

FAX

SUBJECT: COVID-19 Monoclonal Antibody Treatment

TO: Please select ONE infusion center location (avoid sending to multiple infusion centers) Please note: hours of operation are subject to change

Arizona

- | | | |
|--|--|---|
| <input type="checkbox"/> BBMC (Baywood)
Fax: 480-321-3939
Tel: 480-321-4032 | <input type="checkbox"/> BUMC-Phoenix
Fax: 602-839-2267
Tel: 602-839-3963 | <input type="checkbox"/> BUMCT Mab Clinic
Fax: 520-441-4419 |
|--|--|---|

Colorado

- | | |
|---|--|
| <input type="checkbox"/> MMC
Fax: 970-820-6091
Tel: 970-820-4093 | <input type="checkbox"/> NCMC
Fax: 970-810-6992
Tel: 970-810-3940 |
|---|--|

FROM:

Provider Name: _____ Date: _____

Provider Fax: _____ Provider Tel: _____ No. Pages: _____

Comments: _____

ORDER Process:

Please follow the steps outlined below to evaluate patients for Monoclonal Antibody Infusion

1. Obtain positive direct SARS-CoV-2 test documentation
 - a. PCR or direct antigen accepted, antibody tests are not accepted
2. Evaluate patient for high-risk criteria (can be evaluated by phone, face-to-face, or telehealth)
 - a. Note: Patient must be **within 7 days** from symptom onset
3. Complete clinical note that documents high-risk criteria and review of patient fact sheet
4. Complete order set and attach the following:
 - History & Physical note, including
 - i. evaluation of risk factors
 - ii. statement that patient does not have concurrent systemic infection (UTI, SSI, etc.)
 - Patient demographics including insurance information
 - Diagnostics labs (direct positive SARS CoV-2-test)
 - Documentation that patient has received fact sheet OR that the fact sheet has been verbally reviewed with the patient

The infusion center may contact you for any clarifications needed. To facilitate smooth and rapid scheduling for your patient, please be sure to include all documents listed above and accurate contact information.

**OUTPATIENT PROVIDER ORDERS –
TREATMENT OF MILD TO MODERATE
COVID-19 WITH SARS-COV-2 SPECIFIC
MONOCLONAL ANTIBODY**

**FORM MUST BE COMPLETE (no blanks) AND SIGNED BY THE PROVIDER FOR PATIENT
TO BE CONSIDERED FOR SARS-CoV-2 Specific Monoclonal Antibody**

FACILITY: _____ INFUSION CENTER CONTACT INFORMATION: _____

PLEASE PRINT

ORDER MUST BE FAXED FROM PROVIDER'S OFFICE

Date: _____

PATIENT NAME: _____ DOB: _____

Phone: _____ Height (cm): _____ Weight (kg): _____

Allergies: _____

Diagnosis Code: _____ Diagnosis Name (REQUIRED): _____

Authorization # (date received, name of person giving authorization, date range if applicable): _____

Physician Name (PRINT FIRST & LAST): _____

Physician office phone #: _____ Physician Fax #: _____

Contact person and Ext # at physician office: _____

SARS-CoV-2 Specific Monoclonal Antibody Guidelines

- Banner SARS-CoV-2 Specific Monoclonal Antibody Guidelines available in Banner COVID Toolkit.
- **Casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab are investigational drugs and are not currently FDA approved for any indication.**
- The FDA issued four separate Emergency Use Authorization (EUA) to authorize the emergency use of casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, or bebtelovimab respectively for the treatment of mild to moderate COVID-19 with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- As of January 24, 2022, due to the high frequency of the Omicron variant, bamlanivimab/etesevimab and casirivimab/imdevimab, are not currently authorized for use in any U.S. region because of markedly reduced activity against the omicron variant. As of April 5th, Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant.
 - **Bebtelovimab** EUA Provider fact sheet available at: <https://www.fda.gov/media/156152/download>

SARS-CoV-2 Specific Monoclonal Antibody CRITERIA FOR USE

Patient must meet **ALL** criteria to be eligible for bebtelovimab consideration.

- 18 years of age or older weighing at least 40 kg
 - COVID-19 positive by PCR or Antigen testing
 - Within **7 Days** from symptom onset (Date of Symptom Onset: _____)
 - Meets the following oxygen therapy requirements:
 - Not requiring oxygen therapy due to COVID-19 **OR**
 - If on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity, not requiring an increase in baseline oxygen flow rate due to COVID-19
 - Does not have suspected or proven serious, active bacterial, fungal, viral, or other infection (excluding COVID-19) due to possible worsening of cytokine activation
 - High risk - defined as meeting one of more of the following criteria:**

<input type="checkbox"/> Age ≥ 65 years	<input type="checkbox"/> Pregnancy	<input type="checkbox"/> Neurodevelopment disorders or other conditions that confer medical complexity (e.g., genetic, or metabolic syndrome)
<input type="checkbox"/> Major immune suppression (e.g., recently diagnosed hematologic malignancy, cancer chemotherapy, solid organ transplant on immune suppression)	<input type="checkbox"/> Diabetes	<input type="checkbox"/> Medical related technology dependence (e.g., gastrostomy)
<input type="checkbox"/> Obesity with BMI >25 kg/m ²	<input type="checkbox"/> Chronic kidney disease	
<input type="checkbox"/> Cardiovascular disease (including hypertension)	<input type="checkbox"/> Chronic lung disease (e.g., COPD, cystic fibrosis)	
	<input type="checkbox"/> Sickle cell disease	
 - Patient or caregiver received a copy of the fact sheet: **bebtelovimab** at <https://www.fda.gov/media/156153/download> (Also available in Krames in English and Spanish). Patient was informed of risks and benefits of therapy, availability of alternatives and that the drug is an unapproved drug authorized for use under the Emergency Use Authorization. Patient understands they have the option to accept or refuse treatments and, understanding the risks, benefits and alternatives, has agreed to accept treatment with bebtelovimab based on the prevalence of the Omicron BA.2 variant.
- Vaccination Status: Fully Vaccinated (primary series plus booster) Partially Vaccinated (incomplete primary series or completed primary series without booster) Unvaccinated



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Labs

- HCG Qualitative, Urine prior to administration of SARS-COV-2 Specific Monoclonal Antibody, if positive contact physician
 HCG Qualitative, Serum prior to administration of SARS-COV-2 Specific Monoclonal Antibody, if positive contact physician
 Other: _____

Transcription of External COVID-19 Results

Performed on: _____ Time: _____ (remember to adjust the "Performed on date/time" to the date/time of the "specimen collected" found on the lab report)

Lab name: _____ Other lab name: _____

Type of Test: COVID-19 (SARS-CoV-2, NAA) COVID-19-SARS-CoV-2 by PCR COVID-19 Antigen Test Other

Self-administered at-home COVID test requires confirmatory PCR or Antigen test for Monoclonal Antibody therapy

Coronavirus (COVID-19) SARS CoV2: Not Detected Detected Inconclusive

SARS-CoV-2 Specific Monoclonal Antibody DOSING

Bebtelovimab will be used when prevalence of Omicron variant BA.2 is >50%

bebtelovimab 175 mg IV Push Once
Administer over 30 seconds

Flush line with 0.9% Sodium Chloride after the entire contents of the syringe have been administered to ensure delivery of the required dose.

MONITORING

1. Obtain vital signs prior to SARS-COV-V-2 Specific Monoclonal Antibody administration.
2. Monitor vital signs every 30 minutes thereafter.
3. Clinically monitor patients during infusion and for at least 1 hour after infusion completes.
4. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy (see ADVERSE REACTIONS below).

ADVERSE REACTIONS

<u>MINOR REACTIONS</u> (e.g. nausea, itching, joint pain, rash)	<u>SEVERE REACTIONS</u> (e.g. bronchospasm, loss of airway, fainting, severe flushing)
STOP infusion	CALL A CODE OR RAPID RESPONSE
diphenhydrAMINE 50 mg IV Push Once	STOP infusion
famotidine 20 mg IV Push Once	EPINEPHrine 0.3 mg/0.3 mL SubCutaneous Once
dexaMETHasone 10 mg IV Push Once	Oxygen PRN
Notify Physician	Notify Physician

Physician Signature _____ Date / Time _____