Monoclonal Antibodies Key Messages for Staff

Key Message: Background

A new monoclonal antibody from Eli Lilly for the treatment of active COVID-19 in non-hospitalized patients was recently given emergency use authorization (EUA). The State of Michigan has received limited doses for distribution to hospitals. Henry Ford has received and will continue to receive scarce allocations. Because of the limited supply and because of what we know about the effectiveness of this therapy, we, in concert with the Food and Drug Administration (FDA) and the state of Michigan, have developed specific protocols for administration to COVID-19 patients in an outpatient setting who meet the criteria.

For additional details, please see the following key messages, the <u>Tier 1: Clinical Indications For Use of Bamlanivimab (MAB) Guideline</u> and the patient-facing frequently asked questions. These FAQs can be found on HenryFord.com and on OneHENRY.

Key Message: National Distribution Process

The Federal government allocated a certain volume of treatments to each state, based on COVID-19 case rates and the relative rates of older and obese patients in the state. The state is then responsible for allocating to providers who have the capacity to administer the treatments.

Key Message: Treatment overview

The monoclonal antibody therapy is called bamlanivimab and has just been approved by the FDA for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. Bamlanivimab is a preformed antibody directed against the spike protein of the coronavirus and is designed to block the virus' attachment and entry into human cells. It may be beneficial in prevention of hospitalization from COVID-19.

Key Message: Treatment administration

- The treatment is given through a one-time intravenous (IV) infusion.
- The infusion procedure itself takes one hour. But staff and patients should plan for an approximate three-hour visit. This includes checking in, pre-procedure preparation and post-procedure monitoring.
- Patients must be monitored closely after the treatment for the potential of adverse reactions. Possible side effects include anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching and vomiting.

Key Message: Eligibility requirements

Because of the limited supply of the monoclonal antibody treatment, Henry Ford has developed strict eligibility requirements for who can receive this treatment.

The monoclonal antibody treatment should be given to adults or children between the ages of 12 and 17 who meet the following criteria:

- Had a positive COVID-19 test within 4 days
- Onset of symptoms began no more than 5 days ago

Priority will be given to those individuals who have additional risks for severe COVID- 19 infection requirements and meet certain requirements.

The monoclonal antibody treatment should NOT be given to the following patients:

- Asymptomatic COVID positive patients OR
- Hospitalized COVID positive patients OR
- Those requiring supplemental O2 due to covid-19 or those with increased supplemental
 O2 due to Covid-19 if on baseline O2 therapy

Please carefully review <u>Tier 1: Clinical Indications For Use of Bamlanivimab (MAB) Guideline</u>.

Key Message: Workflow for Referrals, Ordering and Administration in Epic

Please see the following tip sheets for how to refer, order and administer the treatment in Epic:

- Tier 1: Clinical Indications For Use of Bamlanivimab (MAB) Guideline
- Ordering a Therapy Plan for Bamlanivimab Monoclonal Antibody
- Administering a Therapy Plan for Bamlanivimab Monoclonal Antibody
- Scheduling an Appointment from the Covid-19 Monoclonal Treatment Referrals Workqueue
- Henry Ford Home Infusion Team Bamlanivimab Referral
- Bamlanivimab- Fact Sheet for Healthcare Providers
- Bamlanivimab- Fact Sheet for Patients, Parents and Caregivers
- COVID-19 Education PPE Guidance for Bamlanivimab Monoclonal Antibody
- Pediatric Age Criteria for Specific HFHS Sites

Key Message: Distribution to Henry Ford Patients

The decision will be made by the Henry Ford provider who either ordered the COVID-19 test for the patient, by the Acute Respiratory Clinic (ARC) or by the patient's primary care Henry Ford provider, if the test was not conducted at Henry Ford.

Please carefully review Tier 1: Clinical Indications For Use of Bamlanivimab (MAB) Guideline.

Key Message: Administration Sites

The monoclonal antibody treatment will be administered at the following designated Henry Ford facilities across all markets. One site per market has been identified given the limited supply of treatment we currently have. In addition, these sites were chosen because they have the necessary operations to manage the storage of the medicine, have the staffing resources to administer and monitor the patient post-infusion, are ready for anaphylactic reaction and can activate EMS, if necessary.

South Market: Henry Ford Hospital K10 - Infectious Disease (ID) Clinic

K10 can accept patients who are 16 years and older

North Market: Henry Ford Medical Center - Columbus: Infectious Disease (ID) Clinic

Columbus Center can accept patients who are 16 years and older

Central Market: Outpatient Infusion Clinic

- Outpatient Infusion Clinic can accept patients who are 14 years or older.
 - o If the case is emergent, it can accept patients who are 12 or 13 years of age

Other Sites: Henry Ford Home Infusion Team

 Henry Ford Home Infusion Team can accept patients who are 12 years of age and older but with limited capacity.

You can also see this tip sheet: Pediatric Age Criteria for Specific HFHS Sites

Key Message – Same Day Appointments

- For K10: The deadline to schedule a same-day appointment is at 1:30 p.m. If a patient is identified for infusion after 1:30 p.m., they will be scheduled for the next available day.
- For Columbus Center: The deadline to schedule a same- day appointment is 10:30 a.m. If a patient is identified for infusion after 10:30 a.m., they will be scheduled for the next available day.
- For Outpatient Infusion Clinic: Same-day appointments will depend upon staffing availability.

Key Message: Communicating to Patients

Patients should be informed of the following:

- Henry Ford has very limited quantities of the monoclonal antibody treatment.
- Those who meet the eligibility requirements will be considered to receive the treatment.
- If a person who just tested positive for COVID-19 is interested in receiving the treatment, they should contact their Henry Ford provider by sending them a MyChart message or calling the Henry Ford clinic.
- Refer the patient to the FAQs on HenryFord.com
- All patients, regardless of receipt of monoclonal antibody treatment or not, must continue
 to practice all public measures such as isolation, wearing a mask, maintaining physical
 distancing and washing hands.