Montana Health Alert Network

DPHHS HAN *UPDATE*

Cover Sheet

DATE

February 28, 2022

SUBJECT

Recent Updates Regarding COVID-19 Therapeutics

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1-406-444-0273

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Montana Health Alert Network

DPHHS HAN

Information Sheet

DATE

February 28, 2022

SUBJECT

Update Regarding COVID-19 Therapeutics

BACKGROUND

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

INFORMATION

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.

On February 24, 2022, the U.S. Food and Drug Administration (FDA) announced a modification to the Emergency Use Authorization (EUA) for AstraZeneca's COVID-19 medication Evusheld. The modification involves a change to the dosing regimen. Evusheld now should be administered as an initial dose of 600 mg (300 mg of tixagevimab and 300 mg of cilgavimab). Individuals who already received the previously authorized initial 300 mg dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive a second Evusheld dose as soon as possible. Recommendations will be made in the near future when more data are available to determine the appropriate timing of redosing (e.g., a repeat dose with 150 mg of tixagevimab and 150 mg of cilgavimab at 3 months or 6 months after the initial dose).

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

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

SOTROVIMAB

The state continues to receive weekly allocations of sotrovimab. A full description of the clinical indications is included in the FDA Emergency Use Authorization Fact Sheet for Healthcare Providers for sotrovimab.

OTHER MONOCLONAL ANTIBODY THERAPEUTICS

On January 24, 2022, the FDA updated the EUA fact sheets for bamlanivimab and etesevimab and casirivimab and imdevimab. FDA now states these two treatments are ***not currently authorized*** for use anywhere in the U.S., due to the prevalence of Omicron. The National Institutes of Health (NIH) updated its clinical guidelines to recommend against the use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) at this time.

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 two weeks. 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

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

RECOMMENDATIONS

HEALTHCARE PROVIDERS

1. Review the February 24, 2022 revision to the FDA Evusheld EUA Fact Sheet for Health Care Providers, which includes a modification to the Emergency Use Authorization with respect to dosing for AstraZeneca's COVID-19 therapeutic Evusheld.
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. Sotrovimab Fact Sheet for Healthcare Providers
    c. Molnupiravir Fact Sheet for Healthcare Providers
    d. 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).
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 February 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.
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. Reporting requirements for inventories and utilization:
    a. Weekly reporting is required for sotrovimab.
        i. Long-term care/skilled nursing facilities report to National Healthcare Safety Network (NHSN).
        ii. Hospitals and hospital pharmacies report to HHSProtect, TeleTracking, Health Departments
        iii. Non-hospital facilities report to HHS TeleTracking
    b. 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. Bebtelovimab Fact Sheet for Healthcare Providers - https://www.fda.gov/media/156152/download

3. Molnupiravir Fact Sheet for Healthcare Providers - https://www.fda.gov/media/155054/download
4. Molnupiravir Fact Sheet for Patients and Caregivers - https://www.fda.gov/media/155055/download
5. Paxlovid Fact Sheet for Healthcare Providers - https://www.fda.gov/media/155050/download
6. Paxlovid Patients and Caregivers - https://www.fda.gov/media/155051/download
7. Evusheld Fact Sheet for Healthcare Providers - https://www.fda.gov/media/154701/download
8. https://www.fda.gov/media/154702/download
9. https://www.fda.gov/media/156151/download
10. https://www.fda.gov/media/156153/download
11. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/
12. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/
13. https://dphhs.mt.gov/covid19vaccine/
14. https://dphhs.mt.gov/publichealth/cdepi/diseases/CoronavirusMT/monoclonalantibody
15. https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx
16. Bamlanivimab and etesevimab Fact Sheet for Healthcare Providers administered together – https://www.fda.gov/media/145802/download
17. Casirivimab and imdevimab Fact Sheet for Healthcare Providers (REGEN-COV) - https://www.fda.gov/media/145611/download
18. Sotrovimab Fact Sheet for Healthcare Providers - https://www.fda.gov/media/149534/download
19. Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medical-conditions.html
20. 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/
21. NIH COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/
22. DPHHS Weekly Montana COVID-19 Epi Profile - https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt/demographics
23. FDA Molnupiravir Checklist Tool for Prescribers - https://www.fda.gov/media/155118/download
24. https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-evusheld-dosing