Montana Health Alert Network

DPHHS HAN

ADVISORY

Cover Sheet

DATE

September 16, 2021

SUBJECT

Recent Updates Regarding Monoclonal Antibody Therapeutics

INSTRUCTIONS

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Montana Health Alert Network

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Information Sheet

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 *etesevimab*[2] (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 Playbook[3] and COVID-19 Monoclonal Antibody Therapeutics[4] 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 patients[5]. 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 Constraints[6].

The Infectious Diseases Society of America[7] 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[8] 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 States[9] 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 here[10].

Relevant Recent Updates

- On June 3, 2021, a ***subcutaneous route of administration***[11] 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 prophylaxis***[12] 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[13];
  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[1] 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[15], the use and distribution of *bamlanivimab* and *etesevimab*, administered together, resumed in Montana.

Other monoclonal antibody products

Sotrovimab[16] is available through GlaxoSmithKline and is not part of the federal government allocation program. Please see GlaxoSmithKline[17] for additional information. Please see the detailed indications in the Fact Sheet for Health Care Providers[16] 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
3. Federal Response to COVID-19: Monoclonal Antibody Playbook: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf
4. ASPR COVID-19 and Monoclonal Antibody Therapeutics: https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx
5. National Institutes of Health COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/
6. NIH 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 Constraints: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-the-prioritization-of-anti-sars-cov-2-monoclonal-antibodies/
7. Infectious Diseases Society of America Monoclonal Antibody Information: https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/monoclonal-antibodies/
8. HHS COMBATCOVID: https://combatcovid.hhs.gov/
9. CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
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
13. CDC Glossary of Key Terms: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html
14. ASPR Pause in the Distribution of *bamlanivimab/etesevimab*: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/bamlanivimab-etesevimab-distribution-pause.aspx

15. Resumption in Use and Distribution of *Bamlanivimab/Etesevimab* in Certain States: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/resumption-in-distribution-bamlanivimabetesevimab.aspx?utm_medium=email&utm_source=govdelivery
16. Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS
17. GSK Sotrovimab Information: https://www.sotrovimab.com/
18. FDA Revocation of Bamlanivimab: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab
19. C19 Therapies Direct Order Request (Amerisource Bergen): https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8
20. CDC Vaccine Effectiveness in Immunosuppressed People: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html