Bamlanivimab

Avera Long-Term Care Pharmacy

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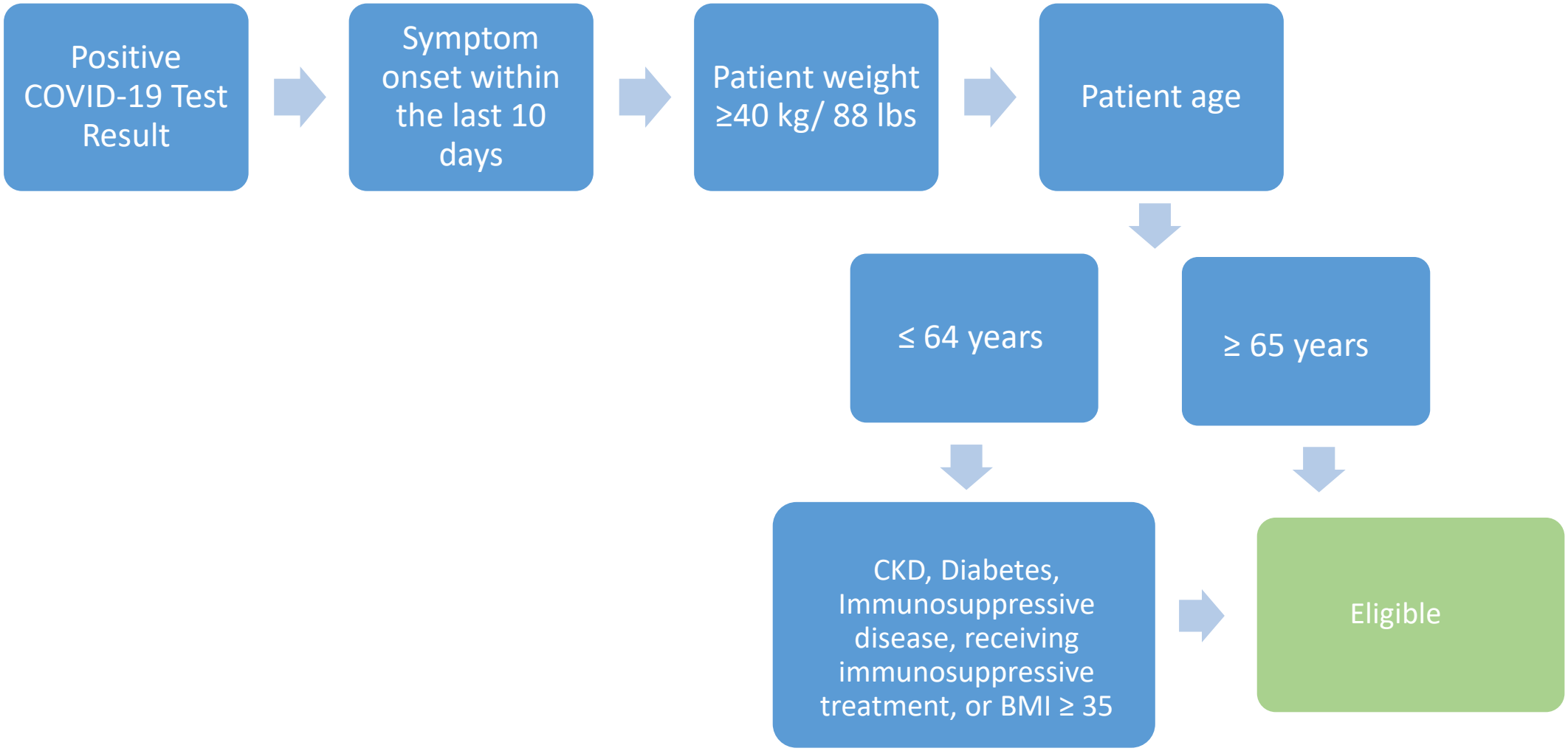
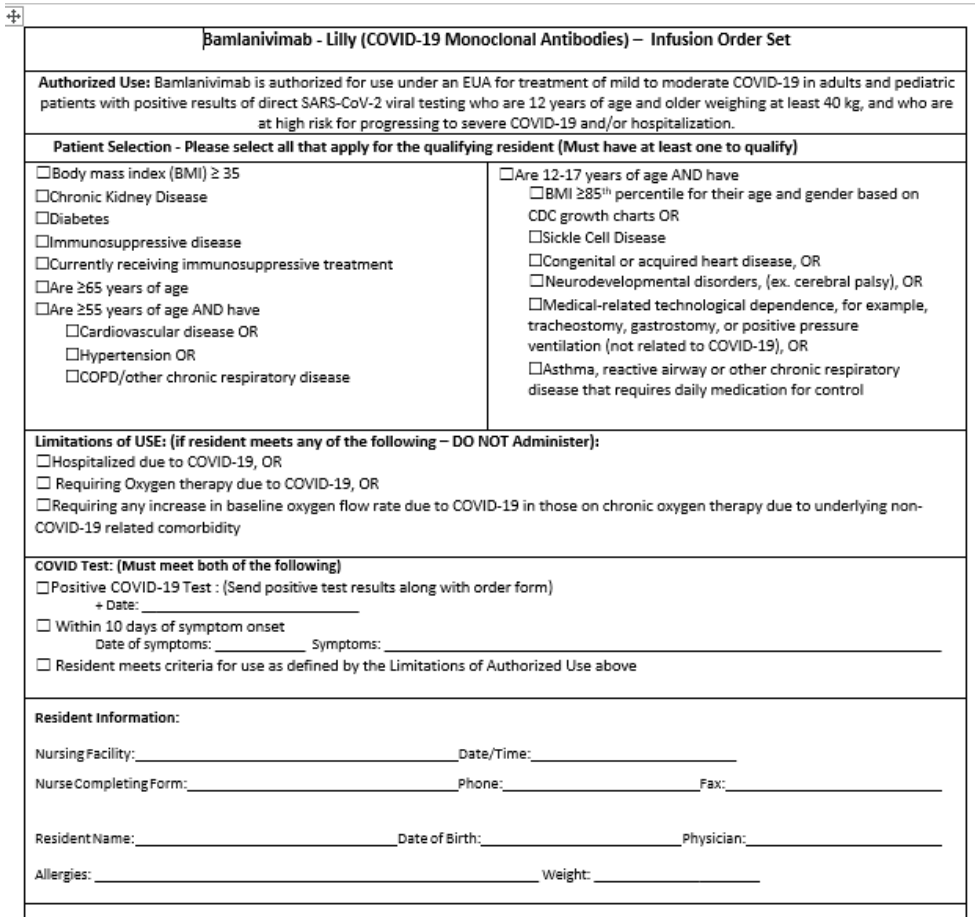
Patient Assessment



Patient Assessment



Bamlanivimab - Lilly (COVID-19 Monoclonal Antibodies) – Infusion Order Set

Authorized Use: Bamlanivimab is authorized for use under an EUA 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.

Patient Selection - Please select all that apply for the qualifying resident (Must have at least one to qualify)

☐Body mass index (BMI) ≥ 35
☐Chronic Kidney Disease
☐Diabetes
☐Immunosuppressive disease
☐Currently receiving immunosuppressive treatment
☐Are ≥65 years of age
☐Are ≥55 years of age AND have
  ☐Cardiovascular disease OR
  ☐Hypertension OR
  ☐COPD/other chronic respiratory disease

☐Are 12-17 years of age AND have
  ☐BMI ≥85th percentile for their age and gender based on CDC growth charts OR
  ☐Sickle Cell Disease
  ☐Congenital or acquired heart disease, OR
  ☐Neurodevelopmental disorders, (ex. cerebral palsy), OR
  ☐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

Limitations of USE: (if resident meets any of the following – DO NOT Administer):
☐Hospitalized due to COVID-19, OR
☐ Requiring Oxygen therapy due to COVID-19, OR
☐Requiring any increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

COVID Test: (Must meet both of the following)
☐Positive COVID-19 Test : (Send positive test results along with order form)
  + Date: _____
☐ Within 10 days of symptom onset
  Date of symptoms: _____ Symptoms: _____
☐ Resident meets criteria for use as defined by the Limitations of Authorized Use above

Resident Information:

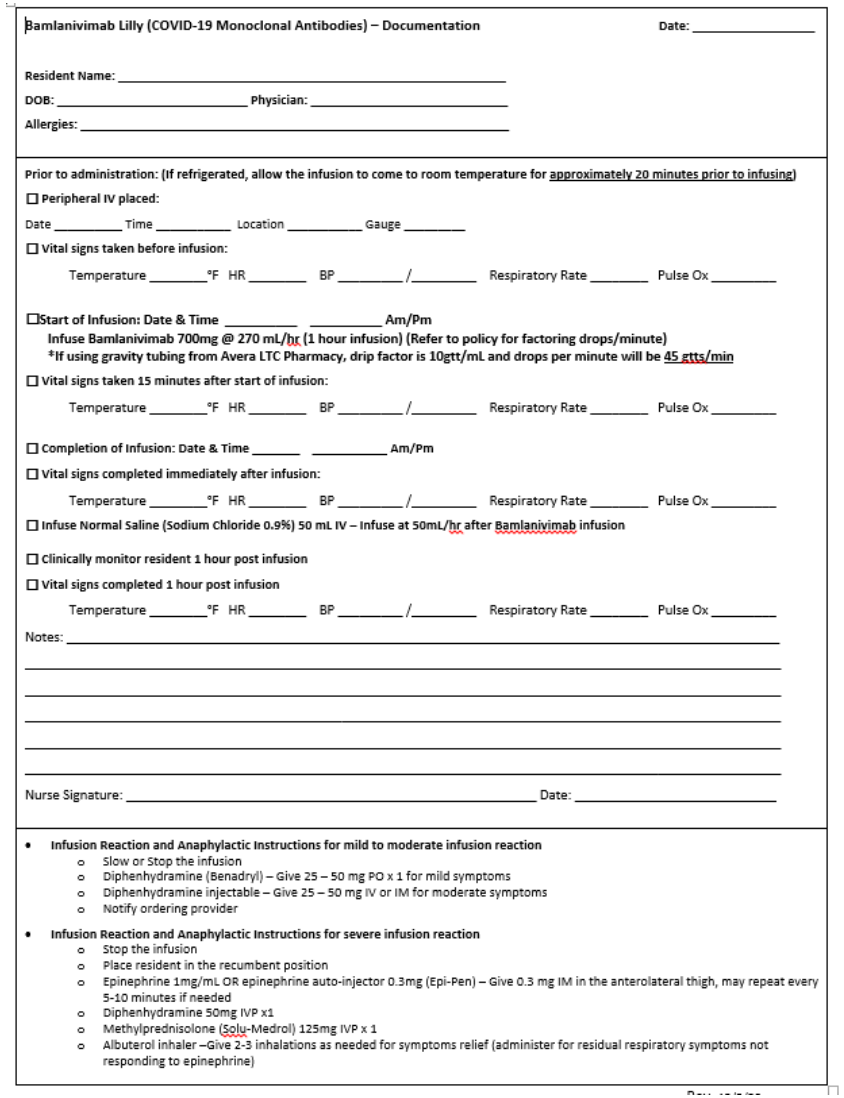
Nursing Facility:_____Date/Time:_____
Nurse Completing Form:_____Phone:_____Fax:_____

Resident Name:_____Date of Birth:_____Physician:_____

Allergies: _____ Weight: _____

- Symptomatic, positive cases who meet the FDA Emergency Use Authorization criteria
- Review Exclusion criteria
- Ability to obtain IV access

Facility Assessment



Bamlanivimab Lilly (COVID-19 Monoclonal Antibodies) – Documentation **Date:** _____

Resident Name: _____

DOB: _____ **Physician:** _____

Allergies: _____

Prior to administration: (If refrigerated, allow the infusion to come to room temperature for approximately 20 minutes prior to infusing)

☐ **Peripheral IV placed:**

Date _____ Time _____ Location _____ Gauge _____

☐ **Vital signs taken before infusion:**

Temperature _____°F HR _____ BP _____/_____ Respiratory Rate _____ Pulse Ox _____

☐**Start of Infusion: Date & Time** _____ _____ **Am/Pm**

Infuse Bamlanivimab 700mg @ 270 mL/hr (1 hour infusion) (Refer to policy for factoring drops/minute)

***If using gravity tubing from Avera LTC Pharmacy, drip factor is 10gtt/mL and drops per minute will be 45 gtts/min**

☐ **Vital signs taken 15 minutes after start of infusion:**

Temperature _____°F HR _____ BP _____/_____ Respiratory Rate _____ Pulse Ox _____

☐ **Completion of Infusion: Date & Time** _____ _____ **Am/Pm**

☐ **Vital signs completed immediately after infusion:**

Temperature _____°F HR _____ BP _____/_____ Respiratory Rate _____ Pulse Ox _____

☐ **Infuse Normal Saline (Sodium Chloride 0.9%) 50 mL IV – Infuse at 50mL/hr after Bamlanivimab infusion**

☐ **Clinically monitor resident 1 hour post infusion**

☐ **Vital signs completed 1 hour post infusion**

Temperature _____°F HR _____ BP _____/_____ Respiratory Rate _____ Pulse Ox _____

Notes: _____

_____

_____

_____

_____

_____

Nurse Signature: _____ Date: _____

- **Infusion Reaction and Anaphylactic Instructions for mild to moderate infusion reaction**
  - Slow or Stop the infusion
  - Diphenhydramine (Benadryl) – Give 25 – 50 mg PO x 1 for mild symptoms
  - Diphenhydramine injectable – Give 25 – 50 mg IV or IM for moderate symptoms
  - Notify ordering provider
- **Infusion Reaction and Anaphylactic Instructions for severe infusion reaction**
  - Stop the infusion
  - Place resident in the recumbent position
  - Epinephrine 1mg/mL OR epinephrine auto-injector 0.3mg (Epi-Pen) – Give 0.3 mg IM in the anterolateral thigh, may repeat every 5-10 minutes if needed
  - Diphenhydramine 50mg IVP x1
  - Methylprednisolone (Solu-Medrol) 125mg IVP x 1
  - Albuterol inhaler –Give 2-3 inhalations as needed for symptoms relief (administer for residual respiratory symptoms not responding to epinephrine)

- Staff availability/ ability
- Staff education

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

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Procurement / Distribution

- Access to Bamlanivimab
  - Health System

- Allocation criteria
  - Nursing staff availability
  - Grouping of patients
  - Time from onset of symptoms

Preparation

- People
  - Pharmacy
  - Communication
  - Nursing
  - Provider/Medical Director
- Forms/Orders
- Bamlanivimab
  - IV room
  - Time considerations
  - IV Lines
  - Anaphylaxis Kits

Key Information about Bamlanivimab for Nursing Home Medical Directors

Background: The FDA has authorized Bamlanivimab, a monoclonal antibody, for emergency use for people with MILD to MODERATE COVID-19 who are at high risk for progressing to severe COVID-19 and/or hospitalization. Studies suggest a decrease in hospitalizations by approximately 30%.

There is NO BENEFIT observed for patients with increased oxygen requirements or hospitalization due to COVID-19, and may in fact, worsen clinical outcomes in this group. It is NOT APPROVED for this group.

High risk conditions relevant to the nursing home population:

- BMI≥35
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatments
- ≥65 years old
- ≥55 years old with CV disease, OR HTN, OR COPD/Chronic respiratory disease

Availability: This is being distributed from the federal government to states based on population and infection rates; it is being allocated to health systems in each state for distribution.

Key Points about administration:

- One time IV infusion of 700 mg; it can be given via gravity (no pump), need a 22 g IV
- Should be given as soon as possible after a positive test, within 10 days of symptom onset
- The infusion is given over at least 60 minutes
- Need to be prepared to treat sever infusion reactions (such as anaphylaxis)
- The patient should be monitored closely during the infusion, and for 1 hour afterwards for the following: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritis, myalgia, dizziness; if these things occur, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care

Side Effects that occur at higher rate than placebo: Nausea, dizziness, headache, pruritis

- Adverse events need to be reported www.fda.gov/medwatch/report.htm

BOTTOM LINE:

This is a promising treatment, but needs some preparatory work to be able to access and safely administer:

1. Work with the local health system/facility pharmacy to access the medication
2. Identify appropriately skilled nursing staff who can be assigned solely to the residents who are undergoing the infusion, and the post-infusion monitoring.
3. Assure that you have sufficient IV supplies
4. Have medications and professional staff readily available to treat infusion reactions/anaphylaxis

Right People

- LTC Specific information
- Medical Director
- Nursing
- Pharmacy
- Communication
- Pharmacy Purchasing
- Data collection – Audit and Study purposes

Do the Math

- We are not in this together
- This is a pandemic and what we do affects the hospital systems

Lessons learned

- Gather a strong team
- Prepare
- Know your facility capabilities
  - Cannot waste time on facilities that are hesitant
- Timing is vital (patients and facilities can turn for the worse in hours)