REFERRAL INSTRUCTIONS: Monoclonal Antibody for COVID-19 Infusions

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 Respiratory ICU @ (530) 893-6804
    - 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
- The RN will call the patient to confirm the scheduled appointment

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
- The RN will check for new referrals each morning
- Once the referral is reviewed and confirmed, the RN will call the patient to set up the infusion time
REFERRAL FORM: Monoclonal Antibody Treatment for COVID-19

INFUSION RN CONTACT: (530) 809-6753

Please complete ALL fields below

<table>
<thead>
<tr>
<th>Date:</th>
<th>Patient Phone Number:</th>
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<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>DOB:</th>
<th>Age:</th>
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- Patient has a positive COVID test AND is SYMPTOMATIC.

Date of test results:  
Date of symptom onset:  
(Symptoms must be present 10 days or less)

**If the positive COVID test resulted from home antigen or home PCR testing, Enloe Medical Center ordering physician review of the case is requested prior to scheduling patient.

- Results: Home Test

### GENERAL INCLUSION CRITERIA – Patient must meet ALL of the following

<table>
<thead>
<tr>
<th>Patient meets all of the following criteria:</th>
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</thead>
<tbody>
<tr>
<td>A resident of Butte, Tehama, Colusa, Glenn, Plumas or Lassen County or a patient receiving Enloe Services</td>
</tr>
<tr>
<td>Patient is not hospitalized due to COVID-19</td>
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<tr>
<td>Not on oxygen OR on chronic oxygen therapy BUT is not requiring an increase in O2 related to COVID-19</td>
</tr>
<tr>
<td>Is 12 years of age or older weighing at least 40 kg</td>
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<tr>
<td>Has transportation available to and from the treatment appointment</td>
</tr>
<tr>
<td>Has received the monoclonal antibody infusion fact sheet and wishes to proceed with evaluation for treatment</td>
</tr>
</tbody>
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### ELIGIBILITY CRITERIA – Must meet ONE of the following

**65 years or older**

**OR**

Individually who are not expected to mount an adequate immune response, must meet one of the criteria below:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids, prednisone 10 mg per day or more, or other drugs that may suppress your immune response

**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.

- Requesting Provider Name (please print):  
- Requesting Provider Contact Number:  
- Requesting Provider Signature:  
- Date:  
- Time:  

Please fax this completed request form & required documentation to (530) 893-6804. Required documentation:

- Positive COVID test results  
- Recent chart note  
- Facesheet

ENLOE MEDICAL CENTER STAFF USE ONLY BELOW THIS LINE

<table>
<thead>
<tr>
<th>Date/Time Received:</th>
<th>MR#:</th>
</tr>
</thead>
</table>

- Yes  
- No  

Documentation provided supports ALL general inclusion items and at least one of the clinical criteria.

**Reviewed with Enloe Medical Center ordering physician and verbal approval to proceed.**
Dear ________________________________.

You have been referred for an infusion of a monoclonal antibody 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 3-4 hours for this process. The infusion will take 60-90 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 Sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called sotrovimab 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 sotrovimab, which you may receive.

Receiving sotrovimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about sotrovimab. Talk to your healthcare provider if you have any questions. It is your choice to receive sotrovimab 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 other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, diabetes, for example, and other conditions including obesity, 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 are the symptoms of COVID-19?
The symptoms of COVID-19 are 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 sotrovimab?
Sotrovimab is an investigational medicine used to treat mild-to-moderate symptoms of 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 of progression to severe COVID-19, including hospitalization or death. Sotrovimab is investigational because it is still being studied. There is limited information about the safety and effectiveness of using sotrovimab to treat people with mild- to-moderate COVID-19.

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

Who should not receive sotrovimab?
Do not take sotrovimab if you have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab.

What are the ingredients in sotrovimab?
Active ingredient: sotrovimab
Inactive ingredients: L-histidine, L-histidine monohydrochloride, L-methionine, polysorbate 80, and sucrose

What should I tell my healthcare provider before I receive sotrovimab?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab
- Are pregnant or plan to become pregnant
• Are breastfeeding or plan to breastfeed
• Have any serious illnesses
• Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

How will I receive sotrovimab?
• You will receive 1 dose of sotrovimab.
• Sotrovimab will be given to you through a vein (intravenous or IV infusion) over 30 minutes.
• You will be observed by your healthcare provider for at least 1 hour after you receive sotrovimab.

What are the important possible side effects of sotrovimab?
Possible side effects of sotrovimab are:
• **Allergic reactions.** Allergic reactions can happen during and after infusion with sotrovimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever; difficulty breathing; low oxygen level in your blood; chills; tiredness; fast or slow heart rate; chest discomfort or 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.

The side effects of getting any medicine through a 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 sotrovimab. Not many people have been given sotrovimab. Serious and unexpected side effects may happen. Sotrovimab is still being studied, so it is possible that all of the risks are not known at this time.

It is possible that sotrovimab could interfere with your body’s own ability to fight off a future infection of SARS-CoV-2. Similarly, sotrovimab 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 sotrovimab, 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](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 not approved 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 to be treated or not to be treated with sotrovimab. Should you decide not to receive sotrovimab, or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is no experience treating pregnant women or breastfeeding mothers with sotrovimab. For a mother and unborn baby, the benefit of receiving sotrovimab 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 sotrovimab?
Tell your healthcare provider right away 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088, or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684).

How can I learn more?
• Ask your healthcare provider
• Visit [www.sotrovimabinfo.com](http://www.sotrovimabinfo.com)
• Call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684)
Visit https://www.covid19treatmentguidelines.nih.gov/
Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The FDA has made sotrovimab 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.

Sotrovimab has not undergone the same type of review as an FDA-approved medicine. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, 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 medicine to be used in the treatment of patients during the COVID-19 pandemic.

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

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