DATE
September 16, 2021

SUBJECT
Recent Updates Regarding 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

Ensure Hospital contacts are sent this information.

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.
DATE
September 16, 2021

SUBJECT
Update Regarding the Monoclonal Antibody Therapeutics Ordering Process

BACKGROUND
The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products, bamlanivimab and etesevimab administered together and casirivimab and imdevimab administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in eligible non-hospitalized adult and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death (see detailed indications outlined in the EUA healthcare provider fact sheets). The therapeutics must be administered within 10 days of symptom onset.

INFORMATION
DPHHS would like to share the following recent update regarding the COVID-19 monoclonal antibody therapeutics. On September 13, 2021, HHS transitioned from the direct ordering process to a state/territory-coordinated distribution system, similar to that used from November 2020 – February 2021. The federal government will determine the weekly amount of mAb products each state and territory receive based on COVID-19 case burden and mAb utilization. State and territorial health departments subsequently identify which sites in their respective jurisdictions receive product as well as the amount each site receives.

REGEN-COV (casirivimab and imdevimab)¹ and bamlanivimab and etesevimab² (administered together) are available at no cost through the federal government allocation program. The Gianforte Administration strongly encourages use of both products when appropriate, as they remain effective against the Delta variant, which is currently the predominant variant circulating in Montana.

RECOMMENDATIONS
Allocation
Montana DPHHS will distribute this week’s allocation based on outstanding orders that Montana providers submitted prior to the transition. The monoclonal antibody products are a community resource. Future allocations will be based on a request from facilities, their current inventory of the monoclonal antibody product in that facility, and the utilization rates of these products per week. If demand outpaces supply in a given week, allocations will be informed by the number of cases per county or through a method developed by DPHHS in consultation with healthcare ethicists.

Administration Logistics
Facilities may review the Federal Response to COVID-19: Monoclonal Antibody Playbook³ and COVID-19 Monoclonal Antibody Therapeutics⁴ for information on the logistics of offering outpatient administration.
COVID Treatment Clinical Considerations

Providers can access the National Institutes of Health (NIH) COVID-19 Treatment Guidelines for non-hospitalized patients⁵. On September 3, 2021, the NIH updated the Guidelines to include COVID-19 Treatment Guidelines Panel’s Statement on the Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment or Prevention of SARS-CoV-2 Infection When There Are Logistical Constraints⁶.

The Infectious Diseases Society of America⁷ provides clinically focused guidelines discussing use of the monoclonal antibodies. Healthcare providers interested in reviewing other clinically-focused COVID-19 information, including centralized access to resources on therapeutics, should visit the CombatCOVID® website sponsored by the U.S. Department of Health and Human Services. The CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States⁹ provides important information on the timing of vaccination and the administration of monoclonal antibody therapeutics.

Utilization tracking

Facilities currently using the monoclonal antibody products must sign up for an HHS Teletracking account to enter weekly utilization data. If a site needs to establish an HHSProtect account for weekly utilization reporting, please email hhs-protect@teletracking.com. Future allocations of the monoclonal antibody products will be based on utilization. It is imperative to maintain accurate inventory counts and utilization data.

Unused products

If a facility has bamlanivimab and etesevimab and/or casirivimab and imdevimab on hand, but does not plan to offer the product to patients, please email Dr. Maggie Cook-Shimanek at Margaret.Cook-Shimanek@mt.gov so that supply can be redistributed to other facilities.

Ordering information

Facilities interested in requesting a portion of the state allocation should contact Dr. Maggie Cook-Shimanek at Margaret.Cook-Shimanek@mt.gov. If your site hasn’t received COVID-19 therapeutics from Amerisource in the past, additional facility data will be required to order and receive shipments.

Infusion Locator

Providers who are interested in referring patients who meet the criteria for the monoclonal antibody treatment can search for a nearby infusion site here¹⁰.

Relevant Recent Updates

- On June 3, 2021, a subcutaneous route of administration¹¹ of casirivimab and imdevimab became available as an alternative route of administration when intravenous infusion is not feasible and would lead to a delay in treatment. The therapeutic goal of both routes of REGEN-COV administration is to prevent progression to severe disease and hospitalization in eligible COVID-19 patients.

- On July 30, 2021, the FDA authorized expanded use of casirivimab and imdevimab to include post-exposure prophylaxis¹² in certain non-hospitalized populations at high risk for progression to severe COVID-19, including hospitalization or death, and who meet the following criteria:
  - the individual is not fully vaccinated, or the individual is not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g., individuals with immunocompromising conditions, including taking immunosuppressive medications); and
• the individual has been exposed to someone infected with SARS-CoV-2 in a manner consistent with the Centers for Disease Control and Prevention (CDC) close contact criteria; or
• the individual is at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, correctional settings). Please see the detailed indications in the Fact Sheet for Health Care Providers for REGEN-COV.

The goal of post-exposure prophylaxis is to prevent the development of symptomatic COVID-19 in exposed individuals at high risk for progressing to severe disease. The FDA notes that post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19 and states that REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

• On August 27, 2021, the use and distribution of bamlanivimab and etesevimab, administered together, resumed in Montana.

Other monoclonal antibody products

Sotrovimab is available through GlaxoSmithKline and is not part of the federal government allocation program. Please see GlaxoSmithKline for additional information. Please see the detailed indications in the Fact Sheet for Health Care Providers for sotrovimab.

Referenced Links

1. FDA Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV: https://www.fda.gov/media/145611/download
2. FDA Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab and Etesevimab: https://www.fda.gov/media/145802/download
4. ASPR COVID-19 and Monoclonal Antibody Therapeutics: https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx
8. HHS COMBATCOVID: https://combatcovid.hhs.gov/
10. HHS Protect Public Data Hub Therapeutics Distribution: https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations
11. Regeneron Important Prescribing Information: https://www.fda.gov/media/143901/download
12. FDA Authorization for Expanded Use of REGEN-COV in Post-Exposure Prophylaxis: https://www.fda.gov/media/145610/download


17. GSK Sotrovimab Information: [https://www.sotrovimab.com/](https://www.sotrovimab.com/)


19. C19 Therapies Direct Order Request (Amerisource Bergen): [https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8](https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8)