

HEALTH ALERT NETWORK | HEALTH ADVISORY | August 8, 2022

Update on COVID-19 therapeutics

Bebtelovimab

Bebtelovimab will become available commercially on August 15 and can be ordered through AmerisourceBergen. Full allocations will continue to the states through the week of August 15 and at a lower threshold after that to support the changeover.

Commercial access to bebtelovimab

Existing AmerisourceBergen accounts:

• Immediate access to bebtelovimab will be granted to all existing AmerisourceBergen accounts

Sites without an AmerisourceBergen account:

- Sites will need to register for an AmerisourceBergen account by contacting asdaccountsetup@amerisourcebergen.com
- AmerisourceBergen will sell to licensed and approved customers regardless of current HPOP participation

For any questions regarding access to bebtelovimab, contact <u>c19therapies@amerisourcebergen.com</u>.

Paxlovid and LAGEVRIO™ (molnupiravir)

Both antivirals remain on allocation and are available locally through pharmacies. If you are unable to locate any in your area, the North Dakota Department of Health (NDDoH) will assist with locating and moving product to the area. The NDDoH can be reached 24/7 at 701-328-0707.

LAGEVRIO™ (molnupiravir) is effective against all strains of COVID-19 currently active in the state. It shows good effectiveness in reducing hospitalization and mortality in patients showing mild to moderate COVID-19 symptoms when the medication is started within five days of symptom onset.

Four lots of Paxlovid manufactured before the Emergency Use Authorization (EUA) issuance were labeled with a nine-month expiration. The U.S. Food and Drug Administration (FDA) has authorized extended expiration dates for these lots to reflect the 12-month product shelf life (see: Paxlovid Shelf Life Extension) when stored according to the conditions detailed in the authorized Fact Sheet for Health Care Providers and Letter of Authorization for Emergency Use Authorization (EUA) 105 for Paxlovid.

The FDA revised the EUA for Paxlovid (nirmatrelvir and ritonavir) to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment

and prescription. Any pharmacist with questions about obtaining Paxlovid should contact the NDDOH for assistance. More information: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations.

EVUSHELDTM

EVUSHELD™ is available and is a pre-exposure prophylactic for patients who are not currently infected with SARS-CoV-2, who have not had recent known close contact with someone who is infected with SARS-CoV-2 **and:**

- Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments and may not mount an adequate immune response to COVID-19 vaccination or
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) or COVID-19 vaccine ingredient(s)

This medication remains on allocation and is available locally, mostly to medical facilities. If you have patients you would like to receive this therapy, the NDDoH (701-328-0707) will assist with locating and moving product to the area.

EVUSHELD™ shelf life has been extended. For more information, visit <u>Shelf-Life Extension of Evusheld</u> <u>under Emergency Use Authorization</u>.

National Institutes of Health (NIH) guidelines for therapeutic management of non-hospitalized adults with COVID-19

Does Not Require Hospitalization or Supplemental Oxygen All patients should be offered symptomatic management (AIII).

For patients who are at high risk of progressing to severe COVID-19, a use 1 of the following treatment options:

Preferred Therapies

Listed in order of preference:

- Ritonavir-boosted nirmatrelvir (Paxlovid)^{b,c} (Alla)
- Remdesivir^{c,d} (BIIa)

Alternative Therapies

For use <u>ONLY</u> when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:

- Bebtelovimab^e (CIII)
- Molnupiravir^{c,f} (Clla)

The Panel recommends against the use of dexamethasone⁹ or other systemic corticosteroids in the absence of another indication (AIII).

Rating of Recommendations: A = Strong; B = Moderate; C = Weak

Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb Nonrandomized trials or observational cohort studies; III = Expert opinion

Upcoming video conference

A video conference will be held on August 15 at 11 a.m. CT. We will update on the latest information regarding bebtelovimab, other COVID-19 therapeutics and North Dakota's continued plans for therapeutics. Instructions on how to attend the video conference are included in the HAN message.

For additional assistance, please contact the NDDoH's Operations Center at 701-328-0707.

Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention; highest level of importance

Health Advisory Health UpdateMay not require immediate action; provides important information for a specific incident or situation
Unlikely to require immediate action; provides updated information regarding an incident or situation

HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##