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COVID Therapeutic Update

Courtney Lovato, PharmD

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Are some patients eligible for 4 doses of COVID vaccine?

YES!!

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Eligible For	IF YOU RECEIVED Pfizer-BioNTech	IF YOU RECEIVED Moderna	IF YOU RECEIVED Johnson & Johnson's Janssen
Additional Primary Shot	People **age 5+** who are moderately or severely immunocompromised **should** get an additional primary shot of Pfizer-BioNTech COVID-19 vaccine Given 28 days after 2nd shot	People age 18+ who are moderately or severely immunocompromised **should** get an additional primary shot of Moderna COVID-19 vaccine Given 28 days after 2nd shot	No additional primary shot is recommended at this time
Booster Shot	• Teens **ages 12–17** should only get a Pfizer-BioNTech COVID-19 vaccine booster shot • People **age 18+** should get a booster shot of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most situations Given 5 months after additional primary shot	People **age 18+** should get a booster shot of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most situations Given 5 months after additional primary shot	People **age 18+** should get a booster shot of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most situations Given 2 months after 1st shot

https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e2.htm

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

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Who Is Moderately or Severely Immunocompromised?

- Been 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 immune response

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COVID-19 Therapeutic Options

Medication	Reduction In hospitalization & death	Route	Treatment Initiation from Symptom Onset	Treatment Duration	Weekly Supply (Week 1/21)
Paxlovid	88%	Oral	Within 5 days	5 days	260 courses
Remdesivir	87%	IV	Within 7 days	3 days (1-2 hr)	Commercially Available
Sotrovimab	85%	IV	Within 10 days	30 minutes	240 courses
Molnupiravir	30%	Oral	Within 5 days	5 days	1030 courses
REGEN-COV	0%	IV	Within 10 days	30 minutes	Not in use
BAM/ETE	0%	IV	Within 10 days	1 hour	Not in use

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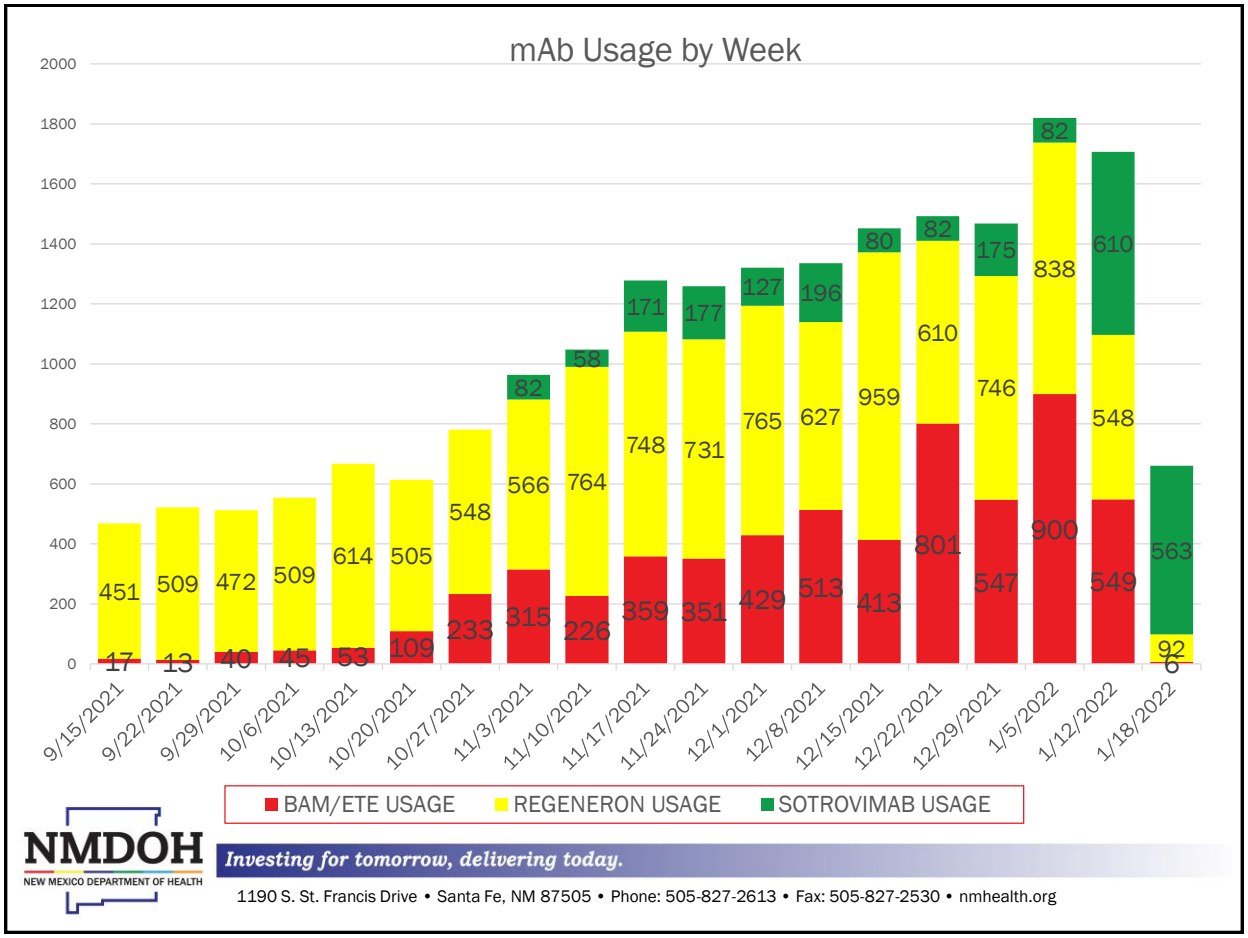
mAb Usage by Week
2000
1800
1600
1400
1200
1000
800
600
400
200
0
9/15/2021
9/22/2021
9/29/2021
10/6/2021
10/13/2021
10/20/2021
10/27/2021
11/3/2021
11/10/2021
11/17/2021
11/24/2021
12/1/2021
12/8/2021
12/15/2021
12/22/2021
12/29/2021
1/5/2022
1/12/2022
1/18/2022
451
509
472
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614
505
548
566
764
748
731
765
627
959
610
746
838
548
563
17
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109
233
315
226
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351
429
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801
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900
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92
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171
177
127
196
80
82
175
610
82
BAM/ETE USAGE
REGENERON USAGE
SOTROVIMAB USAGE
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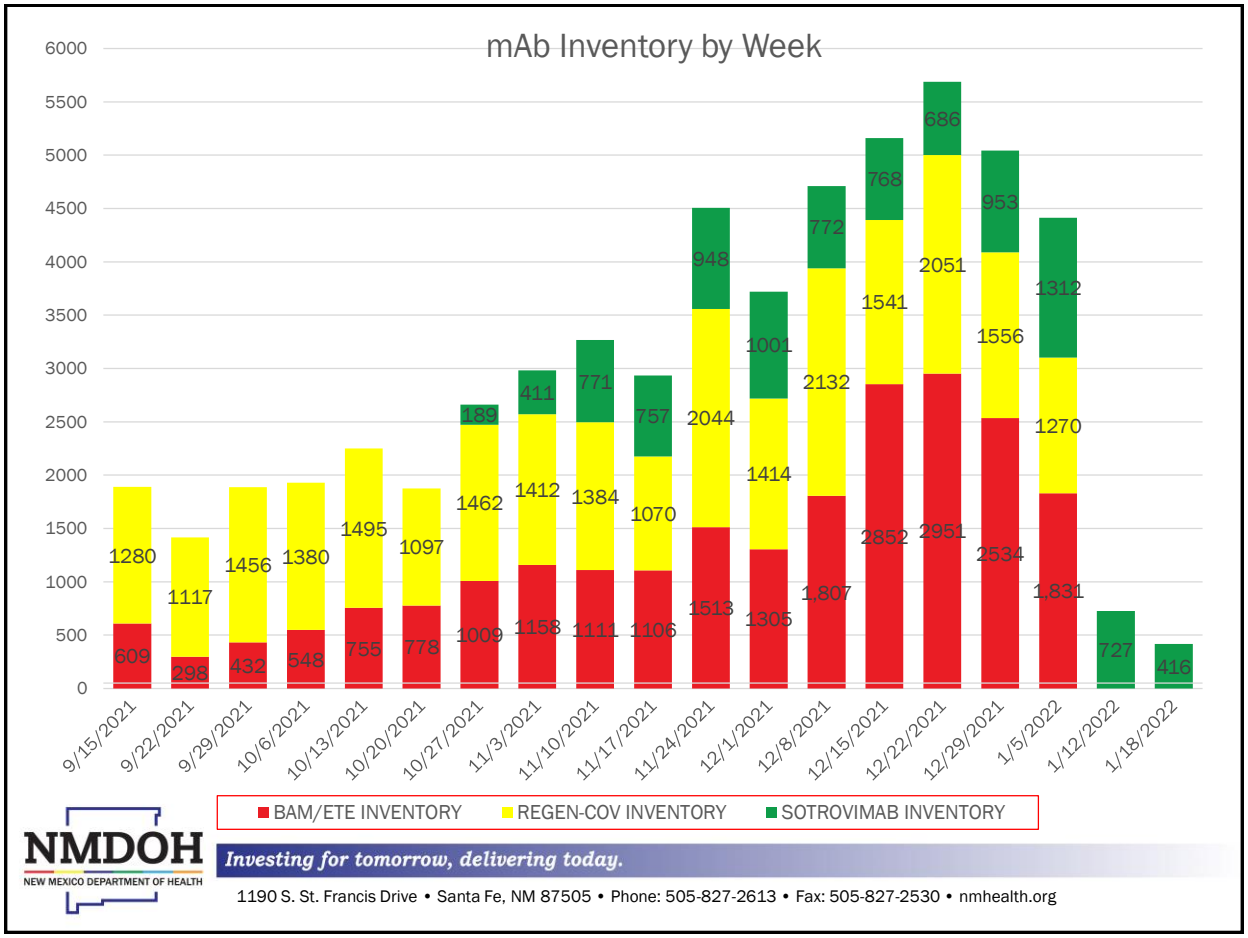
mAb Inventory by Week
6000
5500
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
1280
609
1117
298
1456
432
1380
548
1495
755
1097
778
1462
189
1009
1412
411
1158
1384
771
1111
1070
757
1106
2044
948
1513
1414
1001
1305
2132
772
1807
2852
1541
768
2951
2051
686
2534
1556
953
1,831
1270
1312
727
416
9/15/2021
9/22/2021
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10/6/2021
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11/17/2021
11/24/2021
12/1/2021
12/8/2021
12/15/2021
12/22/2021
12/29/2021
1/5/2022
1/12/2022
1/18/2022
BAM/ETE INVENTORY
REGEN-COV INVENTORY
SOTROVIMAB INVENTORY
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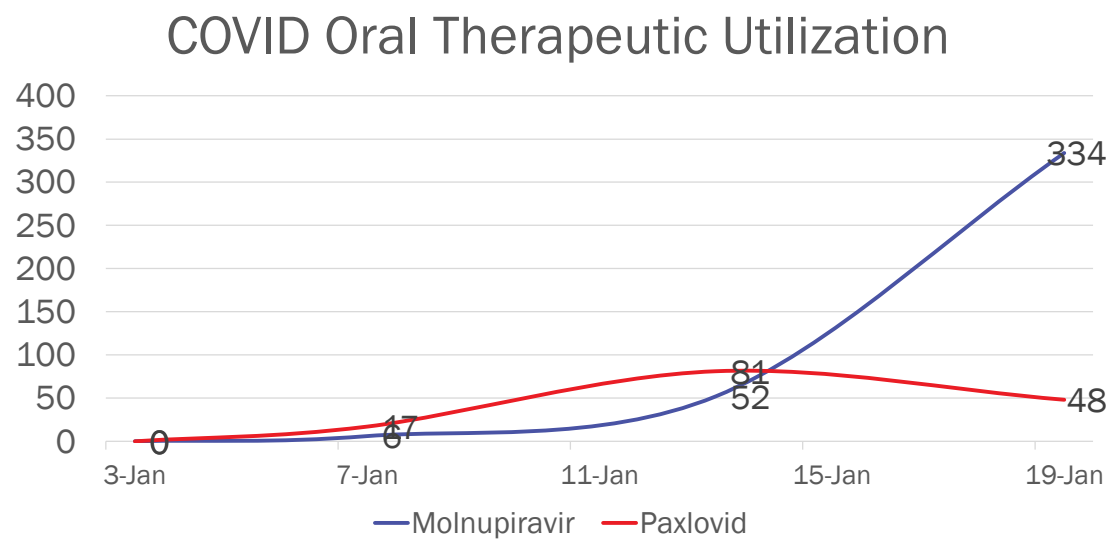

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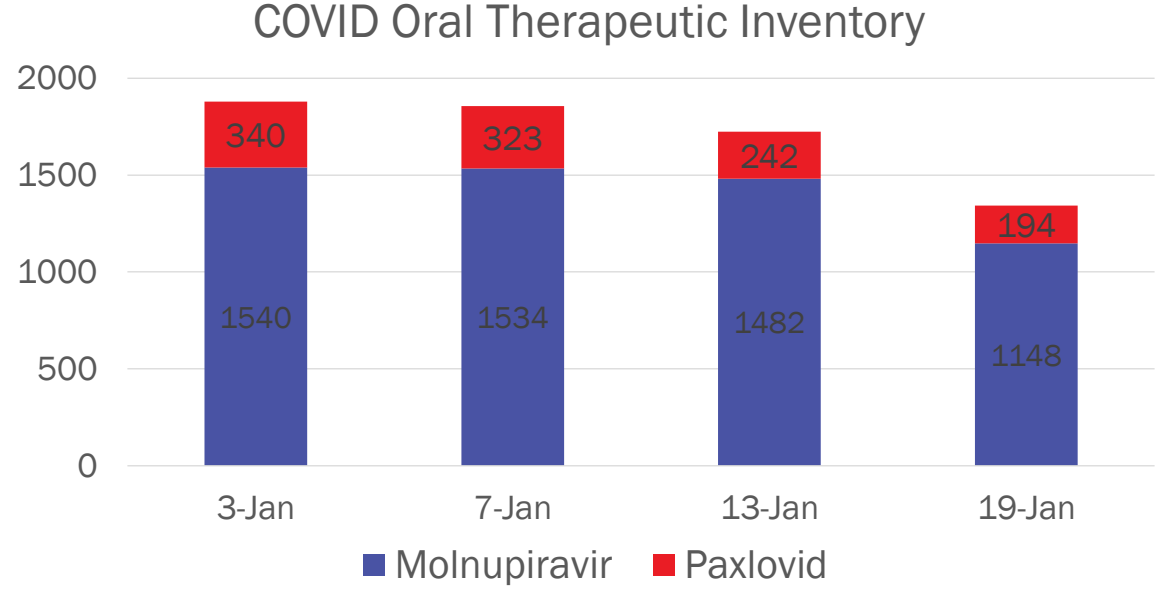

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PHASE 1-D

Patients in *ALL* counties are now eligible.

Sotrovimab & Remdesivir:
OMASS score greater than 6

Paxlovid:
OMASS score greater than 6 *OR* 12-17 years with OMASS score 3 or greater

Molnupriavir:
OMASS score greater than 3

***Check DOH webpage for current criteria as they will change. It will be on the same page as participating pharmacy locations**

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			

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Participating Pharmacies

- Due to very limited supply, there will be a limited network initially.
- As supply increases the network of pharmacies will grow to include additional locations, independents, and chains.
- For a current list of participating pharmacies, check https://cv.nmhealth.org/providers/covid-19-oral-therapeutics-information-for-providers/

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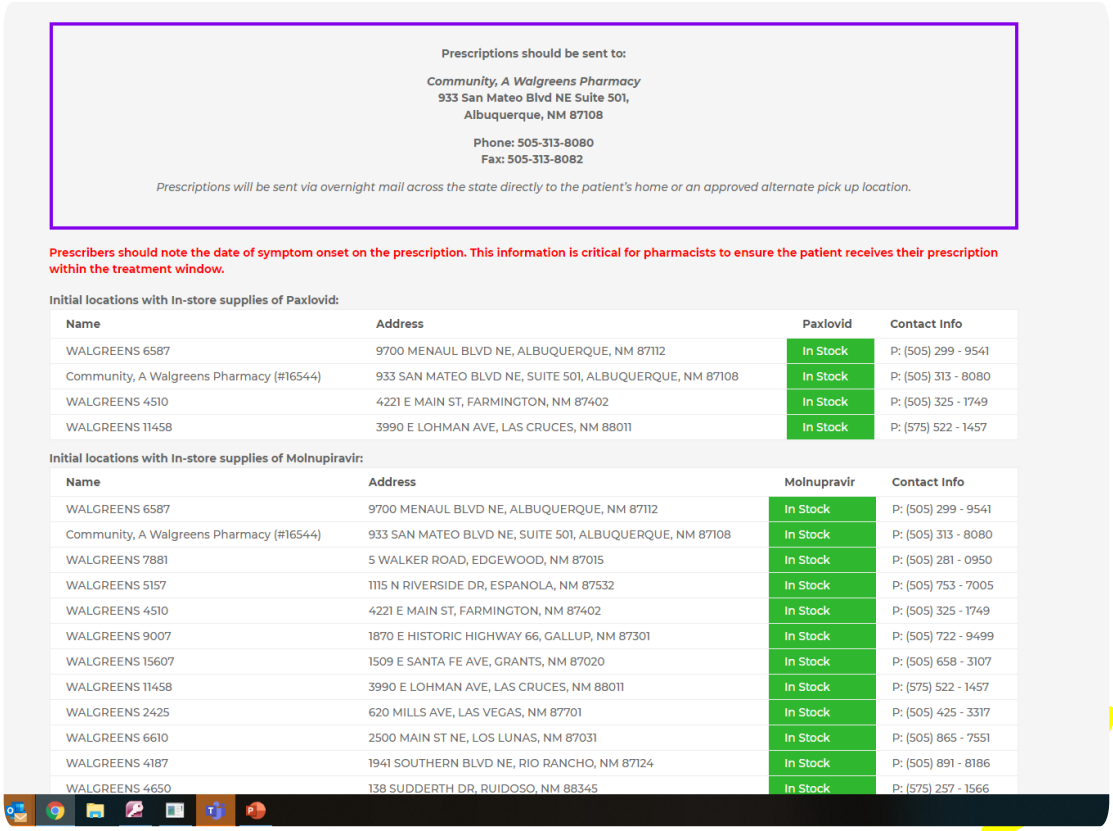

Prescriptions should be sent to:

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 across the state directly to the patient's home or an approved alternate pick up location.

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.

Initial locations with In-store supplies of Paxlovid:

Name	Address	Paxlovid	Contact Info
WALGREENS 6587	9700 MENAUL BLVD NE, ALBUQUERQUE, NM 87112	In Stock	P: (505) 299 - 9541
Community, A Walgreens Pharmacy (#16544)	933 SAN MATEO BLVD NE, SUITE 501, ALBUQUERQUE, NM 87108	In Stock	P: (505) 313 - 8080
WALGREENS 4510	4221 E MAIN ST, FARMINGTON, NM 87402	In Stock	P: (505) 325 - 1749
WALGREENS 11458	3990 E LOHMAN AVE, LAS CRUCES, NM 88011	In Stock	P: (575) 522 - 1457

Initial locations with In-store supplies of Molnupiravir:

Name	Address	Molnupravir	Contact Info
WALGREENS 6587	9700 MENAUL BLVD NE, ALBUQUERQUE, NM 87112	In Stock	P: (505) 299 - 9541
Community, A Walgreens Pharmacy (#16544)	933 SAN MATEO BLVD NE, SUITE 501, ALBUQUERQUE, NM 87108	In Stock	P: (505) 313 - 8080
WALGREENS 7881	5 WALKER ROAD, EDGEWOOD, NM 87015	In Stock	P: (505) 281 - 0950
WALGREENS 5157	1115 N RIVERSIDE DR, ESPANOLA, NM 87532	In Stock	P: (505) 753 - 7005
WALGREENS 4510	4221 E MAIN ST, FARMINGTON, NM 87402	In Stock	P: (505) 325 - 1749
WALGREENS 9007	1870 E HISTORIC HIGHWAY 66, GALLUP, NM 87301	In Stock	P: (505) 722 - 9499
WALGREENS 15607	1509 E SANTA FE AVE, GRANTS, NM 87020	In Stock	P: (505) 658 - 3107
WALGREENS 11458	3990 E LOHMAN AVE, LAS CRUCES, NM 88011	In Stock	P: (575) 522 - 1457
WALGREENS 2425	620 MILLS AVE, LAS VEGAS, NM 87701	In Stock	P: (505) 425 - 3317
WALGREENS 6610	2500 MAIN ST NE, LOS LUNAS, NM 87031	In Stock	P: (505) 865 - 7551
WALGREENS 4187	1941 SOUTHERN BLVD NE, RIO RANCHO, NM 87124	In Stock	P: (505) 891 - 8186
WALGREENS 4650	138 SUDDERTH DR, RUIDOSO, NM 88345	In Stock	P: (575) 257 - 1566

https://cv.nmhealth.org/providers/covid-19-oral-therapeutics-information-for-providers/

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Billing

- The medication is paid for by the federal government.
- The pharmacy will bill the dispensing fees to patient's insurance. However, patients who are uninsured will not be turned away.
- Uninsured and underinsured patients may have their fees billed through the HRSA COVID-19 Cares Program or the HRSA COVID-19 Coverage Assistance Fund. For more information, please visit hrsa.gov/coviduninsuredclaim

Molnupiravir

Health Care Provider Fact Sheet: https://www.merck.com/eua/molnupiravir-hcp-fact-sheet.pdf

Patient Fact Sheet

REQUIRED TO PROVIDE

https://www.fda.gov/media/155055/download

Molnupiravir

MOA: Nucleoside analog

DOSING: 4 (200mg) tablets by mouth twice daily for 5 days.

- With or without food

TREATMENT WINDOW: Must be started within 5 days of symptom onset

AGE: Patients 18 years +

- Not for pediatric patients due to bone/cartilage toxicity in animal models

SIDE EFFECTS: diarrhea, nausea, dizziness

DRUG INTERACTIONS: No drug interactions

RENAL/HEPATIC ADJUSTMENT: No renal/hepatic adjustments

EFFICACY: 30% reduction in hospitalization and death

- Utilize when other treatment options are contraindicated or unavailable to the patient or if patient doesn't meet OMASS criteria for other treatment options due to limited supply.

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Molnupiravir Pregnancy and Birth Conrol

- Not recommended in pregnant individuals
  - Embryo-fetal toxicity in animal studies.
- Males-Contraceptive method for a minimum of 3 months. Studies are ongoing regarding effect on sperm.
- Females-Contraceptive method required during treatment and for four days following treatment.
  - It is recommended females with irregular menses, inconsistent birth control utilization, or no contraceptive utilization receive a pregnancy test prior to receiving medication.

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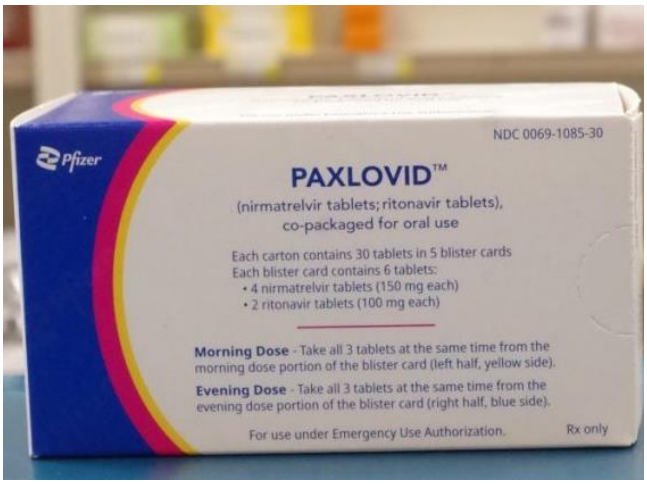
Paxlovid



Health Care Provider Fact Sheet: https://www.fda.gov/media/155050/download

Patient Fact Sheet

REQUIRED TO PROVIDE

https://www.fda.gov/media/155051/download

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Paxlovid (Nirmatrelvir/Ritonavir)

MOA: Peptidomimetic Protease Inhibitor

DOSING: 2 tablets of Nirmatrelvir 150mg (pink) AND 1 tablet of ritonavir 100mg (white) by mouth twice daily for 5 days.

- With or without food

TREATMENT WINDOW: Must be started within 5 days of symptom onset

AGE: Patients 12 years +

SIDE EFFECTS: dysgeusia, diarrhea, hypertension, myalgia

HEPATIC IMPAIRMENT: Not recommended for severe hepatic impairment (Child Pugh Class C)

EFFICACY: 88% reduction in hospitalization and death.

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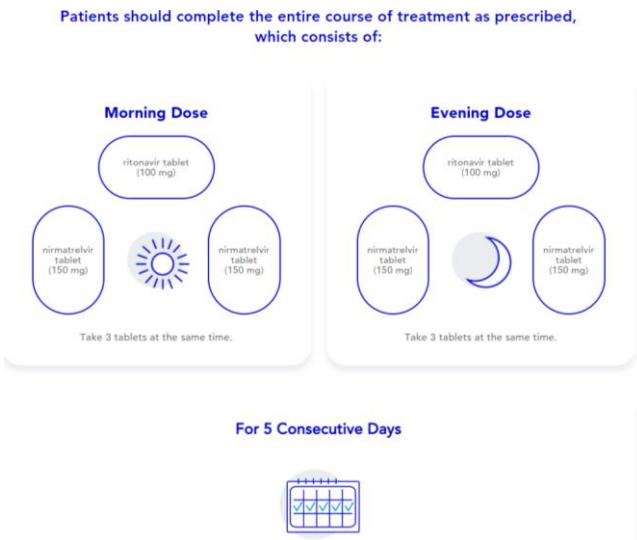
Paxlovid Packaging



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Paxlovid Renal Adjustment

The dosage for PAXLOVID is as follows:

eGFR*	PAXLOVID Dose
Greater than 60 mL/min (*normal renal function or mild renal impairment*)	300 mg nirmatrelvir with 100 mg ritonavir, taken twice daily for 5 days
≥30 to <60 mL/min (*moderate renal impairment*)	150 mg nirmatrelvir with 100 mg ritonavir, taken twice daily for 5 days
<30 mL/min (*severe renal impairment*)	PAXLOVID is not recommended (the appropriate dose has not been determined).

*eGFR=estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula

Each daily blister card contains a morning and evening dose, with each dose consisting of 300 mg nirmatrelvir (two oval, pink 150 mg tablets) and 100 mg ritonavir (one ovaloid, white 100 mg tablet) as shown in Figure A below, which is incongruent with the moderate renal impairment dose.

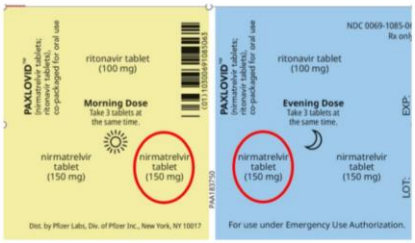

Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card

STEP TWO: Affix the blister card with one sticker from the provided tear pad to carefully cover the empty blister cavities as shown in figure 2 below. The exact placement of this sticker is important to cover the empty blister cavities from the tablets. Ensure the sticker also covers the pre-printed dosing instruction that is on the blister card.

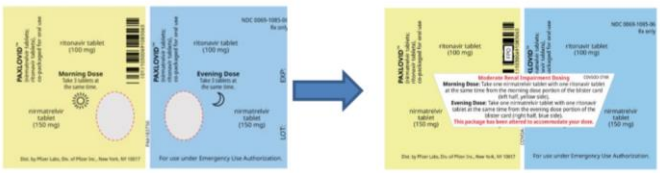

Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets

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Paxlovid Drug Interactions

Potent CYP3A4 Inhibitor

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Medication List

- With a limited pharmacy network, it is critical that patients are asked about all of their medications.

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Paxlovid & Pregnancy

- There is no experience treating pregnant women with Paxlovid
  - There are maternal and fetal risks associated with untreated COVID-19 in pregnancy. Benefit of Paxlovid may outweigh risk. The Society of Maternal Fetal Medicine has issued a statement supporting the use of Paxlovid in pregnant patients who meet the clinical qualifications.

- Ritonavir may impact combine hormonal contraceptive efficacy. A back up method is recommended for patients for pregnancy avoidance.

Additional Questions

Please contact COVID.Therapeutics@state.nm.us

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