

Outpatient COVID-19 Infusion Therapy or Monoclonal Antibodies and other Potential COVID-19 Infusion Therapies

The North Dakota Department of Health (NDDoH) is strongly encouraging health care facilities and providers to develop protocols to identify patients with early COVID-19 disease and initiate treatment **as early as possible** for those with underlying health conditions that predispose them to severe outcomes. These patients should be considered for early treatment with the monoclonal antibodies, convalescent plasma and/or remdesivir. The Food and Drug Administration (FDA) has issued emergency use authorization (EUA) for these treatment regimens.

Providers should review the complete fact sheet for casirivimab and imdevimab , which can be found [here](#).

Providers should review the complete fact sheet for bamlanivimab, which can be found [here](#).

Providers should review the FDA guidance for convalescent plasma at: <https://www.fda.gov/media/141478/download>

Providers should review the FDA EUA guidance for pediatric treatment with remdesivir at: <https://www.fda.gov/media/137566/download>

EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB AUTHORIZED USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- Casirivimab and imdevimab **are not authorized** for use in patients:

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

The benefit of treatment with casirivimab and imdevimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19. Casirivimab and imdevimab have been authorized by FDA for the emergency uses described above. Casirivimab and imdevimab are not FDA-approved for these uses.

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND have
 - cardiovascular disease, OR
 - hypertension, OR
 - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND
 - have a BMI ≥ 85 th percentile for their age and gender based on CDC growth charts (https://www.cdc.gov/growthcharts/clinical_charts.htm), OR
 - sickle cell disease, OR
 - congenital or acquired heart disease, OR
 - neurodevelopmental disorders, for example, cerebral palsy, OR
 - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
 - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Casirivimab and imdevimab must be administered together.

EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- Bamlanivimab **is not authorized** for use in patients:
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Bamlanivimab has been authorized by FDA for the emergency uses described above. Bamlanivimab is not FDA-approved for these uses.

This EUA is for the use of the unapproved product bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization [see Limitations of Authorized Use].

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND
 - have cardiovascular disease,
 - OR hypertension, OR

- chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have a BMI \geq 85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm , OR
 - sickle cell disease, OR
 - congenital or acquired heart disease, OR
 - neurodevelopmental disorders, for example, cerebral palsy, OR
 - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
 - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS

Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product COVID-19 convalescent plasma to treat hospitalized patients with COVID-19.

The EUA for COVID-19 convalescent plasma authorizes the use of COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. This EUA is based on historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the ongoing National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic.

These medications must be administered in a setting in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

REMEDESIVIR FOR CERTAIN HOSPITALIZED PATIENTS

On October 22, 2020, FDA approved Veklury (remdesivir) for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of

COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. This approval does not include the entire population that had been authorized to use Veklury under an Emergency Use Authorization (EUA) originally issued on May 1, 2020. In order to ensure continued access to the pediatric population previously covered under the EUA, the EUA for Veklury continues to authorize Veklury for emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.

All of these therapies must be administered in a setting in which health care providers have immediate access to medications to treat a severe infusion reaction or other reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary or in a setting capable of providing acute care comparable to an inpatient hospital setting. Infusion centers and skilled nursing facilities may be able to structure themselves to fulfill these requirements to provide the acute or emergent care that may be needed with the administration of these therapies.

Please call the NDDoH Division of Disease Control at (701) 328-2378 with any questions.

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Categories of Health Alert Network messages:

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

Health Advisory May not require immediate action; provides important information for a specific incident or situation

Health Update 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##