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| TITLE | Workflow for Monoclonal Antibody Treatment for SARS-CoV-2 Infection |
| TODAY’S DATE | Aug. 04, 2021 |
| SECTION | Organization Wide PPE OB/GYN  Emergency Department Surgery  Inpatient Ambulatory  Nursing Medical staff [physicians and advance care practitioners] |

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| APPLICABLE LOCATIONS | All Bozeman Health locations  Bozeman Health Deaconess Hospital  Big Sky Medical Center  Belgrade Clinic + UrgentCare  Hillcrest Senior Living  b2 UrgentCare b2 MicroCare |

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| APPROVED BY | Incident Command; Monoclonal Antibody Implementation Taskforce; Infectious Disease, Med Tech |
| APPROVAL DATE | August 04, 2021 |

**PURPOSE:**   
Combination monoclonal antibody therapies are monoclonal antibody treatments for infection of SARS-CoV-2. Certain products have been granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) for treatment of mild to moderate coronavirus disease 2019 (COVID-19) who meet specified criteria and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

**POLICY/PROTOCOL**:

**General:**

When treatment with a monoclonal antibody therapy against SARS-CoV-2 may be indicated a provider is to refer the patient to the Infectious Disease Clinic for evaluation. Monoclonal antibody therapy will be scheduled to be administered in the ED Annex.

Depending on supply and demand, consideration may be needed on how to address anticipated scarcity in the future, but for now it is first-come, first served based on order and patient scheduling.

**Procedure:**

A provider who wishes to order a monoclonal antibody therapy for a patient should use the following workflow.

* Test the patient for SARS-CoV-2. Consider use of a rapid test based on timing of symptom onset and expected test turnaround times.
* If patient tests positive for SARS-CoV-2, ensure patient meets inclusion and exclusion criteria as outlined below.
* Providers will place inter professional consults or formal consults with infectious disease. If patient deemed appropriate for treatment, they will be treated under the care of the Infectious Disease consulting provider.
* ID provider will then consent the patient using the Bozeman Health consent form specific to the agent under consideration
  1. Verbal consent will be documented in the record at time of evaluation by provider and at time of infusion
  2. Documentation should reference this is not a curative treatment
  3. Documentation should include education this is not a vaccine
* The ID provider consenting the patient should be familiar with the current state of evidence behind use of the product and consent should include the following steps and information:
  1. As part of the consent process:
     1. Care team must provide the patient/caregiver with the appropriate FDA “Fact Sheet for Patients, Parents, and Caregivers EUA” for the specific medication being considered.
  2. Discuss the following specific information (required under the EUA):
     1. FDA has authorized the emergency use of monoclonal antibody therapy for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization
     2. The patient or parent/caregiver has the option to accept or refuse monoclonal antibody therapy.
     3. The significant known and potential risks and benefits of monoclonal antibody therapy, and the extent to which such potential risks and benefits are unknown.
     4. Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
     5. Patients treated with monoclonal antibody therapy should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.
        1. Patients will need to follow isolation procedures prior and after treatment.
  3. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient’s medical record that the patient/caregiver has been:
     1. Given the “Fact Sheet for Patients, Parents and Caregivers” specific to the agent(s) under consideration,
     2. Informed of alternatives to receiving monoclonal antibody therapy, and
     3. Informed that monoclonal antibody therapy is an unapproved drug that is authorized for use under an Emergency Use Authorization.
* Order the medication per the order set
* Schedule the patient for the outpatient infusion or injection
* The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events\* potentially related to monoclonal antibody therapy treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words “monoclonal antibody therapy treatment (specify agent used) under Emergency Use Authorization (EUA)” in the description section of the report. Recommendations:
  1. Notify pharmacy of any adverse reaction.
  2. Pharmacy will submit adverse event reports to FDA MedWatch
     1. Complete and submit the report online: [**www.fda.gov/medwatch/report.htm**](http://www.fda.gov/medwatch/report.htm)
     2. Submitted reports should include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the statement “[Enter MAB Product Name] treatment under Emergency Use Authorization (EUA)”
     3. \*Serious Adverse Events are defined as:
        1. death;
        2. a life-threatening adverse event;
        3. inpatient hospitalization or prolongation of existing hospitalization;
        4. a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
        5. a congenital anomaly/birth defect;
        6. a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

**Inclusion criteria:**

To meet inclusion criteria as set out by the FDA’s Emergency Use Authorizations for monoclonal antibody therapy, patients must meet the following criteria:

* Patient must have a positive result on direct SARS-CoV-2 testing

AND

* Patient should receive the treatment medication as soon as possible but it must be within 10 days of symptom onset AND
* Patient must meet one of the inclusion criteria as outlined on the below chart

AND

* Patient must not meet the exclusion criteria on the below chart of exclusion criteria

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| **Age** | **Inclusion Criteria1,2** |
| < 16 | EXCLUDED: Bozeman Health will not be administering monoclonal antibody treatments for SARS-CoV-2 at this time due to a paucity of data on safety and efficacy. |
| 16-64 | Patients who have one or more of the following high-risk conditions (AIIa):  ***(If patient age <18 consult pediatric provider to assess patient to initiate order if indicated)***   * Diabetes (type 1 or 2) * Immunosuppressive disease (HIV/AIDS, etc.) * Receiving Immunosuppressive treatment (chemotherapy, etc.) * Obesity Body Mass Index (BMI) > 30 * Cardiovascular disease (including congenital heart disease) * Hypertension * Chronic lung diseases (e.g. chronic obstructive pulmonary disease (COPD), moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension) |
| 16-64 | Other conditions or factors that had limited representation in clinical trials, but are  considered risk factors for progression to severe COVID-19 by the CDC and may be considered for therapy:  ***(If patient age <18 consult pediatric provider to assess patient to initiate order if indicated)***  • An immunocompromising condition or immunosuppressive treatment (AIII) (based on theoretic considerations, many experts strongly recommend therapy for patients who are immunosuppressed despite their limited representation in clinical trials).  • Overweight (BMI 25–30) as the sole risk factor (BIII)  • Chronic kidney disease (BIII)  • Pregnancy (BIII)  • Sickle cell disease (BIII)  • Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies) (BIII)  • Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]) (BIII) |
| >65 | * INCLUDED – ALL patients qualify |

*1 Food and Drug Administration Emergency Use Criteria for Use of Anti-SARS-CoV-2 Monoclonal Antibodies*

2 Pregnancy: Monoclonal antibody treatment would be considered in pregnancy only with involvement of and by recommendation of maternal-fetal medicine.

**Exclusion criteria:**

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| Criteria |
| * Age <16 (Consult pediatrics regarding decision making and options for specialty referral for pediatric patients of concern). * Patients who are hospitalized due to COVID-19 except in a clinical trial * Patients who require oxygen therapy due to COVID-19 * Patients who require an increase in their baseline oxygen flow rate due to COVID-19 (when oxygen therapy is due to underlying non-COVID-19 related comorbidity). |

**REFERENCES:**

* The COVID-19 Treatment Guidelines Panel’s Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19: <https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/> [accessed 7-28-2021]
* Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab: <https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf> [accessed 7-28-2021]
* Fact Sheet for Patients, Parents, and Caregivers EUA of Casirivimab and Imdevimab for Coronavirus Disease 2019: <https://www.fda.gov/media/143893/download> [accessed 7-28-2021]
* Fact Sheet for Health Care Providers EUA of sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19): <https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS> [accessed 7-28-2021]
* Fact Sheet for Patients, Parents, and Caregivers EUA of sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19): <https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-PATIENT-FACT-SHEET.PDF> [accessed 7-28-2021]

**NOTES:**

**OTHER POLICIES/PROTOCOLS TO REFERENCE:**

**SCOPE:**

We anticipate these adjustment to be temporary and reserve the right to revise or discontinue these adjustments with or without notice depending on the current understanding and/or business needs of Bozeman Health relating to COVID-19.