St. Clair Health

St. Clair Hospital

COVID-19 Monoclonal Antibody Infusion Patient Reservation Checklist

Physicians requesting the use of any anti-SARS-CoV-2 monoclonal antibody infusion currently approved under Emergency Use Authorization (EUA) must fax the following information to the St. Clair Hospital Pharmacy Department at **412-942-1420**. Each case will be reviewed per institution and FDA qualification criteria by a multidisciplinary team. Home tests will not be accepted due to concerns with test accuracy.

Please answer the following questions completely:

Patient Name: _____

Physician Office Name: _____

Prescribing Physician: _____

Physician Office Phone Number: _____

Physician Office Fax Number: _____

Please return all three of the following with this reservation checklist:

☐ SARS-CoV-2 Positive Test Copy

☐ Completed COVID-19 Monoclonal Antibody Infusion Patient Consent Form

☐ Completed COVID-19 Monoclonal Antibody Order Set

☐ SARS-CoV-2 Vaccine status (check one): ☐Vaccinated ☐Unvaccinated

☐ If vaccinated, identify severe immunosuppressive condition below:

- ☐ Within 1 year of receiving B-cell depleting therapy
- ☐ Chimeric antigen receptor T cell recipient
- ☐ Receiving tyrosine kinase inhibitor
- ☐ Hematologic malignancy on active therapy
- ☐ Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or are taking immunosuppressive medications for another indications
- ☐ Lung transplant recipient
- ☐ Severe combined immunodeficiency
- ☐ Within 1 year of receiving solid-organ transplant (not lung transplant)
- ☐ Untreated HIV who have a CD4 T lymphocyte cell count < 50 cell/mm^3

Failure to send the completed information above will result in the patient not being reviewed for anti-SARS-CoV-2 monoclonal antibody infusion consideration.

Patient Name: _____

Date of Birth: _____

Phone Number: _____

St. Clair Hospital
Pittsburgh, PA 15243

COVID-19 Monoclonal Antibody Order Set

Physicians requesting the use of approved anti-SARS-CoV-2 monoclonal antibody therapy under Emergency Use Authorization (EUA) must complete this order set for patient consideration. Patient will be reviewed by a multidisciplinary team, who will provide approval or denial The following questions must be answered by the requesting physician prior to authorization process:

Criteria for Use:

1. **SARS-CoV-2 Positive Test** ☐ **Yes** ☐ **No**
   a. Patient must have direct positive test
2. **Outpatient Status** ☐ **Yes** ☐ **No**
   a. Patient is not admitted and does not require hospitalization
3. **Supplemental Oxygen Status** ☐ **Yes** ☐ **No**
   a. Patient is at baseline oxygenation status
4. **High Risk Status** ☐ **Yes** ☐ **No**
   a. Patient has one of the following risk factors (**please circle criteria**):
      i. Age ≥ 65, BMI ≥ 25, CKD, diabetes, immunosuppressive disease, receiving immunosuppressive treatment, pregnancy, cardiovascular disease, hypertension, COPD/other respiratory disease, sickle cell disease, neurodevelopmental disorders, and medical-related technological dependence (tracheostomy, gastrostomy, or positive pressure ventilation) OR
      ii. Age 12-17 and have:
      BMI ≥ 85th percentile for their age and gender based upon CDC growth charts or any of the above risk factors
5. **Duration of Symptoms ≤ 7 days** ☐ **Yes** ☐ **No**
   a. Date of symptom onset :_____ **(must fill in date)**

If approved by multidisciplinary team, patient will be scheduled and receive the following:
Premedication (given 30 minutes prior to infusion):

☐ Famotidine 20 mg by mouth x 1 dose
☐ Acetaminophen 650 mg by mouth x 1 dose
☐ Diphenhydramine 25 mg IV push x 1 dose **PRN infusion reaction**
☒ Pharmacy to select available monoclonal antibody at an approved administration rate according to EUA:
   ☐ Sotrovimab 500 mg in 100 mL NSS IV piggyback with 0.2 micron PES filter over at least 30 minutes
   ☐ Bebtelovimab 175 mg (2 mL) IV push over at least 30 seconds via primed DEHP syringe extension set. After administration, **flush the extension set** with NSS to ensure delivery of the required dose.

Patient must receive anti-SARS-CoV-2 monoclonal antibody infusion by this date: _____

Prescribing physician to schedule patient for follow-up appointment 24-48 hours post infusion

Physician Signature:_____ **Date:** _____ **Time:** _____

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Authorization for COVID-19 Monoclonal Antibody Consent

1. I authorize Dr._____ and whomever he or she may designate as assistants, to order for the above-named patient the administration of the COVID-19 Monoclonal Antibody _____, which is currently authorized for emergency use by the Food & Infusion Administration (FDA).

2. I understand that the COVID-19 Monoclonal Antibody is used in cases of COVID-19. The COVID-19 Monoclonal Antibody is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it's safe and effective. Because the COVID-19 Monoclonal Antibody is investigational, the Food and Infusion Administration (FDA) has not yet approved it for general use; however, the FDA has authorized emergency use of the infusions for use in cases of COVID-19 infection under 21 U.S.C. 360bbb-3 of the Food, Drug, and Administration Act.

3. I acknowledge that the nature, risks and consequences of the use of the COVID-19 Monoclonal Antibody and the possible alternatives to the treatment, including no treatment, and their nature, risks and consequences have been fully explained to me. Some of the known possible side effects of this medication include, but are not limited to, fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These can happen during and after the infusion and should be reported to the healthcare provider right away. These are not all the possible side effects. Serious and unexpected side effects may happen.

4. I acknowledge that I have received the appropriate information sheet "FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF the COVID-19 Monoclonal Antibody FOR CORONAVIRUS DISEASE 2019 (COVID-19)", that I have been given an opportunity to ask questions about the treatment and that all questions which I have asked have been answered to my satisfaction.

5. I acknowledge that there may be unforeseen complications, injury, or even death from both known and unknown causes associated with COVID-19 Monoclonal Antibody administration.

6. I acknowledge that no guarantee or assurance has been made as to the result or cure that might be obtained from the treatment.

Acknowledged by Dr _____ Date_____ Time_____
(Physician Signature required)

I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THE ABOVE STATEMENTS, THAT THE EXPLANATIONS THEREIN REFERRED TO HAVE BEEN MADE CLEAR TO ME, THAT ALL BLANKS OR STATEMENTS REQUIRING INSERTIONS OR COMPLETIONS HAVE BEEN FILLED IN, AND THAT I WISH TO GIVE THE ABOVE AUTHORIZATION AND ACKNOWLEDGEMENT.

Date _____ Time _____ _____
Patient's Signature

If this patient is unable to sign, complete the following lines:

This patient unable to sign because _____

_____ _____
Person Signing on Behalf of Patient Relationship to Patient

Date _____ Time _____ _____
Witness' Signature