



**COVID-19**  
**ORAL THERAPEUTICS PLAN**  
December 27, 2021

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## I. PURPOSE

Paxlovid and molnupiravir received emergency use authorization the week of December 20<sup>th</sup>. These oral COVID-19 medications will be critical additions to our toolbelt of treatments against COVID-19 disease. The new therapeutics will play an especially important role as recent data shows that some monoclonal antibody treatments including bamlanivimab/etesevimab and REGEN-COV are unlikely to retain activity against Omicron. While Sotrovimab is expected to retain activity against Omicron, its supply nationwide is limited. NMDOH currently recommends continued use of all monoclonal antibody options as current genomic surveillance information indicates a low prevalence (<1%) of the Omicron variant. The situation is expected to change rapidly, and oral therapeutics will play a large role in treatment as they are expected to retain efficacy against Omicron variant.

While supplies of oral therapeutics are in short supply, distribution and shipping must occur through a phased patient eligibility criteria and a limited pharmacy network will be necessary. Patients outside of the eligibility criteria for oral therapeutics should be managed using other protocols and therapeutics. Supply is anticipated to increase over the next several months.

## II. PHASED PRESCRIBING CRITERIA

Due to high case rates (6,912 cases in the previous week according to the 12/20/21 COVID-19 Demographics Report) and limited initial oral therapeutic supply (approximately 940 doses available weekly statewide), a phased approach is necessary to prioritize those at greatest risk of severe disease. Prescribing will initially be restricted to patients who are at high risk of severe disease and hospitalization. The state will utilize an oral antiviral and monoclonal antibody screening score (OMASS) to prioritize patients at the highest risk of severe disease. In addition, access to oral therapeutics will be limited initially to counties without monoclonal antibody infusion sites and areas with limited access to monoclonal antibody infusions. New Mexicans in these communities have more difficulty accessing medical care. Prioritizing patients in these communities will help to increase access to COVID-19 treatment and reduce hospitalizations. As supply becomes more readily available, criteria will expand to include all counties and all eligible patients under the EUA.

Despite prioritization efforts, it is still likely that paxlovid supply will be insufficient to meet demand during the first several months. Prescribers should have an alternative treatment plan in the case that the prescription cannot be filled by the pharmacy.

**PHASE 1:**

**Paxlovid Patient Criteria:**

- Treatment can be started within 5 days or less from symptom onset AND
- Positive COVID-19 test AND
- Must reside in an eligible county AND
- **OMASS score of 6 or greater OR**
- **12-17 years of age and an OMASS score of 3 or greater**

**Molnupiravir Patient Criteria:**

- Treatment can be started within 5 days or less from symptom onset AND
- Positive COVID-19 test AND
- Must reside in an eligible county AND
- **OMASS score 3 or greater**

**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*	4
BIPOC (Black, Indigenous, People of Color) status	1

\* Molnupiravir is not recommended for use in pregnancy.

**Eligible Counties:**

1-A			1-B	1-C	1-D
Bernalillo	Hidalgo	San Juan	1-A counties &	1-B counties &	1-C counties &
Catron	Lincoln	Santa Fe	Colfax	Eddy	Chaves
Cibola	McKinley	Sierra	Curry	Lea	Guadalupe
De Baca	Mora	Socorro	Los Alamos	Luna	Roosevelt
Doña Ana	Rio Arriba	Taos	Otero	Quay	
Grant	San Miguel	Torrance		Union	
Harding	Sandoval	Valencia			

**PHASE 2:**

**Paxlovid Patient Criteria:**

- Treatment can be started within 5 days or less from symptom onset AND
- Positive COVID-19 test AND
- **OMASS score of 4 or greater OR**
- **12-17 years of age and an OMASS score of 3 or greater**

**Molnupiravir Patient Criteria:**

- Treatment can be started within 5 days or less from symptom onset AND
- Positive COVID-19 test AND
- **OMASS score 3 or greater**

**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*	4
BIPOC (Black, Indigenous, People of Color) status	1

*\*Molnupiravir is not recommended for use in pregnancy.*

**Eligible Counties:** all counties

**PHASE 3:**

**Paxlovid & Molnupiravir Patient Criteria:**

- Treatment can be started within 5 days or less from symptom onset AND
- Positive COVID-19 test AND
- OMASS score of 3 or greater

**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*	4
BIPOC (Black, Indigenous, People of Color) status	1

*\*Molnupiravir is not recommended for use in pregnancy.*

**Eligible Counties:** all counties

**PHASE 4:**

Patient Criteria	Eligible Counties
Any patient eligible based on EUA criteria.	All counties

**RATIONALE FOR ELIGIBILITY CRITERIA:**

**Oral Antiviral & Monoclonal Antibody Screening Score (OMASS):**

Utilization of a screening tool assists prescribers in prioritizing patients at increased risk of progression to severe disease. The screening tool takes into account a number of risk factors. This tool was adapted from the Mayo Clinic's published Monoclonal Antibody Screening Score (MASS). The Mayo clinic's framework is a validated tool. It was published in March of 2021. The original document is available at [https://www.mayoclinicproceedings.org/article/S0025-6196\(21\)00191-9/fulltext](https://www.mayoclinicproceedings.org/article/S0025-6196(21)00191-9/fulltext) .

The original validated tool was adapted to account for racial groups that were disproportionately affected by COVID-19. Additionally, it was adapted to include pregnancy as a risk factor. At the time of the original tool's creation pregnancy was not an included criteria for treatment. Today pregnant individuals may receive some COVID-19 treatment options.

***Paxlovid OMASS Threshold:*** Paxlovid has been shown to reduce the risk of hospitalization by 88% if taken within the first five days of symptom onset. It is the most effective of the two oral options. However, the state will be receiving only 340 courses for the first 2-week cycle. Due to extremely limited supply, the phase 1 OMASS score threshold for Paxlovid was set at 6 in order to prioritize those patients at greatest risk of severe disease. For individuals 12-17 years of age, the OMASS threshold for phase 1 was set at 3. The rationale for this lower threshold is that Paxlovid will be the only outpatient therapeutic option effective against Omicron for this age group.

***Molnupiravir OMASS Threshold:*** The state will be receiving 1540 courses for the first two-week cycle. Molnupiravir has been shown to reduce the risk of hospitalization by 30% if taken within the first five days of symptom onset. It should be utilized only in patients who are unable to access monoclonal antibody infusion or other more effective COVID treatment options. The phase 1 OMASS score threshold for molnupiravir was set at 3 in order to preserve limited supply.

**Eligible Counties:**

Communities with limited access to COVID-19 monoclonal treatment were prioritized for oral therapeutics.

The following counties do not have a monoclonal antibody infusion provider: Catron, De Baca, Harding, Hidalgo, Mora, Torrance, and Valencia.

The remaining counties were prioritized by utilizing their ratio of monoclonal antibody utilization to COVID cases counts. Data for prioritization was pulled from the four-week period of October 31, 2021 to November 27, 2021.

Phase	County	Weekly Monoclonal Antibody Utilization/Weekly COVID Cases
1-A	Catron	0.00
1-A	De Baca	0.00
1-A	Harding	0.00
1-A	Hidalgo	0.00
1-A	Mora	0.00
1-A	Torrance	0.00
1-A	Valencia	0.00
1-A	Cibola	0.01
1-A	Socorro	0.01
1-A	McKinley	0.01
1-A	San Juan	0.02
1-A	Sierra	0.02
1-A	Doña Ana	0.02
1-A	Rio Arriba	0.02
1-A	Santa Fe	0.03
1-A	San Miguel	0.03
1-A	Sandoval	0.03
1-A	Grant	0.04
1-A	Lincoln	0.04
1-A	Taos	0.05
1-A	Bernalillo	0.06
1-B	Los Alamos	0.06
1-B	Colfax	0.07
1-B	Curry	0.07
1-B	Otero	0.08
1-C	Quay	0.09
1-C	Union	0.10
1-C	Lea	0.10
1-C	Luna	0.10
1-C	Eddy	0.11
1-D	Chaves	0.11
1-D	Roosevelt	0.12
1-D	Guadalupe	0.55

### III. ENSURING HEALTH EQUITY

Oral therapeutics offer the opportunity to increase accessibility of COVID-19 treatments to those who are medically underserved. The following medically underserved have been identified as priority populations for oral therapeutics:

#### **RURAL COMMUNITIES**

Members of rural communities have difficulty accessing healthcare due to healthcare professional shortages in their community and the distance required to travel to urban areas. Counties without a monoclonal antibody infusion site or with reduced access to monoclonal antibodies will be prioritized for oral therapeutics access while availability remains limited. Additionally, the state will leverage an existing network of federally qualified health care centers offering COVID-19 testing to increase oral therapeutics access as supply increases. Finally, barriers to access will be reduced through shipment of oral therapeutic medications to the patient's residence during the initial centralized distribution (refer to Section IV).

#### **TRIBAL, NATIVE, AND PUEBLO COMMUNITIES**

IHS has a robust plan in place for care of tribal communities. Due to the public health emergency, IHS and tribal pharmacies will accept prescriptions from providers outside of the IHS system to reduce barriers to care. NM DOH will support IHS efforts and will ensure that messaging to New Mexicans is clear and collaborative.

#### **NURSING FACILITIES**

Nursing facilities that do not have the ability to provide monoclonal antibody treatment onsite will have access to oral therapeutics through their normal distribution channels. Reducing the need to transport COVID-19 positive nursing facility patients for treatment will minimize transmission exposure and patient risk associated with transport. NM DOH will work with long-term care pharmacies to ensure adequate supply is available for this population.

#### **NEW MEXICANS WITHOUT PRIMARY CARE PHYSICIANS**

The state is committed to reducing barriers to care and will leverage an existing network of federally qualified health care centers offering COVID-19 testing for patients without primary care physicians to receive assessment and treatment referral for COVID-19 disease.

#### **NEW MEXICANS WITHOUT HOMES**

Throughout all phases, NM DOH will coordinate with homeless shelters in eligible counties to ensure homeless patients are able to access oral therapeutics. As supply becomes more readily available, NM DOH will work to onboard pharmacies serving primarily homeless populations as oral therapeutics dispensation sites.

#### **CORRECTIONAL FACILITIES**

NM DOH will work with prisons and jails to ensure that patients meeting the eligibility criteria have access to oral therapeutics.

### **RACIAL HEALTH DISPARITIES**

COVID-19 data shows that Black/African American, Hispanic/Latino, American Indian and Alaska Native persons in the United States experience higher rates of COVID-19-related hospitalization and death compared with non-Hispanic White populations. NM DOH is utilizing a screening tool in its phased criteria that considers a patient's BIPOC (Black, Indigenous, People of Color) status in an effort to reduce racial health disparities.

## **IV. DISTRIBUTION**

Oral therapeutics will be made available in New Mexico through a network of pharmacies and rural community centers. Select rural community centers, chosen due to locations in health professional shortage areas, will have oral therapeutics onsite to dispense directly to eligible patients.

Partner pharmacy locations will accept eligible prescriptions from all authorized prescribers (refer to Section V). Due to limited supply, the network of pharmacies will be limited to a few partners during Phase 1-2. Initially, the state will partner with a single pharmacy partner, Walgreens. As medication supply increases, pharmacy locations across the state will receive oral therapeutics for onsite prescription processing and dispensation. As additional supply becomes available, the pharmacy network will expand to include all federal and state pharmacy partners.

In order to ensure equitable access to the products to residents of all counties, New Mexico will leverage the benefits of a centralized distribution model. Prescriptions for the majority of counties will be filled by a central pharmacy partner, *Community, a Walgreens Pharmacy*. The central pharmacy partner will fill the prescription and mail it for next day arrival direct to the patient's home or as directed by the patient to a nearby authorized pick-up location. A centralized distribution model will reduce patient, provider, and pharmacy time spent locating sites with inventory on hand. It will also ensure that when supply is exhausted providers and patients can receive timely notification and referral for alternative COVID therapeutics.

In addition to the central location, a few Walgreens locations will have inventory on hand. As supply increases, the available locations with on-hand inventory will increase. Please refer to the [cv.nmhealth.org](http://cv.nmhealth.org) *COVID-19 Provider Information* tab, for an up-to-date list of locations.

## V. PRESCRIBING ORAL THERAPEUTICS

### AUTHORIZED PRESCRIBERS

Molnupiravir and Paxlovid may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which the medication belongs. Providers should review the FDA fact sheets for providers and carefully review contraindications and potential drug interactions prior to prescribing either of the new oral therapeutics. Providers should be aware that the pharmacy may not have access to medication lists for patients. Prescribers are responsible for assessing any potential drug interactions prior to prescribing an oral therapeutic.

### POSITIVE COVID-19 TEST

A positive COVID-19 result from any FDA approved COVID-19 diagnostic test including rapid antigen tests is acceptable. Confirmation with PCR is not necessary for the purpose of prescribing oral therapeutics.

Providers should confirm any positive COVID-19 test result with the presence of symptoms that support the positive test result. Oral therapeutics should be provided only to symptomatic patients.

### REQUIRED PATIENT HANDOUT

Prescribing health care providers must provide the patient/caregiver with an electronic or hard copy of the “Fact Sheet for Patients and Caregivers” prior to the patient receiving molnupiravir or paxlovid and must document that the patient/caregiver has been given an electronic or hardcopy of the “Fact Sheet for Patients and Caregivers”

### DATE OF SYMPTOM ONSET

COVID Oral therapeutics shall be reserved for symptomatic patients. Asymptomatic patients shall not be provided a prescription for oral therapeutics.

Both molnupiravir and paxlovid must be started by the patient within 5 days of symptom onset for the therapy to be effective. Providers should ensure that the patient is able to receive medication within the treatment window.

**Prescribers should note the date of symptom onset on the prescription. This information is critical for pharmacists to ensure the patient receives their prescription within the treatment window.**

During initial central distribution, please allow 24-48 hours for medication processing and shipment. It is recommended to send prescriptions for patients within 72 hours of symptom onset until supply is sufficient to decentralize distribution.

### PHASED PATIENT ELIGIBILITY CRITERIA

Prescriptions must be prescribed within current phase criteria. Out-of-phase prescriptions will not be filled. Please refer to Section II for the phase criteria.

**PRESCRIPTION ROUTING**

All prescriptions shall be sent electronically when possible. Providers without the ability to send an E-Rx may send a fax or phoned prescription. Please include in the notes section the date of symptom onset. It is important for the pharmacy team to know this information so that they can ensure the patient receives their medication within the treatment window.

**Additional locations will be added as supply increases. Please refer to the [cv.nmhealth.org](http://cv.nmhealth.org) COVID-19 Provider Information tab, for an up-to-date list of locations.**

**Initial Locations with In-Store supplies of Paxlovid:**

<u>CITY</u>	<u>LOCATION</u>	<u>ADDRESS</u>
<u>Albuquerque</u>	<b>WALGREENS 6587</b>	9700 MENAUL BLVD. NE
<u>Las Cruces</u>	<b>WALGREENS 11458</b>	3990 E LOHMAN AVE
<u>Farmington</u>	<b>WALGREENS 4510</b>	4221 E. MAIN ST.

**Locations with In-Store supplies of Molnupiravir:**

<u>CITY</u>	<u>LOCATION</u>	<u>ADDRESS</u>
<u>Albuquerque</u>	<b>WALGREENS 6587</b>	9700 MENAUL BLVD NE
<u>Edgewood</u>	<b>WALGREENS 7881</b>	5 WALKER ROAD
<u>Española</u>	<b>WALGREENS 5157</b>	1115 N. RIVERSIDE DR
<u>Farmington</u>	<b>WALGREENS 4510</b>	4221 E. MAIN ST
<u>Gallup</u>	<b>WALGREENS 9007</b>	1870 E. HISTORIC HIGHWAY 66
<u>Grants</u>	<b>WALGREENS 15607</b>	1509 E. SANTA FE AVE
<u>Las Cruces</u>	<b>WALGREENS 11458</b>	3990 E LOHMAN AVE
<u>Las Vegas</u>	<b>WALGREENS 2425</b>	620 MILLS AVE
<u>Los Lunas</u>	<b>WALGREENS 6610</b>	2500 MAIN ST NE
<u>Rio Rancho</u>	<b>WALGREENS 4187</b>	1941 SOUTHERN BLVD NE
<u>Ruidoso</u>	<b>WALGREENS 4650</b>	138 SUDDERTH DR
<u>Santa Fe</u>	<b>WALGREENS 6346</b>	525 W. ZIA RD
<u>Silver City</u>	<b>WALGREENS 10808</b>	100 ROSEDALE RD
<u>Taos</u>	<b>WALGREENS 12751</b>	811 PASEO DEL PUEBLO SUR

**All other prescriptions for eligible patients should be sent to:**

*Community, A Walgreens Pharmacy*  
933 San Mateo Blvd NE Suite 501, Albuquerque, NM 87108  
Phone: 505-313-8080  
Fax: 505-313-8082

Prescriptions will be sent via overnight mail directly to the patient’s home or an approved alternate pick up location.

Do not send prescriptions alternative pharmacies or Walgreens not listed above. They do not have medication in stock.

**As pharmacy network expands, prescriptions may be sent to patient's preferred pharmacy.** Please refer to <https://cv.nmhealth.org/providers/> for the current list of participating pharmacy locations.

### **REQUESTED DATA ELEMENTS**

In order for the pharmacy to process oral therapeutics prescriptions in a timely manner. The following information is essential:

- 1. Date of symptom onset**
  - It is important for the pharmacy team to know this information so that they can ensure patient receives medication within the therapeutic window.
- 2. Patient address (if the patient does not have permanent housing please annotate as such)**
  - Alternative shipping location if applicable
- 3. Patient's telephone or an alternate means of contact for the patient**
- 4. Pharmacy insurance information-if available**
- 5. Alternate Therapy-** Supply remains limited. In order to ensure your patient receives timely treatment, please indicate the alternate therapy you would prefer your patient receive if the medication is out of stock. For example, *"If paxlovid is not available, please substitute molnupiravir OR If paxlovid is not available, please contact prescriber for monoclonal antibody referral."*

### **PRESCRIPTION PROCESSING**

- The dispensing pharmacy is responsible for verifying that the patient resides within an eligible county.
- The dispensing pharmacy shall obtain a list of the patient's medications in order to check for potential drug interactions.
- The dispensing pharmacy shall confirm that the patient will be able to receive and start the medication within 5 days of symptom onset.
- During the initial central distribution, prescriptions must be filled and shipped overnight within 24 hours of receipt.
- If a prescription is unable to be filled within 24 hours, the prescription shall not be accepted by the pharmacy. The prescriber and patient shall be notified and referred for alternative COVID therapeutic such as a monoclonal antibody infusion.
- If a prescription is not picked up within 5 days of symptom onset, the prescription shall be returned. The prescriber shall be notified to refer patient for alternative COVID therapeutic such as a monoclonal antibody infusion.

## **VI. EMERGENCY USE AUTHORIZATION**

All currently available COVID-19 oral treatments and monoclonal antibodies have been granted an emergency use authorization (EUA). This is the Food and Drug Administration (FDA) authorization of an unapproved product or unapproved uses of an approved product for emergency use. An emergency

use authorization is not the same as FDA approval. Emergency use authorization medications are considered investigational.