

Munson Healthcare Monoclonal Antibody (mAb) Therapy FAQ for Referring and Ordering Providers

How do I obtain Informed Consent if I am seeing the patient via TeleHealth? Is it ok to get Informed Consent over the phone?

A telephone "signature" can be obtained and is acceptable. Two staff members will listen as the form is read and confirmation is verbally received. Both staff members must sign the form and indicate the name and relationship of the person confirming consent. Fax and email may also be utilized. If using fax/email, remind the signee to have his/her signature witnessed.

Why do I (the ordering provider) have to fill out the consent forms?

Informed consent is not a form but rather, it is a process whereby a provider discussed a proposed treatment with a patient, including the benefits and risks, and the provider and patient decide together whether to pursue the treatment. In certain circumstances, laws or regulations require the informed consent process to be documented in a certain manner. Because Monoclonal Antibody therapy is only available pursuant to an emergency use authorization (EUA), the FDA is requiring certain elements be included in the informed consent discussion that happens between the ordering provider and the patient. This is to ensure that, given the experimental nature of the treatment, certain risks are highlighted that are unique to a treatment new for this particular use. The informed consent discussion must be between the treating provider and the patient. The treating provider then utilizes the EUA Consent Form to document that this process has been carried out.

What are the hours for the MHC mAb Support Line?

M – F; 8am – 4pm

What do I do if it's after hours and I have a qualifying patient?

- For Primary Care Providers: complete the required paperwork and call the mAb Support Line the following business day to complete referral.
- For ED and Urgent Care Providers: fax the 3 required documents to the MHC mAb Support Fax (231-392-7348). The mAb Support Line staff will receive this paperwork and follow up with the patient and his/her indicated Primary Care Provider the following business day. Treatment will be scheduled and the patient will proceed through the process. The ED Provider will remain the "Ordering Provider" but the patient's Primary Care Provider will also be notified so follow-up can occur.

What if the patient does not have a Primary Care Provider?

If you are seeing a patient in the ED or Urgent Care and he/she does not have an established Primary Care Provider, please proceed through referral and ordering so that the qualifying patient can be scheduled for infusion. Then, follow the established process at your facility for handling patients who present to the ED or Urgent Care without a PCP.

Munson Healthcare's Find-A-Doctor: 231-935-5886 www.munsonhealthcare.org/find-a-doctor



Where will the patient be scheduled for therapy?

We will work to schedule the patient at an infusion location and time that is most convenient for them. Patients may be offered appointments at any of the infusion locations, regardless of where the order originated or where they live.

Site-specific availability may be limited. Munson Healthcare is currently able to schedule a maximum of 40 infusions per week across all locations.

Will all infusion locations care for pediatric (12 – 17 yo) patients?

No. Only the Traverse City mAb Infusion location will treat patients < 18 years of age. If you are referring a patient < 18 years old, he/she will need to travel to the Traverse City location to receive the infusion.

What if the patient has to cancel his/her appointment?

We ask that patients make every effort to attend their scheduled appointment. Appointment timeframes are very rigid due to the time-sensitive nature of dose preparation and infusion.

If a patient must cancel their scheduled appointment, please have them call the mAb Support Line (231-935-4880) to speak with the mAb Support Line staff. Staff may be able to reschedule the patient for another treatment time within the 10 day window.

What is the protocol if the patient has an adverse or hypersensitivity reaction?

Each infusion location is prepared to manage hypersensitivity reactions using the standard protocol.

Are we allowing known COVID+ patients to enter our buildings for treatments? Isn't this a risk?

All patients receiving mAb Therapy are COVID+. PPE protocols for patients with known COVID-19 infection will be strictly followed throughout the patient's visit. Infusion locations were selected specifically based on ease with which a patient can enter the building. Patients will be escorted by Munson Healthcare staff at all times to ensure proper infection prevention measures are followed.

Can mAb Therapy be ordered for patient who are pregnant or breastfeeding?

There is limited experience treating pregnant women or breastfeeding mothers with mAb Therapy. For a mother and unborn baby, the benefit of receiving bamlanivimab and etesevimab may be greater than the risk from the treatment. In addition, the FDA has recently updated inclusion criteria for mAb therapy to include pregnant individuals as those who may be at a higher risk for progressing to severe COVID-19.

Can mAb Therapy be ordered for a patient who has already been vaccinated for COVID-19?

Yes. Monoclonal Antibody Therapy is approved for those with a history of a COVID-19 vaccination.

How long should a person wait to get vaccinated for COVID-19 after their mAb infusion?

If a patient has received mAb Therapy, he/she shoud wait 90 days after that infusion before they receive a COVID-19 vaccine.

Additional Questions? Email us: <u>MHC-MABClinic@mhc.net</u> or visit our <u>COVID-19 For Providers</u> website where you will find all necessary forms and resources.