

TO: Vermont Health Care Providers and Health Care Facilities

FROM: Mark Levine, MD, Commissioner of Health

Update on COVID-19 Therapeutics

This HAN includes a change in policy regarding monoclonal antibody use for treatment and prevention, as well as information on oral treatment for COVID-19 and how to access and prescribe new COVID-19 therapeutics. At this time the federal government continues to distribute these products to states in limited quantities based on an algorithm that considers cases and hospitalizations. For the near future the demand will likely exceed the supply. As such, the policies below include an ordering process that considers equity, accessibility, and timeframe.

COVID-19 therapeutics are authorized under an EUA for treatment for high-risk individuals (see fact sheets for precise eligibility). For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

Providers should follow NIH COVID-19 treatment guidelines on patient prioritization when there are logistical or supply constraints:

<https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/>

Monoclonal Antibody Update

1. When the Omicron variant represents the majority (i.e., >80%) of infections in a region, it is expected that Bamlanivimab/Etesevimab and Casirivimab/Imdevimab (REGEN-COV®) will not be effective for treatment or post-exposure prophylaxis (PEP) of COVID-19. While CDC modeling data (Nowcast) for the week ending 12/25/21 projects 44% Omicron prevalence, this is a rapidly evolving situation, and in most cases use of these monoclonals will require clinical judgement, as the genome sequence will not be known at the time a patient tests positive.
 - a. Updated fact sheets below confirm these therapeutics are inactive against the Omicron variant.
 - i. [Bamlanivimab and Etesevimab Fact Sheet](#)
 - ii. [REGEN-COV® Fact Sheet](#)
2. Sotrovimab has been shown to retain efficacy against Omicron. The state has been allocated a limited supply.
 - a. Providers interested in prescribing sotrovimab should reference the updated hospital contact information at the end of this HAN.

New Therapeutics Available

Vermont has received an extremely limited supply of Evusheld[®], Paxlovid[®] and molnupiravir. The federal government will continue to allocate supply based on hospitalization and case data.

Evusheld[®]

The U.S. Food & Drug Administration has released an [EUA](#) for Evusheld[®] which is a pre-exposure prophylactic (long-acting injectable monoclonal antibody) for people who are immunocompromised and have an inadequate response to vaccination. Results from the PROVENT Phase III trial showed a 77% reduction in risk of developing symptomatic COVID-19.

Initial supply will be extremely limited (less than 100 doses statewide) and thus limited to a few distribution sites. As supply increases, available sites will increase. Due to scarcity of supply, fairness can be facilitated via use of a lottery as well as targeted clinician outreach to patients who might be at risk but less likely to have easy access to the drug. Guiding principles are maximization of the chance that Evusheld[®] will prevent hospitalization and other severe outcomes, and fairness. Maximization of the chance that Evusheld[®] prevents hospitalization and other severe outcomes can best be achieved through distribution to the highest risk patients as defined by EUA risk criteria.

To ameliorate structural inequities in access to this free preventive care, we strongly encourage clinicians to review their patient panel and consider outreach to eligible patients who might not know of its existence or who otherwise might benefit from extra encouragement to receive this preventive therapy.

REQUESTED ACTIONS – Evusheld[®]:

1. Review the eligibility criteria in the [FDA fact sheet for Evusheld[®]](#)
2. Orders for Evusheld[®] dosing should include the indication.
3. Treatment is not limited to Vermont residents, though we urge providers to consider the limited availability and prioritize referrals according to NIH guidance while state supply is severely limited.
4. At a time of scarce supply, providers should establish a priority list of their patients when seeking treatment for multiple patients in a given week.

How to Order:

1. Complete an assessment and confirm eligibility of patient.
2. Send order to nearest of the four hospitals below. Due to scarce supply, the hospital will conduct a lottery at the end of the week if the number of orders exceeds the number of doses available to ensure access is equitable.

Locations:

Northeastern Vermont Regional Hospital

- Contact Jillian Knight at 802-748-7421 or ji.knight@nvrh.org

University of Vermont Medical Center

- Submit referral by calling 802-847-7700 or faxing 802-847-5261.
- If selected via lottery, patients will be scheduled on weekends at Main Campus Infusion Center.

Southwestern Vermont Medical Center

1. Go to www.svhealthcare.org
2. Scroll to the bottom to the “Information” section
3. Select, “For Providers | COVID-19”
4. Click “Outpatient provider COVID-19 Evusheld® Antibody Injection Order”

Rutland Regional Medical Center

- Contact Saisha Branchaud at 802.747.1838 or sbranchaud@rrmc.org

Paxlovid™

The U.S. Food and Drug Administration granted Emergency Use Authorization to Pfizer for its oral antiviral drug Paxlovid to treat COVID-19. Paxlovid (nirmatrelvir/PF-07321332 and ritonavir) is authorized for the treatment of mild to moderate COVID-19 in adult and pediatric patients ages 12 years and older weighing at least 40 kg, who are at high risk for progressing to severe COVID-19, including hospitalization or death. Paxlovid is expected to reduce the likelihood of progressing to severe COVID-19 by 88% for patients treated in the first 5 days of illness.

REQUESTED ACTIONS – Paxlovid:

1. Review the eligibility criteria in the [FDA Fact Sheet for Paxlovid](#)
2. Paxlovid should be administered as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. The EUA does not specify that an in-person evaluation is required.
3. Paxlovid is co-packaged with ritonavir tablets and providers should be cognizant of multiple and potentially serious drug interactions.

How to Order:

1. Complete an assessment and confirm eligibility of patient.
2. Send order to a pharmacy location listed below.
3. Encourage patients to pick up the prescription promptly upon notification from pharmacy or the medication may be returned to stock; please prepare patients that orders are filled in the order in which they are received while supplies last.

Locations:

Site	Address
Kinney Drugs	800 US Rt. 302-Berlin, Barre, VT 05641
Kinney Drugs	47 Executive Dr, Shelburne, VT 05482

Kinney Drugs	164 Swanton Rd, St. Albans Town, VT 05478
Kinney Drugs	55 Shattuck Hill Rd, Newport, VT 05855
Springfield Pharmacy	262 River St, Springfield, VT 05156
Rutland Pharmacy	75 Allen St, Rutland, VT 05701
CVS Pharmacy	8 Kocher Dr, Bennington, VT 05201

Molnupiravir

The U.S. Food and Drug Administration granted Emergency Use Authorization to Merck for its oral antiviral drug molnupiravir to treat COVID-19. Molnupiravir is authorized for the treatment of mild to moderate COVID-19 in adults ages 18 years and older, who are at high risk for progressing to severe COVID-19 and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate. Molnupiravir is expected to reduce the likelihood of progression to severe COVID-19 by 30%.

REQUESTED ACTIONS – Molnupiravir:

1. Review the eligibility criteria in the [FDA Fact Sheet for molnupiravir](#). Note: molnupiravir is not recommended for use during pregnancy.
2. Molnupiravir should be administered as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. The EUA does not specify that an in-person evaluation is required.

How to Order:

1. Complete an assessment and confirm eligibility of patient.
2. Send order to one of the pharmacy locations listed below.
3. Encourage patients to pick up prescription promptly upon notification from pharmacy or the medication may be returned to stock; please prepare patients that orders are filled in the order in which they are received while supplies last.

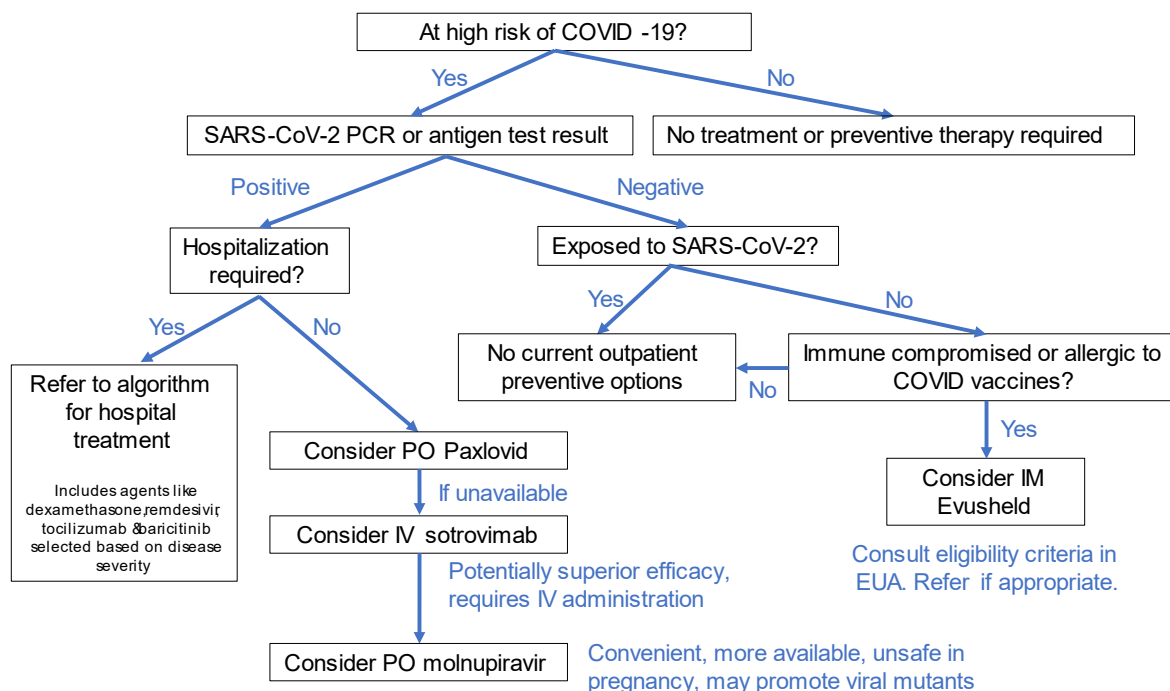
Locations

Site	Address	Town
Kinney Drugs	800 US Rt. 302-Berlin, Barre, VT 05641	Barre
Kinney Drugs	47 Executive Dr, Shelburne, VT 05482	Shelburne
Kinney Drugs	164 Swanton Rd, St. Albans Town, VT 05478	St. Albans
Kinney Drugs	55 Shattuck Hill Rd, Newport, VT 05855	Newport
Kinney Drugs	308 Shelburne Rd, Burlington, VT 05401	Burlington

Kinney Drugs	97 Morrisville Plaza, Morrisville, VT 05661	Morrisville
Kinney Drugs	40 Court St, Middlebury, VT 05753	Middlebury
Kinney Drugs	957 Memorial Dr, St Johnsbury, VT 05819	St. Johnsbury
Springfield Pharmacy	262 River St, Springfield, VT 05156	Springfield
Rutland Pharmacy	75 Allen St, Rutland, VT 05701	Rutland
CVS Pharmacy	8 Kocher Dr, Bennington, VT 05201	Bennington
Brattleboro Pharmacy	413 Canal St., Brattleboro, VT 05301	Brattleboro

Navigating New COVID-19 Therapeutics

Choice of therapeutic for an individual patient should be individualized, but supply issues during current times of scarcity may impact decision making in an effort to treat in the timeliest fashion. Considerations include efficacy, convenience/route of administration, and potential for adverse drug reactions or medication interactions.



Resources:

- [Link](#) to CDC webpage listing age and medical diagnoses associated with elevated risk of severe COVID-19
- [Link](#) to FDA information about sotrovimab (Xevudy), including eligibility criteria:
- [Link](#) to FDA information about tixagevimab/cilgavimab (Evusheld), including eligibility criteria
- [Link](#) to FDA information about nirmatrelvir/ritonavir (Paxlovid)

- [Link](#) to FDA information about molnupiravir
- [Link](#) to NIH prioritization recommendations

Updated hospital contact information for ordering sotrovimab

Infusion sites currently providing mAb infusions and their communication preference for provider referrals are listed below.

- Brattleboro Memorial Hospital (in the process of establishing referral system.)
- Central Vermont Medical Center
 - Call 802-371-4100 and request to be connected with infection prevention's COVID-19 monoclonal antibody referral team.
- Copley Hospital
 - Contact Dr. Donald Dupuis at 802-888-1669
- Gifford Medical Center
 - Call 802-728-7000 and request to be connected to the administrator on call regarding COVID-19 mAbs.
- Grace Cottage Hospital
 - Contact Lisa Eaton, leaton@gracecottage.org
- North Country Hospital
 - Call 802-334-3210 x234, Monday-Friday; on weekends, call house supervisor at 802-334-3238
- Northeastern Vermont Regional Hospital
 - Call 802-748-7951 to speak with Lyndi Medico, Nurse Manager.
- Northwestern Medical Center
 - Email jaboellezz@nmcinc.org
- Porter Medical Center
 - Contact the PMC Infusion Center at 802-388-4701.
- Rutland Regional Medical Center
 - Email jfprendergast@rrmc.or
- Southwestern Vermont Medical Center
 - Email Pamela.Duchene@svhealthcare.org

- Springfield Hospital
 - Email ckirkpatrick@springfieldhospital.org

- University of Vermont Medical Center
 - Please direct questions regarding indications for administration of mAbs to an infectious disease physician for guidance.
 - Please direct scheduling questions concerning mAbs to the UVM Medical Center Infusion Center's charge nurse at 802-847-6275.
 - Internal UVMHC clinicians: Order directly through Epic. It's helpful to have the clinician call the infusion center to expedite scheduling.
 - Outside UVMHC but using the UVMHC infusion center: Obtain the required referral form from the infusion center by calling 802-847-6275.

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

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.