LakeCounty
Health Department and
Community Health Center

Evusheld Information for Community Healthcare Providers

Purpose and Rationale for Evusheld™ Pre-Exposure Prophylaxis (PrEP) to Prevent a COVID-19 Infection

Evusheld, a U.S. Food and Drug Administration (FDA) emergency use authorized (EUA) medication, is used to prevent the acquisition of COVID-19 among immunocompromised individuals who either cannot receive an approved COVID-19 vaccine or may not have mounted an appropriate immune response to any of the approved COVID-19 vaccines before being exposed to the virus. Pre-exposure prophylaxis (PrEP) for COVID-19 with Evusheld aims to reduce the transmission of SARS-CoV-2 and the morbidity and mortality related to infection amongst the most vulnerable individuals in the community. Medical professionals may recommend Evusheld to their patients to offer protection in case they are exposed to the SARS-CoV-2 virus or its variants.

Evusheld is not a replacement for the COVID-19 vaccines or intended for post-exposure prophylaxis for the prevention of COVID-19. Everyone who is eligible to receive a vaccine safely should still do so. Being fully vaccinated against COVID-19 and receiving the booster is still the most effective way to protect and prevent against a SARS-CoV-2 infection, including all currently known variants.

Evusheld is a combination of two monoclonal antibody medications given together, tixagevimab and cilgavimab. The medications are lab-made proteins that act like antibodies made by the immune system to fight a SARS-CoV-2 infection. It is two injections immediately given one after another administered every 6 months.

Workflow for Non-Lake County Health Department (LCHD) Patients to Receive PrEP for COVID-19 Infection

1. Non-LCHD Primary Care Provider (PCP) identifies patients who are eligible and would benefit from Evusheld treatment.
2. The non-LCHD PCP clinical team should call each identified patient to schedule appointment to discuss and assess the need for PrEP for COVID-19.
3. When an appointment is made, the non-LCHD PCP clinical team instructs the patient to bring all medications (including vitamins and herbal supplements) with them to the non-LCHD PCP appointment.
4. Patient presents to their non-LCHD PCP appointment for evaluation for PrEP of COVID-19.
5. The non-LCHD PCP will determine if the patient meets indications for use of PrEP for COVID-19 and does not have contraindications for treatment with Evusheld (see below for details).
6. The non-LCHD PCP **must** discuss the following details:
    a. Description of the Evusheld medication(s)
    b. Education about Evusheld, including its intended purpose and administration
    c. Risks of Evusheld

d. Benefits of Evusheld
e. Potential side effects of Evusheld (including the potential for serious cardiac adverse events and to monitor for symptoms of heart attack or heart failure for 6 months after administration)
f. Requirements for a negative COVID-19 test the day of the Evusheld administration appointment
g. Requirements for one-hour monitoring period after Evusheld injections
h. Determination if the patient is amenable for treatment with Evusheld. If so, the provider will give the patient the Evusheld Fact Sheet (https://www.fda.gov/media/154702/download)

7. The non-LCHD PCP will document in the patient's chart:
    a. A letter of necessity including:
        i. Why the LCHD provider is recommending Evusheld
        ii. The patient's clinical diagnosis
        iii. If the patient has cardiac conditions, and that the provider has reviewed them with the patient and is still recommending Evusheld
        iv. If the patient is pregnant, plans to become pregnant, or is breastfeeding and that the provider has reviewed that the benefits outweigh the unknown risk to the fetus and is still recommending Evusheld
        v. The patient has been counseled by the provider and that the patient is aware of the risks and benefits of Evusheld
        vi. If the patient has antibodies to COVID-19 present, the reason for recommending Evusheld.
    b. No current COVID-19 infection or in isolation
    c. No recent known COVID-19 exposure or quarantine period
    d. COVID-19 vaccination dates, if vaccinated, must be greater than 2 weeks from the last dose
    e. List of current active medications and denial of any known contraindications with medications and Evusheld
    f. Any known allergies
    g. Provided education, review of risk/benefit, side effects, one-hour monitoring period, and fact sheet given to patient
8. The patient and/or non-LCHD PCP will call the LCHD STI Program Coordinator at 847-377-8761 to schedule an appointment for Evusheld medication administration.
9. Prior to the patient's appointment, the non-LCHD PCP will fax the Evusheld documentation to the STI Program at 847-360-2920.
    a. All appointments will be at the STI Clinic at the Belvidere Medical Building (BMB) in Waukegan, IL.
    b. All appointments will be made Monday through Thursday before 1 p.m.

   c. All appointments will be made only after all the required documentation from the non-LCHD PCP is completed in the patient chart.
   d. Documentation from the patient's non-LCHD PCP will be sent to Health Information Management to be scanned into the patient's chart.
10. At the time of the patient's appointment, BMB clinic staff will register the patient for their appointment.
11. The STI clinic provider will see the patient, review the recommendations of the non-LCHD PCP, provide additional education on Evusheld and give the patient the Evusheld Fact Sheet.
12. After assessing the patient as appropriate for medication and reviewing the non-LCHD PCP's recommendation, the STI provider will provide the injections.
13. The patient will be walked by LCHD clinic staff to a location for medical observation for one hour.
14. Any adverse reactions after departure from LCHD should be reported to and managed by the non-LCHD PCP, who should report to the appropriate authorities (see Evusheld Fact Sheet, page 12). Patient will be instructed to call 911 if they experience any adverse reactions requiring medical intervention after the one-hour observation period.
15. For follow-up doses every 6 months, the non-LCHD PCP will reassess the patient's need for Evusheld and document in the patient chart all the requirements in step 7 and fax as instructed in step 9. The patient and/or non-LCHD PCP will call the LCHD STI Program Coordinator at 847-377-8761 to schedule an appointment for Evusheld medication administration.

Evusheld Indications

Evusheld is authorized for individuals:

- Ages 12 years and older, AND
- Who weigh at least 88 pounds, AND
- Who have a moderate to a severe health condition that likely won't allow the body to develop a strong enough response to the COVID-19 vaccine (i.e. immunocompromised due to cancer, untreated HIV/AIDS diagnosis, or autoimmune disease), OR
- Who are taking medications or treatments that prevent a strong enough immune response to the COVID-19 vaccine (i.e. chemotherapy, transplant anti-rejection medications, autoimmune disease medications), OR
- Who are unable to get the vaccine due to severe allergic reactions to all the approved COVID-19 vaccines or their ingredients.

Evusheld is not authorized for individuals who:

- Are currently infected with COVID-19 or in their isolation period, OR
- Are recently exposed to COVID-19 or in their quarantine period, OR
- Received a COVID-19 vaccine in 2 weeks prior to receiving Evusheld

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Evusheld Contraindications

Evusheld is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of Evusheld.

Serious hypersensitivity reactions, including anaphylaxis, have been observed with Human immunoglobulin G1 (IgG1) monoclonal antibodies like Evusheld. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur while taking Evusheld, immediately discontinue administration and initiate appropriate medications and/or supportive care. Clinically monitor individuals after injections and observe for at least one hour.