05 April 2022

LIVE WELL SAN DIEGO

EVUSHELD INFORMATIONAL SHEET SUMMARY

Pre-Exposure Prophylaxis for COVID-19

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 only for pre-exposure prophylaxis. A negative COVID test is required 5 days prior to administration along with a history of 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. Limited data inform the timing of repeat doses and are not included in the current EUA.

Dosing for individuals who initially received 150 mg of tixagevimab and 150 mg cilgavimab: Initial dose ≤3 months prior: 150 mg tixagevimab and 150 mg cilgavimab; Initial dose >3 months prior: 300 mg tixagevimab and 300 mg cilgavimab.

Indications

The individuals who qualify as having moderate to severe immunocompromising conditions under this EUA are 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).
- Have advanced or untreated HIV infection (defined as people with HIV and CD4 T lymphocyte cell counts <200/mm^3, 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:

- Solid organ transplants & bone marrow transplants
- Individuals undergoing **current chemotherapy &** those with **hematologic malignancies** (i.e., multiple myeloma, chronic lymphocytic leukemia)
- **HIV-positive** individuals with CD4 cells <200/mm^3, and individuals taking >**20 mg/day of prednisone**.

Moderately immunocompromised patients include those:

- **Rheumatological conditions** (many on low-dose methotrexate)
- Taking popular **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).

Patients who have an history of **severe anaphylactic reaction** to any approved COVID-19 vaccines are also candidates for therapy.

Additional Information & Resources

	Summary	Links
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 • In-vivo laboratory studies have shown reduced activity against COVID-19 BA.1 and BA1.1 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 – HealthcareProviders
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