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 \( \geq 12 \) years and \( \geq 40 \) kg who are 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., \( \geq 20 \) 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 theoretically 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 (300mg/300mg) gluteal intramuscular injections
- Patients should receive repeat dosing every 6 months
- Platelet count >30,000 cells/mm\(^{3}\) required
- Patients must be consented for administration of the EUA product (documented with .azcovidmab; only required for first dose)
- Patients must be provided with the Patient EUA fact sheet (available with .azcovidmabfact or here: https://www.fda.gov/media/154702/download; only required for first dose)
- Patients must be medically observed for 1 hour after administration
Process for ordering Evusheld:

1) Identify appropriate patients
   - If COVID positive, should be asymptomatic or recovered
   - No serologic testing required
   - Prior vaccination not required, but do NOT use as vaccine alternative

2) Consent patient – only required for first dose
   - 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: administer in clinic if RN available to provide gluteal IM injections
     - May add product to clinic formulary and requisition using normal process
     - Follow usual process for ordering clinic-administered medications
   - Option 2: send for central scheduling in Northville or Brighton injection clinics
     - Enter order for “Evusheld referral”
     - Patient will be called and scheduled
       - May be a significant delay in administration due to limited capacity