab is 60 minutes at the infusion rate of 200mL/hr [20mL bamlanivimab/180mL 0.9% sodium chloride] for both infusion pumps and gravity infusion. Treatment also requires a post-infusion observation period. It is clinically recommended to monitor patients during infusion and observe patients for at least 1 hour after infusion is complete. Sites of care should follow local requirements when determining appropriate observation periods. If patients will occupy chairs for infusion during this period, rather than a post-treatment monitoring area, planning must account for this time as well.

The number of chairs for infusion can be scaled along with the hours of operation to determine the size of the infusion site of care. Infusion sites of care should take into account time for patient intake, IV preparation, infusion and post-infusion observation when determining potential capacity. For example, in Lilly’s monoclonal antibody clinical trial settings, Lilly found a single infusion could take between 165–225 minutes to complete from patient intake to discharge. See Appendix A for more information.

The above values could be used to determine a rough approximation of the number of infusion sites of care that may be needed per region. A region can easily modify the number based on changing the capacity assumptions with the various infusion sites of care. Depending on the dispersion of the population in a region, the region may choose to size some infusion sites of care larger than others.
ALLOCATION AND ORDERING

- **How can the product be ordered?** State health departments will allocate an amount of the product to infusion sites of care. AmerisourceBergen, the contracted distributor, will contact these infusion sites of care directly. They may accept (in part or in full) or decline the allocated product. The receipt of the product requires an account with AmerisourceBergen. Infusion sites of care that would like to be considered for product allocation should contact their state health departments directly.

- **When can orders be placed?** Infusion sites of care cannot order product from their wholesaler(s). AmerisourceBergen will proactively contact infusion sites of care that have received State Health Department allocations to confirm acceptance of the allocation. Product allocations will occur on a weekly basis after the initial allocation, and quantities may fluctuate depending on highest medical need.

- **Where can orders be shipped?** Orders will be shipped via UPS overnight to infusion sites of care that have received state health department allocations and that accepted product upon being contacted by AmerisourceBergen customer service.
Flow of Allocated Product

Below is a depiction of the basic flow of allocated product. Through a government allocation program, the Federal Government, in partnership with state health departments, will provide the contracted distributor, AmerisourceBergen, with a list of infusion sites of care approved for a product allocation on a periodic basis. The distributor will then contact the approved infusion sites of care, confirm they would like to receive the allocated amount of product and then ship the product.

*Weekly allocation decisions will be proportionally based on confirmed COVID-19 cases in each state and territory over the previous seven days, based on data from the U.S. Department of Health and Human Services' Protect data collection platform.*
SECTION 04

INFUSION SITE OF CARE REQUIREMENTS
INFUSION SITE OF CARE REQUIREMENTS

Preparation, Storage and Handling

Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies and with National Infusion Center Association (NICA) standards for outpatient infusion.*

National Infusion Center Association Parenteral Medication Preparation Guidelines

According to NICA standards, prepared product is intended for immediate administration to an individual patient. Administration of parenteral medications should begin immediately, ideally within one hour of beginning preparation. If extenuating circumstances preclude immediate administration, manufacturer guidelines regarding stability and storage must be followed; however, storage should not exceed 4 hours unless the product was prepared in accordance with United States Pharmacopeia (USP) General Chapter 797 pharmacy standards for compounding sterile products.

- Use aseptic technique and applicable good clinical practice for intravenous solution preparations of bamlanivimab in accordance with NICA standards.
- Only use materials which are listed as compatible with bamlanivimab for preparation and administration of the infusion solutions (see Compatible Materials section below).
- Gather the recommended materials for infusion:
  - Polyvinylchloride (PVC) infusion set containing a 0.20/0.22 micron filter.
- Use new, sterile syringes and needles to prepare each dosing solution of bamlanivimab.
- Refrigerate bamlanivimab drug product when not in use at 2°C to 8°C (36°F to 46°F).
- Bamlanivimab should be free of any visible particulate matter. Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter.
- All medication must be stored, inventoried and destroyed according to applicable regulations.
- Bamlanivimab is administered by intravenous (IV) infusion either using an infusion pump or gravity infusion. Consider use of a rate control or infusion rate monitoring device if using gravity infusion. Tubing with an integrated rate flow regulator can also be considered if an infusion pump is not available.
- The IV solutions are intended for immediate patient administration. If immediate administration is not possible (and the solution has been prepared according to USP 797 guidelines), store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature [2°C to 8°C (36°F to 46°F)] or up to 7 hours at room temperature [20°C to 25°C (68°F to 77°F)] including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration. The hold time includes preparation, solution hold, infusion and flush. Any solution which exceeds these time period requirements and/or is not compounded according to USP 797 guidelines MUST BE DISCARDED and a fresh solution MUST BE PREPARED.

*Find more information on National Infusion Center Association (NICA) standards for outpatient infusion.*
Compatible Materials
Individual infusion sites of care should follow best medical practices when determining materials to use. Procurement of materials from a specific vendor or vendors is not required. If alternate materials are used, the compatibility of these materials should be confirmed with that vendor. Bamalanivimab has no known incompatibilities with conventional medical supplies and equipment. During clinical trials, Lilly has used the following materials:
• Polypropylene syringes
• Stainless steel needles
• Polyvinylchloride (PVC) IV bags with or without DEHP
• Polyvinylchloride (PVC) infusion sets with or without DEHP containing an in-line polyethersulfone (PES)* filter
(Please see footnote.)

Storage
Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze, shake or expose to direct light.

Preparation and Administration
• The 700 mg dose MUST BE prepared using 0.9% sodium chloride.
  • Preparation of 700 mg dose of bamalanivimab for IV infusion*
  • Administration of a dose of 700 mg of bamalanivimab in an IV infusion*
    *Applicable state/local/federal agencies, regulatory bodies, and industry standards (e.g. USP 797, NICA Standards for In-Office Infusion).

  • Bamalanivimab solution for infusion should be prepared by a qualified health care professional using aseptic technique.
  • Refer to section Preparation Summary Table for 700mg Dose of Bamalanivimab Solution for Intravenous Infusion for additional dose preparation information.
  • Remove ONE (1) vial of bamalanivimab injection, 700mg/20mL (drug product) from refrigerated storage at 2°C to 8°C (36°F to 46°F), and equilibrate the vial to room temperature, not exceeding 30°C or 86°F for approximately 20 minutes (or no longer cool to the touch). Do not expose to direct heat.
  • Do not shake or vigorously agitate the vial. Visually inspect the vial for the presence of any visible particulate matter and discoloration. Bamalanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution. If visible particulate matter is observed, appropriately discard the vial, obtain a new vial, and restart the preparation, beginning at the prior step.
  • Prepare the IV solution using the following approach using aseptic technique.
    • The IV solution can be prepared using a filled 250mL IV bag. Using a syringe with an 18-gauge needle, withdraw a total of 70mL of 0.9% sodium chloride from the IV bag and discard that volume, leaving 180mL in the IV bag.
    • Using a new, sterile syringe with an 18-gauge needle, withdraw 20mL of bamalanivimab from the prepared vial and inject the contents into the prepared IV bag, so that the combined total volume is 200mL.
    • Gently invert the prepared IV bag by hand approximately 10 times to ensure homogeneity of the contents. Do not shake or vigorously agitate the prepared bag. Avoid foaming. Visually inspect the bag after preparation. The contents of the bag should be free of any visible particulate matter. Obtain new vial(s) and re-prepare the dose if visible particulate matter is observed.

*If alternate materials are used, the compatibility of these materials should be confirmed with that vendor. Bamalanivimab has no known incompatibilities with conventional medical supplies and equipment.
• Attach an infusion set containing a 0.20/0.22 µm filter to the IV bag.
• Prime the infusion set and adjust for a flow rate of 200mL/hr for both infusion pumps and gravity infusion. Administer the infusion solution over 60 minutes.

Infusion sites of care can use the following chart to calculate a 60 minute drip rate when administering via gravity infusion.

<table>
<thead>
<tr>
<th>VTBI (mL)</th>
<th>Duration (min)</th>
<th>Drip factor (drops per milliliter)</th>
<th>Drops per minute</th>
<th>Drops per 15 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>60</td>
<td>10 gtt/mL</td>
<td>33 gtt/min</td>
<td>8 drops per 15 seconds</td>
</tr>
<tr>
<td>200</td>
<td>60</td>
<td>12 gtt/mL</td>
<td>40 gtt/min</td>
<td>10 drops per 15 seconds</td>
</tr>
<tr>
<td>200</td>
<td>60</td>
<td>15 gtt/mL</td>
<td>50 gtt/min</td>
<td>13 drops per 15 seconds</td>
</tr>
<tr>
<td>200</td>
<td>60</td>
<td>20 gtt/mL</td>
<td>67 gtt/min</td>
<td>17 drops per 15 seconds</td>
</tr>
<tr>
<td>200</td>
<td>60</td>
<td>60 gtt/mL</td>
<td>200 gtt/min</td>
<td>50 drops per 15 seconds</td>
</tr>
</tbody>
</table>

• At the discretion of the infusion site of care medical staff, the proposed infusion rate may be reduced and the corresponding infusion time increased for infusion reactions or patient circumstances.
• This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible (and the solution has been prepared according to USP 797 guidelines), store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration. The hold time includes preparation, solution hold, infusion and flush. Any solution which exceeds these time period requirements and/or is not compounded according to USP 797 guidelines MUST BE DISCARDED and a fresh solution MUST BE PREPARED.
• After the entire infusion volume of 200mL has been administered, flush the infusion line as per infusion site of care requirements or with sufficient volume to flush residual volume from tubing to ensure patient receives entire dose. Discard unused product.
• For additional information, please see Fact Sheet for Healthcare Providers.
### Preparation Summary Table for 700mg Dose of Bamlanivimab Solution for Intravenous Infusion

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bamlanivimab dose</td>
<td>700mg</td>
</tr>
<tr>
<td>Volume of bamlanivimab drug product (and # of vials) needed</td>
<td>20mL (1 vial)</td>
</tr>
<tr>
<td>Volume of 0.9% sodium chloride to discard from 250mL IV bag</td>
<td>70mL</td>
</tr>
<tr>
<td>Nominal bamlanivimab dosing solution concentration</td>
<td>3.5mg/mL</td>
</tr>
<tr>
<td>Total infusion volume prepared and administered</td>
<td>200mL</td>
</tr>
<tr>
<td>Infusion rate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>200mL/hr.</td>
</tr>
<tr>
<td>Infusion time&lt;sup&gt;1&lt;/sup&gt;</td>
<td>60 min.</td>
</tr>
</tbody>
</table>

<sup>1</sup>At the discretion of the infusion site of care medical staff, the proposed infusion rate may be reduced and the corresponding infusion time increased for infusion reactions or patient circumstances.

**Note:** Upon completion of intravenous infusion, the infusion line should be flushed as per infusion site of care requirements or with approximately 25mL of 0.9% sodium chloride with the flush volume administered to the patient to ensure delivery of the required dose.
SECTION 5

RECOMMENDED INFUSION SITE OF CARE RESOURCES AND EQUIPMENT CONSIDERATIONS
Staffing requirements may vary by state. Follow your local requirements when determining the staff needed for your infusion site of care. Based on Lilly’s clinical trial experience, the following roles should be considered to ensure the safest care environment for patients receiving bamlanivimab antibody infusion.

*Infusion sites of care should have appropriately trained medical staff to administer infusion treatments and identify and manage potential adverse reactions. It is recommended that participants who experience a systemic hypersensitivity reaction be treated per the local standard of care.*

<table>
<thead>
<tr>
<th>Role</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient intake</td>
<td>Person with basic administrative skills</td>
</tr>
<tr>
<td>Drug infusion preparation</td>
<td>Health care professional trained in IV admixture preparation (such as a nurse, pharmacist, pharmacy tech)</td>
</tr>
<tr>
<td>Infusion: start IV</td>
<td>Health care professional trained to start an IV</td>
</tr>
<tr>
<td>Infusion: administer infusion</td>
<td>Health care professional trained in administering IV infusion</td>
</tr>
<tr>
<td>Infusion monitoring</td>
<td>Healthcare professional trained in:</td>
</tr>
<tr>
<td></td>
<td>• assessing infusion-related reactions</td>
</tr>
<tr>
<td></td>
<td>• treating infusion-related reactions</td>
</tr>
<tr>
<td></td>
<td>• vital sign monitoring</td>
</tr>
<tr>
<td>Post-infusion observation</td>
<td>Healthcare professional trained in:</td>
</tr>
<tr>
<td></td>
<td>• assessing infusion-related reactions</td>
</tr>
<tr>
<td></td>
<td>• treating infusion-related reactions</td>
</tr>
<tr>
<td></td>
<td>• vital sign monitoring</td>
</tr>
<tr>
<td></td>
<td>• providing discharge education for the patient</td>
</tr>
<tr>
<td>Patient release</td>
<td>Person with basic administrative skills</td>
</tr>
<tr>
<td>Waste removal and cleaning</td>
<td>Person trained in COVID-19 cleaning and disinfection</td>
</tr>
</tbody>
</table>

**Notes:**
- At least one health care professional should have Advanced Cardiovascular Life Support (ACLS) or Basic Life Support (BLS) certification or equivalent.
- The same health care professional may perform more than one role.
- State or county requirements may dictate specific qualifications for some roles.
INFUSION SITE OF CARE MATERIALS

Equipment requirements may vary by state. Follow your local requirements when determining the equipment needed for your infusion site of care. Based on Lilly’s clinical trial experience, the following equipment should be considered to ensure the safest infusion site of care environment for patients receiving bamlanivimab antibody infusion. Additional recommended equipment and emergency medical supplies can be found in Appendix B.

Below are recommended non-consumable materials which are needed in an infusion site of care:

- Infusion pumps (if available)
- Infusion pump bracket for IV pole (if available)
- Chairs for infusion
- Mobile IV poles
- Emergency medical management equipment and backboard, including a reaction management kit (see Appendix B)
- Privacy screens
- Chairside table
- Locking refrigerator with temperature monitoring capability
- Transilluminator (vein finder)
- Vital sign monitoring equipment (see Appendix B)

Below are recommended consumable items which are needed in an infusion site of care:

<table>
<thead>
<tr>
<th>Consumable Items</th>
<th>Recommended supplies are based on Lilly’s clinical trial experience.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPE</td>
<td>Infusion supplies*</td>
</tr>
<tr>
<td>Gloves</td>
<td>IV and catheters**</td>
</tr>
<tr>
<td>Gowns</td>
<td>0.20/0.22µm filter</td>
</tr>
<tr>
<td>Eye and face protection (e.g., goggles, safety glasses, face shields)</td>
<td>250mL PVC IV bags (infusion prep), if required</td>
</tr>
<tr>
<td>NIOSH-certified, disposable N95 filter facepiece respirators or better</td>
<td>250mL 0.9% sodium chloride (infusion prep)</td>
</tr>
<tr>
<td></td>
<td>Pre-filled saline syringes</td>
</tr>
<tr>
<td></td>
<td>Appropriately sized syringes</td>
</tr>
<tr>
<td></td>
<td>Alcohol wipes</td>
</tr>
<tr>
<td></td>
<td>2x2 gauze pads</td>
</tr>
<tr>
<td></td>
<td>Adhesive bandages</td>
</tr>
<tr>
<td></td>
<td>Tegaderm bio-occlusive dressing</td>
</tr>
<tr>
<td></td>
<td>Absorbent underpads (blue pads)</td>
</tr>
<tr>
<td></td>
<td>Extension set tubing</td>
</tr>
<tr>
<td></td>
<td>Sterile needles - stainless steel 18ga</td>
</tr>
<tr>
<td></td>
<td>IV administration sets (tubing)</td>
</tr>
<tr>
<td></td>
<td>Sharps containers</td>
</tr>
<tr>
<td></td>
<td>Transpore tape</td>
</tr>
</tbody>
</table>

* Listed supplies are reflective of quantities/volumes used in Lilly clinical trials. Infusion sites of care may substitute alternate quantities and volumes as needed based on best medical practices and local requirements.

**24g catheter is sufficient
SECTION 06

EDUCATION AND AWARENESS
EDUCATION AND AWARENESS

Attacking the coronavirus will require a diverse set of approaches, including both vaccines and treatments, such as antibodies.

Q. What’s the difference between vaccines and monoclonal antibody drugs?

A. While there are some similarities, here’s how they are different:

- Monoclonal antibody drugs, like bamlanivimab, provide passive immunity by giving the body antibodies to protect itself. Vaccines provide active immunity by helping the body make its own antibodies to protect itself.
- Monoclonal antibody drugs are designed to start working faster than vaccines, while protection provided by vaccines will generally last longer.
- Generally, scientists are able to develop antibody treatments faster than they are able to develop vaccines.

Developing any approach against COVID-19 involves assessing key factors:

- **Viral exposure**
  A vaccine will not help an already-infected patient

- **Stage of disease**
  When to apply the medicine to prevent the infection or treat the disease

- **At-risk populations**
  Factors linked to worse outcomes (e.g., age, concurrent diseases)
NEUTRALIZING ANTIBODIES AS POTENTIAL TREATMENTS

Identified and characterized using various methods, including from the blood of COVID-19 survivors, neutralizing antibodies target the viral spike protein that SARS-CoV-2 uses to gain entry into host cells. Neutralizing antibodies, therefore, are specifically designed to treat COVID-19.

Q. What are antibodies?

A. Antibodies are naturally made in our bodies to fight infection.

- Whenever the immune system meets a new foreign substance in the body, it makes new antibodies that attack the foreign substance. The next time that substance shows up, the immune system can produce the same antibodies to help the body fight it off before it can make a person sick. These types of naturally occurring antibodies provide active immunity.
- Vaccines work in a similar way, helping the body make antibodies to attack specific foreign substances and providing active immunity in the body.
- Antibody drugs are different. They are man-made antibodies that are given directly through an infusion or injection rather than prompting the body to make the antibodies for itself. This type of immunity is called passive immunity.

Find more information about monoclonal antibody drugs and vaccines from the CDC, State Health Departments, and the following resources:

- [www.coronaviruspreventionnetwork.org](http://www.coronaviruspreventionnetwork.org)
- [www.infusioncenter.org/](http://www.infusioncenter.org/)
- [Fact Sheet for Healthcare Providers](http://www.infusioncenter.org/)
- [Fact Sheet for Patients, Parents and Caregivers (English)](http://www.infusioncenter.org/)
- [Fact Sheet for Patients, Parents and Caregivers (Spanish)](http://www.infusioncenter.org/)
- [FDA Letter of Authorization](http://www.infusioncenter.org/)
Monoclonal Antibodies

Antibodies are naturally made in our bodies to fight infection.

Without Antibodies

A virus enters a cell

Cell lining

With Antibodies

Antibodies block the virus from entering the cell

What are antibodies?

Antibodies are naturally made in our bodies to fight infection.

What are MONOCLONAL ANTIBODIES?

Monoclonal antibodies (mAbs) are antibodies developed in a laboratory to help our bodies fight infection.

Nearly 100 mAbs are FDA approved to treat health conditions including cancers and autoimmune diseases.

mAbs are also being studied for the treatment and prevention of COVID-19.

How are mAbs administered?

mAbs are given through intravenous infusion (i.e., through a vein) or injection.

OR

How often infusions or injections of mAbs are needed depends on the specific mAbs.

What are common side effects of mAbs?

Allergic reactions  Flu-like symptoms  Nausea & Vomiting  Diarrhea  Low blood pressure

PreventCOVID.org

ama-assn.org  cancer.org  mayoclinic.org  medicine.net  nature.com  synabs.be  uptodate.com

Lilly Bamlanivimab Antibody Playbook  |  26
APPENDIX A

LILLY MONOCLONAL ANTIBODY CLINICAL TRIAL MODELING INFORMATION
LILLY MONOCLONAL ANTIBODY
CLINICAL TRIAL MODELING INFORMATION

Assuming the infusion site of care setup details provided below, this information can be used to model the estimated number of infusions (patients) an infusion site of care can serve, depending on its capacity.

Each infusion site of care will vary in terms of the amount of chairs for infusion, staffing considerations, work day length and more. The information provided here is meant as a general guide based upon Lilly’s clinical trial experience. In some cases, ideal criteria are included, such as for observation time. In other instances, such as the consent and intake time, there are estimated ranges shown, with “+” or “-” conditions in parentheses.

### Infusion Timing

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent and intake time</td>
<td>30 min (+/- 15 min)</td>
<td>Consent and intake may occur outside of the infusion chair, such as at the prescriber’s location, and consent and intake time may vary per patient.</td>
</tr>
<tr>
<td>IV prep time</td>
<td>30 min</td>
<td>This step usually does not take place until the patient is in the chair for infusion and vascular access has been obtained.</td>
</tr>
<tr>
<td>Infusion time</td>
<td>60 min (+30 min)</td>
<td>Infusion time should be a minimum of 60 minutes, although more time may be necessary.</td>
</tr>
<tr>
<td>Observation time*</td>
<td>60 min</td>
<td>It is clinically recommended to monitor patients during infusion and observe patients for at least 1 hour after infusion is complete, although more time may be necessary. Sites of care should follow local requirements when determining appropriate observation periods.</td>
</tr>
<tr>
<td>TOTAL TIME</td>
<td>165–225 min</td>
<td>This represents the estimated total time from consent through observation of the patient.</td>
</tr>
</tbody>
</table>

*It is recommended that infusion sites of care have a protocol in place for patients who refuse to stay for post-infusion observation. For example, this may include an AMA form, release of responsibility waiver, etc.
APPENDIX B

BASIC EQUIPMENT RECOMMENDATIONS
BASIC EQUIPMENT RECOMMENDATIONS

Equipment requirements may vary by state. Follow your local requirements when determining the equipment needed for your infusion center. Based on Lilly’s clinical trial experience, the following equipment should be considered to ensure the safest care environment for patients receiving bamlanivimab antibody infusion.

Basic Equipment Recommendations

<table>
<thead>
<tr>
<th>Drug preparation</th>
<th>Lockered refrigerator with min/max temp monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prep table or area</td>
</tr>
<tr>
<td></td>
<td>18ga needles</td>
</tr>
<tr>
<td></td>
<td>Appropriate sized syringes</td>
</tr>
<tr>
<td></td>
<td>250mL PVC IV bags (infusion prep), if required</td>
</tr>
<tr>
<td></td>
<td>250mL 0.9% sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Sterile alcohol prep pads</td>
</tr>
<tr>
<td></td>
<td>PPE gloves all sizes</td>
</tr>
<tr>
<td></td>
<td>PPE face shields or goggles</td>
</tr>
<tr>
<td></td>
<td>PPE N95 masks</td>
</tr>
<tr>
<td></td>
<td>Sharps containers</td>
</tr>
<tr>
<td></td>
<td>Drug transport bags (if using mobile pharmacy)</td>
</tr>
<tr>
<td></td>
<td>Alcohol sanitizing wipes</td>
</tr>
<tr>
<td></td>
<td>Step-by-step instruction sheet (with images)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient intake and release</th>
<th>Signage with patient instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phone for intake worker</td>
</tr>
<tr>
<td></td>
<td>Schedule or list of appointments</td>
</tr>
<tr>
<td></td>
<td>Office supplies (e.g. pens, stapler, scissors, paper clips, etc.)</td>
</tr>
<tr>
<td></td>
<td>Clipboard with patient intake and monitoring sheet</td>
</tr>
<tr>
<td></td>
<td>Patient intake and monitoring form</td>
</tr>
<tr>
<td></td>
<td>Check-in table</td>
</tr>
<tr>
<td></td>
<td>Chair(s) for check-in staff</td>
</tr>
<tr>
<td></td>
<td>Bleach sanitizing wipes</td>
</tr>
<tr>
<td></td>
<td>Hand sanitizer</td>
</tr>
<tr>
<td></td>
<td>PPE gloves all sizes</td>
</tr>
<tr>
<td></td>
<td>PPE face shields or goggles</td>
</tr>
<tr>
<td></td>
<td>PPE N95 masks</td>
</tr>
<tr>
<td></td>
<td>PPE gowns</td>
</tr>
</tbody>
</table>
### Basic Equipment Recommendations

#### Infusion area supplies
- Chairs for infusion
- Chairside table
- IV poles
- IV pump (or gravity feed)
- Vital signs monitoring equipment (BP, HR, resp rate, temp, O2 sat)
- Supply cart or other storage cabinet
- Hand sanitizer
- Hand soap
- Biohazard trash can
- Bleach wipes (cleaning non-electronic equipment)
- Alcohol wipes (cleaning electronic equipment)
- Medical emergency supplies
- Sterile alcohol prep pads
- IV catheters
- IV extension tubing
- Tourniquet
- PVC infusion sets
- 0.20/0.22µm filter
- Gauze pads
- Adhesive bandages
- 0.9% sodium chloride flush syringes
- Bio-occlusive dressing
- Tape
- 50mL 0.9% sodium chloride bags
- PPE-gloves all sizes
- PPE-face shields or goggles
- PPE-N95 masks
- PPE-gowns

#### Observation area
- Vital signs monitoring equipment (BP, HR, resp rate, temp, O2 sat)
- Table for staff
- Chairs for patients and staff
- Bleach sanitizing wipes
- Hand sanitizer
- PPE-gloves all sizes
- PPE-face shields or goggles
- PPE-N95 masks
- PPE-gowns
### MEDICAL EMERGENCY SUPPLIES AND MEDICATIONS

Emergency medical management equipment should contain the following items:

*Some medications listed below should only be administered by HCP with ACLS training

<table>
<thead>
<tr>
<th>Essential</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medications</strong></td>
<td></td>
</tr>
<tr>
<td>Albuterol inhaler</td>
<td>Adenosine injection</td>
</tr>
<tr>
<td>Diphenhydramine injection</td>
<td>Atropine sulfate</td>
</tr>
<tr>
<td>Epinephrine 0.1 mg/mL (1 mg/10mL) OR epinephrine auto-injector 0.3 mg</td>
<td>Chewable ASA</td>
</tr>
<tr>
<td>Solu-Medrol injection</td>
<td>Dextrose 50% injection</td>
</tr>
<tr>
<td></td>
<td>Insta glucose</td>
</tr>
<tr>
<td></td>
<td>Nitroglycerine</td>
</tr>
<tr>
<td></td>
<td>Ondansetron injection</td>
</tr>
<tr>
<td></td>
<td>Sodium bicarb injection</td>
</tr>
</tbody>
</table>

| **IV supplies** | | |
| 0.9% Sodium chloride flush (10mL) | IV admin set |
| 0.9% Sodium chloride bag (500mL) | IV start kit |
| | IV catheter |
| | Non-DEHP cath/extension set |
| | 5% dextrose bag |

| **Airway** | | |
| Barrier mask for CPR | Nasopharyngeal/oral airway suction |
| Ambu Bag | |

| **Emergency medical management** | | |
| Infusion sites of care should have a standard operating procedure in place instructing infusion site of care staff how emergency events should be managed, including appropriate contacts (911, physician, etc.), ACLS protocol and any follow-up activities. | |
CCHCS/CDCR Referral for Outpatient Treatment with Monoclonal Antibodies for COVID-19

Please supply the following information to help determine patient eligibility and treatment availability

Basic Demographic Information

Patient name: __________________________ CDCR#: __________________
Date of birth: _______________ Age: _______________
Patient’s CDCR institution: _______________ Patient’s preferred language: _______________
Referring provider’s name: _______________ Referring provider’s phonenumber: _______________
Referring institution leadership phone number: __________________

Is the patient ambulatory and can the patient walk up four steps? ☐ Yes ☐ No

Provider has reviewed FDA EUA with patient and consent signed:
(Bamlanivimab): ☐ Yes ☐ No (Casirivimab/imdevimab): ☐ Yes ☐ No

Prior Dose of any monoclonal antibody treatment for COVID-19 ☐ Yes ☐ No

COVID19 Related Information

Date of symptom onset: __________ Date of positive PCR* test for SARS-CoV-2 (COVID-19): __________

Patient on home oxygen at baseline? ☐ Yes ☐ No If yes, baseline oxygen requirement ____L/min

What is the patient’s current oxygen requirement? ☐ None (room air) ☐ _______L/min

Relevant Medical History

Patient’s weight (kg): __________ Patient’s height (inches): __________ BMI: __________

Current medications: ____________________________________________________________

Allergies: __________________________________________________________________________ Is the patient pregnant? ☐ Yes ☐ No

Past medical history: __________________________________________________________________

Please check if patient has history of any of the following:

Prior infection with COVID-19 ☐ Yes ☐ No If yes, Date of prior positive __________

Patients who showed most benefit in Blaze 1^ randomized controlled trial:
☐ Age > 65
☐ Body Mass Index (BMI) > 35

Groups with the next highest benefit in the Blaze 1^ randomized control trial:
☐ Chronic kidney disease
☐ Diabetes
☐ Immunosuppressive disease (not including diabetes)
☐ Use of immunosuppressive agents

Other EUA approved conditions:
☐ Age > 55 and Cardiovascular Disease
☐ Age > 55 and Hypertension
☐ Age > 55 and Chronic obstructive pulmonary or other chronic lung disease

* All positive point of care tests require PCR confirmation

You are being given a medicine called bamlanivimab for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab, which you may receive.

Receiving bamlanivimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about bamlanivimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is bamlanivimab?
Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19.

The FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section “What is an Emergency Use Authorization (EUA)?” at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive bamlanivimab?
Tell your healthcare provider about all of your medical conditions, including if you:
- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab?
- Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour.
- You will receive one dose of bamlanivimab by IV infusion.

What are the important possible side effects of bamlanivimab?
Possible side effects of bamlanivimab are:
- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever,
chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?
Like bamlanivimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with bamlanivimab. Should you decide not to receive bamlanivimab or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with bamlanivimab?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?
- Ask your healthcare provider
- Visit www.bamlanivimab.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bamlanivimab has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.
The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).

Literature issued November 2020

Eli Lilly and Company, Indianapolis, IN 46285, USA
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BAM-0001-EUA PAT-20201109
Guía informativa para pacientes, padres y cuidadores
Autorización de uso de emergencia (EUA) de bamlanivimab para la enfermedad por coronavirus 2019 (COVID-19)

Le están administrando un medicamento llamado bamlanivimab para el tratamiento de la enfermedad por coronavirus 2019 (COVID-19). Esta guía informativa contiene información de utilidad para comprender los riesgos y beneficios potenciales de tomar bamlanivimab, que puede recibir.

Recibir bamlanivimab puede beneficiar a ciertas personas afectadas de COVID-19.

Lea esta guía informativa para saber más sobre el bamlanivimab. En caso de duda, consulte con su proveedor de atención sanitaria. Usted decide si quiere recibir bamlanivimab o dejar de tomarlo en cualquier momento.

¿Qué es la COVID-19?
La COVID-19 está causada por un virus llamado coronavirus. Las personas pueden contraer la COVID-19 a través del contacto con otra persona que tenga el virus.

Los trastornos causados por la COVID-19 varían entre muy leves (incluidas algunas personas sin síntomas notificados) y graves, incluidos trastornos que causan defunción. Si bien la información hasta el momento sugiere que la mayoría de los trastornos causados por la COVID-19 son leves, se pueden producir trastornos graves que podrían provocar el empeoramiento de sus otras afecciones médicas. Las personas de cualquier edad con afecciones médicas graves y de larga duración (crónicas) como cardiopatías, enfermedad pulmonar y diabetes, por ejemplo, parecen tener un mayor riesgo de ser hospitalizadas por la COVID-19.

¿Cuáles son los síntomas de la COVID-19?
Los síntomas de la COVID-19 incluyen fiebre, tos y dificultad para respirar, y pueden aparecer entre 2 y 14 días después de la exposición. Pueden producirse trastornos graves, incluidos problemas respiratorios, que podrían provocar el empeoramiento de sus otras afecciones médicas.

¿Qué es bamlanivimab?
El bamlanivimab es un medicamento en investigación que se usa para el tratamiento de la COVID-19 en adultos y adolescentes a partir de 12 años de edad no hospitalizados con síntomas entre leves y moderados con un peso de 88 libras (40 kg) o superior y que tengan un alto riesgo de desarrollar síntomas graves por COVID-19 o de necesitar hospitalización. El bamlanivimab se encuentra en fase de investigación porque todavía se está estudiando. No se dispone de mucha información sobre la seguridad o la eficacia del uso de bamlanivimab para tratar a personas afectadas de COVID-19.

La Administración de Alimentos y Medicamentos de los Estados Unidos (FDA) ha autorizado el uso de emergencia de bamlanivimab para el tratamiento de la COVID-19 bajo una Autorización de Uso de Emergencia (EUA). Para obtener más información sobre la EUA, consulte la sección: “¿Qué es una autorización de uso de emergencia (EUA)?” que aparece al final de esta guía informativa.

¿Qué debo decirle a mi profesional sanitario antes de recibir bamlanivimab?
Informe a su profesional sanitario sobre todas sus afecciones médicas, incluyendo lo siguiente:
- Si sufre alguna alergia
- Si está embarazada o tiene pensado quedarse embarazada
- Si está en período de lactancia o tiene pensado estarlo
- Si padece alguna enfermedad grave
- Si está tomando algún medicamento (con receta, de venta libre, vitaminas y productos a base de plantas medicinales).

¿Cómo recibiré bamlanivimab?
- Se le administrará bamlanivimab en vena (vía intravenosa o I.V.) durante al menos 1 hora.
- Recibirá una dosis de bamlanivimab mediante infusión intravenosa.
¿Cuáles son los posibles efectos secundarios importantes del bamlanivimab?

Los posibles efectos secundarios del bamlanivimab son:

- **Reacciones alérgicas.** Se pueden producir reacciones alérgicas durante y después de la infusión de bamlanivimab. Informe a su profesional sanitario de inmediato si tiene alguno de los siguientes signos y síntomas de reacciones alérgicas: fiebre, escalofríos, náuseas, dolor de cabeza, dificultad para respirar, presión arterial baja, sibilancias, hinchazón de los labios, cara o garganta, erupción cutánea, incluida la urticaria, picazón, dolor muscular y mareos.

Los efectos secundarios de recibir un medicamento por vía intravenosa pueden incluir dolor breve, sangrado, hematomas en la piel, molestias, hinchazón y posible infección en el lugar de la infusión.

Estos no son los únicos efectos secundarios posibles del bamlanivimab. Se ha administrado bamlanivimab a un número reducido de personas. Pueden producirse efectos secundarios graves e inesperados. El bamlanivimab todavía se encuentra en fase de estudio. Por ello, es posible que no se conozcan todos los riesgos asociados en este momento.

Es posible que el bamlanivimab pueda interferir con la capacidad propia del cuerpo de defenderse contra una infección por SARS-CoV-2 en el futuro. De igual modo, el bamlanivimab podría reducir la respuesta inmunitaria del cuerpo a una vacuna para el SARS-CoV-2. No se han realizado estudios específicos que aborden estos posibles riesgos. Consulte con su profesional sanitario en caso de duda.

¿Qué otras opciones de tratamiento existen?

Al igual que el bamlanivimab, la FDA puede permitir el uso de emergencia de otros medicamentos para tratar a las personas con la COVID-19. Consulte la página [https://www.covid19treatmentguidelines.nih.gov/](https://www.covid19treatmentguidelines.nih.gov/) para obtener información sobre el uso de emergencia de otros medicamentos que no están aprobados por la FDA para tratar a las personas con COVID-19. Es posible que su profesional sanitario hable con usted sobre los ensayos clínicos para los que podría ser idóneo.

Usted decide si quiere ser tratado o no con bamlanivimab. Si decide no recibir bamlanivimab o dejar de tomarlo en algún momento, esto no cambiará la atención médica que recibe habitualmente.

¿Qué ocurre si estoy embarazada o en período de lactancia?

Disponemos de muy poca experiencia en cuanto al tratamiento de mujeres embarazadas o en período de lactancia con bamlanivimab. Para la madre y el feto, el beneficio de recibir bamlanivimab podría ser superior al riesgo derivado del tratamiento. Si está embarazada o en período de lactancia, comente sus opciones y su situación específica con su profesional sanitario.

¿Cómo debo notificar los efectos secundarios del bamlanivimab?

Informe a su profesional médico de inmediato si tiene algún efecto secundario que le moleste o que no desaparezca.


¿Cómo puedo obtener más información?

- Consulte con su proveedor de atención sanitaria
- Visite la página [www.bamlanivimab.com](http://www.bamlanivimab.com)
- Póngase en contacto con su departamento de salud pública local o estatal
¿Qué es una autorización de uso de emergencia (EUA)?

La FDA de los Estados Unidos ha puesto a disposición bamlanivimab bajo un mecanismo de acceso de emergencia llamado EUA. La EUA está respaldada por una declaración del Secretario de Salud y Servicios Humanos (HHS) sobre la existencia de circunstancias que justifican el uso de emergencia de medicamentos y productos biológicos durante la pandemia de la COVID-19.

El bamlanivimab no se ha sometido al mismo tipo de revisión que cualquier otro producto aprobado o autorizado por la FDA. La FDA puede emitir una EUA cuando se cumplen ciertos criterios, que incluyen que no haya alternativas adecuadas, aprobadas y disponibles. Además, la decisión de la FDA se basa en la totalidad de los datos científicos disponibles que muestran que es razonable creer que el producto cumple con ciertos criterios de seguridad, funcionamiento y etiquetado y que puede ser eficaz en el tratamiento de pacientes durante la pandemia de la COVID-19. Todos estos criterios deben cumplirse para que el producto pueda utilizarse en el tratamiento de pacientes durante la pandemia de la COVID-19.

La EUA para bamlanivimab permanecerá vigente mientras dure la declaración de la COVID-19 que justifica el uso de emergencia de estos productos, a menos que ésta se cancele o revoque (después de lo cual el producto ya no se podrá usar).

Datos publicados en noviembre de 2020

Eli Lilly and Company, Indianápolis, IN 46285, EE. UU.

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