

DEPARTMENT OF HEALTH

TO:Vermont Health Care Providers and Health Care Facilities**FROM:**Mark Levine, MD, Commissioner of Health

Consider COVID-19 Therapeutics for Eligible Patients

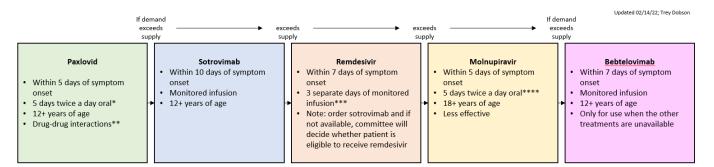
Current supply of therapeutics permits inclusion of all NIH risk groups

BACKGROUND:

Highly effective therapies against COVID-19 continue to be available for outpatients testing positive for SARS-CoV-2 who are <u>at risk of developing severe illness</u>. These therapies include the monoclonal antibody preparations sotrovimab (Xevudy) and bebtelovimab as well as the antivirals remdesivir (Veklury), nirmatrelvir/ritonavir (Paxlovid), and molnupiravir (MK-4482).

National supply of COVID-19 therapeutics has increased while case counts have dropped dramatically. This makes rationing monoclonals and antivirals unnecessary, although it remains critical to utilize these therapeutic options solely for their proven indications.

Additionally, the injectable monoclonal antibody bebtelovimab received EUA for the treatment of mild to moderate coronavirus disease in adults and pediatric patients (12 years of age and older weighing at least 40k): with positive results of direct SARS-CoV-2 viral testing AND who are at high risk of progression to severe COVID-19, including hospitalization or death AND, for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. See the algorithm below for details. Refer to the full FDA <u>Provider Fact Sheet</u> for additional information. At this time effectiveness data is not available, but it is expected to retain activity against currently circulating variants.



- Factors affecting best treatment options include, but are not limited to, the clinical efficacy of the treatment option, the availability of the treatment option, the feasibility of administering parenteral medications (i.e., sotrovimab, remdesivir), the potential for significant drug-drug interactions (i.e., the interactions associated with using ritonavir-boosted nirmatrelvir [Paxlovid])
- All of these anti-SARS-CoV-2 therapeutics, which were evaluated initially in unvaccinated individuals, provide the greatest benefit for nonhospitalized patients who have risk factors for progression to severe COVID-19

https://www.covid19treatmentguidelines.nih.gov/

* Reduce dose in moderate renal impairment (eGFR ≥30 to <60 mL/min) 150 mg nirmatrelvir and 100 mg ritonavir. Not recommended in severe renal impairment (eGFR <30 mL/min).

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** <u>https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/</u> https://www.covid19-druginteractions.org/checker

*** Not recommended if eGFR <30 mL/minute or ALT/AST > 5 times upper limit of normal **** Not recommended in pregnancy

For more information about outpatient therapies for high-risk COVID-19, please refer to the Health Update of December 30, 2021.

For a list of updated sites, please use this tool to locate available therapeutics near you. <u>https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/</u>

REQUESTED ACTION:

It is not currently necessary to restrict use of anti-SARS-CoV-2 monoclonals and antiviral drugs to the highest risk patients.

Review eligibility criteria of available therapeutics and prescribe only to patients who meet FDA-approved indications.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or <u>vthan@vermont.gov.</u>

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention. *Health Advisory:* Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.

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