Saint Agnes Medical Center
1303 E. Herndon Ave. · Fresno, CA 93720 · (559) 450-3000

PATIENT NAME:
DOB:
ALLERGIES:
Height: Weight:

Polyclonal Antibody Criteria Sheet and Order Set

Indications:

EUA use of polyclonal antibodies casirivimab with imdevimab) are for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are at "high risk" for progressing to severe COVID-19, including hospitalization or death.

Polyclonal antibodies are **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.

ADVISORY: Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete. Infusion-related reactions have been observed with administration of casirivimab with imdevimab.

Signs and symptoms of infusion related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, and diaphoresis. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care and contact prescriber.

Authorized Dosage:

REGEN-COV: 600 mg of Casirivimab plus 600 mg of Imdevimab for single intravenous (IV) infusions, administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset.

Patient Selection Prioritization for Polyclonal Antibodies

☐ Tier 1	☐ Tier 2
Adults with BMI ≥ 35 and/or Age ≥ 65	The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19: • Older age (for example, age ≥65 years of age) • Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts. • Pregnancy • Chronic kidney disease • Diabetes • Immunosuppressive disease or immunosuppressive treatment • Cardiovascular disease (including congenital heart disease) or hypertension • Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension) • Sickle cell disease • Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies) • Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)) Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

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Date of Sx Onset	
Days Since Sx Onset	
Date of Positive SARS-CoV-2 Test	
Date patient will meet endpoint of Tier criteria	
Prescriber reviewed appropriate fact sheet w/patient	☐ casirivimab with imdevimab

Medication Order

☐ **Casirivimab with Imdevimab: 600 mg each in 100 mL NS (Final volume 110 mL) infused over 21 minutes.**

- Use an infusion set containing a 0.2 micron filter (reference #2432-0007) to the IV bag.
- Do not shake or vigorously agitate the prepared bag.
- After the entire infusion volume has been administered, flush the infusion line with Sodium Chloride 0.9%, 30mL.
- Observe the patient for at least 1-hour after the infusion is complete.

Medications to Treat Mild & Severe Infusion Reaction (Anaphylaxis)

For a MILD infusion reaction, including isolated itching, flushing, or hives

- Diphenhydramine, 25 mg IV, inject once, PRN, Mild Infusion Reaction
- Famotidine, 20 mg, IV, Inject, Once, PRN, Mild Infusion Reaction

Notify prescriber for any severe reaction symptoms.
The most common signs and symptoms are cutaneous (e.g., sudden onset of generalized urticaria, angioedema, flushing, pruritus). However, 10-20 percent of patients have no skin findings.

Danger signs: Rapid progression of symptoms, respiratory distress (e.g., stridor, wheezing, dyspnea, increased work of breathing, persistent cough, cyanosis), vomiting, abdominal pain, hypotension, dysrhythmia, chest pain, collapse.

For a SEVERE Infusion reaction: promptly and simultaneously give:

- Sodium chloride 0.9 % bolus 1,000 mL IV, Administer over 0.5 Hours, Once, PRN, anaphylaxis
- Sodium chloride 0.9% Flush 30 mL; Flush IV line with 30 mL after infusion is finished.
- EPINEPHrine (ADRENALIN) injection 0.3 mg, intramuscular, Every 5 min PRN, Anaphylactic Symptoms, for 3 doses, May give every 5-15 minutes as needed for up to 3 doses
- Methylprednisolone, 125 mg, IV, Inject, Once, PRN, Anaphylactic Symptoms
  Comments: 1st, administer EPINEPHrine, 2nd, methylPREDNISolone, 3rd, diphenhydrAMINE
- Diphenhydramine, 50 mg, IV, Inject, Once, PRN, Anaphylactic Symptoms
  Comments: 1st, administer EPINEPHrine, 2nd, methylPREDNISolone, 3rd, diphenhydrAMINE
- Place patient in recumbent position, if tolerated, and elevate lower extremities.
- Oxygen: Give 8 to 10 L/minute via facemask or up to 100% oxygen, as needed.
- Albuterol: For bronchospasm resistant to IM epinephrine, give 2.5 mg via nebulizer x 1.

Serious and/or unexpected adverse events attributable to casirivimab with imdevimab must be reported to Eli Lilly in addition to the FDA MedWatch program, either online or via submission of Form FDA 3500.

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Patient Referral

If you have a patient that meets at least one of the high-risk criteria in **Tiers 1 or 2** please refer them for treatment by following these steps:

1. To schedule a patient at Saint Agnes Outpatient Respiratory Infusion Room, call **559-450-5656.** Appointments available M-F, 8:30 a.m.-5 p.m.

   Note: Treatment will be provided to eligible patients on a first-come, first-served basis. In the event your preferred therapy is not available, you will be contacted.

   a. *For SAMC ED patients, fax order directly. Patient will be contacted the next business day.*
   b. *For SAMF Patients,* order the COVID INFUSION REFERRAL order set in Athena.
      a. *C*lick on **View More** at the bottom of the referral to view the required fields to complete the referral (no fax needed).

2. Fax completed Polyclonal Antibody Criteria Sheet and Order Set to **559-450-5288.**

   IMPORTANT: Do NOT fax order until you have a confirmed appointment.

Patient was seen in: ☐ ED ☐ FURI ☐ EH ☐ Other (clinic name) _____

_____
Patient name Contact no.

_____
Physician name Signature

_____ _____ _____
Date Office number Provider contact no.

Is Physician a member of Saint Agnes Medical Staff? ☐ YES ☐ NO

If NO, please provide the following:

_____ _____ _____
NPI DEA State license no.

Patients treated with casirivimab and imdevimab 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

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- **Casirivimab and Imdevimab** EUA Fact Sheets

  Providers:
  https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf

  Patients:
  https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient.pdf (English)

  https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient-spanish.pdf (Spanish)