VAIL HEALTH

COVID-19 TREATMENTS UNDER EMERGENCY USE AUTHORIZATION CONSENT FORM

Vail Health includes services of Vail Health Hospital

Name	**FIN**
Phone Number	DOB

- *As your Health Care Provider has discussed with you, you have been diagnosed with COVID-19 (or SARS-CoV-2). At the present time, there are few* Food and Drug Administration (FDA) approved, or clinically proven therapies for treatment of COVID-19. As new clinical data emerges, local treatment guidelines have been developed and will be updated as new information becomes available. CDC guidelines reflect what is known about therapies that may work against the SARS-CoV-2 virus, have been used to treat other coronaviruses, or may theoretically target the underlying causes of virus- related severe lung conditions that make breathing difficult.
- The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed orsuspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization

TREATMENT

- In order for you to be treated with the available therapies, you must sign this form to show that you agree to the use of investigational or off label treatments, that you have been informed of the benefits and risks of taking such therapies as well as the benefits and risks of declining or refusing such use. The particular therapy chosen is based upon availability. You will be provided a patient informational handout regarding the ordered treatment prior to receiving medication or infusion therapy. **You have the right to refuse to take this treatment(s) for any reason.**

MONOCLONAL ANTIBODY TREATMENT:

BACKGROUND

Monoclonal Antibodies are unapproved investigational medicines which are used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. The FDA has issued an Emergency Use Authorization (EUA) to permit the use of these unapproved medications. Clinical trials are ongoing to study its safety and efficacy.

POSSIBLE BENEFITS

It is possible that the medications listed above may help to control your symptoms, slow or stop the growth of the virus, shorten the duration or lessen the severity of the illness in you. Possible benefits primarily include improvement in lung function (ability to breathe without assistance) and normalization of blood pressure. However, there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse.

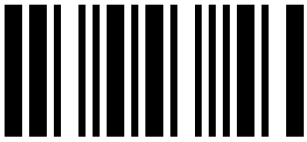
POSSIBLE RISKS AND KNOWN SIDE EFFECTS

It is possible that the medication prescribed may not improve your symptoms and not shorten the duration nor severity of the illness. It is possible that the medication will unexpectedly interfere with your ability to improve, hasten damage to the lungs or other organs, and shorten your life.

Monoclonal Antibody Risks

There is limited clinical data available for these treatments and unexpected adverse events may occur that have not been previously reported. Side effects may include allergic reactions and injection site reactions. It is possible that these treatments could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. These treatments may also reduce your body's immune response to a vaccine for SARS-CoV-2. If you receive this therapy, it could reduce or delay your response to any COVID-19 vaccine for up to 90 days following the infusion and should consider waiting 90 days for a COVID-19 vaccine. *Alternatives*: There are few approved therapies for the treatment of COVID-19 specifically.

- **Allergic reactions.** Allergic reactions can happen during and after infusion or injection of monoclonal antibodies. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea,



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headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling Tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. **These reactions may be severe or life threatening.**

- **Worsening symptoms after treatment**: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.
- The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.
- These are not all the possible side effects of monoclonal antibodies. Not a lot of people have been given these medications. Serious and unexpected side effects may happen. These medications are still being studied so it is possible that all of the risks are not known at this time.
- It is possible that these medications could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, these medications may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks.
- For more information about risks and side effects, please ask your Health Care Provider. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your Health Care Provider may give you medication to help lessen the side effects. Some side effects are temporary. In some cases, side effects can be serious and can last a longtime. Sometimes they never go away.

ORAL ANTIVIRAL MEDICATION (PAXLOVID)

BACKGROUND

PAXLOVID is an investigational antiviral medicine used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

POSSIBLE RISKS AND SIDE EFFECTS

Be sure to discuss your health history, conditions and treatments with your provider. It is important to tell your provider all medications that you are taking. Some medications may interact with PAXLOVID and may cause interactions or serious side effects.

PAXLOVID has not been studied for use in pregnant or breastfeeding patients.

• Liver Problems: Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, stomach area (abdominal) pain.

• Resistance to HIV Medicines: If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.

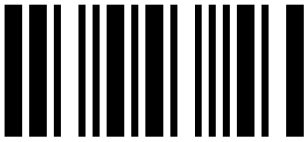
• Other possible side effects include:
  - o altered sense of taste
  - o diarrhea
  - o high blood pressure
  - o muscle aches

These are not all the possible side effects of PAXLOVID. Not many people have taken PAXLOVID. Serious and unexpected side effects may happen. PAXLOVID is still being studied, so it is possible that all of the risks are not known at this time.

ORAL ANTIVIRAL MEDICATION (MOLNUPIRAVIR)

BACKGROUND

MOLNUPIRAVIR is an investigational antiviral medicine used to treat mild-to-moderate COVID-19 in adults (18 years of age and older) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. MOLNUPIRAVIR is investigational because it is still being studied. There is limited information about the safety and effectiveness of using MOLNUPIRAVIR to treat people with mild-to-moderate COVID-19.



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POSSIBLE RISKS AND SIDE EFFECTS

Be sure to discuss your health history, conditions and treatments with your provider. MOLNUPIRAVIR is not recommended for use in pregnancy: your provider may do a pregnancy test to see if you are pregnant before starting treatment. You may need to talk with your health care provider about reliable birth control methods if you are able to become pregnant or if you are sexually active with partners who are able to become pregnant. MOLNUPIRAVIR may cause serious side effects, including:

- MOLNUPIRAVIR may cause harm to your unborn baby
  - For individuals who can become pregnant, use a reliable method of birth control consistently and correctly during treatment and for 4 days after the last dose
  - For individuals who are sexually active with partners who can become pregnant, it is not known if MOLNUPIRAVIR can affect sperm. A reliable method of birth control should be used consistently and correctly during treatment and for at least 3 months after the last dose
- Other possible side effects include:
  - Diarrhea
  - Nausea
  - Dizziness

These are not all the possible side effects of MOLNUPIRAVIR. Not many people have taken MOLNUPIRAVIR. Serious and unexpected side effects may happen. MOLNUPIRAVIR is still being studied, so it is possible that all the risks are not known at this time

WHAT OTHER TREATMENT CHOICES ARE THERE?

- FDA may allow for the emergency use of other medicines to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.
- It is your choice to be treated or not to be treated with the COVID-19 treatment. Should you decide not to receive this medication or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

- Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of the above COVID-19 treatments does not replace vaccination against COVID-19. The available treatments are not authorized for pre-exposure prophylaxis for prevention of COVID-19.
- I have had the opportunity to review the Emergency Use Authorization Fact Sheet for Recipients.
- I am aware that there is no guarantee that administration of this medication will improve my condition or prevent my becoming infected with the COVID-19 virus.

AUTHORIZATION TO ADMINISTER the COVID Treatment ordered by my provider

❑ **YES**, I wish to receive the COVID-19 treatment as ordered by my provider.

❑ **YES,** I consent to my child, aged under 18 years old, to receive the COVID-19 treatment as ordered by my provider.

❑ **NO,** I do not wish to receive any of the COVID-19 treatments listed under Emergency Use Authorization.

I have read or had explained to me, and I understand the risks and benefits of receiving the available COVID-19 treatments. I have had a chance to ask questions, which were answered to my satisfaction. I hereby release this provider, Vail Health Hospital, its employees and its volunteers from any liability for any results which may occur from the administration of this medication.

BY SIGNING THIS CONSENT, I REAFFIRM THAT:

- The information I have submitted is true, complete and correct to the best of my knowledge;
- I have been offered the HIPAA Notice of Privacy Practices & Patient Rights and Responsibilities available through the Vail Health website.

Patient Signature:_____ Date: _____

Parent/Legal Guardian:_____ Date:_____

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