

Public Health Update February 7, 2022 Availability of monoclonal antibody therapies for COVID-19

Situation

Starting February 7, 2022, the following monoclonal antibody (mAb) therapies will be available, free-of-charge, on the second floor of Elite Medical Center, 150 E Harmon Ave, Las Vegas. Appointments are available starting at 1:00 pm February 7 and thereafter will be available 7 days a week between the hours of 8:30 am and 4:30 pm. Appointments must be made in advance (no-walk-ins accepted) by calling 702 481-4209. Healthcare providers may make an appointment on behalf of their patients or may encourage their patients to make the appointment themselves.

Evusheld[™]

The FDA has issued an emergency use authorization (EUA) for the emergency use of Evusheld. Evusheld is available for the *pre-exposure prophylaxis* of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with COVID-19 and who have not had a known recent exposure to someone with COVID-19; **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 response to COVID-19 vaccination¹; OR
- For whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Additional notes:

- Evusheld is NOT authorized for the treatment of COVID-19 and is NOT authorized for post-exposure prophylaxis in those who have been exposed to someone with COVID-19.
- Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in those for whom vaccination is recommended.
- For additional information, visit <u>https://www.fda.gov/media/154701/download</u>

¹ 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 <200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV); or 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 (TNF) blockers, and other biological agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents).

<u>Sotrovimab</u>

The FDA has also issued an EUA for the emergency use of sotrovimab. Sotrovimab is available for the *treatment* of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a positive COVID-19 test with onset of symptoms within the last 10 days who are at high risk for progression to severe COVID-19, including hospitalization and death. High-risk criteria are defined as having at least one of the following:

- Age 65 years of age or older
- Obesity or overweight (adults with BMI>25 or children with BMI>85 percentile for their age and gender)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders or other conditions that confer medical complexity
- Medical-related technological dependence
- Other medical conditions or factors that may place individuals at high risk for progression to severe COVID-19.

Additional notes:

- Sotrovimab is NOT authorized for use as pre-exposure or post-exposure prophylaxis.
- Sotrovimab is NOT authorized for use in patients who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).
- For additional information, visit <u>https://www.fda.gov/media/149534/download</u>

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Health Advisory: provides important information for a specific incident or situation; may not require immediate action
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action action