COVID-19 Monoclonal Antibodies

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Monoclonal Antibodies (mAbs)

- Bamlanivimab (Eli Lilly) and casirivimab/imdevimab (Regeneron) are available under EUA
- mAbs directly neutralize the COVID-19 virus and are intended to prevent progression of disease
- Likely most effective when given early in infection
- Product delivered via single administration (i.e., IV infusion)
  - 60-minute administration duration
  - 60-minute observation period
Monoclonal Antibody Patients

- Not authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

- EUAs for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
  - with positive results of direct SARS-CoV-2 viral testing, and
  - who are at high risk of progressing to severe COVID-19 and/or hospitalization.
Monoclonal Antibody Patients

High risk defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) $\geq 35$
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are $\geq 65$ years of age
- Are $\geq 55$ years of age AND have cardiovascular disease; OR hypertension; OR chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 - 17 years of age AND have BMI $\geq 85$th percentile for their age and gender based on CDC growth charts; OR sickle cell disease; OR congenital or acquired heart disease; OR neurodevelopmental disorders, for example, cerebral palsy; OR a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19); OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control
Can I get a COVID-19 vaccine if I have had antibody treatment?
We do not yet know how effective vaccines are in someone who has previously received an antibody treatment for a COVID-19 infection, or whether the antibody treatment could interfere with your body's own immune response to a vaccine. Once you have had COVID-19, you are very unlikely to be reinfected for three months afterward. So, if you receive an antibody treatment, you should delay receiving a vaccine for three months as a precaution. See CDC: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

Can I have antibody treatment if I have been vaccinated?
In the absence of data we are only able to provide suggestions for consideration by providers; the ultimate decision on how to treat an individual in this situation ultimately rests with the provider. For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells. We [FDA] recommend that subsequent vaccination, if administered, occur at least two weeks following the administration of a monoclonal antibody.

These recommendations are subject to change as additional data become available.
Allocation of Monoclonal Antibodies

Until the national supply of mAbs is sufficient, the Iowa Department of Public Health and the United States government will help facilitate allocation across Iowa.

Hospitals and clinics
via State allocations every two weeks

USG
Determines state allocations based on confirmed cases and hospitalizations

IDPH
Determines allocations for sites based on usage and on-hand information

Distributor
Ships directly to sites identified by IDPH

Long-term care pharmacies
via Special Projects for Equitable and Efficient Distribution (SPEED)

IDPH
Receives request and sends request for pharmacy to receive bamlanivimab.

USG
Receives requests from IDPH, contacts pharmacy to coordinate receipt of bamlanivimab, and places orders to distributor.

Distributor
Ships directly to pharmacy.
1. Review EUA and Provider Fact Sheet

https://www.fda.gov/media/143602/download  https://www.fda.gov/media/143603/download

Protecting and Improving the Health of Iowans
2. Check whether your pharmacy has bamlanivimab

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>City</th>
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<tbody>
<tr>
<td>Guardian Pharmacy of Iowa LLC</td>
<td>Ankeny</td>
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<tr>
<td>NuCara LTC Pharmacy #3</td>
<td>Iowa City</td>
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<tr>
<td>NuCara LTC Pharmacy #4</td>
<td>Waterloo</td>
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<tr>
<td>NuCara LTC Pharmacy #5</td>
<td>Ottumwa</td>
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<tr>
<td>Omnicare of the Quad Cities</td>
<td>Davenport</td>
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<tr>
<td>Omnicare of Urbandale</td>
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<tr>
<td>PCA Iowa Rx, LLC dba PCA Des Moines Pharmacy</td>
<td>Urbanbale</td>
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<td>PHARMERICA</td>
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<td>PHARMSCRIPT OF IA LLC</td>
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- Some long term care pharmacies currently have bamlanivimab.
- Check with your pharmacy to see if bamlanivimab is available.

Long term care pharmacies that have been shipped bamlanivimab as of 1/24/21.
3. Explore other options for treating patients

- If your pharmacy does not have bamlanivimab, check whether your local hospital administers mAbs using the locator tool.
- If your local hospital administers mAbs:
  - Could patients be treated at the hospital?
  - Could the hospital treat patients at your facility?
- If hospital involvement is not the best option for your facility, assess your facility’s readiness to prepare and administer bamlanivimab.
4. Readiness checklist

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Allocate dedicated space and develop plan to manage patient flow</td>
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<tr>
<td>- Clear process for patients that are coming to clinical site including scheduling requirements</td>
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<tr>
<td>- Admission process for COVID-19 positive patients designed to minimize risk of spread per facility requirements / directions / guidelines</td>
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<tr>
<td>- Dedicated room available for treatment</td>
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<tr>
<td>Ensure dedicated source of supplies; which may be difficult to procure</td>
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<tr>
<td>- Needed infusion components obtained</td>
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<tr>
<td>- Example: IV kits, infusion chair, IV pole, vital sign monitoring equipment, emergency medications</td>
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<tr>
<td>Assign sufficient personnel to meet expected demand</td>
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<tr>
<td>- Sufficient staffing plans in place for Nurse/IV tech, Physician, Pharmacist</td>
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<td>- Likely need dedicated team to treat patients</td>
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<tr>
<td>Prepare for drug administration process</td>
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<tr>
<td>- Pre-visit: Clear treatment and monitoring plan developed for during infusion</td>
</tr>
<tr>
<td>- Treatment: 1-hour treatment and 1-hour post-treatment observation</td>
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<tr>
<td>- Emergency protocol defined for addressing potential infusion reactions or complications</td>
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<tr>
<td>- Post-treatment: Clear process for patient follow-up defined using telemedicine as possible</td>
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<tr>
<td>Ensure process for reimbursement in place (non-drug administrative costs)</td>
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<tr>
<td>Prepare for reporting needs for adverse events and record keeping</td>
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Also consider:
- Role of pharmacy
- Role of compounding pharmacy
5. Request bamlanivimab

When your facility is ready, submit a request to receive bamlanivimab. If your facility has an urgent need, please contact cassie.kennedy@idph.iowa.gov or (515) 330-5755.

Special Projects for Equitable and Efficient Distribution (SPEED)

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USG
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Helpful Links

General Resources
- Operation Warp Speed Monoclonal Antibody Playbook
- National Infusion Center Association COVID-19 Antibody Treatment Resource Center
- IDPH Monoclonal Antibodies
- HHS ASPR Outpatient Therapeutics Mini-Series

Bamlanivimab (Eli Lilly)
- Bamlanivimab Letter of Authorization (EUA)
- Bamlanivimab Provider Fact Sheet
- FDA Frequently Asked Questions on the EUA for Bamlanivimab Lilly Bamlanivimab Information
- Lilly Bamlanivimab Antibody Playbook
- Bamlanivimab Pocket Resource Card
- Bamlanivimab Overview, Allocation, and Distribution

Casirivimab/Imdevimab (Regeneron)
- Casirivimab/imdevimab Letter of Authorization (EUA)
- Casirivimab/imdevimab Provider Fact Sheet
- FDA Frequently Asked Questions on the EUA for Casirivimab + Imdevimab
- Important Prescribing Information: A Letter from Regeneron to Healthcare Providers on Preventing Medication Errors
- Regeneron Casirivimab/imdevimab Information
- Regeneron Casirivimab/imdevimab Guidebook
- Casirivimab/imdevimab Overview, Allocation and Distribution

Billing and Coding
- COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing
- CMS Monoclonal Antibody COVID-19 Infusion Insurance Coverage of Monoclonal Antibody Treatment
- Drug Supply Chain Security Act (DSCSA)
Contact

For questions, please contact Cassie Kennedy at cassie.kennedy@idph.iowa.gov or (515) 330-5755.