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_2 (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.

PHO

Patient Label

☐ ☐ 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
  - o 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

☐ 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^3

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

Primary Endpoint: Hospitalization or death at day 29				
Medication	**Paxlovid[1]**	**Sotrovimab[2]**	**Remdesivir[3]**	**Molnupiravir[4,5]**
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/