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

PATIENT NAME:
DOB:
ALLERGIES:
Height: Weight:

Pre-exposure Prophylaxis Polyclonal Antibody Criteria Sheet
Evusheld (tixagevimab co-packaged with cilgavimab and administered together)

Instructions:

Please Read and Complete All Sections on Pages 2-4.

Call 559-450-5656 to schedule the patient.

Incomplete orders will not be scheduled.

These Instructions are for patients with immunocompromising conditions and those who cannot receive a COVID-19 vaccine

Indications:

EUA Evusheld (tixagevimab with cilgavimab), a SARS-CoV-2 spike protein-directed attachment inhibitor, is given for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **or**
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents),

Limitations of Authorized Use

- Evusheld is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

ADVISORY:

- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder
- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

Diagnosis

_____

Diagnosis limiting Covid-19 Vaccination

Medication Order

☐ Prescriber attests that this patient has meet the EUA criteria set by the FDA for Evusheld.

☐ Prescriber reviewed the Evusheld fact sheet with the patient.

Authorized Dosage:

300 mg (3 mL) of tixagevimab and 300 mg (3 mL) of cilgavimab administered as two separate consecutive intramuscular (IM) injections.

Preparation:

- Tixagevimab and cilgavimab are each supplied in individual single-dose vials. **Do not shake the vials.**
- Visually inspect the vials for particulate matter and discoloration. Tixagevimab and cilgavimab are clear to opalescent, colorless to slightly yellow solutions. Discard the vials if the solution is cloudy, discolored or visible particles are observed.
- Withdraw 3 mL of tixagevimab solution from 2-vials (2 x 1.5 mL) and 3 mL of cilgavimab solution from 2-vials (2 x 1.5 mL) into TWO separate syringes. Discard unused portion in vials.
- Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other.
- The total time from vial puncture to administration must not exceed 4 hours.

Monitoring: **Clinically monitor individuals after injections and observe for at least 1 hour.**

Patient Referral

IMPORTANT: **Do NOT fax order until you have a confirmed appointment.**
If you have a patient that meets EUA criteria, 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, 7:00 a.m.-5 p.m.

   Note: Treatment will be provided to eligible patients on a first-come, first-served basis.

2. Fax completed Order Set directly to the Infusion Room **559-450-2224.**

Patient was seen in: (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.

- EUA Fact Sheets for Evusheld (tixagevimab with cilgavimab),

  Providers:
  Evusheld Healthcare Providers FS (fda.gov)

  Patients:
  Fact Sheet for Patients, Parents And Caregivers Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for Coronavirus Disease 2019 (COVID 19) (fda.gov) (English)

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
- 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 4-Puffs via MDI x 1.

Report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to EVUSHELD by submitting FDA Form 3500 online. Please also provide a copy of this form to AstraZeneca by Fax at 1-866-742-7984 or call 1-800-236-9933.