Montana Health Alert Network

DPHHS HAN *UPDATE*

Cover Sheet

DATE

March 24, 2021

SUBJECT

COVID-19 Vaccination Open to All Starting April 1st, 2021, and an Update to Monoclonal Antibody Therapeutics

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

Immunization Section
1-406-444-5580

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

Please ensure that DPHHS is included on your HAN distribution list.
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

Montana Health Alert Network

DPHHS HAN

Information Sheet

DATE

March 24, 2021

SUBJECT

COVID-19 Vaccination Open to All Starting April 1st, 2021, and an Update to Monoclonal Antibody Therapeutics

BACKGROUND

COVID-19 Vaccination

As of March 23, 2021, over 400,000 doses of vaccine have been administered with over 160,000 individuals fully vaccinated.

COVID-19 therapeutics

Several updates have occurred following February 8, 2021, publication of *DPHHS HAN Advisory 2021-3, 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*.
https://dphhs.mt.gov/Portals/85/publichealth/documents/HAN/2021/HANAD2021-3.pdf?ver=2021-02-08-082623-880

INFORMATION

Update regarding COVID-19 Vaccination Expansion

Beginning April 1, 2021, the State of Montana will allow vaccination of ***all individuals***, aged 16 years and older, due to an increase in vaccine supplies, the addition of more vaccine partners, and successful vaccine administration at the local level. Jurisdictions may continue to prioritize allocation among their local populations to match local supply and demand as needed. Jurisdictions wishing to vaccinate all eligible individuals prior to April 1, 2021, are encouraged to consult with the DPHHS immunization program to review plans.

Update on COVID-19 therapeutics

A summary of updates in the Recommendations Section below includes valuable information on the *bamlanivimab* and *etesevimab* Emergency Use Authorization (EUA); data regarding SARS-CoV-2 susceptibility; direct ordering information for all monoclonal antibody therapeutics; and updates to monoclonal antibody therapeutic clinical guidelines.

RECOMMENDATIONS

Monoclonal antibody therapeutics update

On February 9, 2021, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of *bamlanivimab* and *etesevimab* together 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 aged 12 years and older, weigh at least 40 kilograms, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Providers managing patients who are appropriate candidates for *bamlanivimab* and *etesevimab* used together under the FDA EUA, and who have access to these products through their facilities, should review the following information and requirements before treating patients with *bamlanivimab* and *etesevimab*.

FDA EUA for *bamlanivimab* and *etesevimab*:
https://www.fda.gov/media/145801/download

Fact Sheet for Patients, Parents and Caregivers regarding EUA for *bamlanivimab* and *etesevimab*:
https://www.fda.gov/media/145802/download

Frequently Asked Questions on EUA for *bamlanivimab* and *etesevimab*:
https://www.fda.gov/media/145808/download

SARS-CoV-2 variants update as related to monoclonal antibody therapeutics

The U.S. Department of Health and Human Services has established a SARS-CoV-2 Interagency Group to rapidly characterize emerging variants and actively monitor their potential impact on critical SARS-CoV-2 countermeasures, including monoclonal antibody therapeutics.
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

Montana DPHHS publishes the COVID-19 Variants Identified in Montana to illustrate counties where variants of concern and variants of interest have been detected.
https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt/demographics

On March 18, 2021, the U.S. FDA authorized revised Fact Sheets for Healthcare Providers to include information on the susceptibility of SARS-CoV-2 variants to each of the monoclonal antibody COVID-19 therapeutics.

Bamlanivimab:
https://www.fda.gov/media/143603/download

Casirivimab and *imdevimab:*
https://www.fda.gov/media/145611/download

Bamlanivimab and *etesevimab:*
https://www.fda.gov/media/145802/download

Health care providers should review the Antiviral Resistance information in Section 15 of the Fact Sheet for details regarding specific SAR-CoV-2 variants present in their community and whether those variants are susceptible to the monoclonal antibody therapeutics available at their institution. Given the sustained increase in variants resistant to bamlanivimab alone, and the availability of alternative authorized monoclonal antibodies, the U.S. Government in coordination with Eli Lilly, will stop the distribution of bamlanivimab alone starting March 24, 2021.Direct ordering monoclonal antibody therapeutics.

All monoclonal antibody therapeutics are available by direct ordering through the distributor, Amerisource Bergen. *Etesevimab* is now available for direct order to complement existing *bamlanivimab* inventories.

Overview of Direct Order Process for COVID-19 Therapeutics:
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf

COVID-19 Therapies Direct Order Request:
https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

Clinical practice guideline updates for monoclonal antibody therapeutics

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

National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of the *Bamlanivimab* Plus *Etesevimab* Combination:
https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-plus-etesevimab-eua/

Infectious Disease Society of America (IDSA) COVID-19 Treatment Guidelines:
https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/

Questions

Please contact Dr. Maggie Cook-Shimanek at Margaret.Cook-Shimanek@mt.gov if you have questions.