Bebtelovimab and Sotrovimab
Order Form for Patients ≥ 12 Years Old (≥40 kg)

PATIENT NAME:	DOB:
ALLERGIES:	POSITIVE COVID-19 TEST ON*:
FDA PATIENT FACT SHEET PROVIDED ON: * Not applicable for post-exposure prophylaxis use ** Per FDA EUA, patient education and patient fact sheet must be provided to the patient prior to administration.	

PATIENT SCREENING

- ☐ Age (≥ 12 y.o.): _____ (Required)
- ☐ Weight (≥ 40 kg): _____ (Required)
- ☐ **Mild to moderate COVID-19:** with positive test for SARS-CoV-2 (antigen or PCR, including self-attested home test) within 7 days of symptom onset **and** who are at high-risk for progressing to severe COVID-19 and/or hospitalization (see below) **and** for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate (bebtelovimab)

Patient meets at least one of the following high-risk criteria:

- ☐ Is ≥ 65 years of age
- ☐ Has a body mass index (BMI) ≥ 25
- ☐ Pregnancy
- ☐ Has chronic kidney disease
- ☐ Has diabetes
- ☐ Has immunosuppressive disease
- ☐ Is currently receiving immunosuppressive treatment
- ☐ Cardiovascular disease or hypertension
- ☐ Chronic lung diseases
- ☐ Neurodevelopmental disorders or other conditions that confer medical complexity
- ☐ Sickle cell disease
- ☐ Having a medical-related technological dependence not related to COVID-19 (e.g., tracheostomy, gastrostomy)
- ☐ Is 12-17 years of age and has: BMI ≥ 85th percentile for their age and gender based on CDC growth charts; sickle cell disease; congenital or acquired heart disease; neurodevelopmental disorders; medical related technological dependence; OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- ☐ Other medical conditions or factors that place the patient at high risk for progressing to severe COVID-19
  Describe: _____

Monoclonal Antibodies are 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 flowrate due to COVID-19 for those on chronic oxygen therapy due to an underlying non-COVID-19 condition.

- ☐ Patient does not meet any of the above contraindications

DRUG AND ADMINISTRATION FOR TREATMENT OF MILD TO MODERATE COVID-19

Based on availability of monoclonal antibodies:

☐ **Sotrovimab Treatment:** 500 mg sotrovimab. Per EUA, remove one vial of sotrovimab from refrigerator and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes. Gently swirl vial (DO NOT SHAKE) before use without creating air bubbles. Add 8mL of sotrovimab (1 vial) to a prefilled infusion bag and administer as a single intravenous infusion (IV) over at least 15 minutes as instructed in Health Care Provider Fact Sheet.

[a] Sotrovimab is a clear, colorless, or yellow to brown solution. Discard if particulate matter or discoloration is observed prior to administration.
[b] Prior to infusion, gently rock the infusion bag back and forth by hand for 3 to 5 minutes. Avoid forming air bubbles.

☐ **Bebtelovimab:** 175 mg bebtelovimab. Per EUA, remove bebtelovimab vial from refrigerator and allow to equilibrate to room temperature for approximately 20 minutes. Withdraw 2 mL of bebtelovimab (1 vial) into disposable syringe. Attach syringe to syringe extension set and prime. Administer as a single intravenous injection over at least 30 seconds as instructed in Health Care Provider Fact Sheet.

[a] Bebtelovimab is preservative-free and should be administered immediately.
[b] Use polycarbonate and polyvinylchloride without di-ethylhexylphthalate (DEHP) syringe extension set

Developed 2/28/2022

To be documented at time of administration:

Sotrovimab Lot Number: _____ **Expiration Date** _____

Bebtelovimab Lot Number: _____ **Expiration Date** _____

_____

Administering Provider **Signature** **Date**

POST-INFUSION

- ☐ Flush administration set with 0.9% sodium chloride to deliver residual volume.
- ☐ For bebtelovimab only, leave IV in place for observation period; remove prior to discharge.
- ☐ Monitor patient for hypersensitivity reaction for a period of 60 minutes following infusion.
- ☐ Send record of treatment and post-infusion summary (page 3) to prescriber at fax number below

MANAGEMENT OF HYPERSENSITIVITY

Patients must be clinically monitored during infusion and observed for at least one hour after infusion is complete. Vital signs must be measure before infusion and ≤ q 30 minutes, and when indicated until conclusion of observation period.

Management of Minor Infusion-Related Symptoms	
Nausea/Vomiting	☒ Ondansetron (Zofran): 4 mg ODT (oral dissolving tablet) or 4 mg IV
Headache/Fever	☒ Acetaminophen: 650-1,000 mg PO
*** Minor infusion related symptoms such as nausea, headache, fever, and dizziness can often improve with slowing infusion rate. For minor symptoms early in the infusion, decrease infusion rate by 25-50%.	
Management of Severe (anaphylactic and non-anaphylactic) Administration-Related Symptoms	
*** Immediately stop infusion or injection, obtain vital signs, initiate supplemental oxygen, as indicated. Activate the emergency medical system (EMS; e.g., call 911 if applicable) and notify the patient's physician/clinician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient and initiates treatment, as appropriate.	
Management of Anaphylactic Symptoms	
Anaphylaxis	☒ **Epinephrine 0.3 mg IM (includes autoinjector); if signs of hypotension and/or respiratory distress with wheezes or stridor are present, repeat dose every 5 to 15 minutes for up to two doses and diphenhydramine as described below.** ☒ Diphenhydramine 50 mg IM or IV (administer alone for moderate symptoms)
*** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen as indicated, administer medications as above, limit epinephrine to shock or severe respiratory distress. Call EMS and continue supportive care, while monitoring patient closely until arrival. Notify the prescribing physician/clinician as soon as able.	

ADDITIONAL ORDERS

ORDERING PRESCRIBER

Prescriber Name: _____

Prescriber Signature: _____

As the ordering prescriber, I allow for product selection and authorize the administering practitioner to substitute for another monoclonal antibody identified on this order form, unless the box below is checked.

☐ **Dispense as written (DAW) *** checking DAW could result in significant delays in treatment based on availability of medication supplies *****

Direct Contact Number: (___) _____ – _____ **Fax Number:** (___) _____ – _____

Order date: _____ ☐ **Check if administered under a standing order**

REPORTING REQUIREMENTS

In accordance with the Michigan Public Health Code (MCL 331.531), the following survey must be completed for each patient treated with monoclonal antibody (MAB) therapy supplied through the State of Michigan: https://forms.office.com/Pages/ResponsePage.aspx?id=sgF4Zzdipk67RItjfx6ergRINfmr3E1Njq-ZF3K4vsBUMjRaVE43VjM1MFJRTllCVzBMMk9HWVVBTiQlQCN0PWcu.

POST ADMINISTRATION SUMMARY

☐ No administration related problems

Additional Comments:

Patients, Parents and Caregivers EUA Resources:

☐ Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Sotrovimab for Coronavirus Disease 2019 (COVID-19): **https://www.fda.gov/media/149533/download.**

☐ Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Bebtelovimab for Coronavirus Disease 2019 (COVID-19): **https://www.fda.gov/media/156153/download**

Patient Consent: by signing this I attest to have read, or had explained to me, the patient fact sheet for the monoclonal antibody that I am receiving and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I understand the potential risks and benefits associated with monoclonal antibody therapy and agree to receive the administration of this medication.

_____

Form Completed by/Relationship to Patient **Signature** **Date**

Standing Orders: Note if administration is done under a standing order issued by an authorized prescriber, the administering clinician should complete all applicable sections of this form in accordance with the Standing Order. The name of the prescriber issuing the Standing Order should be documented under "Prescriber Name" and the Standing Order box checked on Page 3.