Monoclonal Antibody Infusion Scheduling Instructions
Evusheld

From Oaklawn Medical Group Office or Express care site:

- Complete form A-45, attached. Please make sure to fill out all required fields, including physician signature and date of symptom onset. A new form is required to be filled out for each patient.
- Fax the completed form to 269-789-4924. The patient will not be scheduled until the form is received.
- Send an urgent patient case in Athena to surgery scheduling using the surgeryorders bucket. Put "Monoclonal Antibody Infusion" in the subject line.
- Tell your patient that you will call them with the appointment time and date.
- Await a response from scheduler to patient care (in provider staff bucket). **No need to call Surgery Scheduling.**

From a site outside Oaklawn Medical Group:

- Complete form A-45, attached. Please make sure to fill out all required fields, including physician signature and date of symptom onset. A new form is required to be filled out for each patient.
- Fax the completed form to 269-789-4924. The patient will not be scheduled until the form is received.
- After faxing the completed form, please call 269-789-3915 Option 1 for Surgery Scheduling. Please hold for your call to be answered. **Please do not leave a voicemail during business hours.**
- If after hours, weekends, or holidays, please wait to call on the next business day and hold until your call can be answered.

Please be sure to tell patients that they will be contracted with their appointment date and time based on available staff and medication and not all patients will be accommodated. Patients should plan to arrive to Registration 30 minutes before their appointment and plan to be here for 2-3 hours. Visitors are not allowed to accompany patients unless there is an extenuating circumstance, this will need to be noted at the time of scheduling. There may be up to 4 patients in a room receiving infusions at the same time. Patients are required to remain masked throughout the duration of their infusion.

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Oaklawn

PATIENT NAME/PHONE NUMBER:	DOB:
ALLERGIES:	
FDA PATIENT FACT SHEET* PROVIDED ON:	
* Per FDA EUA, patient education and patient fact sheet must be provided to the patient prior to administration.	

PLEASE CHECK EVERY BOX THAT APPLIES FOR YOUR PATIENT

Vaccination Status:

☐ None ☐ First Dose Type: _____ Date: _____ ☐ Second Dose Type: _____ Date: _____ ☐ Third Dose Type: _____ Date: _____

Evusheld

☐ Medical condition or treatment that may result in moderate to severe immune compromise and an inadequate immune response to the 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 CAR-T-cell therapy or hematopoietic cell transplant (HCT) (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)

LIMITATIONS OF AUTHORIZED USE:

- Evusheld is not authorized for use in individuals:
  - For treatment of COVID-19
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- 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.

Monoclonal antibody treatments are NOT AUTHORIZED for use in patients with: Who are hospitalized due to COVID-19; OR Who require oxygen therapy due to COVID-19; OR Who require an increase in baseline oxygen flow-rate due to COVID-19 for those on chronic oxygen therapy due to an underlying non-COVID-19 related co-morbidity. ☐ Patient does not meet any of the listed contraindication.

Prescribed DRUG

☐ **Evusheld (tixagevimab/cilgavimab)**

- Evusheld must be administered by a qualified healthcare provider.
- Administer the two components of Evusheld consecutively.
- Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other.

To be documented at time of infusion:

Tixagevimab **Dose:**_____ **LOT Number:** _____ **Expiration Date:** _____

Cilgavimab **Dose:**_____ **LOT Number:** _____ **Expiration Date:** _____

Initial Dosing:

- Due to the decreased neutralization activity in Evusheld against the Omicron subvariants BA.1 and BA.1.1 (BA.1+R346K), the initial dosage of Evusheld in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 300 mg of tixagevimab and 300 mg of cilgavimab administered as two consecutive intramuscular (IM) injections.
- Dosing for individuals who have already received the previously authorized dose (150 mg tixagevimab/150 mg cilgavimab) show receive a second Evusheld dose (150 mg tixagevimab/150 mg cilgavimab) as soon as possible. Any subsequent repeast dosing should be timed from the date of the second Evusheld dose.
- For the 300 mg tixagevimab and the 300 mg cilgavimab dose, ensure that the administration sites are appropriate for the volume (3mL per injection).
- For the 150 mg tixagevimab and the 150 mg cilgavimab dose, ensure that the administration sites are appropriate for the volume (3mL per injection).
- Clinically monitor individuals after injections and observe for at least 1 hour.

Evusheld EUA Fact Sheet: https://www.fda.gov/media/154701/download.

Administering Provider **Signature** **Date**

MANAGEMENT OF HYPERSENSITIVITY

Patients must be clinically monitored during infusion and observed for at least one hour after infusion is complete. Vital signs must be measure before infusion and ≤ q 30 minutes, and when indicated until conclusion of observation period.

Management of Minor Infusion-Related Symptoms	
Nausea/Vomiting	Ondansetron (Zofran): 4 mg ODT (oral dissolving tablet) or 4 mg IV
Headache/Fever	Acetaminophen: 650-1,000 mg PO
*** Minor infusion related symptoms such as nausea, headache, fever, and dizziness can often improve with slowing infusion rate. For minor symptoms early in the infusion, decrease infusion rate by 25-50%.	

Management of Severe (non-anaphylactic) Infusion-Related Symptoms
*** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen, as indicated. Activate the emergency medical system (EMS; e.g., call 911 if applicable) and notify the patient's physician/clinician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient.

Management of Anaphylactic Symptoms	
Anaphylaxis	**Epinephrine 0.3 mg IM; if signs of hypotension and/or respiratory distress with wheezes or stridor are present, repeat dose every 5 to 15 minutes for up to two doses.** Diphenhydramine 50 mg IM or IV (administer alone for moderatesymptoms)
*** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen as indicated, administer medications as above, limit epinephrine to shock or severe respiratory distress. Call EMS and continue supportive care, while monitoring patient closely until arrival. Notify the patient's physician/clinician as soon as able.	

ADDITIONAL ORDERS

ORDERING PRESCRIBER

Prescriber Name:_____ Prescriber Signature: _____

Direct Contact Number:_____ Fax Number: _____

Order date: _____

REPORTING REQUIREMENTS

In accordance with the Michigan Public Health Code (MCL 331.531), the following survey must be completed for each patient treated with monoclonal antibody (MAB) therapy supplied through the State of Michigan:

https://forms.office.com/Pages/ResponsePage.aspx?id=sgF4Zzdipk67RItjfx6ergRINfmr3E1Njq-ZF3K4vsBUMjRaVE43VjM1MFJRTllCVzBMMk9HWVVBTiQlQCN0PWcu.

POST INFUSION SUMMARY
☐ No infusion related problems **Additional Comments:**

Patients, Parents and Caregivers EUA Resources:

☐ **Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Evusheld for Coronavirus Disease 2019 (COIV-19): https://www.fda.gov/media/154701/download.**

Patient Consent: by signing this I attest to have read, or had explained to me, the patient fact sheet for the monoclonal antibody that I am receiving and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I understand the potential risks and benefits associated with monoclonal antibody therapy and agree to receive the infusion of this medication.

Form Completed by/Relationship to Patient	Signature	Date

Please fax completed form to **269-789-4924** and call Scheduling at **269-789-3915** option 1 to schedule the patient.

APPOINTMENT DATE/TIME: _____