Montana Health Alert Network

DPHHS HAN

ADVISORY

Cover Sheet

DATE

February 8, 2021

SUBJECT

Monoclonal antibody therapeutics for use in non-hospitalized patients with mild to moderate COVID-19 disease who are at elevated risk for progressing to severe disease and/or hospitalization

INSTRUCTIONS

DISTRIBUTE to your local HAN contacts. This HAN is intended for general sharing of information.

- Time for Forwarding: **As Soon As Possible**
- Please forward to DPHHS at hhshan@mt.gov
- **Remove this cover sheet before redistributing and replace it with your own**

For LOCAL HEALTH DEPARTMENT reference only

DPHHS Subject Matter Resource for more information regarding this HAN, contact:

Epidemiology Section
1-406-444-0273

For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING AND REPLACE IT WITH YOUR OWN

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hhshan@mt.gov

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.
Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory

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Information Sheet

DATE

February 8, 2021

SUBJECT

Monoclonal antibody therapeutics for use in non-hospitalized patients with mild to moderate COVID-19 disease who are at elevated risk for progressing to severe disease and/or hospitalization

BACKGROUND

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products *Bamlanivimab* and the cocktail *Casirivimab/Imdevimab* for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV2 viral testing who are 12 years of age and older weighing at least 40 kilograms, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
Bamlanivimab: https://www.fda.gov/media/143603/download
Casirivimab/Imdevimab Cocktail: https://www.fda.gov/media/143892/download

The U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) oversees the allocation of this therapeutic and coordinates its distribution. Montana DPHHS receives a portion of the national monoclonal antibody therapeutic allocation every two weeks and distributes this product throughout the state.

INFORMATION

Bamlanivimab, Casirivimab, and *Imdevimab* are investigational recombinant monoclonal antibodies (mAbs) that target the receptor binding domain of the spike protein of SARS-CoV-2. The mAbs are likely to be most effective when given early in infection with an intent to prevent the progression of disease and hospitalization. The product is delivered by a single outpatient intravenous infusion over one hour followed by one hour of post-infusion monitoring.

Providers may consider the monoclonal antibody products for patients with mild to moderate COVID-19 infection who are at elevated risk for progressing to severe COVID-19 and/or hospitalization. The EUA requires administration of the treatment as soon as possible after confirmed positive test result (e.g., PCR or antigen test) and within 10 days of symptom onset. As defined in the EUA, high risk patients meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age

- Are ≥55 years of age AND have
    - cardiovascular disease, OR
    - hypertension, OR
    - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
    - BMI ≥85th percentile for their age and gender based on CDC growth charts, OR https://www.cdc.gov/growthcharts/clinical_charts.htm
    - sickle cell disease, OR
    - congenital or acquired heart disease, OR
    - neurodevelopmental disorders, for example, cerebral palsy, OR
    - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
    - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

The monoclonal antibody therapeutics are NOT authorized for use in 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.

The monoclonal antibody therapeutics may only be administered in settings in which health care providers have immediate access to medications to treat severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system, as necessary.

RECOMMENDATIONS

Clinicians

Providers and facilities should review the HHS/ASPR *Therapeutics: Monoclonal Antibody Playbook* to evaluate if their facility has the appropriate space, staffing, and supplies to offer monoclonal antibody infusions in their community.
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_1Feb2021.pdf

Providers managing patients who are appropriate candidates for *Bamlanivimab* or *Casirivimab* and *Imdevimab* under the FDA EUA and who have access to these products through their facilities, must review the following information and requirements before treating patients:

- *Bamlanivimab*
    - FDA EUA for *Bamlanivimab*
      https://www.fda.gov/media/143602/download
    - Fact Sheet for Patients, Parents and Caregivers EUA of *Bamlanivimab*
      https://www.fda.gov/media/143604/download

- Frequently Asked Questions on the EUA for *Bamlanivimab*
  https://www.fda.gov/media/143605/download

- *Casirivimab* and *Imdevimab*
  - FDA EUA for *Casirivimab* and *Imdevimab*
    https://www.fda.gov/media/143891/download
  - Fact Sheet for Patients, Parents and Caregivers EUA of *Casirivimab* and *Imdevimab*
    https://www.fda.gov/media/143893/download
  - Frequently Asked Questions on EUA for *Casirivimab* and *Imdevimab*
    https://www.fda.gov/media/143894/download

The Fact Sheets for Health Care Providers contain valuable information about who may receive the monoclonal antibody therapeutics under the FDA EUA, preparation and storage information, dosing and administration instructions, and other specific instructions for health care providers and mandatory requirements for administration.

- Fact Sheet for Healthcare Providers EUA of *Bamlanivimab*
  https://www.fda.gov/media/143603/download
- Fact Sheet for Health Care Providers EUA of *Casirivimab* and *Imdevimab*
  https://www.fda.gov/media/143892/download

Providers should familiarize themselves with indications for use of the therapeutics that have received FDA EUA and review the medical treatment guideline recommendations on the use of these new investigational therapeutics, including:

- National Institutes of Health (NIH) COVID-19 Treatment Guidelines
  https://www.covid19treatmentguidelines.nih.gov/
- Infectious Disease Society of America (IDSA) COVID-19 Treatment Guidelines
  https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/

Valuable information regarding the timing of vaccination and the use of monoclonal antibody therapeutics is available in the CDC's *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States*.
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Two key points from the current guidance include:

- ***COVID-19 vaccination should be deferred for at least 90 days after receipt of monoclonal antibodies, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.***
- For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies) or timing of such treatments.

To date, over 3,500 doses of the monoclonal antibody products have been distributed to geographically dispersed facilities throughout Montana and an estimated 1,000 infusions have been successfully delivered.

Providers who are interested in referring patients who meet the criteria for the monoclonal antibodies can search for a nearby infusion site using one of the following locator tools:

- HHS Protect Public Data Hub to find the nearest Therapeutics Distribution Location OR
  https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations

- National Infusion Center Association Infusion Center Locator
  https://covid.infusioncenter.org/

The next state allocation of monoclonal antibody therapeutics is expected on Wednesday, February 3rd. Please contact Dr. Maggie Cook-Shimanek at Margaret.Cook-Shimanek@mt.gov if you have questions or are interested in requesting monoclonal antibody therapeutics for your facility.