

# Expanding Use of Monoclonal Antibodies in our Communities

April 15, 2021



**ALL FOR YOU**

# COVID monoclonal antibody (mAB) expansion project

- Monoclonal antibodies are an important tool to keep patients out of the hospital
- With funding support from HHS, HFHS is opening a new monoclonal antibody (mAB) infusion center in southwest Detroit and expanding mAB therapy services at three of its hospitals that care for patients in underserved communities – Henry Ford Hospital in Detroit, Henry Ford Macomb Hospital in Clinton Township and Henry Ford Allegiance Health in Jackson. HHS is also providing staffing and equipment support to manage these infusion centers.
- The new infusion center is at the Community Health and Social Services (CHASS), a federally qualified health center whose physician services are contracted through Henry Ford serving underserved Black and Latino patient populations.
- Henry Ford also will continue to operate infusion sites at its Columbus and Fairlane Medical Centers

# Clinical criteria for administration of mAB

- Bamlanivimab and etesevimab are IgG1 antibodies authorized for use under an Emergency Use Authorization (EUA) for treatment of mild to moderate COVID-19 disease in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Bamlanivimab and etesevimab should be administered as soon as feasible after a positive viral test for SARS-CoV-2 AND within 10 days of symptom onset.
- Earlier treatment is likely to confer the most benefit. This applies to both adults and pediatric patients 12 years of age and older weighing at least 40 kg who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- The drug is given by one intravenous infusion
- Need to administer to COVID-19 patients without hypoxia
- Patients may not receive COVID-19 vaccines within 90 days of COVID-19 monoclonal antibody administration
  - Wait 3 months (3 half-lives) so that monoclonal antibodies do not bind to spike protein

Last month, the drug manufacturer Regeneron released findings of a Phase 3 clinical trial that showed an antibody cocktail reduced the risk of hospitalization or death by 70% in patients who received the drug intravenously compared to those who received a placebo. Their data also showed the drug's effectiveness against multiple COVID-19 variants including the B.1.1.7 strain that is the dominate one circulating in Michigan.

# Clinical criteria for mAB – adult patients

Who DOES qualify for consideration of Bamlanivimab and Etesevimab therapy:

- Within 10 days of symptom onset PLUS at least one clinical criteria for defining “high risk” in adults (18 years of age and older)
- Body mass index (BMI)  $\geq 35$ , OR
- Have chronic kidney disease, OR
- Have diabetes, OR
- Have immunosuppressive disease, OR
- Are currently receiving immunosuppressive treatment, OR
- Are  $\geq 65$  years of age, OR
- Are  $\geq 55$  years of age AND have:
  - Cardiovascular disease, OR
  - Hypertension, OR
  - Chronic obstructive pulmonary disease (COPD) or other chronic respiratory disease

# Clinical criteria for mAB – pediatric patients

Within 10 days of symptom onset PLUS at least one clinical criteria for defining "High Risk" in pediatric patients (12-17 years old) - at least one of the following comorbidities

- BMI  $\geq$ 85th percentile for age/gender based on CDC growth charts, OR
- Sickle cell disease, OR
- Congenital or acquired heart disease, OR
- Neurodevelopmental disorders (eg cerebral palsy), OR
- Medical-related technological dependence (eg tracheostomy, gastrostomy or positive pressure ventilation (not related to covid-19 infection), OR
- Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

# Clinical criteria cont.

## Monoclonal antibody therapy is not indicated for:

- Patients 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 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

# How to refer a patient for treatment

- HFHS has set up a mAB “hub” staffed with APPs, nurses and nurse assistants to screen, register and schedule referred patients.
- For physicians on the HFHS instance of Epic (including Community Care Connect), simply order “Ambulatory Referral to Monoclonal Antibody Infusion (mAB)” in Epic. The order will trigger hub staff to contact the patient to arrange treatment.
- Physicians not on Epic should call the Referring Physician Office at 877-434-7470. The RPO will then connect with the hub, which arranges treatment.

Infusions are being done:

- On the campuses of Henry Ford Macomb Hospital, Henry Ford Hospital and Henry Ford Allegiance Health in Jackson
- At the CHASS federally qualified health center in southwest Detroit.
- Any patient – HFHS or not – is welcome at any site as long as there is a referral. Treatment is free. If the patient has insurance it will be billed but the patient will incur no cost.