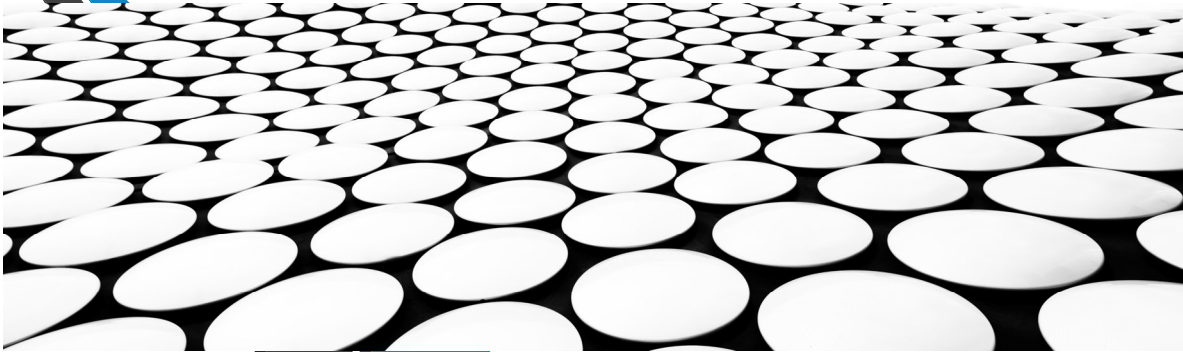


# Administration of Monoclonal Antibody Treatment in the SNF

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There is Light at the End of the Tunnel



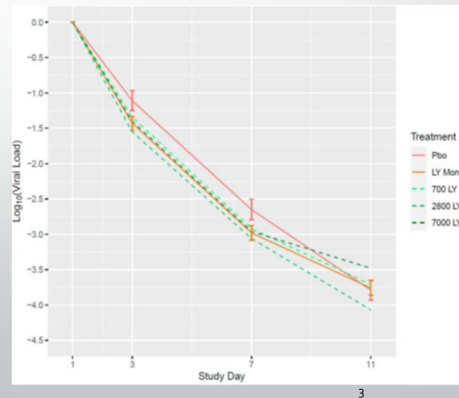
## Mechanism of Action

- Bamlanivimab is a recombinant neutralizing human IgG<sub>1</sub>K monoclonal antibody (mAb) to the spike protein of SARS-CoV-2, and is unmodified in the Fc region.
- Bamlanivimab binds to spike protein and blocks attachment to the human ACE2 receptor.

### End Points of BLAZE-1 Trial

- Primary –
  - Decrease in Viral Load
- Secondary –
  - Decrease in Hospitalization/ER vs Placebo (1-2% vs 6%)
  - High risk population (2-5% vs 10%)

Figure:  
SARS-CoV-2 viral load change from baseline



## EUA Authorization of Bamlanivimab by FDA

- Bamlanivimab is authorized for use for treatment of **mild to moderate** COVID-19 in adults 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.
- Bamlanivimab is **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.

## Adverse Reactions

- **Infusion-related** Reactions including Hypersensitivity and Anaphylaxis
  - Fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.
  - If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications (IV Benadryl/Epinephrine) and/or supportive care.
- **Adverse Events** (Bamlanivimab 700 mg IV vs placebo)
  - Nausea (3% vs 4%), Diarrhea (1% vs 5%), Dizziness (3% vs 2%), Headache (3% vs 2%), Pruritus (2% vs 1%) and Vomiting (1% vs 3%).

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## Administration Protocol

- **Coordinated Effort between State Health Department, Local Hospitals and Pharmacies, Facilities and Staff**
- Place **Orders** into PCC. Enter the Care Plan for each resident.
- Consent needs obtained using the **Patient Fact Sheet** (Lilly) and documented in PCC.
- **Pharmacy** will deliver premixed IV bags of bamlanivimab to the SNF. Refrigerate upon arrival.
- Remove BAM IV bag 30 minutes prior to infusion and bring to room temperature. **Infuse 700 mg/200ml NS** over 60 minutes using IV infusion set with inline filter and IV pump.
- Monitor VS (BP HR RR O<sub>2</sub>Sat Temp) q15 min during infusion and for one hour after. Flush line and port with NS at end of infusion.

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## Administration Protocol

- Monitor for reactions per above Protocol, administer Benadryl, etc. if needed and adjust rate or discontinue infusion if needed.
- Have on hand (emergency ER Box and out of Cubex): IV Pole, IV Pump, IV Start Kit, **Benadryl** 50 mg vial Inj (syringe and needle to administer), **Epinephrine** 1 mg vial inj (syringe and needle to administer), ondansetron 4 mg po, cetirizine 10 mg po (house stock), famotidine 40 mg po, Solu-Medrol inj.
- Document IV insertion, complete PCC nursing note when infusion begins and baseline VS, PCC nursing note when infusion completes, and a final PCC nursing note 1 hour after infusion ends.
- The NP administering the infusion should document a note in PCC as well.

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## Ohio Infusion Center – Risk Assessment Scoring

**Symptom Onset Date:** Must be within 10 days


**Require a score of 8 or greater.**

Illness Severity:	3- Moderate (fever, SOB, abnormal CXR)
	1-Mild (fever with mild respiratory symptoms, sore throat, malaise)
Age >65	3
BMI>35	3
Immunosuppressed	3
CKD Stage 3 or above	2
Diabetes with HBA1c>8	2
Age >65 with COPD	2
Age >55 with HTN or CAD/CHF	1

## CVS to Pilot Administration in LTC facilities

- Department of Health and Human Services selected CVS to pilot the administration of a limited supply of Bamlanivimab to eligible COVID-19 patients in long-term care facilities or at their homes.
- CVS Health’s specialty pharmacy and infusion care business, **Coram**, began administering 1,000 doses of monoclonal antibody therapies.
- 7 Cities:
  - Boston, Chicago, **Cleveland**, Los Angeles, Milwaukee, Minneapolis and Tampa

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		<b>Bamlanivimab (EUA use)</b> Physician Referral and Prescription Order Form Complete and Fax to (610) 992-3950	
<b>Patient Information:</b> Name _____ Date of Birth ____/____/____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F Weight _____kg Height _____cm Room Number: _____ Drug Allergies: _____ Is patient able to provide consent? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, name of Guardian/Legally authorized representative: _____ Phone #: _____			
<b>Diagnosis:</b> COVID-19 _____ Date symptoms presented _____ Date COVID-19 test performed _____ Date COVID-19 test resulted _____		<b>Significant PMH:</b> Diabetes _____ Hypertension _____ Dialysis/CKD _____ Immunocompromised/receiving treatment _____	
<input type="checkbox"/> EUA Medication information reviewed with patient/caregiver including emergency use authorization, potential side effects, and infusion related reactions			
<b>Patient Facility Information:</b> Facility Name _____ Facility Address _____ City _____ State _____ Zip code _____			
<b>Bamlanivimab Orders:</b> Administer bamlanivimab 700mg IV over at least 60 minutes via dial-a-flo Dispense: One dose NO REFILLS Dispense anaphylaxis kit as follows to manage infusion reactions: Epinephrine 0.3mg/0.3 ml IM to anterior thigh every 15 min PRN anaphylaxis. Dispense 2 doses. Diphenhydramine 50 mg IM or IV slowly over 5 minutes as needed for anaphylaxis. Dispense 2 doses. Dispense ancillary supplies and equipment needed to provide this home infusion therapy.			
<b>Ordering Physician or Nurse Practitioner Information:</b> Physician or Nurse Practitioner Full Name: _____ NPI number _____ Address _____ City _____ State _____ Zip _____ Office contact _____ Phone _____ Fax _____			
MD/NP Signature (Required) _____		Date: _____	
If Verbal order: Received by: _____ Read back & confirmed on: _____			

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## UnitedHealth, Eli Lilly partner to study Bamlanivimab

- UnitedHealth will enroll 500,000 Medicare Advantage members who are diagnosed with COVID in the study and follow them through their treatment via daily symptom tracking and in-home testing.
- For those who need Bamlanivimab, the drug will be administered via home infusion.
- Patients who volunteer for the study will be directed to download Optum's ProtectWell app and complete questionnaires each day. Those with symptoms will take an in-home test for COVID-19, and those who are positive will be contacted by an Optum infusion nurse to schedule a treatment.
- For the study, patients will receive the therapy with no copay for the drug or infusion services

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## Payment during Public Health Emergency

- The federal government has paid \$1,250 per dose for 300,000 doses of Bamlanivimab.
- The United States has the option to buy another 650,000 doses.
- CMS announced that coverage would extend to beneficiaries in nursing homes at no cost during the public health emergency.

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## Regeneron

- Regeneron COVID-19 antibody cocktail has shown the most benefit in patients who had not mounted their own immune response prior to treatment.
- The company is also seeking an EUA.

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