Montana Health Alert Network

DPHHS HAN

UPDATE

Cover Sheet

DATE

August 11, 2021

SUBJECT

Recent Updates Regarding the Monoclonal Antibody Therapeutics

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1-406-444-0273

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1-406-444-5580

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

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Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.
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Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.
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Recent Updates Regarding the Monoclonal Antibody Therapeutics

BACKGROUND

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab administered together and sotrovimab 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 updates regarding the COVID-19 monoclonal antibody therapeutics.

- On April 16, 2021, the FDA revoked the EUA for bamlanivimab administered alone due to an increase in the proportion of potentially resistant variants
- On June 25, 2021, the FDA paused distribution of the bamlanivimab and etesevimab combination product due to an increase in the proportion of potentially resistant variants.

RECOMMENDATIONS

The FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies.

- REGEN-COV (casirivimab and imdevimab) is available ***at no cost*** through the federal government allocation program. This product is available for direct order here. Recent updates include the following.
    - On June 3, 2021, a ***subcutaneous route of administration*** 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*** 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.

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

Variant update: Section 15 of the REGEN-COV (casirivimab and imdevimab) and sotrovimab Fact Sheet For Health Care Providers discusses antiviral resistance. Both of these products remain effective against the Delta variant, which is currently the predominant variant circulating in Montana.

COVID Treatment Clinical Considerations: The National Institutes of Health (NIH) publishes COVID-19 Treatment Guidelines for non-hospitalized patients. The Infectious Diseases Society of America 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 States provides important information on the timing of vaccination and the administration of monoclonal antibody therapeutics.

Administration Logistics: Facilities can review the Federal Response to COVID-19: Monoclonal Antibody Playbook and COVID-19 Monoclonal Antibody Therapeutics for additional information on the logistics of offering outpatient administration.

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.

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

Referenced Links

1. FDA Revocation of Bamlanivimab: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab
2. 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
3. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Regen-COV: https://www.fda.gov/media/145611/download

4. C19 Therapies Direct Order Request (Amerisource Bergen): https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8
5. Regeneron Important Prescribing Information: https://www.fda.gov/media/143901/download
6. FDA Authorization for Expanded Use of REGEN-COV in Post-Exposure Prophylaxis: https://www.fda.gov/media/145610/download
7. FDA Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COV: https://www.fda.gov/media/145611/download
8. CDC Vaccine Effectiveness in Immunosuppressed People: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
9. CDC Glossary of Key Terms: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html
10. 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
11. GSK Sotrovimab Information: https://www.sotrovimab.com/
12. National Institutes of Health COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/
13. Infectious Diseases Society of America Monoclonal Antibody Information: https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/monoclonal-antibodies/
14. HHS COMBATCOVID: https://combatcovid.hhs.gov/
15. 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
16. Federal Response to COVID-19: Monoclonal Antibody Playbook: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf
17. ASPR COVID-19 and Monoclonal Antibody Therapeutics: https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx
18. HHS Protect Public Data Hub Therapeutics Distribution: https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations