**A Prescription Guide for Providers**

**Evusheld** is a combination of tixagevimab plus cilgavimab monoclonal antibodies issued under Emergency Use Authorization (EUA) for individuals: (1) who do not have COVID-19, (2) who have not been recently exposed to COVID-19, **AND** (3) who are severely to moderately immunocompromised **OR** who are not able to be fully vaccinated **with any available COVID-19 vaccine** due to a history of severe adverse reaction to a COVID-19 vaccine or any of its components.

**Dosage and Administration**

Evusheld is indicated for pre-exposure prophylaxis for COVID-19 negative persons with no known recent exposures. If a person has received a COVID-19 vaccine, Evusheld should be administered at least 2 weeks after vaccination. The drug is not authorized for treatment of COVID-19. One dose of Evusheld, administered as two separate gluteal 3 mL injections consecutively (one 300-mg injection per monoclonal antibody), likely provides protection in the 3-month range with new variants. A one-hour observation period is required following treatment.

**Dosing** for individuals who initially received 150 mg of tixagevimab and 150 mg cilgavimab >3 months prior: 300 mg tixagevimab and 300 mg cilgavimab. **Repeat dose:** 300 mg of tixagevimab and 300 mg of cilgavimab should be given 6 months after the date of the most recent EVUSHELD dose.

**Indications**

Individuals who qualify as having moderate to severe immunocompromising conditions under this EUA include those who:

- Are receiving active treatment for solid tumors and hematologic malignancies.
- Received a solid-organ transplant and are taking immunosuppressive therapy.
- Received chimeric antigen receptor T cell therapy or a hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Have a moderate or severe **primary immunodeficiency** (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome, etc).
- Have advanced or untreated HIV infection (CD4 T lymphocyte cell counts <200/mm³, a history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV).
- Are receiving active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, anti-metabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, **tumor-necrosis factor (TNF)** blockers, or other immunosuppressive or immunomodulatory biologic agents (e.g., B cell–depleting agents).
SUMMARY

Severely immunocompromised patients include:
• Individuals who have received solid organ or bone marrow transplant
• Individuals undergoing chemotherapy or those with hematologic malignancies (i.e., multiple myeloma, chronic lymphocytic leukemia)
• HIV-positive individuals with CD4 cells <200/mm³, or individuals taking >20 mg/day of prednisone.

Moderately immunocompromised patients include those:
• Taking methotrexate for rheumatological conditions
• Taking anti-TNF medications such as Humira (adalimumab) for ulcerative colitis and Otezla (apremilast) for psoriasis
• Taking medications with risk for serious infections (active tuberculosis (TB); reactivation of latent TB; invasive fungal infections; and bacterial, viral, or other opportunistic infections).

Individuals who have a history of severe anaphylactic reaction to any approved COVID-19 vaccine are also candidates for therapy.

Additional Information & Resources

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| Pregnancy and Reproductive Health | • There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.  
• There are no available data on the presence of tixagevimab or cilgavimab in human milk or animal milk, the effects on the breastfed infant, or the effects of the drug on milk production.  
Fact Sheet - Healthcare Providers |
| Efficacy | • In a double-blind placebo controlled clinical trial (PROVENT), Evusheld, (tixagevimab 150 mg plus cilgavimab 150 mg), recipients saw a 77% reduced risk of developing COVID which was maintained for 6 months (pre-Omicron)  
• In-vivo laboratory studies have shown reduced activity against COVID-19 BA.1 and BA.1.1 subvariants. Limited duration (<3 months) protection against subvariants is possible.  
AZD7442 PROVENT Phase II prophylaxis trial  
Efficacy of Antibodies and Antiviral Drugs against Covid-19 Omicron Variant |
| Adverse Reactions | Rare serious cardiac adverse events (myocardial infarctions and heart failure) have been reported. All had cardiac risk factors or a history of cardiac disease.  
Fact Sheet – Healthcare Providers |
| Fact Sheet for Prescribers | FDA Emergency Use Authorization for EVUSHELD  
Fact Sheet - HealthcareProviders |
| Fact Sheet for Patients/ Caregivers | FDA Fact Sheet for Patient, Parents, and Caregivers  
FDA Patient/Caregiver Fact Sheet (Spanish) |
| NIH Guidelines | NIH Summary Recommendations for Prevention of SARS-CoV-2 Infection  
NIH Treatment Guidelines |

For the latest updates on COVID-19, visit:  
www.sandiegocounty.gov/COVIDHealthProfessionals