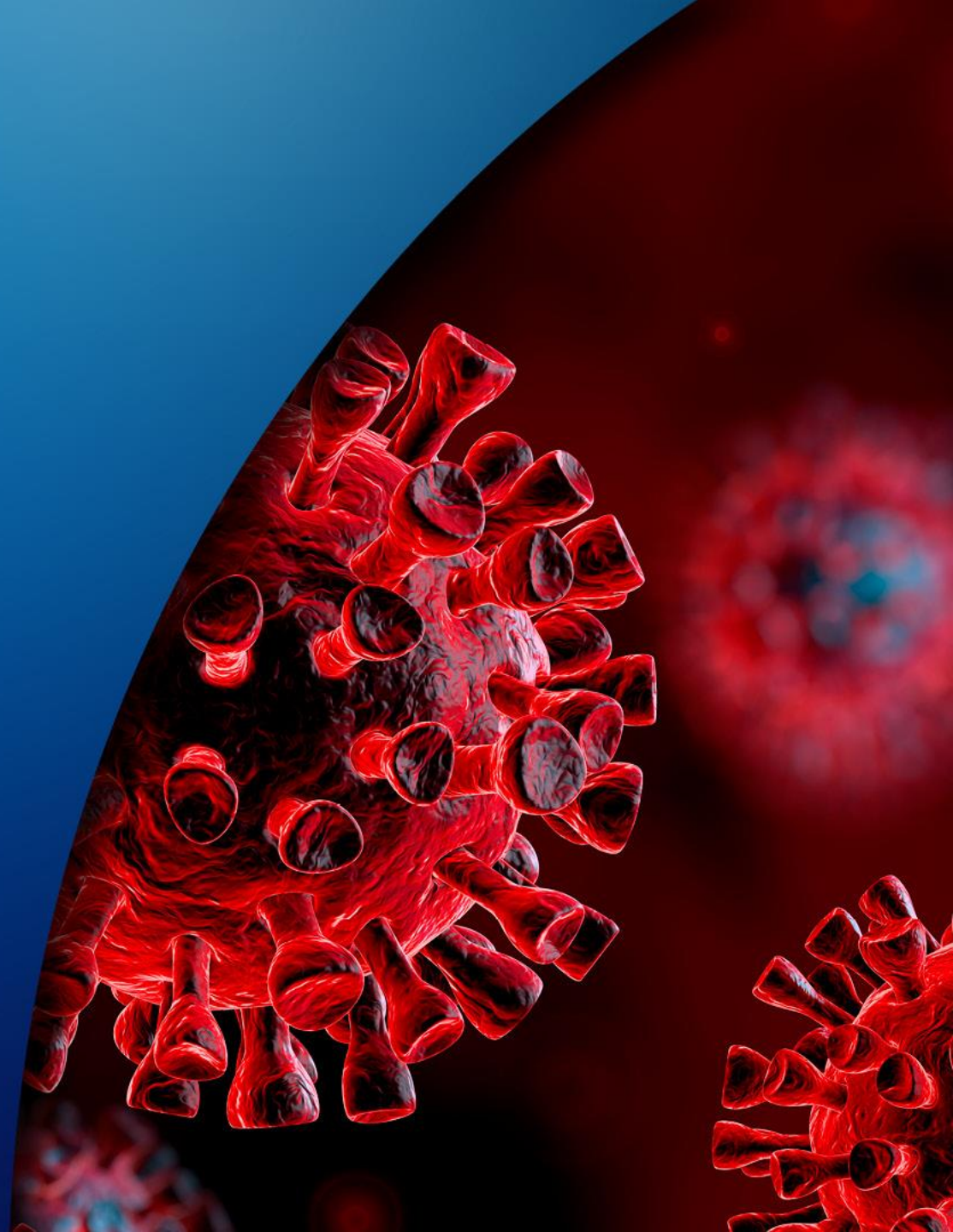
Monoclonal Antibody Infusion Therapy at Carilion Clinic



CARILION CLINIC

FDA Emergency Use Authorization (EUA)

- On November 9, 2020 the FDA approved EUA of Bamlanivimab covid monoclonal antibody for patients with positive direct Covid test (antigen or PCR), mild to moderate symptoms of less than or equal to 10 days duration, and risk factors for progression to more severe illness.
- The EUA was based on studies showing decreased ED visits, decreased hospitalizations, and trend to decreased mortality.
- On November 21, the FDA approved EUA for a second monoclonal antibody Casirivimab and Imdevimab for the same indication.
- On February 9, 2021 a third monoclonal antibody Etesevimab was approved for use with Bamlanivimab. (Bamlanivimab alone is no longer used.)
- Carilion Clinic received an allotment of these monoclonal antibodies from the Federal Government for patient treatment.
- Carilion Clinic established a new Infusion Center in Roanoke for the administration of the monoclonal antibody treatment; in addition to, the existing Infusion Center in the New River Valley.

Patient Considerations

- **Consider referral for Patient if:**
  Positive for COVID-19 with mild-to-moderate symptoms at risk for progressing to severe disease/hospitalization with any one of the following criteria:
  - BMI ≥ 35
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Receiving immunosuppressive treatment
  - Age ≥ 65 years
  - Age ≥ 55 years AND have any of the following: cardiovascular disease, or hypertension, or COPD/other chronic respiratory disease

- **Use is Not Authorized if Patient:**
  - is hospitalized due to COVID-19; or
  - requires new oxygen therapy due to COVID-19; or
  - requires an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to an underlying non-COVID-19 related comorbidity.

- **Additionally, do not refer patients who have:**
  - had symptoms for more than 10 days,
  - known positive SARS-CoV-2 antibodies,
  - history of COVID-19 within the last 90 days,
  - patients who are asymptomatic, or
  - received prior treatment with mAb or convalescent plasma for COVID-19 during this current illness.

Monoclonal antibody therapy for COVID-19 is an investigational treatment that should not be considered the standard of care for any patient population

Pediatric Patient Considerations

- **Consider referral for Pediatric patient**

  12-17 yo weighing ≥ 40kg with any one of following criteria:

  - BMI ≥ 85th percentile for age/gender
  - Sickle Cell Disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorder
  - Medical-related technological dependence, i.e. tracheostomy, gastrostomy, positive pressure ventilation (not related to COVID-19)
  - Asthma, reactive airway or other chronic respiratory disease requiring daily med for control

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Prioritizing Recipients

- **Demand may exceed supply. Who will be prioritized?**
  - ✓ Patients who are referred will be assigned a risk score and prioritized based on risk for severe symptoms and hospitalization.
  - ✓ Patients are prioritized on a daily basis until they:
    - receive the drug,
    - opt out,
    - or are no longer eligible (i.e. duration of symptoms increases to > 10 days, or symptoms progress in severity, etc).
- **How are we ensuring equitable access?**
  - ✓ Removing cost as a barrier
  - ✓ Working to develop referral pathways for those diagnosed at Carilion Clinic and/or external providers

Are my patients eligible- Before Referring

- **What information do I need to refer a patient?**
  - ✓ Direct SARS-CoV-2 test result (e.g., PCR, rapid antigen test) that is positive
  - ✓ Date of positive SARS-CoV-2 test
  - ✓ Patient symptoms of COVID
  - ✓ Date of symptom onset
  - ✓ Patient health history, including age, weight/BMI, and underlying risk factors for severe disease or hospitalization, as noted above.
  - ✓ The referral must be discussed with your patient first, including a discussion of the risks and benefits. Please set appropriate expectations regarding access and how Carilion Clinic is allocating the drug. [Patients referred who meet the criteria have been treated within < 2 days.]

FDA Fact Sheets

FDA developed Patient Fact Sheets

- https://www.fda.gov/media/143893/download
- https://www.fda.gov/media/145803/download

FDA developed Provider Fact Sheets

- https://www.fda.gov/media/145611/download
- https://www.fda.gov/media/145802/download

What can my patients expect

- ✓ The patient should expect a call from our scheduling center
- ✓ The infusion appointment will take place at one of the Carilion Clinic Locations in Roanoke or New River Valley; Monday- Friday (Saturday hours may become available in the future)

- ✓ The appointment duration is 3-4 hours
  - ✓ The infusion takes approximately 30 minutes - 1 hour
  - ✓ Patients are monitored for 1 hour after the treatment

After the Treatment

- **What happens after the infusion visit?**
  - ✓ Patients should self-monitor for adverse effects and notify their referring health care provider with any concerns.
  - ✓ Side effects should be reported to FDA MedWatch at www.fda.gov/medwatch
  - ✓ Call 540-981-7700 and ask for the ID physician on call.
  - ✓ Call 911 / EMS for concerns for life-threatening reaction.
  - ✓ Patients should isolate at home until transmission-based precautions can be discontinued.
  - ✓ Patients should notify their health care provider immediately for worsening symptoms of COVID-19.
  - ✓ CDC recommends COVID vaccine be postponed until 90 days after: COVID infection treated with monoclonal antibody.