Montana Health Alert Network

DPHHS HAN

UPDATE

Cover Sheet

DATE

April 5, 2022

SUBJECT

Recent Updates Regarding COVID-19 Therapeutics

INSTRUCTIONS

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

- Time for Forwarding: **As Soon As Possible**
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- **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:

DPHHS CDCP

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 HAN Website:
www.han.mt.gov

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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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DPHHS HAN

Information Sheet

DATE

April 5, 2022

SUBJECT

Update Regarding COVID-19 Therapeutics

BACKGROUND

There are recent Food and Drug Administration (FDA) updates involving the coronavirus disease 2019 (COVID-19) medication supply purchased by the federal government and allocated by the state.

INFORMATION

On March 25th, the FDA announced sotrovimab is not authorized for use in regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant and updated the product Fact Sheet to reflect this restriction. The Centers for Disease Control and Prevention (CDC) Nowcast data from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% is all Health and Human Services (HHS) U.S. regions. Data included in the health care provider fact sheet show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 subvariant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Healthcare providers should use one of the other COVID-19 medications for treatment or pre-exposure prophylaxis in eligible populations that are expected to retain activity with omicron BA.2, as below.

ORAL ANTIVIRAL MEDICATIONS

Two oral COVID-19 antiviral medications, molnupiravir and Paxlovid, have received EUA for use in non-hospitalized patients at high risk for progression to severe COVID-19. DPHHS is working with the Federal Retail Pharmacy Program to distribute these therapeutics across the state and currently receives allocations of these products every week. DPHHS has flexibility in offering to specific pharmacy sites as well as not all Montana counties have access to one of the federal partners.

The oral antivirals may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which the oral antivirals belong (i.e., anti-infectives). Both oral antivirals must be initiated within 5 days of symptom onset. A test-to-treat model is an ideal strategy for the oral antiviral products, given the short window between symptom onset and treatment required by the EUA. Both EUAs direct readers to the

Centers for Disease Control and Prevention (CDC) *People with Certain Medical Conditions* for information on medical conditions and factors associated with increased risk for progression to severe COVID-19 and state the healthcare providers should consider the benefit-risk for an individual patient. Healthcare providers should carefully review the EUA prior to prescribing these medications.

PAXLOVID

- Paxlovid Fact Sheet for Healthcare Providers
- Paxlovid Patients and Caregivers
- National Institutes of Health: The COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications

MOLNUPIRAVIR

- Molnupiravir Fact Sheet for Healthcare Providers
- Molnupiravir Fact Sheet for Patients and Caregivers
- FDA Molnupiravir Checklist Tool for Prescribers

HHS hosts a locator for participating Test to Treat sites that provide end-to-end care, including COVID-19 testing, patient evaluation, and prescription of the oral antiviral medications.

MONOCLONAL ANTIBODY THERAPEUTICS

BEBTELOVIMAB

On Friday, February 11th the FDA granted EUA for bebtelovimab, an investigational medicine used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]):

- 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, ***and***

- for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate.

Bebtelovimab is administered as an intravenous injection within 7 days of symptom onset. There is limited information known about the safety and effectiveness of using bebtelovimab for the treatment of mild-to-moderate COVID-19.

- Bebtelovimab Fact Sheet for Healthcare Providers
- Bebtelovimab Fact Sheet for Patients, Parents, and Caregivers

MONOCLONAL ANTIBODY FOR PRE-EXPOSURE PROPHYLAXIS

EVUSHELD

Evusheld (AZD7442) is tixagevimab and cilgavimab, which are neutralizing IgG1 monoclonal antibodies that bind to distinct, non-overlapping epitopes within the receptor binding domain of the spike protein of SARS-CoV2. Evusheld is authorized for the pre-exposure prophylaxis of

adults and certain pediatric individuals with immune compromised systems and thus are not expected to mount an adequate immune response following vaccination, or for whom vaccination is not indicated due to health conditions or a history of severe allergic reactions.

- Evusheld Fact Sheet for Health Care Providers
- Evusheld Fact Sheet for Patients, Parents, and Caregivers

Visit the DPHHS COVID-19 Therapeutics webpage for additional information and Montana distribution locations. Sites offering the COVID-19 medications are available on the HHS Therapeutics Distribution Locator for Provider Use.

RECOMMENDATIONS

HEALTHCARE PROVIDERS

1. Review the April 5, 2022, statement *FDA updates Sotrovimab emergency use authorization* and use other authorized COVID-19 therapeutics to treat eligible patients.
2. Review the CDC guidance for *People with Certain Medical Conditions* and the FDA EUA Fact Sheets for Healthcare Providers for appropriate patient selection for COVID-19 treatment.
    a. Paxlovid Fact Sheet for Healthcare Providers
    b. Molnupiravir Fact Sheet for Healthcare Providers
    c. Bebtelovimab Fact Sheet for Healthcare Providers
3. Develop a test-to-treat strategy for high risk individuals who test positive for COVID-19, given the short window between symptom onset and treatment required by the EUAs (e.g., within 5 days of symptoms onset for the oral antiviral products). Review the HHS *Test to Treat site locator* to identify participating Montana locations.
4. Review the HHS Therapeutics Distribution Locator for Provider Use which provides sites of the monoclonal antibody and oral antiviral administration.
5. Review the National Institutes of Health April 1, 2022 statement Therapeutic Management of Nonhospitalized Adults with COVID-19.
6. Reinforce the central importance of receiving COVID-19 vaccination and a booster dose, when eligible.

PUBLIC HEALTH AGENCIES

1. Develop a test-to-treat referral approach for high risk individuals who test positive for COVID-19, given the short window between symptom onset and treatment required by the EUAs (e.g., within 5 days of symptoms onset for the oral antiviral products), in addition to a need for a healthcare provider order for all of these treatments. Advise individuals who test positive early about treatment options and the need for medical consultation prior to receipt of these treatment. Review the HHS *Test to Treat site locator* to identify participating Montana locations.
2. Review the DPHHS COVID-19 Therapeutics webpage for administration site locations.
3. Reinforce the central importance of receiving COVID-19 vaccination and a booster dose, when eligible.

FACILITIES OFFERING COVID-19 THERAPEUTICS

1. Daily reporting is required for bebtelovimab, Evusheld, Paxlovid, and molnupiravir through HPoP. Please find additional information on facility-level reporting here.

Facilities interested in requesting a portion of the state allocation should contact Dr. Maggie Cook-Shimanek at Margaret.Cook-Shimanek@mt.gov.

Referenced Links

1. ASPR Therapeutic Distribution Locator for Provider Use - https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
2. ASPR Test to Treat locator: https://aspr.hhs.gov/TestToTreat/Pages/default.aspx
3. Bebtelovimab Fact Sheet for Healthcare Providers - https://www.fda.gov/media/156152/download
4. Molnupiravir Fact Sheet for Healthcare Providers - https://www.fda.gov/media/155054/download
5. Molnupiravir Fact Sheet for Patients and Caregivers - https://www.fda.gov/media/155055/download
6. FDA Molnupiravir Checklist Tool for Prescribers - https://www.fda.gov/media/155118/download
7. Paxlovid Fact Sheet for Healthcare Providers - https://www.fda.gov/media/155050/download
8. Paxlovid Patients and Caregivers - https://www.fda.gov/media/155051/download
9. Evusheld Fact Sheet for Healthcare Providers - https://www.fda.gov/media/154701/download
10. Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medical-conditions.html
11. NIH COVID-19 Treatment Guidelines Panel's Statement: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/
12. NIH Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/