

# Monoclonal Antibody Infusion Playbook

## Overview

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This document is intended to provide as a resource for determination of site appropriateness and staff readiness for administration of monoclonal antibody treatments. This document will be updated frequently as the situation and information around monoclonal antibody treatments continues to develop.

## Background

Two products have been granted Emergency Use Authorization for treatment of mild-moderate COVID-19 in adults or pediatric patients (12 or older weighing at least 40 kg) with positive, direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe disease.

~~11/9: Bamlanivimab (LY-CoV555)~~

11/21: Casirivimab & Imdevimab (REGN-COV2)

~~2/25: Bamlanivimab & Etesevimab (update)~~

*Note: Bamlanivimab as a stand alone or combination therapy is no longer being administered by AAH.*

## Playbook Includes

### Site Selection and Readiness

- Site Considerations
- Phase One and Phase Two definitions
- Requirements based on site type

### Site Requirements

- Phase One: 'All in One' – Emergency Departments
- Phase Two: Hospital Based
- Phase Two: Immediate Care Center / Urgent Care
- Phase Two: Ambulatory Setting

### Educational Resources

- Order Set Questions
- Service to and Therapy Plan Questions
- Patient Eligibility
- Links to educational materials on the COVID-19 Information Center

# Site Selection and Readiness

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This section is to provide considerations and resources to help determine readiness and potential support needs in order to begin monoclonal antibody infusions. Once a site is ready to proceed the Monoclonal Antibody Site Request Form must be completed. All sites including EDs, regardless if there are no needs for HIT, supply, or other resources should be entered on this form. It can be found on the COVID-19 Information Center > Surge Planning.

## Site Considerations

### Administration Models

#### Phase One: "All in One"

- Testing and drug infusion completed in the same department
  - Or space adjacent (still considered "the department")
- Can be accomplished in the Emergency Departments

#### Phase Two: Referral Model

- Patients are referred from testing site to infusion site
- Referral options
  - Patients who meet criteria, have interest and assent:
    - Enter service to monoclonal antibody infusion coordinator to manage dose availability, location, clinical eligibility timeframe
    - For eligible patients who present to ambulatory/HOD sites with infusion capability
  - Referral into ED for infusion is a local decision based on ED volumes/capacity, patient access/convenience, and HIT, billing, and registration complexity

### Pharmacy Support

- Pharmacy hours of operation
- Infusion preparation
- Refrigerator storage
- System dose distribution plan
- Note: No pharmacy involvement in ambulatory workflow

### Infection Prevention

- Direct entrance & exit to infusion area (limiting exposure to others)
- No visitors in infusion area
- Area dedicated to COVID-19 Positive patients only
- Patient masked during entire therapy
- Provide Hand hygiene for patient & Team Members
- TM PPE: [Follow PPE grid](#) COVID-19 Positive
- Cleaning & Disinfection: Follow COVID-19 Resource for Cleaning
- Dedicated bathroom – consider bedside commode
- Minimize unnecessary equipment in infusion area
- Avoid open infusion areas (room with closed door preferred)

## HIT Infrastructure Needs

- For new or repurposed areas, evaluate the equipment, network and other infrastructure in place along with the Epic build needed to support the infusion workflow in that space
- Potential for new schedule build
- User identification for access and training
- Charging and revenue cycle requirements

## Requirements: All in One – Emergency Departments

| Area                         | Requirements  |
|------------------------------|---|
| Clinical Ops and Workflow    | -Ability to manage additional infusion workload<br>-Point of Care testing training for team members (pending delivery and training, existing testing modalities can be used)                                    |
| Pharmacy Workflow            | -Standard workflow<br>-Plan for after hours preparation in sites without pharmacy onsite 24/7   |
| HIT and Clinical Informatics | -HIT is building infusion orderables and order sets<br>-Overflow bed build as needed<br>-Epic access for redeployed team members  |
| Rev Cycle/ Billing           | -Facility and admin charges only - follow the current practice<br>-Financial assistance offered as needed<br>-Registration with complete order, consent and documentation for infusion with start and stop time |

## Requirements: Infusion Hub – Hospital Based

| Area                         | Requirements   |
|------------------------------|--|
| Clinical Ops and Workflow    | -Ability to manage additional infusion workload<br>-Infection prevention plan for patient segregation  |
| Pharmacy Workflow            | -Same as ED – orderables/order sets<br>-Standard workflow<br>-Plan for after-hours preparation in sites without pharmacy onsite 24/7<br>-PSA must validate sufficient refrigerator space for drug storage if off campus HOD selected<br>-Medspeed delivery processes for inventory if off campus HOD |
| HIT and Clinical Informatics | -Centralized management/coordination of HIT builds<br>-Build is dependent on location chosen.<br>-Epic access management - Need Ops and Registration contact to work with  |
| Rev Cycle/ Billing           | -Registration with complete order, consent and documentation for infusion with start and stop times  |

### Requirements: Immediate Care Center/Urgent Care (Infusion and/or Referral)

Update May 2021: AAH will be switching over from Bamlanivimab as a sole entity COVID-19 monoclonal antibody to Casirivimab & Imdevimab (REGN-COV2). This change is due to emerging SARS-CoV2 variants which are demonstrating resistance to Bamlanivimab and Bamlanivimab + Etesevimab. This will preclude preparation at urgent care centers and non-hospital clinics at this time.

### Requirements: Infusion Hub – Ambulatory (non-UC/ICC)

Update May 2021: AAH will be switching over from Bamlanivimab as a sole entity COVID-19 monoclonal antibody to Casirivimab & Imdevimab (REGN-COV2). This change is due to emerging SARS-CoV2 variants which are demonstrating resistance to Bamlanivimab and Bamlanivimab + Etesevimab. This will preclude preparation at urgent care centers and non-hospital clinics at this time.

# Education Resources

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This section is to provide educational information in order to support monoclonal antibody infusions.

## Orders

Order Set – for Phase One ‘All In One’ sites

- Order is to be entered by physician after patient eligibility and COVID positive status are confirmed
- Ordering physician must also review Facts Sheet with patient and gain patient ascent
- Within Epic, the order itself has questions attached to it which the ordering provider must complete to assist with this process (below)

| Questionnaire  |  |
|--|--|
| Question   | Answer   |
| Patient has Mild to Moderate Disease, not requiring hospitalization or oxygen supplementation due to COVID?  | Yes  |
| Does the patient meet all eligibility criteria:<br>ADULT High-Risk Indication:   | Yes<br>Age >= 55 years AND at least one of the following: Cardiovascular Disease, Hypertension, COPD / Other Respiratory Disease |
| Has the patient, or parent/caregiver, been given the "Fact Sheet for Patients, Parents and Caregivers", informed of alternatives to receiving authorized bamlanivimab, and informed that bamlanivimab is an unapproved drug authorized for this use? | Yes  |

Therapy Plans – for Phase Two ‘Referral’ sites / Hospital Based Infusion Hubs

- Therapy Plan is to be entered by physician after patient eligibility and COVID positive status are confirmed
- Ordering physician must also review Facts Sheet with patient and gain patient ascent
- Within Epic, the order itself has questions attached to it which the ordering provider must complete to assist with this process – same as above.

A Quick Start guide has also been created to assist with ordering process. It can be found on the COVID-19 Information Center.

[IV Therapy-Ordering monoclonal antibodies](#)

[Monoclonal antibody QSG - Orders, therapy plan & service to instructions](#)

## AAH Monoclonal Antibody Criteria

Casirivimab + Imdevimab are authorized for treatment of mild-moderate COVID-19 disease in adult 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.

*Effective 5/2021 AAH will no longer be administering Bamlanivimab + Etesevimab as a combination drug and will be moving to Casirivimab + Imdevimab.*

- Mild / Moderate disease: symptoms present that could include any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging. Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2)  $\geq 94\%$  on room air at sea level.
  - **Not authorized for use in patients hospitalized for COVID-19.**
  - **Not authorized for use in patients requiring oxygen therapy due to COVID-19**
  - **Not authorized for use in asymptomatic patients**
  - **Not eligible for redosing – single dose only**
  - **Not authorized for use in those requiring an increase in baseline oxygen due to COVID-19 if on chronic oxygen therapy due to an underlying non-COVID-19 comorbidity.**
- COVID-19 confirmed by direct positive viral testing: PCR or antigen
- Age 12 or older, weighing at least 40 kg
- High risk for progressing to severe disease and/or hospitalization (see below)
- Administration w/in 10 days of symptom onset, sooner is better.

Table 1. High-Risk Criteria: ADULTS

| High Risk is defined as symptomatic patients who meet AT LEAST ONE of the following criteria                                      |  |
|---|--|
| BMI $\geq 35$   |  |
| Age $\geq 65$ years   |  |
| Currently receiving immunosuppressive treatment   |  |
| Immunosuppressive disease   |  |
| Chronic Kidney Disease  |  |
| Diabetes  |  |
| Age $\geq 55$ years AND at least one of the following: cardiovascular disease OR hypertension OR COPD / other respiratory disease |  |

Table 2. High-Risk Criteria: CHILDREN 12-17 years

| High Risk is defined as Symptomatic patients who meet AT LEAST ONE of the following criteria   |  |
|--|--|
| BMI ≥ 85 <sup>th</sup> percentile for their age and gender based on CDC growth charts<br><a href="https://www.cdc.gov/growthcharts/clinical_charts.htm">https://www.cdc.gov/growthcharts/clinical_charts.htm</a> |  |
| Currently receiving immunosuppressive treatment  |  |
| Immunosuppressive disease  |  |
| Diabetes   |  |
| Chronic Kidney Disease   |  |
| Sickle cell disease  |  |
| Congenital or acquired heart disease   |  |
| Neurodevelopment disorders (i.e. cerebral palsy)   |  |
| Asthma, reactive airway or other chronic respiratory disease requiring daily medication  |  |
| Medical-related technology dependence (i.e. tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))   |  |

## Educational Materials

### Internal Resources / Links:

Accompanying information can be found on the COVID-19 Information Center > Medications Section

- Monoclonal Antibody Webinar
  - [overview](#) and [recording](#)

### External Resources / Links:

- [FDA Frequently Asked Questions on the EUA for Bamlanivimab](#)
- [FAQ: Allocation, Distribution, and Administration of Bamlanivimab](#)
  - *NOTE: This is not the Advocate Aurora Health Ethical Distribution Framework as developed by the Scarce Resource Allocation Team*
- [Regeneron webpage](#), including:
  - [FDA Letter of Authorization](#)
  - [Fact Sheet for Healthcare Providers](#)
  - Fact Sheet for Patients and Caregivers ([English](#))
  - Fact Sheet for Patients and Caregivers ([Spanish](#))
- [FDA Frequently Asked Questions on the EUA for Casirivimab + Imdevimab](#)
- [FAQ: Allocation, Distribution, and Administration of Casirivimab + Imdevimab](#)
  - *NOTE: This is not the Advocate Aurora Health Ethical Distribution Framework as developed by the Scarce Resource Allocation Team*
- [Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction](#)
  - Updated: December 3, 2020
  - This document provides information around coding and billing monoclonal antibody COVID-19 infusions