Banner Health

OUTPATIENT PROVIDER ORDERS – TREATMENT OF MILD TO MODERATE COVID-19 WITH SARS-COV-2 SPECIFIC MONOCLONAL ANTIBODY FOR PEDIATRICS AGE 12-17

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 - PEDIATRICS

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

- ❑ 12-17 years of age 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 for patients 12-17 years must meet at least one of the following criteria:**
  - ❑ Asthma
  - ❑ Immunosuppressive disease or on immunosuppressive treatment
  - ❑ Medical related technology dependence (e.g., tracheostomy or on positive pressure ventilation)
  - ❑ Obesity (" https://www.cdc.gov/growthcharts/clinical_charts.htm " BMI ≥ 85th percentile for their age and gender)
- ❑ 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.
- ❑ Yes ❑ No Patient is fully vaccinated and expected to have mounted an adequate immune response

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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

MINOR REACTIONS (e.g. nausea, itching, joint pain, rash)	**SEVERE REACTIONS** (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

PRINT SAVE AS EMAIL RESET

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