Process for Community Referral: Bamlanivimab/Regeneron Infusion

NOTE: ORDERS MUST BE REVIEWED AND AUTHENTICATED BY RESPONSIBLE PHYSICIAN.

Bamlanivimab/Regeneron (Outpatient only)

Bamlanivimab/Regeneron are neutralizing IgG1 monoclonal antibodies that binds to the receptor binding domain of the spike protein of SARS-CoV-2.

November 9, 2020: FDA issued **Emergency Use Authorization (EUA)** of Bamlanivimab/Regeneron for the treatment of mild to moderate COVID-19. Refer to EUA Letter - Bamlanivimab & Fact Sheet for Health Care Providers for full details of authorization and corresponding responsibilities.

Supply: The federal government is responsible for the appropriate allocation of Bamlanivimab/Regeneron. Weekly allocation decisions will be proportionally based on confirmed COVID-19 cases in each state over the previous 7 days based on data from the U.S. DHHS. Additionally, not all sites have the capability to infuse Bamlanivimab/Regeneron in the outpatient setting, so **the scheduling team and pharmacy will identify the weekly quantity available for infusion and schedule patients accordingly.**

"In order to mitigate the risks of using this unapproved product under the EUA and to optimize the potential benefit of Bamlanivimab/Regeneron, the following items are required. Use of Bamlanivimab/Regeneron under this EUA is limited to the following (all requirements **must** be met)."

This authorization only permits Bamlanivimab/Regeneron to be used to treat:

- Adults & pediatric patients (age ≥12 and weight ≥40 kg)
- Positive SARS-CoV-2 viral testing
- High risk* for progressing to severe COVID-19 and/or hospitalization
- **Outpatient setting** with immediate access to medications to treat severe infusion reactions (anaphylaxis) and the ability to activate EMS

*High risk (at least one of the following criteria):

- BMI ≥35
- CKD
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatment
- Age ≥65 years
- Age ≥55 years AND one of the following:
  - Cardiovascular disease
  - Hypertension
  - COPD/other chronic respiratory disease
- Age 12-17 AND one of the following:
  - BMI ≥ 85th percentile
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders (i.e. cerebral palsy)
  - Medical-related technological dependence (i.e. tracheostomy, gastrostomy, or positive pressure ventilation)
  - Asthma, reactive airway or

Not authorized for:

- Patients who are **hospitalized** due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Patients who require an increase in baseline oxygen flow rate due to COVID-19
- Prevention of COVID-19

Patients with known hypersensitivity to any ingredient of Bamlanivimab/Regeneron must not receive Bamlanivimab/Regeneron.

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Dose: 700 mg IV infused over 60 minutes once
No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, during pregnancy or while lactating, or for
disease severity or inflammation.

- Timing: Administer dose as soon as possible after positive viral test and within 10 days of symptom onset
- Monitoring: Observe patients during infusion and for ≥1 hour after infusion is complete

Instructions for Healthcare Providers:

- Document in the medical record that patient has been counseled and provided with copy of Fact Sheet for Patients (English) or Fact Sheet for Patients (Spanish). As the healthcare provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" prior to the patient receiving Bamlanivimab/Regeneron, including:
  - FDA has authorized the emergency use of Bamlanivimab/Regeneron for the 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.
  - The patient or parent/caregiver has the option to accept or refuse Bamlanivimab/Regeneron.
  - The significant known and potential risks and benefits of Bamlanivimab/Regeneron, and the extent to which such potential risks and benefits are unknown.
  - Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
  - Patients treated with Bamlanivimab/Regeneron should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
- Mandatory reporting of all medication errors and serious adverse events potentially related to Bamlanivimab to FDA MedWatch & Eli Lilly within 7 calendar days.

Ordering Information

- **If you need assistance, please call the infusion center at 386-917-7833**
- The Link for an order for a Referral for Bamlanivimab/Regeneron Infusion is: CLICK HERE
- All items on the order are prechecked. Per EUA Guidelines, you must attest that you have reviewed the risks and benefits, alternatives to treatment, ensure the patient meets criteria for the drug and the patient fact sheet must be reviewed, printed and provided to the patient. If your patient agrees, they will be monitored at home via Remote Patient Monitoring and Home Physician Group.
- Fax order and patient face sheet (demographics) 386-917-7854

Instructions for patients:

- AdventHealth Fish Memorial Infusion Annex is located at 1061 Saxon Blvd, Orange City, Ste 203
- If you have someone drive you to this location please use the Summit Bldg East end entrance for drop off/pick up, there will be signs
- Please be advised your infusion may take approximately 3hrs
- If you drive yourself, please use the Summit Bldg East end parking lot. There is designated parking for patients close to the door. Enter the building, use the elevators on your right and proceed to Infusion Center Suite 203
- Please wear a mask
- Ring the buzzer for Suite 203 and inform the greeter that you are checking in to Suite 203 Infusion Annex
- Please bring ear buds or headphones to use with your device if you will be using audio
- Please follow the instruction of the staff upon arrival. There will be a greeter to check you in at the door
- Please call 386-917-7833 to cancel your appointment, if you will be more than 15 min delayed or if you are lost
- **No visitors or guests allowed during treatment –** please call 386-917-7833 with any questions or concerns

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- Please bring photo identification and your insurance information