

Interim DOH Guidance on Use of EVUSHELD™ for COVID-19

Update (April 5th, 2022):

All categories of the tiered system are now recommended for eligibility to receive EVUSHELD™

Recommendations

On Dec. 10, 2021, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization ([EUA](#)) to permit the emergency use of monoclonal antibody (mAb) therapy EVUSHELD™ (tixagevimab/cilgavimab - AZD7442), from AstraZeneca for pre-exposure prophylaxis (PrEP) of SARS-CoV-2 infection in individuals 12 years of age and older. The [EUA](#) was reissued on February 24, 2022 to reflect recommended dosing changes. With this product being readily available for allocation in WA, sites that are able to administer this within the EUA guidelines to eligible patients are encouraged to request an allocation from DOH in order to make this available for patients across the state. A provider needs only to have a valid medical license to request/administer to patients that meet eligibility criteria. Sites with supply currently are shown in the [COVID-19 Therapeutics Locator](#).

Per the [EUA](#), eligible patients for EVUSHELD™ must have:

- No history of recent exposure to an individual diagnosed with COVID-19
- A moderate to severely compromised immune system
- At least 2 weeks after receiving their final COVID-19 vaccination, OR a contraindication to COVID-19 vaccination such as a history of severe adverse reactions to a COVID-19 vaccine and/or component of vaccine

The following conditions represent those for which diagnosed individuals may receive the greatest benefit from SARS-CoV-2 monoclonal antibody pre-exposure prophylaxis with EVUSHELD™. It is not exhaustive.

- Lung transplant recipient (any time frame)
- Small bowel transplant recipient (any time frame)
- Recipient of more than one active transplant, different organs (any time frame), e.g., kidney-pancreas, heart-kidney
- Any solid organ transplant
- Allogeneic stem cell transplant
- Autologous stem cell transplant

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- Receipt of immunosuppressive medication within the past 12 months (including for solid organ transplant)
- Active treatment with anti-thymocyte globulin (ATG)
- Active treatment with alemtuzumab
- Active treatment with anti-B-cell therapy (e.g., rituximab)
- B-cell malignancies, on active treatment (e.g., B-cell lymphomas, chronic lymphocytic leukemia, acute B-cell lymphoblastic leukemia, etc.) or maintenance therapy
- Multiple myeloma, on active treatment or maintenance therapy
- Receipt of anti-CD19 or anti-BCMA (CAR)-T-cell immunotherapy
- Primary or secondary T-cell immunodeficiency, including severe combined immunodeficiency
- Acute myeloid leukemia under active treatment
- Any solid tumor on active myelosuppressive chemotherapy
- Active treatment with high-dose corticosteroids (i.e., more than 20 mg prednisone or equivalent per day when administered for two weeks or longer)
- Active treatment with immunosuppressive or immunomodulatory biologic agents
- Advanced or untreated HIV infection or AIDS-defining illness Persons 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)

Background

AstraZeneca's EVUSHELD™ is a combination of two anti-SARS-COV-2 monoclonal antibodies (tixagevimab/cilgavimab). Tixagevimab and cilgavimab are long-acting monoclonal antibodies specifically directed against the spike protein of SARS-CoV-2 designed to block the virus' attachment and entry into human cells. Tixagevimab and cilgavimab bind to different, non-overlapping sites on the spike protein of the virus. The manufacturer has reported that EVUSHELD™ retains neutralizing activity against the Omicron variant. However, some studies suggest EVUSHELD™ may have reduced effectiveness against Omicron compared to previous variants.

Unlike other mAb products currently under EUA, tixagevimab/cilgavimab is a long-acting mAb designed for use as a pre-exposure prophylactic (PrEP) medication only in pediatric individuals aged 12 and older (weighing ≥ 40 kg) and adults who are either unable to mount an adequate immune response to COVID-19 vaccination or are unable to get a COVID-19 vaccine due to concern for severe adverse reactions. The product is administered via intramuscular injection. One dose of EVUSHELD™, administered as two separate consecutive intramuscular injections (one injection per monoclonal antibody, given in immediate succession). EVUSHELD™ is **not** authorized for individuals for the treatment of COVID-19 or for post-exposure prophylaxis of COVID-19. EVUSHELD™ may only be prescribed by a healthcare provider licensed under State law to prescribe drugs for an individually identified patient and who has the education and training to make the clinical assessment necessary for appropriate use of EVUSHELD™.

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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.

The product is only authorized for those individuals who are not currently infected with the SARS-CoV-2 virus **and** who have not recently been exposed to an individual infected with SARS-CoV-2. The authorization also requires that individuals either have:

- moderate to severely compromised immune systems due to a medical condition or due to taking immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination (see below - examples of such medical conditions or treatments can be found in the [fact sheet for health care providers](#)); **OR**
- a history of severe adverse reactions to a COVID-19 vaccine and/or component(s) of those vaccines, therefore vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended.

Moderate and severe immunocompromising conditions and treatments include but are not limited to (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>).

Per the [EUA and Fact Sheet for Healthcare Providers](#), the 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 less than 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., more than 20 mg prednisone or equivalent per day when administered for two weeks or longer); 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)

Resources

Fact sheet for healthcare providers - <https://www.fda.gov/media/154701/download>

Fact Sheet for Patients, Parents And Caregivers - <https://www.fda.gov/media/154702/download>
[Media release](#) - EVUSHELD™ was found to retain neutralizing activity against Omicron variant in an independent FDA study.

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NIH guidance: [Anti-SARS-CoV-2 Monoclonal Antibodies | COVID-19 Treatment Guidelines \(nih.gov\)](#)

[NIH Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints](#)

IDSA guidance: [IDSA Guidelines on the Treatment and Management of Patients with COVID-19 \(idsociety.org\)](#)

CDC guidance:

- [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers](#)
- [CDC Altered Immunocompetence](#)
- [CDC Yellow Book – Chapter 5 Immunocompromised Travelers](#)
- [Interim Ethical Framework for Administration of tixagevimab/cilgavimab During the Covid-19 Pandemic](#)

More COVID-19 Information and Resources

- Stay up-to-date on the [current COVID-19 situation in Washington](#), [Governor Inslee's proclamations](#), [symptoms](#), [how it spreads](#), and [how and when people should get tested](#). See our [Frequently Asked Questions](#) for more information.
- The risk of COVID-19 is not connected to race, ethnicity or nationality. [Stigma will not help to fight the illness](#). Share accurate information with others to keep rumors and misinformation from spreading.
- [WA State Department of Health 2019 Novel Coronavirus Outbreak \(COVID-19\)](#)
- [WA State Coronavirus Response \(COVID-19\)](#)
- [Find Your Local Health Department or District](#)
- [CDC Coronavirus \(COVID-19\)](#)
- [Stigma Reduction](#)