

BCH Antibody Therapy

Monoclonal antibody therapies remain in limited supply and the specific monoclonal given will be based on availability of products and current variant of SARS-CoV-2 in circulation. Guidance below reflects use of the tier system set out by Colorado Department of Public Health and Environment. **Note: Therapy requires physician referral for patients that meet the criteria below.** Therapy will not be provided if the criteria below are not met upon review by a BCH clinician.

Onset of symptoms and documented SARS-CoV-2 PCR test within the past 10-days, **AND**
Has mild-moderate COVID-19 symptoms (e.g., cough, fever, headache, malaise, fatigue), **AND**
Does NOT require new or increasing oxygen supplementation for hypoxia due to COVID-19, **AND**
Is NOT hospitalized due to COVID-19, **AND ONE OF THE FOLLOWING:**

Immunocompromised*,
age 18 years or older, not
expected to mount immune
response to vaccination.

Unvaccinated individuals,
age 18 years or older
with ≥ 1 clinical risk factors
for progression.**

Vaccinated individuals
65 years or older.

* Immunocompromised patients are defined as:

- Patients who are within one year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab or alemtuzumab).
- Patients receiving Bruton tyrosine kinase inhibitors.
- Chimeric antigen receptor (CAR)-T cell recipients
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
 - Calcineurin inhibitors (tacrolimus and cyclosporine – excludes topical/ophthalmic administration routes)
 - mTOR-inhibitors (everolimus, sirolimus – excludes topical routes)
 - Mycophenolate, azathioprine, cyclophosphamide in the last 1 month
 - Maintenance prednisone $> 0.5\text{mg/kg}$ or equivalent $\geq 40\text{mg/day}$ prednisone or equivalent in patients 70kg and above)
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients
- Patients who are within one year of receiving a solid-organ transplant (other than lung transplant)
- Solid-organ transplant recipients with recent treatment for acute rejection with T cell depleting agents (e.g. alemtuzumab, rabbit antithymocyte globulin (ATG)) or B cell depleting agents (e.g. rituximab, ocrelizumab, epratuzumab, ofatumumab and belimumab)
- Patients with severe combined immunodeficiencies
- Patients with untreated HIV who have a CD4 T lymphocyte cell count < 50 cells/mm³

** Clinical risk factors for severe disease progression:

- Older age (age ≥ 65 years)
- Obesity or overweight (BMI ≥ 25 kg/m², or BMI ≥ 85 th percentile if age 12-17 years)
- Pregnancy
- Chronic kidney disease
- Diabetes mellitus
- Moderate to severe cardiovascular disease (including congenital heart disease and cerebrovascular disease)
- Moderate to severe chronic lung disease (e.g., COPD, asthma, interstitial lung disease, cystic fibrosis or pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy, genetic, metabolic syndromes or severe congenital abnormalities)
- Medical-related technological dependence (e.g., tracheostomy, gastrostomy or positive pressure ventilation)

Process for referral and monoclonal therapy:

Monoclonal antibodies are available at the Community Medical Center Emergency Department (1000 W South Boulder Road in Lafayette) by provider referral only for patients that meet criteria.

To refer a patient for monoclonal therapy:

1. Providers should contact the CMC ED by calling 303-415-4300 and selecting option "6" to speak with the ED physician on call to review patient criteria for treatment, provide a referral and share the patient's information.
2. The CMC ED will contact patient for a suggested time frame for arrival. Patients should be made aware that the timeframe may need to change due to ED volumes.
3. Patient will be instructed to park in a designated Infusion Center parking space and call 303-415-4301 to register by phone.
4. CMC nursing staff will prepare the patient's monoclonal therapy infusion as recommended.
5. Patient will be escorted to the procedural room and an IV will be started.
6. Patient will be seen by an ED provider during visit.
7. Infusion therapy will last approximately 40 minutes.
8. After infusion is complete, patient will remain for observation for 1 hour.
9. Patient will be discharged after observation period is complete.