REFERRAL INSTRUCTIONS: Monoclonal Antibody Infusion for COVID-19

ENLOE MEDICAL CENTER

Infusion RN contact: (530) 809-6753

Process for Referral:

- The provider (MD, DO, PA, NP) will determine if the patient meets criteria for MAB infusion
- EMC providers must utilize Epic to complete the referral process
- All other providers must complete the referral for treatment
    - Fax required documents to the Procedural Care Unit @ (530) 893-6010
        - Referral for Monoclonal Antibody Treatment for COVID-19
        - COVID-19 positive test results
        - Recent chart notes
        - Patient's face sheet
- The RN will only notify the referring provider if the patient cannot be scheduled or does not meet treatment criteria
- The provider will make available the *Enloe's Patient Instructions*
- Once the referral is reviewed and confirmed, the RN will call the patient to set up the infusion time.

Process for ED/Prompt Care – The process will be the same as above during daytime hours.
The following process will be implemented should a patient that meets criteria present after 5:00 p.m.

- EMC providers must complete the referral process in Epic as stated above
- The provider will inform the patient that they will be called by the Infusion RN
- The patient will be discharged home from the ED or Prompt Care
- Once the referral is reviewed and confirmed, the RN will call the patient to set up the infusion time

Monoclonal Antibody Treatment Referral for COVID-19

ENLOE MEDICAL CENTER

Please complete ALL fields below.

INFUSION RN CONTACT: (530) 809-6753

Date:_____ Patient Phone Number:_____

Patient Name:_____ DOB:_____ Age:_____

❑ Patient has a positive COVID test

Date of test results: _____ Date of symptom onset:_____ (Symptoms must be present 7-10 days depending on the medication.)

❑ Results: Home Test

SECTION I

GENERAL INCLUSION CRITERIA – Patient must meet ALL of the following

Patient meets all of the following criteria:

- Patient is not hospitalized due to COVID-19
- Not on oxygen **OR** on chronic oxygen therapy BUT is not requiring an increase in O2 related to COVID-19
- Is 12 years of age or older weighing at least 40 kg
- Has transportation available to and from the treatment appointment
- Has received the monoclonal antibody infusion fact sheet and wishes to proceed with evaluation for treatment
- Alternative COVID-19 treatment options are not accessible or clinically appropriate
- Patient is at high risk for progression to severe COVID-19, including hospitalization or death

SECTION II

ELIGIBILITY CRITERIA – Must meet ONE of the following

❑ Age 65 years or older
❑ BMI great than 25
❑ Cancer
❑ Cardiovascular conditions such as heart failure, CAD, cardiomyopathy, hypertension, congenital heart disease
❑ Cerebrovascular disease including CVA
❑ Chronic kidney disease (GFR less than or equal to 45)
❑ Chronic liver disease
❑ Chronic respiratory disease such as COPD, cystic fibrosis, interstitial lung disease, pulmonary hypertension, moderate to severe asthma. (Mild persistent and intermittent asthma are not a clinical inclusion criteria.)
❑ Diabetes (type 1 or type 2)
❑ HIV
❑ High risk for deterioration
❑ Immunosuppressive disease or currently receiving Immunosuppressive treatment
❑ Medical technologies dependance not related to COVID such as, positive pressure ventilation, tracheostomy, gastrostomy etc.
❑ Neurodevelopmental disorders such as, cerebral palsy, down syndrome, dementia,
❑ Pregnancy
❑ Sickle cell or thalassemia disease
❑ Smoking, current or former
❑ Social determinants
❑ Solid organ or blood stem cell transplant
❑ Substance use disorder

DISCLAIMER: *Monoclonal Antibody infusion allocations vary from week to week. Patients are scheduled based on meeting inclusion criteria and product availability. The requesting provider will be notified should a patient not meet qualifying criteria or if medication is unavailable.*

Requesting Provider Name (please print): _____

Requesting Provider Contact Number: _____

Requesting Provider Signature: _____ Date:_____ Time:_____

Please fax this completed request form & required documentation to (530) 893-6010. Required documentation:

- Positive COVID test results
- Recent chart note
- Facesheet

ENLOE MEDICAL CENTER STAFF USE ONLY

Date/Time Received:_____ @_____ MR#:_____

Patient Information

PATIENT INFORMATION:
Monoclonal Antibody Infusion for COVID-19

Dear _____,

You have been referred for an infusion to help prevent hospitalization or return to the Emergency Department due to COVID-19. Your provider should have provided you with the risk and benefits as well as evaluated you for inclusion criteria.

Supplies of this infusion are limited. You may be scheduled to receive the infusion but are not guaranteed based on availability of the infusion. If the infusion is no longer available, we will notify you prior to your appointment.

Infusion Site Information:

- Hours: Vary
- Location: Enloe Medical Center – Main Campus
  1531 Esplanade, Chico, CA 95926
- The MAB entrance is located on the corner of Esplanade and 6th Ave. Look for the "MAB" Signs. There is limited street parking available in front of the clinic entrance on the frontage road labeled "MAB Parking". Please park your car. Do not utilize the valet parking system.
- Please wear a mask. Come to the door that faces the Esplanade labeled "MAB Entrance". Ring the doorbell. Staff will meet you at the door and escort you into the infusion area.

What to Expect:

- An IV will be started in your arm.
- Your heart rate, blood pressure, and oxygen will be monitored during and after the infusion.
- You should anticipate 2-4 hours for this process. The infusion will take up to 90 minutes to complete and you will be monitored for another hour afterwards.
- Once monitoring requirements are completed, you will be discharged home.

After the Infusion:

- You may drive yourself home.
- If you develop worsening symptoms, notify your provider or call 911 in the event of an emergency.

Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Bebtelovimab for Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you or your child with bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate. This Fact Sheet contains information to help you understand the potential risks and potential benefits of receiving bebtelovimab, which you or your child have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make bebtelovimab available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). Bebtelovimab is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about bebtelovimab. Talk to your healthcare provider about your options or if you have any questions. It is your choice for you or your child to receive bebtelovimab or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus (SARS-CoV-2). You 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 or your child's other medical conditions to become worse. Older people and people of all ages with severe, or long lasting (chronic) medical conditions like heart disease, lung disease, diabetes, and obesity, for example, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What is bebtelovimab?

Bebtelovimab is an investigational medicine used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]):

- with positive results of direct SARS-CoV-2 viral testing, **and**

- who are at high risk[1] for progression to severe COVID-19, including hospitalization or death, **and**
- for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate.

There is limited information known about the safety and effectiveness of using bebtelovimab for the treatment of mild-to-moderate COVID-19.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

Bebtelovimab is not authorized for use in people who:
- are likely to be infected with a SARS-CoV-2 variant that is not able to be treated by bebtelovimab based on the circulating variants in your area (ask your health care provider about FDA and CDC's latest information on circulating variants by geographic area), **or**
- are hospitalized due to COVID-19, **or**
- require oxygen therapy and/or respiratory support due to COVID-19, **or**
- require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.

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

How will I or my child receive bebtelovimab?
Bebtelovimab will be given as an injection through a vein (intravenously or IV) over at least 30 seconds. You will be observed by your healthcare provider for at least 1 hour after you receive bebtelovimab.

What are the important possible side effects of bebtelovimab?
- **Allergic reactions.** Allergic reactions can happen during and after injection with bebtelovimab. Tell your healthcare provider right away if you or your child develop any of the following signs and symptoms of allergic reaction: fever, difficulty breathing, low oxygen level in your blood, chills, tiredness, fast or slow heart rate, chest discomfort or

[1] For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

pain, weakness, confusion, nausea, headache, shortness of breath, low or high blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness, feeling faint, and sweating. These reactions may be severe or life threatening.

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

These are not all the possible side effects of bebtelovimab. Not many people have received bebtelovimab. Serious and unexpected side effects may happen. All of the risks are not known at this time.

It is possible that bebtelovimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bebtelovimab may reduce the body's immune response to a vaccine for SARS-CoV-2. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?
Like bebtelovimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice for you or your child to be treated or not to be treated with bebtelovimab. Should you decide not to receive it or for your child to not receive it, it will not change your or your child's standard medical care.

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

How do I report side effects with bebtelovimab?
Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, or call 1-800-FDA-1088 or to Eli Lilly and Company, Inc. as shown below.

Email	Fax Number	Telephone Number
mailindata_gsmtindy@lilly.com	1-317-277-0853	1-855-LillyC19 (1-855-545-5921)

How can I learn more about COVID-19?
- Ask your healthcare provider

- Visit https://www.cdc.gov/COVID19
- Contact your local or state public health department

What is an Emergency Use Authorization?

The United States FDA has made bebtelovimab available under an emergency access mechanism called an Emergency Use Authorization (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.

Bebtelovimab for the treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) **and** who are at high risk of developing severe COVID-19, including hospitalization or death, **and** for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

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 bebtelovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of bebtelovimab, unless terminated or revoked (after which bebtelovimab may no longer be used under the EUA).

Additional Information

For general questions, visit the website or call the telephone number provided below.

Website	Telephone Number
www.LillyAntibody.com/bebtelovimab	1-855-LillyC19 (1-855-545-5921)

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Eli Lilly and Company, Indianapolis, IN 46285, USA

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