# UNMH Adult & Pediatrics Outpatient/Ambulatory/ED COVID-19 Therapeutic Guidelines

## Guidelines Apply to the Following Areas

- Ambulatory Care
- ED patients without plans for admission
- Adult Urgent care
- UNMH Cancer Center
- Psychiatric Emergency Services (PES)

## Contents



## Key points

- UNMH Guidelines based on both IDSA and NIH Guidelines for COVID-19 infection treatment.
- Patients must have confirmed COVID-19 infection to be eligible for all COVID therapeutics. This can either be PCR or antigen testing. Antigen testing is more reliable in symptomatic patients and is likely a true positive with high community rates of infection (i.e., no PCR confirmation needed).
- Eligibility for outpatient treatments (per NIH + IDSA Guidelines) is targeted for individuals at high risk for disease progression without need for hospital admission.
- COVID-19 infection risk calculators: Johns Hopkins, COVID-19 Mortality Risk Calc, 19 and me – COVID Risk Score Calculator.
- Therapeutic selections currently dependent upon OMASS scoring system to improve equitable distribution across New Mexico for monoclonals, oral and IV antiviral medications. This is likely subject to frequent changes and will be updated in this document when it occurs.
- **Time from symptom onset is an important factor** to determine potential COVID-19 therapies. Most offer more impact if taken/administered earlier in disease course (i.e., when virus is actively replicating but before immune response).
- COVID-19 therapeutic supplies have and likely will vary over time and also impacts therapeutic selection.

## Decision making for which COVID-19 Therapeutic

**Goal**: To prescribe outpatient therapeutics for patients who do not require hospitalization BUT are at high risk for disease progression with COVID-19 infection.
**Qualifying Pediatric patients**: aged ≥12 years **AND** ≥40kg

1. **Determine time from symptom onset:**

| COVID Therapeutic | Time from Symptom Onset |
|---|---|
| COVID monoclonals (e.g., Sotrovimab) | < 10 days |
| Remdesivir | < 7 days |
| Paxlovid or molnupiravir | < 5 days |

2. **Determine OMASS Score:**

**Table 2: Oral Antiviral & Monoclonal Antibody Screening Score (OMASS)**
adapted from Mayo Clinic's published Monoclonal Antibody Screening Score (MASS)

| RISK FACTOR | POINTS |
|---|---|
| Age 65 years and older | 2 |
| BMI 35 kg/m2 and higher | 2 |
| Diabetes mellitus | 2 |
| Chronic kidney disease | 3 |
| Cardiovascular disease in a patient 55 years and older | 2 |
| Chronic respiratory disease in a patient 55 years and older | 3 |
| Hypertension in a patient 55 years and older | 1 |
| Immunosuppressed and unlikely to have responded to vaccines (eg: CD20 inhibitors, BTK inhibitors, campath, recent CAR-T, organ transplant) | 3 |
| Pregnancy*,[8] | 4 |
| BIPOC (Black, Indigenous, People of Color) status[9] | 1 |
| Any other underlying medical condition associated with high risk for severe COVID-19 disease according to the CDC | 1 |

3. **If patients eligible for therapeutics, then**
   a. Discuss therapy with patient and if relevant, provide EUA paperwork to patient, parent or caregiver.
   b. Place referral **or** order medications in Powerchart.
   c. If a patient is referred for monoclonals or IV remdesivir, inform them that they will be contacted by phone by the Presbyterian Infusion Center (i.e., please answer your phone when you receive a call).
   d. If a patient has a prescription placed for paxlovid or molnupiravir, then go to NM DOH Oral Therapeutics website for the latest guidance on prescribing.

## Questions? Need more help?

For Adults: "COVID-19 Adult Therapeutics Questions" Team via TigerConnect.
For Pediatrics: "COVID-19 Peds Monoclonal Ab Referral" Team via TigerConnect.

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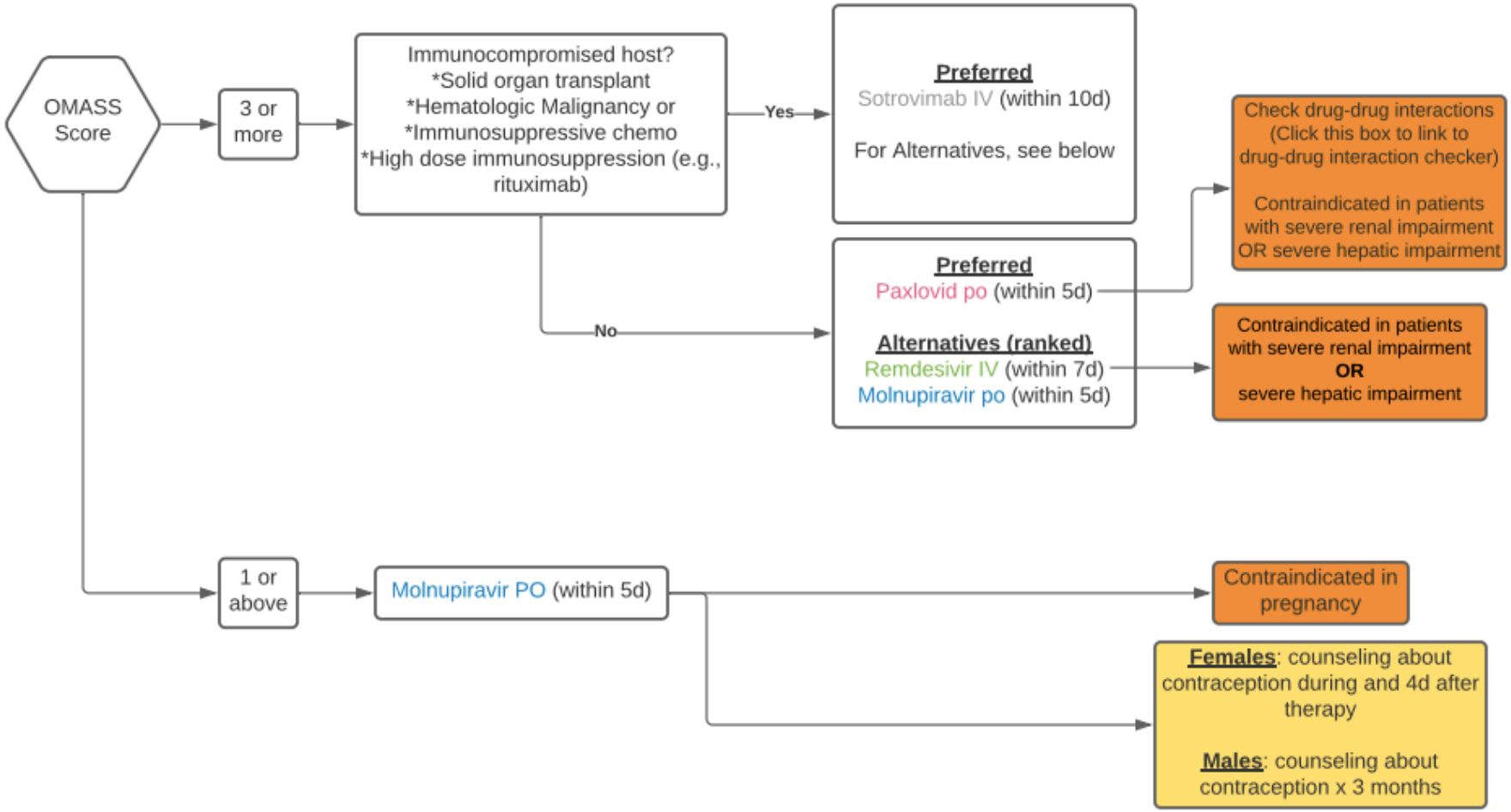
## Decision Support for Selecting Outpatient Therapy

Current NM DOH Phase: I-A




## Drug-Drug Interaction Assessment Tools

www.uptodate.com (preferred)
https://covid19-druginteractions.org/

## Further Guidance/Details About Recommended Therapies

| | |
|---|---|
| **Paxlovid*** (Nirmatrelvir/Ritonavir)<br><br>Link to EUA for providers | • **Dosing**: 300mg Nirmatrelvir/100mg Ritonavir po q12 for 5 days<br>  ○ 50% dose reduction of nirmatrelvir component for moderate renal impairment (eGFR ≥30 to < 60 mL/min).<br>• **Baseline labs**: consider LFTs, particularly if underlying liver disease<br>• **Contraindications**:<br>  ○ Patients with severe renal impairment (eGFR < 30 mL/min)<br>  ○ Patients with severe hepatic impairment (Child-Pugh Class C)<br>  ○ Individuals with uncontrolled or undiagnosed HIV-1 infection at risk for developing resistance to ritonavir<br>• **Drug-drug interactions**: Brief list of contraindicated meds for coadministration. Do not co-administer with some drugs highly dependent on CYP3A for clearance **and** some potent CYP3A inducers due to presence of ritonavir interaction. |
| **Remdesivir*** | • **Dosing**: 200mg IV on day 1, followed by 100mg IV daily for 2 additional days<br>• **Baseline labs**: LFTs and creatinine recommended prior to treatment.<br>• **Note**: PINETREE study that showed reduction of hospitalizations and severe disease was among non-vaccinated patients with COVID-19 infection. |
| **Molnupiravir**<br><br>Link to EUA for providers | • **Dosing**: 800mg po q12 hours for 5 days<br>• **Baseline labs**: none.<br>• **Contraindications**: Not recommended for use during pregnancy (embryo-fetal toxicity).<br>• **Counseling and documentation requirements for prescribers:**<br>  ○ *Make sure to complete the checklist in the EMR before prescribing!*<br>  ○ For females of childbearing potential: counsel to use effective contraception correctly and consistently for duration of treatment **and** for 4 days after last dose.<br>  ○ For males if sexually active with childbearing potential, contraception advised during treatment and for at least 3 months after the last dose.<br>  ○ Breastfeeding: not recommended during treatment and for 4 days after the last dose.<br>• **Drug-drug interactions**: None based on current studies. |
| **Monoclonal*Antibodies**<br><br>Link to EUA for Sotrovimab | • Sotrovimab is the only monoclonal currently effective against the omicron variant. **Do NOT use** Bamlanivimab/etesimvab or casirivimab/imdevimab for postexposure prophylaxis or treatment based on dominance of omicron variant.<br>• **Criteria for use**: COVID+ test **+** COVID-19 infection without hypoxia **+** symptom onset within 10 days **+ meets EUA criteria for use**<br>• **Do not give COVID vaccination** within 90 days from monoclonal administration. |

| | |
|---|---|
| **Corticosteroids** | • Generally, steroids are not recommended for ambulatory/outpatient COVID-19 infection.<br>• Exception(s): when hospital resources are limited, inpatient admission not possible **or** patient not willing to pursue hospital admission, AND close follow-up is arranged.<br>  ○ Patients with hypoxia discharged from the ED may be given a course of dexamethasone.<br>  ○ In these scenarios, give a short course of steroids recommended for the duration of the supplemental oxygen (10 days maximum).<br>  ○ For patients with hypoxia or who need close clinical follow up: Make sure to involve Care Management for referral to follow up by paramedics/AMR **AND** refer patient to COVID Follow up Clinic.<br>• Dexamethasone 6 mg preferred (equivalent steroid dose if dexamethasone not available). |

*Dosing is the same for the qualifying Pediatric patients

## Further Guidance About Therapies NOT Recommended

| | |
|---|---|
| **Ivermectin** | • Not FDA approved for COVID-19 treatment and not recommended by the IDSA or NIH for treatment of COVID.<br>• Use of ivermectin for COVID-19 pneumonia is only recommended in the setting of a clinical trial (Link to CDC Health Advisory for Ivermectin). |

## How to Prescribe AND Where Are These Therapies Available/Administered?

| | How to Prescribe | Where Available/Administered? |
|---|---|---|
| **Monoclonal Antibodies** | • Adhoc referral title: **COVID-19 Monoclonal Ab Infusion Clinic Referral Adult** | Presbyterian Infusion Center |
| **Remdesivir** | | |
| **Paxlovid** | • Search in Power Orders for "COVID-19 Oral Antiviral," "Paxlovid," or "Molnupiravir"<br>• When prescribing, make sure to include the patient's OMASS score, date of symptom onset, and date of positive test.<br>• When in **Power Orders**: Needs to be in "Inpatient & ED" or "Prescriptions & Orders" (i.e., not "Discharge medications")<br>Type: Inpatient & ED<br>• All drug-drug interactions will not be checked in the EMR using this method until a later Cerner update. | NM COVID Oral Therapeutics Website<br>(up to date information from pharmacies with oral antiviral supplies) |
| **Molnupiravir** | | |

## Symptomatic Management for All Patients

- Symptomatic treatment includes using over-the-counter antipyretics, analgesics, or antitussives for fever, headache, myalgias, and cough.
- Patients with dyspnea may benefit from resting in the prone position rather than the supine position.
- Educate patients about breathing exercises, as severe breathlessness may cause anxiety.
- Patients should be advised to drink fluids regularly to avoid dehydration.
- Rest is recommended as needed during the acute phase of COVID-19, and ambulation and other forms of activity should be increased according to the patient's tolerance.
- Patients should be educated about the variability in time to symptom resolution and complete recovery.

## Resources/References

*Overview of COVID Therapeutics*

- ID Society of America (IDSA):
  - www.idsociety.org/cliniciancalls
  - Realtime Antivirals
- FDA – COVID-19 Therapeutics Clinical Implementation Guide
- CDC Presentation: Clinician Outreach and Communication Activity (COCA) – COVID Therapeutics (Jan 12, 2022) (slide deck)

*NM DOH Resources*

COVID-19 Oral Treatments
Current list of NM Pharmacies with oral therapeutics

*Fact Sheets or Information for Patients (EUAs)*

| English | Spanish |
|---|---|
| NM DOH Monoclonal Information | ----- |
| Sotrovimab Handout for Patients Parents and Caregivers (EUA) | Sotrovimab Handout for Patients, Parents and Caregivers (EUA) |
| Paxlovid Handout for Patients, Parents and Caregivers (EUA) | Paxlovid Handout for Patients, Parents and Caregivers (EUA) |
| Remdesivir Patient Information (Approved drug) | Remdesivir Patient Information (Approved drug) |
| Molnupiravir Handout for Patients and Caregivers (EUA) | Molnupiravir Handout for Patients and Caregivers (EUA) |

*Fact Sheets for Healthcare Providers*

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Paxlovid (EUA)
Sotrovimab (EUA)
Remdesivir (Approved)
Molnupiravir (EUA)

*National Guidelines for COVID-19 Treatment*
NIH Guidelines
IDSA Guidelines

## Summary: Outpatient/Ambulatory/ED/UC/PES/Cancer Center Rx of COVID-19 Infection

| Therapy Category | Drug Name | **NIH** High Risk for Progression to Severe COVID-19 | **IDSA** High Risk for Progression to Severe COVID-19 |
|---|---|---|---|
| **Antiviral Therapy** | Paxlovid | **Yes** | **Yes** |
| | Remdesivir | **Yes** | **Yes** |
| | Molnupiravir | **Yes** | **Yes** |
| **Immunosuppression** | Corticosteroids | **In certain circumstances** | **No** |
| **Monoclonal antibodies** | Sotrovimab | **Yes** | **Yes** |
| **Not approved or insufficient data** | Fluvoxamine | — | — |
| | Convalescent Plasma | — | — |
| | Hydroxychloroquine | — | — |
| | Ivermectin | — | — |
| | Lopinavir-Ritonavir | — | — |

"—" indicates "Not recommended, Insufficient Evidence or N/A"

Green shading represents preferred therapy for COVID treatment when applicable.

**Contraindicated drugs to co-administer with Paxlovid**
Please note there may be other drugs with clinically significant interactions. A drug interaction check should be performed for every patient being prescribed Paxlovid.

- Alpha$_1$-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

## Appendix: Outpatient COVID-19 Treatment Data Summary (Source)

| | Sotrovimab | Paxlovid | Molnupiravir | Remdesivir (PINETREE) |
|---|---|---|---|---|
| **Time from Symptom Onset (days)** | 5 | 5 | 5 | 7 |
| **~Cost for a course** | $2,100 | $529 | $700 | $1,872 |
| **Absolute RR (Risk difference)** | 4.6% | 5.5% (p<0.0001) | 2.9% (-5.9 to -0.1) | 4.6% |
| **Relative RR (RRR)** | 79% (50 to 91%) | 88% | 30.3% | 87% |
| **Hazard Ratio (95% CI)** | 0.21 (0.09-0.50) P=0.002 | 0.12 | 0.69 (0.48-1.01) | 0.13 (0.03-0.59) P=0.008 |
| **Number Needed to Treat (NNT)** | 21.7 | 18 | 33.8 | 21.7* |

*Note: PINETREE study excluded non-vaccinated individuals.