

# Screening & REQUEST FORM for COVID-19 Treatment with Monoclonal Antibodies & Antivirals

**\*\*\*SUBMISSION OF THIS REQUEST FORM IS NOT A GUARANTEE OF TREATMENT\*\***

## Instructions:

1. Licensed provider to legibly complete this form in its entirety (both pages) and email this form **FROM AN ACTIVE EMAIL** to: **monoclonal@vailhealth.org**
2. Submission of this form is not a guarantee of treatment. If drugs are not available **or the form is not complete**, this will be rejected after 48 hours and no drug will be provided. If an ordered drug is available, this form will be **treated as a prescription**.
3. Patient will receive a phone call with appointment date/time or pharmacy instructions, typically within 24-48 hours.

## PATIENT INFORMATION:

NAME: \_\_\_\_\_ DATE OF BIRTH: \_\_\_\_\_

PHONE #: \_\_\_\_\_

ADDRESS: \_\_\_\_\_ E-MAIL: \_\_\_\_\_

ALLERGIES: \_\_\_\_\_

Home medication list (may attach list if needed): \_\_\_\_\_

## SECTION 1: The patient must meet ALL criteria in this section. Check all that apply.

- Outpatient only
  - Not requiring supplemental O<sub>2</sub> (Oxygen saturations <89% on room air or baseline oxygen (monoclonal antibody)
  - Positive COVID-19 test within past 5 days (oral antiviral) or 10 days (monoclonal antibody) AND
  - Age at least 12 years AND > 40 kg (age ≥ 18 for molnupiravir) AND
  - Symptomatic onset within 5 days (oral antiviral) or 10 days (monoclonal antibody)
- Date of Symptom Onset:** \_\_\_\_\_ **Date of Positive COVID Test:** \_\_\_\_\_

## SECTION 2: The patient must be at high risk of progression to severe COVID-19 disease as evidenced by the following:

- Major immune suppression (e.g., recently diagnosed hematologic malignancy, cancer chemotherapy, solid organ transplant on immune suppression, advanced HIV infection)\*\*

### OR presence of TWO of the risk factors below for monoclonal antibodies or ONE for oral antivirals. Check all that apply.

- Advanced age (≥ 60 years of age for oral antivirals and ≥ 65 years of age for monoclonal antibodies)
- Diabetes
- Unvaccinated against COVID-19
- Obesity (BMI >30)
- Chronic kidney disease
- Immunosuppressive disease or immunosuppressive treatment (see page 3 for examples)\*
- Serious heart conditions (heart failure, coronary artery disease, cardiomyopathies, hypertension)
- Chronic obstructive pulmonary diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Active cancer
- Pregnancy
- Current smoker, sickle cell disease, neurodevelopmental disorder (ex: cerebral palsy, Down's syndrome)
- Medically-related technological dependence (ex: tracheostomy)

## SECTION 3: Indicate if the patient has any conditions below that may be a contraindication to specific therapies.

### Yes No

- Does the patient have renal impairment with eGFR <60mL/min? **Required to be checked if ordering Paxlovid**  
If Yes, Paxlovid requires reduced dosing or should be avoided.
- Does the patient have hepatic disease with Child Pugh Class C or higher?  
If Yes, Paxlovid contraindicated.



- Is the patient pregnant?  
If Yes, do not use molnupiravir
- Is the patient currently demonstrating an increased need for oxygen therapy?  
If Yes, do not use monoclonal antibodies

**SECTION 4: Is the patient taking any drugs that may interact with Paxlovid or ritonavir?**

**If Yes, Paxlovid contraindicated.**

- Alpha1-adrenoreceptor antagonist: alfuzosin
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Anti-gout: colchicine
- Antimycobacterials: rifampin
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- Herbal products: St. John's Wort (hypericum perforatum)
- HMG-CoA reductase inhibitors: lovastatin, simvastatin (avoid drug or hold statin therapy for 5 days)
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

**Additionally, please reference the drug interaction list prior to ordering/consenting patient:**

<https://www.covid19-druginteractions.org>

**SECTION 5: Medication prioritization, based on medication availability and if more than one medication is marked below:**

1. Oral antivirals will be administered first, unless patients have a contraindication
2. Monoclonal antibodies per provider specific request and patient meets current tier requirements

If only one medication is preferred, please indicate:  Oral antiviral only  Monoclonal antibody IV only

**Patient prioritization will occur when inventory is restricted, utilizing criteria below (NIH Guidelines).**

Based on risk factors from page 1 and weekly medication allocations, each week patients may be prioritized by Vail Health Ethics Committee based on following tiers. (Ex: If less than 10 monoclonal doses for the whole week, monoclonals for Tier 1 & Tier 2 only)

**Tier 1:** Immunocompromised individuals not expected to mount adequate immune response to COVID-19 vaccine or SARS-CoV-2 infection due to underlying conditions. OR

Unvaccinated ≥ 75 years of age or unvaccinated ≥ 65 years of age with additional risk factor.

**Tier 2:** Unvaccinated ≥ 65 years of age or unvaccinated < 65 years of age with additional risk factor

**Tier 3:** Vaccinated ≥ 75 years of age or vaccinated ≥ 65 years of age with additional risk factor (higher risk if no booster).

**Tier 4:** Vaccinated ≥ 65 years of age or vaccinated < 65 years of age with additional risk factor (higher risk if no booster).

**Ordered Drug: (Provider-**Must mark** any that will be acceptable for this patient---only 1 will be provided, if available)**

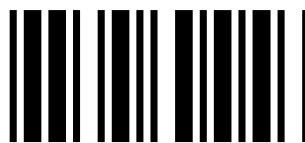
- Paxlovid orally - 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir tablet BID for 5 days OR
  - For eGFR 30-59 ml/min, reduce dose to 150 mg nirmatrelvir with 100 mg ritonavir tablet BID for 5 days
- Sotrovimab 500 mg IV x 1 (or alternate monoclonal antibody based on variant prevalence & supply)
- Molnupiravir orally 800 mg BID x 5 days

**Provider Responsibilities and Acknowledgements – **Must Initial** – will not accept order without**

\_\_\_\_\_(Initial) Provider must review EUA FACT SHEETS for the product prescribed with the patient and discuss risks versus benefits and instruct patient to complete consent form. Please send both documents to [monoclonal@vailhealth.org](mailto:monoclonal@vailhealth.org)

- Please check if consents/EUA discussion provided via telehealth.

\_\_\_\_\_(Initial) This form will be used as a prescription order if therapy is available. If no therapy is available, this form is void. Vail Health clinical staff may transcribe the order most appropriate for this patient.



\_\_\_\_\_(Initial) Report ALL SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to ANY OF THESE AGENTS to the FDA with Form 3500 online or by contacting the FDA at 1-800-FDA-1088 to request this form.

\_\_\_\_\_(Initial) Discuss limited medication availability with patients, and that the treatment may change based on availability.

Provider Comments (ex: patient counseling with drug interactions, holding medication during Paxlovid): \_\_\_\_\_

Printed Provider Name \_\_\_\_\_ Contact email: \_\_\_\_\_

Provider Signature \_\_\_\_\_ Date \_\_\_\_\_

Provider NPI# or DEA#: \_\_\_\_\_ Provider Cell Phone # \_\_\_\_\_

Please note: Infusion appointment days vary based on staffing and needs. The clinic is not open 7 days/week.

If selected for monoclonal antibody therapy, the following orders apply at Vail Health Infusion Center:

- Insert peripheral IV
- Monoclonal Antibodies for treatment SAR-CoV-2, based on availability and subject to change based on local variant prevalence, in the following order:
  - 1) Sotrovimab 500mg IV piggyback one time, observe for 1 hour post infusion
  - 2) Casirivimab + Imdevimab (Regeneron) 1200 mg IV piggyback one time, observe for 1 hour post infusion
  - 3) Bamlanivimab + Etesivimab 2100mg IV piggyback one time, observe for 1 hour post infusion
- Sodium Chloride 0.9% to prime IV infusion set and flush line after infusion
- Ondansetron (Zofran) 4mg IV PRN nausea
- Diphenhydramine (Benadryl) 50mg IV or IM PRN allergic reaction
- Epinephrine 1mg/mL concentration 0.3mg IM PRN severe allergic reaction/anaphylaxis

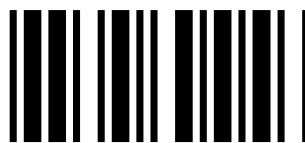
**\*Moderately to Severely Immunocompromising Conditions** ([per CDC Vaccine Recommendations](#)):

- Receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

**\*\*Severely Immunocompromising Conditions** ([per NIH COVID Treatment Guidelines](#)):

- Patients within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
- Patients receiving Bruton tyrosine kinase inhibitors
- Chimeric antigen receptor T cell recipients
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients
- Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)
- Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents
- Patients with severe combined immunodeficiencies
- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm<sup>3</sup>

**Treatment Efficacy** (from independent EUA studies; no head to head comparisons available)



Primary Endpoint: Hospitalization or death at day 29				
Medication	Paxlovid <sup>1</sup>	Sotrovimab <sup>2</sup>	Remdesivir <sup>3</sup>	Molnupiravir <sup>4,5</sup>
Relative Risk Reduction vs placebo	88%	79%	87%	30%
Absolute Risk Reduction vs placebo	6%	5%	4.6%	3%
Number Needed to Treat	18	20	22	34
Patients (N)	2,246	1,057	562	1,433

1. [Pfizer EUA for Paxlovid](#). Fact sheet for healthcare providers. US FDA website. December 22, 2021. Accessed January 4, 2022.
2. [GlaxoSmithKline EUA for sotrovimab](#). Fact sheet for healthcare providers. US FDA website. December 22, 2021. Accessed Jan 19, 2022.
3. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients (PINETREE). N Engl J Med. 2021 Dec 22. Online ahead of print. Accessed January 19, 2022. <https://pubmed.ncbi.nlm.nih.gov/34937145/>
4. [Merck EUA for molnupiravir](#). Fact sheet for healthcare providers. US FDA website. December 23, 2021. Accessed January 4, 2022.
5. Molnupiravir for Oral Treatment of Covid-19 in Nonhospitalized Patients. N Engl J Med. 2021 Dec 16. Online ahead of print. Accessed January 19, 2022. <https://pubmed.ncbi.nlm.nih.gov/34914868/>

