STATE OF MICHIGAN

DEPARTMENT OF HEALTH AND HUMAN SERVICES

LANSING

GRETCHEN WHITMER
GOVERNOR

ROBERT GORDON
DIRECTOR

January 22, 2021

Dear Health Care Provider:

The purpose of this letter is to communicate the availability of monoclonal antibody treatment availability within the State of Michigan.

On November 9, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy bamlanivimab. On November 21, 2020, the FDA issued another EUA for a combination monoclonal antibody product casirivimab plus imdevimab. Both therapeutic products are available for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients (≥12 years old and ≥40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization.

The issuance of an EUA is different than FDA approval. The FDA has the authority to issue an EUA for an investigational drug during a public health emergency when the known and potential benefits of the drug appear to outweigh the known and potential risks for the drug and no other approved alternatives exist.

Bamlanivimab and casirivimab plus imdevimab are approved for persons with mild or moderate COVID-19 (i.e., outpatients) early in the course of illness and are given through a one-hour intravenous infusion followed by a one-hour observation period. Administration may be challenging for health care facilities because it requires appropriate space in the facility, implementation of strict infection control measures, and appropriately trained staff to administer the infusion and monitor patients to ensure safety.

While the safety and effectiveness of these investigational therapies appear promising, the data are still very limited. Clinical trials are ongoing to collect additional data on their safety and effectiveness.

- Bamlanivimab – SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19
- Casirivimab plus Imdevimab – Fact Sheet For Health Care Providers

The U.S. Department of Health and Human Services (HHS) has purchased 300,000 doses of bamlanivimab and 300,000 doses of casirivimab plus imdevimab from their manufacturers and began distributing allocations of bamlanivimab to states in November 2020. During the initial phase of distribution, MDHHS allocated doses of monoclonal antibody therapies to hospitals interested in receiving it based on the number of confirmed COVID-19 patients in the hospital that week. Since then and to date, MDHHS has been able to distribute the medications to all hospitals and health care systems that have requested but would like to expand access to interested community-based infusion centers.

To date, MDHHS has distributed either bamlanivimab and/or casirivimab plus imdevimab to the hospitals and health care systems throughout the State of Michigan. Availability of monoclonal antibody therapies, as well as referrals for treatment, may vary from site to site. A viewable map of therapeutics distribution throughout Michigan is available at https://protect-public.hhs.gov/pages/therapeutics-distribution, with expansion anticipated in the coming weeks.

MDHHS has also expanded access to bamlanivimab, particularly for Skilled Nursing Facilities, through the following pharmacies that support long-term care, as well as assisted living and senior living communities.

- Binson's Pharmacy (Flint, MI)
- Omnicare of Escanaba (Escanaba, MI)
- Omnicare of Southern Michigan (Livonia, MI)
- Omnicare of Grand Rapids (Grand Rapids, MI)
- Hometown Pharmacy Chelsea LTC
- Hometown Pharmacy Parchment LTC
- Hometown Pharmacy Traverse City LTC
- Pharmerica Grand Rapids
- Pharmerica Midland
- Pharmerica Warren
- Pharmscript of MI
- Polaris Pharmacy Services of Michigan
- Remedi SeniorCare

MDHHS is also actively engaging community-based infusion centers to expand access. Any health care facility able to meet the requirements in the bamlanivimab provider fact sheet and/or casirivimab plus imdevimab provider fact sheet will be eligible to receive the medication from MDHHS. Facilities interested in receiving either product from MDHHS should contact Jason Smith at smithj20@michigan.gov.

Health care providers administering these products need to follow all the guidance in the bamlanivimab provider fact sheet and/or casirivimab plus imdevimab provider fact sheet, including but not limited to the eligibility criteria, preparation and administration instructions and communication requirements.

Health care providers must communicate to patients or parents/caregivers, as age appropriate, information consistent with the "Bamlanivimab Fact Sheet for Patients, Parents and Caregivers" or "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving the medication, including:

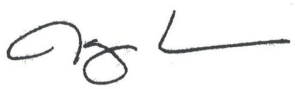
- FDA has authorized the emergency use of bamlanivimab or casirivimab plus imdevimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- The patient or parent/caregiver has the option to accept or refuse bamlanivimab or casirivimab plus imdevimab.
- The significant known and potential risks and benefits of bamlanivimab or casirivimab plus imdevimab, and the extent to which such potential risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
- Patients treated with bamlanivimab or casirivimab plus imdevimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

Health care providers must document in the patient's medical record that the patient/caregiver has been:

- Given the "Bamlanivimab Fact Sheet for Patients, Parents and Caregivers" or "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers"
- Informed of alternatives to receiving these medications, and
- Informed that these medications are unapproved drugs that are authorized for use under the Emergency Use Authorization

The federal government is distributing antibody therapies at no cost to patients. However, health care providers may bill insurance companies to administer the drug. More information on insurance coverage of antibody treatments can be found at Centers for Medicare and Medicaid Services COVID-19 Vaccines and Monoclonal Antibodies.

Sincerely,



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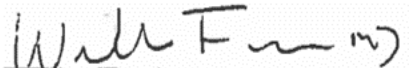
Chief Medical Executive
Chief Deputy Director for Health
Michigan Department of Health and Human Services



William Fales, M.D., FACEP
State Medical Director
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JK:kt