



COUNTY OF SAN LUIS OBISPO HEALTH AGENCY
PUBLIC HEALTH DEPARTMENT

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Date: December 17, 2021

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Access to Evusheld™ in San Luis Obispo County

Evusheld™, AstraZeneca's long-acting anti-SARS-COV-2 monoclonal antibody, received an Emergency Use Authorization (EUA) from the FDA for use as **pre-exposure prophylaxis** for COVID-19 on December 8, 2021. While a number of monoclonal antibody products are available for the treatment of COVID-19, Evusheld™ is the first to receive an EUA for pre-exposure prophylaxis. Evusheld™ is NOT approved for the management of individuals in isolation for COVID-19, nor for those in quarantine due to a recent exposure.

Evusheld™ should not be considered a replacement for vaccination. COVID-19 vaccines provide more effective protection from COVID-19 for most individuals.

Patients Eligible for Evusheld™

The FDA EUA authorizes use of Evusheld™ in the following groups:

1. Individuals who are not currently infected with SARS-CoV-2 AND who have not had a known recent exposure to an individual infected with SARSCoV-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 is not recommended due to a **history of a severe adverse reaction to a COVID-19 vaccine** and/or COVID-19 vaccine component.

Moderate and severe immunocompromising conditions and treatments 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 CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
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- Advanced or untreated HIV infection (people with HIV and CD4 cell counts below 200, 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 factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Effectiveness and Administration of Evusheld™

In individuals predicted to be poor responders to vaccination or individuals in whom vaccination is contraindicated, Evusheld™ reduced the risk of developing symptomatic COVID-19 by 77% compared to placebo.

Evusheld™ is a combination of two long-acting monoclonal antibodies – tixagevimab and cilgavimab. The drug is administered via two intramuscular injections given concurrently.

Evusheld™ is authorized for redosing every 6 months.

Allocation and Limited Supply

The initial supply of Evusheld™ is expected to be very limited. When supplies are limited, patients least likely to mount an adequate immune response following COVID-19 vaccination should be prioritized.

The U.S. Department of Health and Human Services (HHS) is allocating the limited supply of Evusheld™ to states on an ongoing basis. San Luis Obispo County expects to receive its first allocation early next week.

Patient Referral for Evusheld™

For the time being, Evusheld™ is available to San Luis Obispo County residents via referral from Healthcare Providers only. Currently, Central Coast Home Health will act as the lone provider of Evusheld™ for County residents.

Providers are directed to refer eligible patients by calling Brandi Colombo at **(805)543-2244, Extension 747**.

For More Information

FDA Fact Sheet for Healthcare Providers: Emergency Use Authorization for Evusheld™. <https://www.fda.gov/media/154701/download>

FDA Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization of Evusheld™. <https://www.fda.gov/media/154702/download>

CDC Vaccines & Immunizations Interim Clinical Considerations. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>