Patient Consent for Treatment Form

NAME OF DRUGS: **Bebtelovimab**

SITE OF TREATMENT: Central Maine Healthcare (CMMC,BH,RH)

PHONE NUMBER: 207-795-2200

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. Before you decide whether you would like to be treated with this medication, your medical provider would like you to review this information. If you decide that you would like to receive this treatment, you will be asked to sign this form. A copy of this form and an FDA approved fact sheet will be given to you for your reference.

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 risk1 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.

For more information on what is a EUA and the specific populations that are authorized please refer to the Fact Sheet for Patients, Parents and Caregivers that you have received.

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 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.

TREATMENT PLAN

The following procedures and assessments will be performed prior to, during, and after treatment with this medication.

Assessments	Pre-dose	On Treatment	Post-dose / follow up
Medical History	**X**		
Vital signs	**X**	**X**	**X**
Physical Exam	**X**		**X**
Monitor for Adverse Reactions/Events		**X**	**X**

Your medical provider may choose to perform other assessments (for example lab work) to monitor your health based on any other medical conditions you may have.

RISKS

There are some known risks and adverse reactions to using this medication. You will be provided with the FDA-approved fact sheet that accompanies the emergency use authorization for this medication. You will also be provided with a copy of this consent form. Talk to your medical provider about any questions or concerns you have regarding these potential risks or adverse reactions prior to starting this treatment.

MEDICAL HISTORY

You may have a greater chance of experiencing known risks/adverse reactions if you have certain medical problems or conditions. Please tell your medical provider about all of your health conditions. In particular, please mention if you have any of the following health problems:

- Any allergies
- Any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking medications, including prescription, over the counter medications, vitamins, and herbal products

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)

COSTS
You may incur the cost of this medication and/or associated procedures if they are not covered by your insurance.

YOUR PERSONAL INFORMATION
Your personal information will be protected under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended from time to time (collectively, HIPAA) as stated in the **Central Maine Medical Center Consent**, Use and Disclosure Statement. Some of your personal information may be retained in the Clinical Research Department for a limited period of time to optimize your individual care and in accordance with federal regulations. Your information will be made accessible to Eli Lilly and Company as well as the FDA and other regulatory agencies that choose to review it.

Patient Statements:

- I have read this consent form, or had it read to me. I understand the risks and benefits associated with taking this medication as authorized by the FDA for emergency use and have had the opportunity to ask and have questions answered.
- I would like to pursue treatment for COVID-19 with bebtelovimab
- I understand that this medication has not been approved to treat COVID-19.
- I will be given a signed copy of this document for my records.
- I have received a copy of the FDA-approved Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of bebtelovimab for Coronavirus Disease 2019 (COVID-19)
- By signing this form, I am not waiving any of my legal rights.

_____

Patient Name

_____ _____

Patient/ Caregiver/ Legally Authorized Representative Signature Date and Time

Provider Statements:

- I have reviewed the information in this form with the patient (and Legally Authorized Representative, if applicable).
- I have answered the patient's (and Legally Authorized Representative's, if applicable) questions to the best of my ability.

_____

Provider's Printed Name

_____ _____

Provider's Signature Date and Time