Monoclonal Antibody Infusion Playbook

Overview
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)

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 (under development)
- Patient Eligibility
- Links to educational materials on the COVID-19 Information Center

High Level Workflows
- Emergency Department
- Hospital Outpatient Setting
- Immediate Care Center / Urgent Care (under development)
- Ambulatory Setting (under development)
- Site Submission, Approval, and Prioritization Process
Site Selection and Readiness

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

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

Requirements: Infusion Hub – Hospital Based

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

<table>
<thead>
<tr>
<th>Area</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| **Clinical Ops and Workflow** | - Ability to manage additional infusion workload  
- Emergency response capability  
- Staff competent to manage infusion  
- IV pump availability (interoperability not required)  
- Referral coordination process - still in development |
| **Pharmacy Workflow**       | - Pharmacy not embedded in ICC/UC workflows – requires nursing training for drug preparation & inventory mgmt.  
- PSA must validate sufficient refrigerator space for drug storage  
- PSA must validate Medspeed delivery for drug inventory receipt |
| **HIT and Clinical Informatics** | - HIT is building infusion orderables, order sets, treatment plans  
- Overflow bed build as needed  
- Epic access for redeployed team members  
- Referral model dependent  
- Monoclonal antibody scheduling and registration workflow and build to support |
| **Rev Cycle/ Billing**      | - Registration and scheduling needed  
- Financial assistance offered as needed  
- Complete order, consent and documentation for infusion with start and stop times |

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

<table>
<thead>
<tr>
<th>Area</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| **Clinical Ops and Workflow** | - Ability to manage additional infusion workload  
- Emergency response capability  
- Staff competent to manage infusion  
- IV pump availability (interoperability not required)  
- Verify/reserve dose availability prior to offering infusion option to patient  
- Referring provider must order the infusion |
| **Pharmacy Workflow**       | - Pharmacy not embedded in non-hospital based workflows – requires nursing training for drug preparation & inventory mgmt.  
- PSA must validate sufficient refrigerator space for drug storage  
- PSA must validate Medspeed delivery for drug inventory receipt |
| **HIT and Clinical Informatics** | - Build is dependent on the location chosen and whether it is a new department or repurposing of an existing department.  
- Will likely need schedule and registration build as a minimum |
| **Rev Cycle/ Billing**      | - Registration and scheduling needed  
- Financial assistance offered as needed  
- Need to understand how the charge will be created for coding/charge review. Documentation will need infusion start and stop times |
Education Resources
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)

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

Therapy Plans – for Phase Two ‘Referral’ sites
- 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 (under development)
- A Quick Start guide has also been created to assist with
AAH Bamlanivimab Criteria

Bamlanivimab is 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.

- **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) ≥94% on room air at sea level.
  - 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 ≥ 35                        |                                 |
| Age ≥ 65 years                  |                                 |
| Currently receiving immunosuppressive treatment |                                 |
| Immunosuppressive disease       |                                 |
| Chronic Kidney Disease          |                                 |
| Diabetes                        |                                 |
| Age ≥ 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

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

Educational Materials

Internal Resources / Links:
Accompanying information can be found on the COVID-19 Information Center > Medications Section
- Monoclonal Antibody Webinar
  - overview and recording
- COVID-19 Briefing for Physicians and APCs 11/25/20—COVID Monoclonal Abs
  - overview and recording
- Bamlanivimab Resource Document link
- Bamlanivimab 700 mg IV Infusion Preparation link

External Resources / Links:
- [Lilly Bamlanivimab webpage](https://www.lilly.com/products/bamlanivimab.html), including:
  - FDA Letter of Authorization
  - Fact Sheet for Healthcare Providers
  - Fact Sheet for Patients and Caregivers ([English](https://www.lilly.com/content/dam/lilly-prod/lilly-prod-factsheets/bamlanivimab-factsheets/bamlanivimab-factsheet-english.pdf))
  - Fact Sheet for Patients and Caregivers ([Spanish](https://www.lilly.com/content/dam/lilly-prod/lilly-prod-factsheets/bamlanivimab-factsheets/bamlanivimab-factsheet-spanish.pdf))
  - Lilly Bamlanivimab Antibody Playbook
- 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:
  o [FDA Letter of Authorization](#)
  o [Fact Sheet for Healthcare Providers](#)
  o Fact Sheet for Patients and Caregivers *(English)*
  o 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**
  o **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**
  o Updated: December 3, 2020
  o This document provides information around coding and billing monoclonal antibody COVID-19 infusions
Workflows

The intention of this section is to outline high level workflows for each site setting type (ED, HOD, Ambulatory, ICC/UC). As each site will have distinctive elements to be accounted for, details and additional steps or processes may be identified at a site, market, or PSA level.

This section is under development and information will be added the week of 12/6/2020.