Michigan Medicine Evusheld Administration Criteria

Evusheld (tixagevimab-cilgavimab) is NOT a substitution for vaccine. All patients, including those unlikely to have an antibody response, should ideally have received 3 doses of mRNA COVID-19 vaccine, or two doses if initial dose was J&J, prior to consideration of Evusheld. Vaccination induces long-lasting T-cell responses independent of antibody production which provide additional protection against severe COVID-19. Please note that lack of vaccination is not a contraindication to administration of Evusheld, but Evusheld should not be used as a substitute for vaccination in patients who are otherwise eligible to be vaccinated.

At this time, Evusheld supply is adequate to meet demand at Michigan Medicine. Thus, Evusheld may be administered to any patient age ≥12 years and ≥40 kg who are considered to be moderately to severely immunocompromised and not expected to mount an adequate vaccine response. Examples of moderate to severe immunocompromise include, but are not limited to, the following:

a) Patients with acute or chronic hematologic malignancy, with or without therapy
b) Patients with solid tumors receiving active treatment
c) Patients on B-cell depleting therapy (e.g., rituximab, ocrelizumab)
d) Hematopoietic cell transplantation (HCT) / chimeric antigen T-cell therapy (CAR-T) within 6 months of transplant or ongoing graft-versus-host-disease (GVHD) / ongoing immunosuppression
e) Solid organ transplant recipients
f) Severe primary immunodeficiency not expected to respond to vaccination
g) Advanced or untreated HIV infection
h) Active treatment with high-dose corticosteroids (e.g., ≥20 mg/day prednisone equivalent), antimetabolite therapy, or other transplant, chemotherapeutic, or biologic agents that are immunosuppressive

At this time, only first doses are being scheduled in central administration clinics and Michigan Medicine is not proactively contacting patients to schedule subsequent / second doses of Evusheld. A patient who contacts an individual clinic may receive a second dose of Evusheld in a primary clinic only.

Vaccine considerations:

- Evusheld may decrease the efficacy of COVID-19 vaccines
- Patients should wait at least 14 days from receipt of a COVID-19 vaccine to receive Evusheld
- There is no waiting period after receipt of Evusheld before a patient can receive a COVID-19 vaccine

Administration:

- Evusheld is administered as two separate 3.0-mL gluteal intramuscular injections (initial dose) or two 1.5-mL gluteal intramuscular injections (subsequent dose)
- Platelet count >30,000 cells/mm³ required
- Patients must be consented for administration of the EUA product (documented with .azcovidmab)
- Patients must be provided with the Patient EUA fact sheet (available with .azcovidmabfact or here: https://www.fda.gov/media/154702/download
- Patients must be medically observed for 1 hour after administration
ALLOCATION CRITERIA FOR EVUSHELD (TIXAGEVIMAB/CILGAVIMAB)
FOR PREVENTION OF COVID-19

Process for ordering Evusheld:

1) Identify appropriate patients
   - Cannot be COVID positive
     o If so, patients must wait at least 20 days and have no fever / improving symptoms
   - No serologic testing required
   - Prior vaccination not required, but do NOT use as vaccine alternative

2) Consent patient
   - Discuss with patient and obtain verbal consent (nurses, physicians, and pharmacists may provide consent)
   - Provide EUA patient caregiver / factsheet: https://www.fda.gov/media/154702/download
   - Document consent using .azcovidmab

3) Schedule patient
   - Option 1: schedule in clinic if RN available to provide gluteal IM injections
     o May add product to clinic formulary and requisition using normal process
     o Follow usual process for ordering clinic-administered medications
   - Option 2: send for central scheduling in Taubman clinic
     o Only available for INITIAL doses
     o Send patient call encounter to TC TXP LIVKID CALL CENTER
       ▪ Add “Evusheld injection” to the comment area
     o Patient will be called and scheduled
       ▪ May be a significant delay in administration due to limited capacity

Antimicrobial Subcommittee Approval: N/A
P&T Approval: N/A

Revision History:
1/27/22: Revised criteria for use
2/17/22: Clarified vaccine recommendations
3/8/22: Revised process for administration

The recommendations in this guide are meant to serve as treatment guidelines for use at Michigan Medicine facilities. If you are an individual experiencing a medical emergency, call 911 immediately. These guidelines should not replace a provider’s professional medical advice based on clinical judgment, or be used in lieu of an Infectious Diseases consultation when necessary. As a result of ongoing research, practice guidelines may from time to time change. The authors of these guidelines have made all attempts to ensure the accuracy based on current information, however, due to ongoing research, users of these guidelines are strongly encouraged to confirm the information contained within them through an independent source.

If obtained from a source other than med.umich.edu/asp, please visit the webpage for the most up-to-date document.