VERMONT
DEPARTMENT OF HEALTH

Health Update
March 3, 2021

TO: Vermont Health Care Providers and Health Care Facilities
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SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19

Background: National recommendations regarding the use of SARS-CoV-2 monoclonal antibodies for the treatment of COVID-19 have been issued by the National Institutes of Health and the Infectious Diseases Society of America. The following information is derived from these guideline documents.

The SARS-CoV-2 genome encodes four major structural proteins [spike (S), divided into two subunits, S1 and S2; envelope (E); membrane (M); and nucleocapsid (N)] as well as nonstructural and accessory proteins. A significant proportion of people with COVID-19 produce neutralizing antibodies to SARS-CoV-2 about 10 days after disease onset, with higher antibody levels observed in those with severe disease. The neutralizing activity of COVID-19 patients' plasma is correlated with the magnitude of antibody responses to SARS-CoV-2 S and N proteins. Monoclonal antibodies targeting the S protein therefore have the potential to prevent SARS-CoV-2 infection and to improve symptomatology and limit progression to severe disease in patients with mild to moderate COVID-19.

Several **monoclonal antibodies to SARS-CoV-2** have been developed and characterized, and evaluation of their efficacy for the treatment and prevention of COVID-19 is ongoing.

- In November 2020, the U.S. Food and Drug Administration (FDA) issued two emergency use authorizations (EUAs), one for **bamlanivimab** and one for the combination of **casirivimab plus imdevimab**. The EUAs allow for use of the drugs in non-hospitalized patients (aged ≥12 years and weighing ≥40 kg) with laboratory confirmed SARS-CoV-2 infection and mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. If used, the drugs should be administered as soon as possible after a positive SARS-CoV-2 test result and within 10 days of symptom onset. It is administered intravenously as a one-time dose of bamlanivimab 700 mg. Casirivimab and imdevimab are monoclonal antibodies that are administered intravenously together as a combined one-time dose of casirivimab 1200 mg and imdevimab 1200 mg.
- On February 9, 2021, the FDA issued an EUA for **bamlanivimab plus etesevimab** for the treatment of mild to moderate COVID-19 in certain outpatients. National recommendations for the use of bamlanivimab plus etesevimab are expected soon.
- The issuance of an EUA does not constitute FDA approval.

Current national guidelines regarding the use of bamlanivimab or the casirivimab plus imdevimab combination: According to the National Institutes of Health COVID-19 treatment guidelines, there are currently insufficient data to recommend either for or against the use of bamlanivimab or the casirivimab plus imdevimab combination for the treatment of outpatients

with mild to moderate COVID-19. Further, bamlanivimab and the casirivimab plus imdevimab combination should not be considered standard of care for the treatment of patients with COVID-19.

According to the Infectious Disease Society of America treatment guidelines:

- Among ambulatory patients with COVID-19, the IDSA guideline panel suggests against the routine use of bamlanivimab.
- Among ambulatory patients with COVID-19, the IDSA guideline panel suggests against the routine use of the casirivimab plus imdevimab combination.

Where to refer COVID-19 patients in Vermont for treatment with SARS-CoV-2 monoclonal antibodies: Currently, the federal government notifies states of the state's allocation of monoclonal antibody products. Then the monoclonal antibody products are shipped directly to established infusion sites based on bi-weekly distribution orders. The web-based COVID-19 outpatient treatment locator maintained by the U.S. Department of Health and Human Services (HHS) is now available to assist healthcare providers and patients in finding potential locations for treatment with monoclonal antibody therapeutics. Sites that have received recent shipments will appear on the map.

Currently available **contact information** for sites offering SARS-CoV-2 monoclonal antibody treatment in Vermont:

1. **Gifford Hospital:** Call 802-728-7000 and request to be connected to the administrator on call regarding monoclonal antibody treatment for COVID-19.
2. **Northeastern Vermont Regional Hospital:** Call 802-748-7951 to speak with Lyndi Medico, Nurse Manager.
3. **Rutland Regional Medical Center:** Call 802-772-2416 to speak with Jonathon Prendergast, RN.

REQUESTED ACTIONS:

1. Be familiar with current national recommendations regarding use of monoclonal antibodies for the treatment of COVID-19.

2. Be familiar with the location of sites where monoclonal antibody infusions for the treatment of COVID-19 are available.

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.