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January 5, 2022

Colleagues,

Happy New Year and thank you for all your hard work this past year!

Here are some updates that happened during the holiday season:

- New CDC guidance for isolation and quarantine – shortened both to 5 days
- New MDHHS guidance supporting CDC isolation and quarantine recommendations for general public and K-12 education (waiting for updates on congregate settings)
- Updated CDC guidance on managing healthcare personnel with COVID-19 or exposure to it (see attached slides)
- Impending approval of booster shots for ages 12-15 and when that will be available in Saginaw County
- New guidance allowing boosters as early as 5 months after primary series rather than 6 months
- Approval of third doses for immunocompromised individuals ages 5 and older

I wanted to update you on the latest information on therapeutics for COVID-19. You will find power point slides (HCP Update) attached to this letter. These power point slides will provide you an overview of important information on Covid-19 management. In addition, please read the attached CDC Health Advisory (CDC HAN). In this document, you will find the most recent data and guidance on monoclonal antibodies, oral antivirals, and pre-exposure therapeutics for high-risk groups. The other attachment discusses the prioritization and distribution of the oral antivirals. Finally, Paxlovid and Molnupiravir (oral antivirals) are available at Meijer pharmacies. Both meds are at Meijer on Tittabawassee and Molnupiravir (only) is at Gratiot. Remember that patients must meet criteria to get these medications. You will find directions on how to write these medications, eligibility requirements, and on how to send a prescription to Meijer pharmacy in the Prescribing Guidance and Script Temp attachment. Phone prescriptions will not be accepted.

I wish you the best, and stay safe,

Dr. Delicia Pruitt, MD, MPH, FAAFP
Medical Director

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We value your opinion! Click [here](#) to provide your feedback.

2022 Updates

Dr. Delicia Pruitt, MD, MPH

Updates

- New CDC guidance for isolation and quarantine -- shortening both to 5 days
- New MDHHS guidance supporting CDC isolation and quarantine recommendations for general public and K-12 education (uncertain for congregate settings)
- Updated CDC guidance on managing healthcare personnel with COVID-19 or exposure to it
- Impending approval of booster shots for ages 12-15 and when that will be available in Saginaw County
- New guidance allowing boosters as early as 5 months after primary series rather than 6 months
- Approval of third doses for immunocompromised individuals ages 5 and older

Work Restrictions for HCP With SARS-CoV-2 Infection and Exposures

HCP are considered “boosted” if they have received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC. HCP are considered “vaccinated” or “unvaccinated” if they have NOT received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC.

For more details, including recommendations for healthcare personnel who are immunocompromised, refer to Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 (conventional standards) and Strategies to Mitigate Healthcare Personnel Staffing Shortages (contingency and crisis standards).

Work Restrictions for HCP With SARS-CoV-2 Infection

Vaccination Status	Conventional	Contingency	Crisis
Boosted, Vaccinated, or Unvaccinated	10 days OR 7 days with negative test [†] , if asymptomatic or mildly symptomatic (with improving symptoms)	5 days with/without negative test, if asymptomatic or mildly symptomatic (with improving symptoms)	No work restriction, with prioritization considerations (e.g., asymptomatic or mildly symptomatic)

Work Restrictions for Asymptomatic HCP with Exposures

Vaccination Status	Conventional	Contingency	Crisis
Boosted	No work restrictions, with negative test on days 2 [‡] and 5–7	No work restrictions	No work restrictions
Vaccinated or Unvaccinated, even if within 90 days of prior infection	10 days OR 7 days with negative test	No work restriction with negative tests on days 1 [‡] , 2, 3, & 5–7	No work restrictions (test if possible)

[†]Negative test result within 48 hours before returning to work

[‡]For calculating day of test: 1) for those with infection consider day of symptom onset (or first positive test if asymptomatic) as day 0; 2) for those with exposure consider day of exposure as day 0

Remdesivir

- A recent randomized placebo-controlled outpatient study evaluated three daily intravenous (IV) infusion of remdesivir given within seven days of symptom onset.
- This study found that the reduction in hospitalization rates was similar to that achieved by using anti-SARS-CoV-2 monoclonal antibody-based therapy (7).
- Remdesivir is expected to be effective against the Omicron variant based on in vitro data; however, in vivo data are currently limited (8).
- Outpatient use of remdesivir requires support of IV infusion centers with appropriate skilled staffing.

Antivirals

- Paxlovid (ritonavir-boosted nirmatrelvir) and molnupiravir, are now available under Emergency Use Authorization by FDA for treating COVID-19 in outpatients with mild to moderate disease.
- Each drug is administered twice daily for five days.
- There are considerable differences in efficacy, risk profiles, and use restrictions between the two oral antivirals.
- From their individual clinical trials, compared to placebo, severe outcomes (hospitalization or death) were reduced by 88% for Paxlovid compared to 30% for molnupiravir (9).
- Initiating treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy

Paxlovid

- Paxlovid is currently in very limited supply and use should be prioritized for higher risk populations.
- Due to the potential for severe drug-drug interactions with ritonavir, a medication used for HIV treatment, CDC strongly suggests that healthcare providers not experienced in prescribing Paxlovid refer to the NIH Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines.
- Healthcare providers could also contact a local clinical pharmacist or an infectious disease specialist for advice.

Paxlovid

- Used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older
- Weighing at least 88 pounds (40 kg)]
- With positive results of direct SARS-CoV-2 viral testing
- Who are at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid

- **Dosing of PAXLOVID (see full Fact Sheet for Healthcare Providers)**
- PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets. Nirmatrelvir must be co-administered with ritonavir.
- • Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
- • Administer orally with or without food.
- • Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.
- • **Dose reduction for moderate renal impairment (eGFR ≥ 30 to < 60 mL/min):** 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.
- • PAXLOVID is not recommended in patients with severe renal impairment (eGFR < 30 mL/min).
- • PAXLOVID is not recommended in patients with severe hepatic impairment (Child-Pugh Class C).
- • Alert the patient of the importance of completing the full 5-day treatment course and to continuing isolation in accordance with public health recommendations to maximize viral clearance and minimize transmission of SARS-CoV-2.

Paxlovid: Side Effects

- Possible side effects of PAXLOVID are:
- Liver Problems, loss of appetite, jaundice, dark-colored urine, pale colored stools and itchy skin, abdominal pain.
- Resistance to HIV Medicines. If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.
- Other possible side effects include: altered sense of taste, Diarrhea, high blood pressure, muscle aches

Contraindication

- Do not take PAXLOVID if:
- Allergy to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.

Taking following medicines:

- Alfuzosin o Pethidine, piroxicam, propoxyphene o Ranolazine o Amiodarone, dronedarone, flecainide, propafenone, quinidine o Colchicine o Lurasidone, pimozide, clozapine o Dihydroergotamine, ergotamine, methylergonovine o Lovastatin, simvastatin o Sildenafil (Revatio®) for pulmonary arterial hypertension (PAH) o Triazolam, oral midazolam o Apalutamide o Carbamazepine, phenobarbital, phenytoin o Rifampin o St. John's Wort (hypericum perforatum)

Molnupiravir

Molnupiravir is expected to be active against all circulating variants of concern, including Omicron (8).

Molnupiravir should only be used when other options are not available, due to its lower efficacy.

Molnupiravir use is not recommended in pregnancy because of potential mutagenicity.

Molnupiravir is also not recommended in patients who are breastfeeding or pediatric patients due to limited data within these populations and concerns for potential bone growth toxicity in the young.

Limitation of Use

- **Limitations of Authorization Use**
- • PAXLOVID and molnupiravir are not authorized in patients under 12 and 18 years of age, respectively.
- • Medications are not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- • Medications are not authorized for pre-exposure or post-exposure prophylaxis of COVID-19.
- • Medications are not authorized for use longer than 5 consecutive days.

Instructions on Prescribing Antivirals

- 1. Prescriber determines if medication is currently available in the area.
 - a. Paxlovid limited to Metro Detroit, Flint, Saginaw areas. (see [Meijer COVID-19 Therapeutics Website- Tittabawassee](#))
 - b. Molnupiravir is expected to be in all Meijer pharmacies by January 3, until then, see Page 2 below for current availability. Note this should only be prescribed when timely access to other authorized therapies (e.g., monoclonal antibodies) is delayed.
- 2. Determine if patient meets eligibility criteria for medication including review of patient's current medications for interactions (with Paxlovid).
- 3. Prescriber discusses risk and benefits with patient and provides a copy of the *FDA Fact Sheet for Patients and Care Givers* for either [Paxlovid](#) or [molnupiravir](#).

Instructions on Prescribing Antivirals

- 4. Prescriber determines closest pharmacy to patient that has desired medication.
- 5. Complete applicable prescription either via fillable PDF form or print to paper to complete.
 - a. All requested information must be provided, or prescription will not be filled.
 - b. Prescriber must sign prescription.
 - c. Include fax number of pharmacy (lower right corner of prescription) to facilitate faxing
 - d. Phone prescriptions will not be accepted.
- 6. Have prescription faxed to pharmacy. If faxing is unavailable, may provide copy to patient but this
 - will delay processing.
- 7. Meijer will make filling this prescription a priority. During pharmacy business hours should ready for
- pick up within 30 minutes. Patient should avoid entering the store for prescription pick up.

Script

(Must meet all below and FDA Emergency Use Authorization Criteria)

- ☐ Positive test for SARS-CoV-2
- ☐ Symptom onset within 5 days:
- ☐ Age \geq 12 YO and weight $>$ 40 kg
- ☐ No medication interactions identified

Specify Symptom Onset Date:

Priority Eligibility Criteria
(Must meet one of criteria below)

- ☐ Age \geq 12 YO with moderate to severe immunocompromise regardless of vaccine status **or**
Specify Condition:

- ☐ Age \geq 75 YO and not maximally vaccinated (completion of all recommended vaccinations for age group, including booster)

Patient Order

Medication: nirmatrelvir 150 mg tablet and ritonavir 100 mg tablet

Instructions: Take 1 nirmatrelvir tablet by mouth with 1 ritonavir tablet by mouth, with both tablets taken together twice daily for 5 days.

Dispense: #10 nirmatrelvir tablets and #10 ritonavir tablets (use renal adjustment sticker)

Refills: No Refills

Prescriber Name

Prescriber Signature

This is an official **CDC HEALTH ADVISORY**

Distributed via the CDC Health Alert Network
Friday, December 31, 2021, 5:00 PM ET
CDCHAN-00461

Using Therapeutics to Prevent and Treat COVID-19

Summary

The SARS-CoV-2 [Omicron](#) variant has quickly become the [dominant variant of concern](#) in the United States and is present in all 50 states. The Centers for Disease Control and Prevention (CDC) recommends that eligible individuals should get all [vaccines and booster shots](#) as the best preventive measure available against severe disease, hospitalizations, and death due to COVID-19. Therapeutics are also available for preventing and treating COVID-19 in specific [at-risk populations](#). These therapeutics differ in efficacy, route of administration, risk profile, [and whether they are authorized by the U.S Food and Drug Administration \(FDA\) for adults only or adults and certain pediatric populations](#). Some therapeutics are in short supply, but availability is expected to increase in the coming months. This Health Alert Network (HAN) Health Advisory serves to familiarize healthcare providers with available therapeutics, understand how and when to prescribe [and prioritize](#) them, and recognize contraindications.

Background

On November 24, 2021, a new variant of SARS-CoV-2, B.1.1.529 (Omicron), was reported to the [World Health Organization](#) (WHO). On December 1, 2021, the first case of COVID-19 attributed to Omicron was reported in the United States. CDC has been working with state, tribal, local, and territorial public health officials to monitor the spread of the Omicron variant in the United States and has identified a [rapid increase in infections](#) consistent with what has been observed in other countries. Current [CDC recommendations for vaccines and booster shots](#) are expected to protect against severe illness, hospitalizations, and deaths from infection with the Omicron variant. Some studies have found lower effectiveness of the primary series of vaccines against infection and demonstrated the importance of booster doses (1-3). The United States Government is continuously working with private and public partners to bring new therapeutic options for use against SARS-CoV-2 variants of concern, including the Omicron variant.

Monoclonal Antibodies

The Omicron variant, with its numerous mutations in the spike protein, is not neutralized by [bamlanivimab and etesevimab](#) or [casirivimab and imdevimab](#), the most frequently prescribed monoclonal antibody-based COVID-19 treatments (4-5). Despite some reduction in neutralization concentrations, [sotrovimab](#) remains effective against all variants of concern, including Omicron (6). However, sotrovimab is currently in limited supply, and [its use should be prioritized](#) for nonhospitalized patients with risk factors for progression to severe COVID-19, including individuals who are unvaccinated, have not received all [vaccines and booster shots as recommended by CDC](#), individuals with clinical risk factors, older age (for example ≥ 65 years of age), and [individuals not expected to mount an adequate immune response](#). Sotrovimab can be used in these [high-risk individuals](#) when Paxlovid (described below) is not indicated due to potential severe drug-drug interactions or if Paxlovid is not available.

Antivirals

- [Remdesivir](#) is a nucleoside analog approved by FDA for the treatment of hospitalized patients with COVID-19. A recent randomized placebo-controlled outpatient study evaluated three daily intravenous (IV) infusion of remdesivir given within seven days of symptom onset. This study

found that the reduction in hospitalization rates was similar to that achieved by using anti-SARS-CoV-2 monoclonal antibody-based therapy (7). Remdesivir is expected to be effective against the Omicron variant based on in vitro data; however, in vivo data are currently limited (8). Outpatient use of remdesivir requires support of IV infusion centers with appropriate skilled staffing.

- Two oral antivirals, [Paxlovid](#) (ritonavir-boosted nirmatrelvir) and [molnupiravir](#), are now available under Emergency Use Authorization by FDA for treating COVID-19 in outpatients with mild to moderate disease. Each drug is administered twice daily for five days. There are considerable differences in efficacy, risk profiles, and use restrictions between the two oral antivirals. From their individual clinical trials, compared to placebo, severe outcomes (hospitalization or death) were reduced by 88% for [Paxlovid](#) compared to 30% for molnupiravir (9). Healthcare providers need to be familiar with these distinctions to make clinical decisions and inform patients. In addition, initiating treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy. [Paxlovid](#) is currently in very limited supply and use should be prioritized for [higher risk populations](#). Due to the potential for severe drug-drug interactions with ritonavir, a medication used for HIV treatment, CDC strongly suggests that healthcare providers not experienced in prescribing [Paxlovid](#) refer to the [NIH Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines](#). Healthcare providers could also contact a local clinical pharmacist or an infectious disease specialist for advice. Like Paxlovid, molnupiravir is expected to be active against all circulating variants of concern, including Omicron (8). Molnupiravir should only be used when other options are not available, due to its lower efficacy. [Molnupiravir use is not recommended](#) in pregnancy because of potential mutagenicity. [Molnupiravir is also not recommended](#) in patients who are breastfeeding or pediatric patients due to limited data within these populations and concerns for potential bone growth toxicity in the young.

Pre-exposure therapeutics for high-risk groups

AstraZeneca's [EVUSHELD](#), which includes two long-acting anti-SARS-CoV-2 monoclonal antibodies, is the only Emergency Use Authorization pre-exposure prophylaxis product available. EVUSHELD is expected to be effective against the Omicron variant; however, treatment effectiveness should be monitored. EVUSHELD is intended for the highest risk immunocompromised patients who are not expected to have an effective response to vaccination. EVUSHELD is indicated for pre-exposure prophylaxis only and not for treatment of patients with COVID-19.

Recommendations for Healthcare Providers

- As with all therapeutics, the best use of therapeutics includes an appropriate clinical assessment and an up-to-date and informed risk-benefit discussion to address any questions or concerns from patients.
- Obtain further information on clinical use of products through [NIH's COVID-19 Treatment Guidelines](#), the [Assistant Secretary for Preparedness and Response Public Health Emergency COVID-19 Therapeutics site](#), and through professional societies such as [IDSA's Guidelines on the Management of Patients with COVID-19](#).
- Check with state and local health departments on key sites that have been identified for distribution of therapeutics, including cancer treatment centers and oncology providers.
- If the Delta variant still represents a significant proportion of infections in a region and other options are not available or are contraindicated, eligible patients can be offered [bamlanivimab and etesevimab](#) or [casirivimab and imdevimab](#), with the understanding that these treatments would be ineffective against the Omicron variant. This concern can be mitigated if [virus-specific diagnostic testing](#) in a given patient indicates infection with the Omicron variant is unlikely.
- Prioritize high risk patients, particularly if therapeutics are in short supply, using [NIH COVID-19 Treatment Guidelines when supply constraints exist](#). This document presents a tiered approach to prioritization.
- Continue to encourage COVID-19 vaccination, including booster vaccination.

Recommendations for Public Health Departments and Public Health Jurisdictions

- State and local health departments should be aware of locations of available therapeutics within their jurisdictions.
- Health departments should communicate ongoing and up-to-date information on therapeutics for COVID-19 and their availability to healthcare providers within their jurisdiction until product locators become readily available.

For More Information

- [Omicron Variant: What You Need to Know | CDC](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
- [CDC COVID Data Tracker](#)
- [COVID-19 Treatment Guidelines: What's New](#)
- [COVID-19 Treatment Guidelines: Antiviral Therapy](#)
- [NIH Statement on Therapies for High-Risk, Nonhospitalized Patients | COVID-19 Treatment Guidelines](#)
- [NIH Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines](#)
- [The COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints](#)
- [Side by Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19](#)

References

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The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

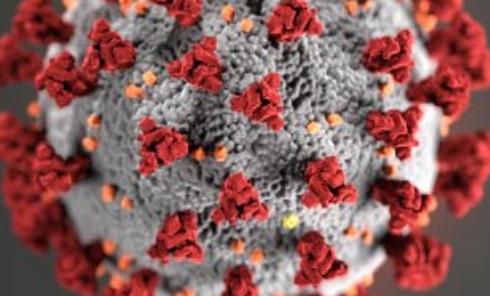
Health Alert Requires immediate action or attention, highest level of importance

Health Advisory May not require immediate action; provides important information for a specific incident or situation

Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation

HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##



Interim Priority Eligibility Criteria and Prescribing Requirements for Authorized Oral Antiviral Medications for Outpatient Treatment of Mild to Moderate COVID-19

Michigan.gov/Coronavirus

December 31, 2021

This document provides information on priority eligibility and prescribing requirements for the use of the oral antiviral medications PAXLOVID¹ and molnupiravir², both currently under emergency use authorization (EUA) by the FDA for the outpatient treatment of mild to moderate COVID-19. Prescribers must adhere to the requirements specified in the applicable FDA Fact Sheet for Healthcare Providers and by the state requirements specified below. With limited supply and high demand for these medications, Priority Eligibility Criteria have been established for antiviral and monoclonal antibody therapy based on modifications to NIH Treatment Panel Tier 1 Criteria³ ([see Page 6](#)) These interim criteria and prescribing requirements will remain in effect until supply is able to meet demand and will be periodically reviewed as appropriate.

Ethical Use of Medications: Given the limited availability of these medications, it is essential that all prescribers apply ethical principles in determining eligibility for these medications. Medications should only be prescribed in bonified clinician-patient relationships. Additional information on [ethical principles during scarce resource allocations](#) can be obtained through MDHHS.⁴

Authorized Prescribers: Per the FDA EUA, both medications may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under Michigan law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

See full applicable [Fact Sheet for Healthcare Providers](#) for the justification for emergency use of drugs during the COVID-19 pandemic, information on alternatives, and additional information on COVID-19.

Medications Not Approved: Both medications are authorized but not approved for any use, including for use as treatment of COVID-19. They may only be administered under the EUA specifications, and not “off label”. **Not approved for preventative or prophylactic purposes.**

Limitations of Authorization Use

- PAXLOVID and molnupiravir are not authorized in patients under 12 and 18 years of age, respectively.
- Medications are not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- Medications are not authorized for pre-exposure or post-exposure prophylaxis of COVID-19.
- Medications are not authorized for use longer than 5 consecutive days.

¹ [EUA 105 Pfizer Paxlovid LOA \(12222021\) \(fda.gov\)](#)

² [Molnupiravir LOA 12232021 \(fda.gov\)](#)

³ [Statement on Patient Prioritization for Outpatient Therapies | COVID-19 Treatment Guidelines \(nih.gov\)](#)

⁴ [Michigan Guidelines for Implementation of Crisis Standards of Care and Ethical Allocation of Scarce Resources \(MDHHS\)](#)

Prescribing Requirements

Because of the limited availability of these medications, certain requirements for prescribing are needed to assure that those at highest risk have access to these medications including:

1. Prior to prescribing, must communicate to the patient and/or caregiver information consistent with the applicable “FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS” and provide them with a copy (electronically is acceptable) of this prior to prescribing the medication.
2. Prescriber needs to determine closest dispensing pharmacy that has product.
-Use Locator for Meijer Pharmacies: <https://rx.meijer.com/covid19/therapeuticprogram>
3. Electronic prescriptions are preferred.
4. Telephone prescriptions will not be accepted.
5. Paper prescriptions (including faxed) may be used but must have required information, patient’s phone number and qualifying criteria as described in 6 below.
6. In addition to standard prescribing information, prescriptions must specify in the comments/notes section:
 - a. The specific applicable Priority Eligibility Criteria validating the high-risk condition that qualifies for medication administration.
 - 1) e.g., “Eligibility: Immunocompromised secondary to taking rituximab”
 - 2) e.g., “Eligibility: Unvaccinated and age 76”
 - 3) e.g., “Eligibility: Unvaccinated, age 80, and severe COPD”
 - b. The date of symptom onset (antiviral medication must be started within 5 days of symptom onset).
 - c. Prescriptions lacking this information will not be filled and may delay or prevent access to therapy.

Antiviral Therapy Dispensing Sites

- *Paxlovid* currently has limited availability through the following sites:
 - Selected Federally Qualified Health Centers and Tribal Health Centers
 - Selected [Meijer Pharmacies](#) (see Appendix)
 - Selected retail pharmacies in areas not served by Meijer (based on supply)
- *Molnupiravir* currently has limited availability through the following sites:
 - All Meijer Pharmacies (based on supply)
 - Selected retail pharmacies in areas not served by Meijer (based on supply)

Monoclonal Antibody Therapy

Treatment with mAb continues to be an important therapy for mild to moderate COVID infection and is preferred over treatment with molnupiravir whenever it can be readily accessed. Based on current evidence, mAb therapy is also a comparable alternative to Paxlovid for patients who do not have access to the oral medication, have contraindications to the medication (e.g., pregnancy), or are beyond 5 days (but within 10 days) of symptom onset. Treatment with mAb should be considered for patients who are in eligible lower risk tiers in the [Priority Eligibility Criteria](#). Prescribers should maintain awareness of locations administering mAb therapy to support timely referrals for their patients as appropriate. Additional information on mAb sites can be found on www.michigan.gov/covidtherapy

Priority Eligibility Criteria and Prescribing for Paxlovid™

Prescribers **must comply** with requirements of the US Food and Drug Administration's [Factsheet for Healthcare Providers Emergency Use Authorization for Paxlovid™](#) and with the State of Michigan Priority Eligibility Criteria for this medication. Patients must have tested positive for SARS-CoV-2.

PAXLOVID is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg), and

- with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and
- who are at high risk for progression to severe COVID-19, including hospitalization or death, and
- **who meet the current [Priority Eligibility Criteria \(see Page 6\)](#)**
- Immunocompromised patients who have received Evusheld for pre-exposure prophylaxis should not receive Paxlovid based on scarce resource allocation principles.

Dosing of PAXLOVID (see full Fact Sheet for Healthcare Providers)

PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets. Nirmatrelvir must be co-administered with ritonavir.

- Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
- Administer orally with or without food.
- Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.
- **Dose reduction for moderate renal impairment (eGFR ≥ 30 to < 60 mL/min):** 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.
- PAXLOVID is not recommended in patients with severe renal impairment (eGFR < 30 mL/min).
- PAXLOVID is not recommended in patients with severe hepatic impairment (Child-Pugh Class C).
- Alert the patient of the importance of completing the full 5-day treatment course and to continuing isolation in accordance with public health recommendations to maximize viral clearance and minimize transmission of SARS-CoV-2.

Dosage Forms of PAXLOVID

- Tablets: nirmatrelvir 150 mg
- Tablets: ritonavir 100 mg

Warning and Precautions for PAXLOVID

- The concomitant use of PAXLOVID and certain other drugs may result in potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions.
- Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir.
- HIV-1 Drug Resistance: PAXLOVID use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

Priority Eligibility Criteria and Prescribing for Paxlovid™ (continued)

Contraindications for PAXLOVID

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

Warning and Precautions

There is insufficient human data on Paxlovid in pregnancy. See the Fact Sheet for additional information. Paxlovid should be used with caution in pregnancy and only when mAb therapy is unavailable and after full discussion with patient of potential risks and benefits.

Medication Interactions and Potential for Severe Adverse Events with PAXLOVID

Co-administration of PAXLOVID can alter the plasma concentrations of other drugs and other drugs may alter the plasma concentrations of PAXLOVID. Consider the potential for drug interactions prior to and during PAXLOVID therapy and review concomitant medications during PAXLOVID therapy.

Priority Eligibility Criteria and Prescribing for Molnupiravir

Prescribers **must comply** with requirements of the US Food and Drug Administration's [Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir](#) and with the State of Michigan Priority Eligibility Criteria for this medication. Patients must have tested positive for SARS-CoV-2.

Molnupiravir is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults (18 years of age), and

- with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and
- who are at high risk for progression to severe COVID-19, including hospitalization or death, and
- for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate, and
- who meet the current [Priority Eligibility Criteria \(see Page 6\)](#)

Dosing and Administration of Molnupiravir (see full Fact Sheet for Healthcare Providers)

- 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food.
- Take molnupiravir as soon as possible after a diagnosis of COVID19 has been made, and within 5 days of symptom onset.
- Completion of the full 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2.
- Molnupiravir is not authorized for use for longer than 5 consecutive days because the safety and efficacy have not been established.

Dosage Forms of Molnupiravir

- Capsules: 200 mg

Warning and Precautions for Molnupiravir

- Use in Pregnancy /Embryo-Fetal Toxicity: **Molnupiravir is not recommended for use during pregnancy.**
- Bone and Cartilage Toxicity: Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth.

Contraindications for Molnupiravir

- No contraindications have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.
- **Not to be used in pregnancy**

Medication Interactions with Molnupiravir

No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.

Priority Eligibility Criteria for COVID-19 Outpatient Therapy

(December 31, 2021)

Tier	Eligibility Criteria	Paxlovid	Molnupiravir	Sotrovimab ⁴
	<i>Treatment must be started within:</i>	5 days	5 days	10 days
	<i>Availability:</i>	<ul style="list-style-type: none"> • Region 2N, 2S, 3 -Select Meijer • Selected FQHCs • Selected THC's 	<ul style="list-style-type: none"> • Limited Statewide -Select Meijer -Other sites 	<ul style="list-style-type: none"> • Statewide -Variable sites
1A	<ul style="list-style-type: none"> • Any age (per applicable EUA) with moderate to severe immunocompromise regardless of vaccine status or • Age ≥ 75 YO and not maximally vaccinated¹ 	Yes	Alternative ²	Yes
1B	<ul style="list-style-type: none"> • Age 65-74 YO, not maximally vaccinated¹, and with MI priority risk factor³ 	Not currently eligible	Alternative ²	Yes
2	<ul style="list-style-type: none"> • Age 65-74 YO and not maximally vaccinated¹ • Age < 65 YO, not maximally vaccinated¹ with MI priority risk factors³ 	Not currently eligible	Not currently eligible	Yes⁵
3A	<ul style="list-style-type: none"> • Age ≥ 75 YO and maximally vaccinated • Age 65-74 YO, maximally vaccinated, and with MI priority risk factors³ 	Not currently eligible	Not currently eligible	Yes⁵
3B	<ul style="list-style-type: none"> • Age 65-74 YO, maximally vaccinated, and with CDC risk factors 	Not currently eligible	Not currently eligible	Not currently eligible
4	<ul style="list-style-type: none"> • Age ≥ 65 YO and maximally vaccinated • Age < 65 YO, maximally vaccinated, and with CDC risk factors 	Not currently eligible	Not currently eligible	Not currently eligible

mAb=monoclonal antibody, FQHC=Federally Qualified Health Centers, THC=Tribal Health Centers

¹Maximally vaccinated includes completion of all recommended vaccinations for age group, including booster

²Alternatives include any other FDA authorized treatment including mAb therapy or Paxlovid that is available in a timely manner

³MI priority risk factors include:

- Obesity (BMI ≥ 35)
- Chronic respiratory disease (e.g., COPD, moderate or severe asthma requires daily inhaled corticosteroid, bronchiectasis, CF, ILD)
- Pregnancy (mAb therapy only) (Note: In pregnancy, molnupiravir should not be used and Paxlovid used with caution when other mAb is unavailable)
- Chronic Kidney Disease (stage III, IV, or end stage CKD-GFR) (special considerations with Paxlovid)
- Cardiovascular disease (e.g., HTN, valvular disease, CVA, PAD, CHF)
- Diabetes

⁴Sotrovimab is currently the only mAb therapy with activity against the Omicron variant and is in limited supply. Other mAb medications may be considered for non-Omicron.

⁵Use in lower tiers should be done only when higher tiers are able to be treated in a timely manner. Higher tier patients are a priority.

Appendix – Oral Antiviral Access through Meijer Pharmacy

Molnupiravir from Merck

Molnupiravir is being stocked at all Meijer Pharmacies in the State of Michigan based on availability.

Paxlovid from Pfizer

Due to the very limited supply and potential high demand, Paxlovid is being stocked in only 10 Meijer Pharmacies in Regions 3, 2 North and 2 South. The actual locations stocking Paxlovid is in the chart below. Availability of the medication will be listed as one of the 3 categories below on the Meijer website:

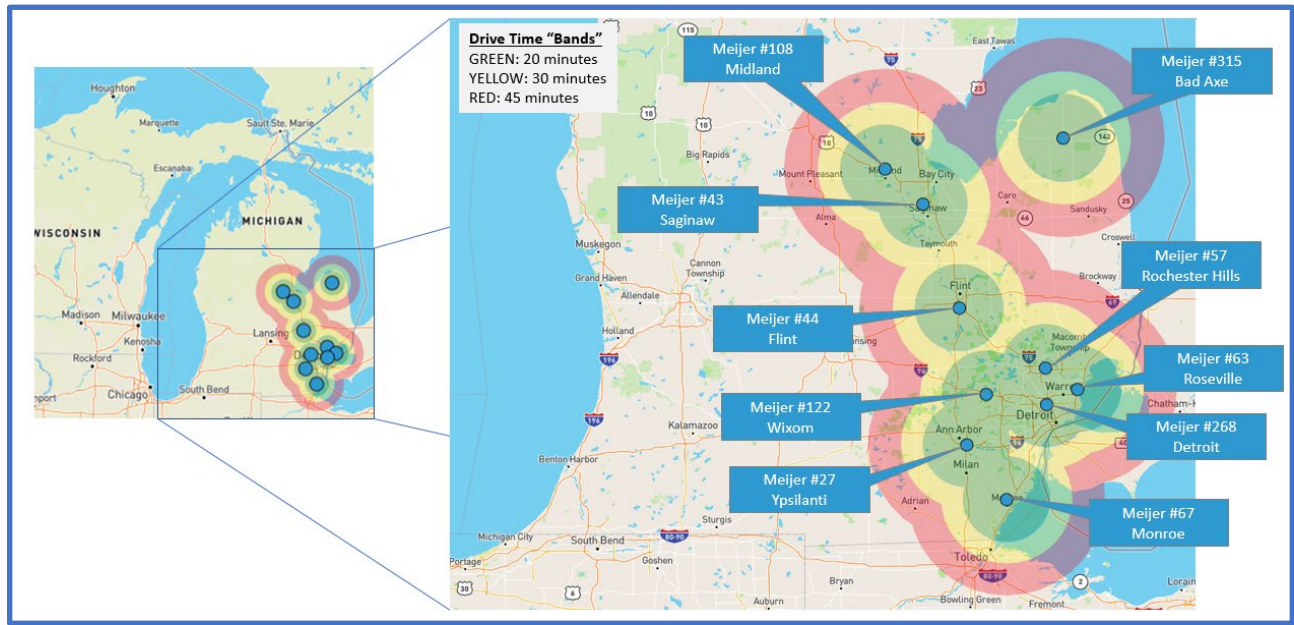
<https://rx.meijer.com/covid19/therapeuticprogram>

- **Yes** = Stock is expected to be available
- **Yes – Limited** = Supplies are projected to run out in the next 1 to 2 days. Please call and verify before referring patients.
- **No** – There is no inventory available.

Paxlovid Oral Therapeutic Program – 10 Store Locations

Meijer Store #	Common Name	Address	City	State	Zip	Pharmacy Phone	Available
27	YPSILANTI	3825 Carpenter Road	Ypsilanti	MI	48197	734-677-7110	Yes
43	TITTABAWASSEE RD.-SAGINAW	3360 Tittabawassee Road	Saginaw	MI	48604	989-249-6010	Yes
44	W. HILL RD.-FLINT	2474 W. Hill Road	Flint	MI	48507	810-766-8310	Yes
57	S. ROCHESTER RD.-ROCHESTER HILLS	3175 S. Rochester Road	Rochester Hills	MI	48307	248-844-5010	Yes
63	ROSEVILLE	30800 Little Mack Road	Roseville	MI	48066	586-415-6110	Yes
67	MONROE	1700 N. Telegraph Road	Monroe	MI	48162	734-384-8010	Yes
108	MIDLAND	7300 Eastman Avenue	Midland	MI	48642	989-837-5310	Yes
122	WIXOM	49900 Grand River Avenue	Wixom	MI	48393	248-449-8510	Yes
268	W. EIGHT MILE RD.-DETROIT	1301 W. Eight Mile Rd.	Detroit	MI	48203	313-369-5210	Yes
315	BAD AXE	100 Pigeon Rd.	Bad Axe	MI	48413	989-623-1442	Yes

Map of Meijer Pharmacies Dispensing Paxlovid



Michigan Department of Health and Human Services

Interim Instructions on Prescribing Paxlovid and Molnupiravir for COVID-19

Paxlovid and molnupiravir are oral antiviral medications that are now available on a limited basis through certain Meijer Pharmacies under an emergency use authorization issued by the FDA. E-prescribing will be the preferred way of prescribing these medications. Until e-prescribing is available, the following process should be used to prescribe these medications using a printed and faxed prescription. Prescribers must have reviewed and be in compliance with the [Interim Priority Eligibility Criteria and Prescribing Requirements for Authorized Oral Antiviral Medications for Outpatient Treatment of Mild to Moderate COVID-19](#) and with the *FDA Fact Sheet for Healthcare Providers* for either [Paxlovid](#) or [molnupiravir](#).

Instructions

1. Prescriber determines if medication is currently available in the area.
 - a. Paxlovid limited to Metro Detroit, Flint, Saginaw areas. (see [Meijer COVID-19 Therapeutics Website](#))
 - b. Molnupiravir is expected to be in all Meijer pharmacies by January 3, until then, see Page 2 below for current availability. Note this should only be prescribed when timely access to other authorized therapies (e.g., monoclonal antibodies) is delayed.
2. Determine if patient meets eligibility criteria for medication including review of patient's current medications for interactions (with Paxlovid).
3. Prescriber discusses risk and benefits with patient and provides a copy of the *FDA Fact Sheet for Patients and Care Givers* for either [Paxlovid](#) or [molnupiravir](#).
4. Prescriber determines closest pharmacy to patient that has desired medication.
5. Complete applicable prescription either via fillable PDF form or print to paper to complete.
 - a. All requested information must be provided, or prescription will not be filled.
 - b. Prescriber must sign prescription.
 - c. Include fax number of pharmacy (lower right corner of prescription) to facilitate faxing
 - d. Phone prescriptions will not be accepted.
6. Have prescription faxed to pharmacy. If faxing is unavailable, may provide copy to patient but this will delay processing.
7. Meijer will make filling this prescription a priority. During pharmacy business hours should ready for pick up within 30 minutes. Patient should avoid entering the store for prescription pick up.
8. Advise patient that:
 - a. Medication should be picked up and started as soon as possible and must be picked up within 5 days of symptom onset.
 - b. The medication is provided at no cost. Meijer will request insurance information, if available, for dispensing costs. There should not be out of pocket charges to patient.
 - c. Patients should use the drive-through window to pick-up prescription.
 - d. If patient has barriers to transportation that would delay picking up the medication, free home delivery may be arranged by having patient contact Meijer. Delivery will be made a priority but will likely result in a delay over pharmacy pick-up.

Michigan Meijer Stores with oral COVID-19 Treatments (12/31 to 1/3 Only)

Green highlighted stores have Paxlovid only. Peach has Paxlovid and molnupiravir. Remaining stores molnupiravir only. Please refer to <https://rx.meijer.com/covid19> for current instock status of the Paxlovid. Prescriptions must be e-prescribed or written - **no phone in prescriptions will be accepted.**

Store #	Pharmacy Name	ADDRESS	CITY	ST	ZIP	County	Phone	FAX	HOURS
19	Meijer Inc #19	700 West Norton Avenue	Muskegon	MI	49441-4751	Muskegon	231-733-5710	231-733-5765	M-F 9-8; S-S 10-6
20	Meijer Inc #20	2425 Alpine, NW	Grand Rapids	MI	49544	Kent	616-363-6010	616-365-6065	M-F 9-8; S-S 10-6
21	Meijer Inc #21	5800 Gull Road	Kalamazoo	MI	49048	Kalamazoo	269-337-2910	269-337-2965	M-F 9-8; S-S 10-6
22	Meijer Inc #22	5121 S. Westnedge	Portage	MI	49002	Kalamazoo	269-337-2110	269-337-2165	M-F 9-8; S-S 10-6
23	Meijer Inc #23	5125 West Saginaw	Lansing	MI	48917	Eaton	517-886-8110	517-886-8165	M-F 9-8; S-S 10-6
25	Meijer Inc #25	2055 West Grand River	Okemos	MI	48864	Igham	517-347-9110	517-347-9165	M-F 9-8; S-S 10-6
26	Meijer Inc #26	0-550 Baldwin Avenue	Jenison	MI	49428	Ottawa	616-667-2010	616-667-2065	M-F 9-8; S-S 10-6
27	Meijer Inc #27	3825 Carpenter Road	Ypsilanti	MI	48197-9606	Washtenaw	734-677-7110	734-677-7165	M-F 9-8; S-S 10-6
29	Meijer Inc #29	G-2333 South Center Road	Burton	MI	48519	Genesee	810-744-9710	810-744-9765	M-F 9-8; S-S 10-6
30	Meijer Inc #30	2777 Airport Road	Jackson	MI	49202-1239	Jackson	517-783-0010	517-783-0065	M-F 9-8; S-S 10-6
32	Meijer Inc #32	45001 Ford Road	Canton	MI	48187-2907	Wayne	734-844-2710	734-844-2765	M-F 9-8; S-S 10-6
33	Meijer Inc #33	3955 US 31 Hwy. South	Traverse City	MI	49684-4491	Grand Traverse	231-933-1810	231-933-1865	M-F 9-8; S-S 10-6
34	Meijer Inc #34	5150 Coolidge Highway	Royal Oak	MI	48073-1001	Oakland	248-280-5010	248-280-5065	M-F 9-8; S-S 10-6
35	Meijer Inc #35	14640 Pardee Road	Taylor	MI	48180-4739	Wayne	734-374-4210	734-374-4265	M-F 9-8; S-S 10-6
36	Meijer Inc #36	5500 Clyde Park, SW	Wyoming	MI	49509	Kent	616-530-7110	616-530-7165	M-F 9-8; S-S 10-6
41	Meijer Inc #41	1920 Pipestone Road	Benton Harbor	MI	49022-2315	Berrien	269-934-6710	269-934-6765	M-F 9-8; S-S 10-6
42	Meijer Inc #42	8400 Gratiot Road	Saginaw	MI	48609-4804	Saginaw	989-781-6510	989-781-6565	M-F 9-8; S-S 10-6
43	Meijer Inc #43	3360 Tittabawassee Road	Saginaw	MI	48604-9453	Saginaw	989-249-6010	989-249-6065	M-F 9-8; S-S 10-6
44	Meijer Inc #44	2474 W. Hill Road	Flint	MI	48507	Genesee	810-766-8310	810-766-8365	M-F 9-8; S-S 10-6
45	Meijer Inc #45	217 East U.S. 223	Adrian	MI	49221	Lenawee	517-266-2110	517-266-2165	M-F 9-8; S-S 10-6
46	Meijer Inc #46	8650 W. Grand River	Brighton	MI	48116	Livingston	810-220-3110	810-220-3165	M-F 9-8; S-S 10-6
57	Meijer Inc #57	3175 Rochester Road	Rochester Hills	MI	48306	Oakland	248-844-5010	248-844-5065	M-F 9-8; S-S 10-6
63	Meijer Inc #63	30800 Little Mack Road	Roseville	MI	48066-1700	Macomb	586-415-6110	586-415-6165	M-F 9-8; S-S 10-6
67	Meijer Inc #67	1700 Telegraph Road	Monroe	MI	48162-9204	Monroe	734-384-8010	734-384-8065	M-F 9-8; S-S 10-6
108	Meijer Inc #108	7300 Eastman Road	Midland	MI	48642	Midland	989-837-5310	989-837-5365	M-F 9-8; S-S 10-6
122	Meijer Inc #122	49900 Grand River Ave.	Wixom	MI	48393	Oakland	248-449-8510	248-449-8565	M-F 9-8; S-S 10-6
268	Meijer Pharmacy #268	1301 W. Eight Mile Rd.	Detroit	MI	48203	Wayne	313-369-5210	313-369-5265	M-F 9-8; S-S 10-6
315	Meijer Pharmacy #315	100 Pigeon Rd	Bad Axe	MI	48413	Huron	989-623-1442	989-623-1465	M-F 9-8; S-S 10-6

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
Standardized Prescription for Paxlovid™ for Treatment of COVID-19
-Standard Dosing (eGFR > 60 mL/min)-

Patient Information

Patient Name: _____

Patient Age: _____ **Patient DOB:** _____ **Patient Phone Number:** _____

Core Requirements

(Must meet all below and FDA Emergency Use Authorization Criteria)

Positive test for SARS-CoV-2

Symptom onset within 5 days Specify Symptom Onset Date: _____

Age \geq 12 YO and weight >40 kg

No medication interactions identified

Priority Eligibility Criteria

(Must meet one of criteria below)

_____ Age \geq 12 YO with moderate to severe immunocompromise regardless of vaccine status **or**

Specify Condition: _____

_____ Age \geq 75 YO and not maximally vaccinated (completion of all recommended vaccinations for age group, including booster)

Patient Order

Medication: nirmatrelvir 150 mg tablet and ritonavir 100 mg tablet

Instructions: Take 2 nirmatrelvir tablets by mouth with 1 ritonavir tablet by mouth, with all three tablets taken together twice daily for 5 days.

Dispense: #20 nirmatrelvir tablets and #10 ritonavir tablets

Refills: No Refills

Prescriber Name

Prescriber Signature

Prescriber Phone Number: _____

Pharmacy Fax Number: _____



Prescriber should fax to closest dispensing pharmacy with available supply

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
Standardized Prescription for Paxlovid™ for Treatment of COVID-19
-Renal Dosing (eGFR \geq 30 and <60 ml/min)-

Patient Information

Patient Name: _____

Patient Age: _____ **Patient DOB:** _____ **Patient Phone Number:** _____

Core Requirements

(Must meet all below and FDA Emergency Use Authorization Criteria)

Positive test for SARS-CoV-2

Symptom onset within 5 days:

Specify Symptom Onset Date: _____

Age \geq 12 YO and weight >40 kg

No medication interactions identified

Priority Eligibility Criteria

(Must meet one of criteria below)

____ Age \geq 12 YO with moderate to severe immunocompromise regardless of vaccine status **or**

Specify Condition: _____

____ Age \geq 75 YO and not maximally vaccinated (completion of all recommended vaccinations for age group, including booster)

Patient Order

Medication: nirmatrelvir 150 mg tablet and ritonavir 100 mg tablet

Instructions: Take 1 nirmatrelvir tablet by mouth with 1 ritonavir tablet by mouth, with both tablets taken together twice daily for 5 days.

Dispense: #10 nirmatrelvir tablets and #10 ritonavir tablets (use renal adjustment sticker)

Refills: No Refills

Prescriber Name

Prescriber Signature

Prescriber Phone Number: _____

Pharmacy Fax Number: _____



Prescriber should fax to closest dispensing pharmacy with available supply

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
Standardized Prescription for Molnupiravir for Treatment of COVID-19

Patient Information

Patient Name: _____

Patient Age: _____ **Patient DOB:** _____ **Patient Phone Number:** _____

Core Requirements

(Must meet all below and FDA Emergency Use Authorization Criteria)

Positive test for SARS-CoV-2

Symptoms within 5 days: _____ Specify Symptom Onset Date: _____

Age >18 YO

Patient not Pregnant

Alternative authorized FDA therapy is not readily available

Priority Eligibility Criteria

(Must meet one below)

Age > 18 YO with moderate to severe immunocompromise regardless of vaccine status **or**

Specify Condition: _____

Age >75 YO and not maximally vaccinated (completion of all recommended vaccinations for age group, including booster)

____ Age 65-74 YO not maximally vaccinated (completion of all recommended vaccinations for age group, including booster) AND at least one of the following (check all applicable):

Obesity (BMI > 35)

Chronic respiratory disease (e.g., COPD, moderate/severe asthma on daily medication, bronchiectasis, CF, ILD)

Chronic Kidney Disease (stage III, IV, or end stage CKD-GFR) (special considerations with Paxlovid)

Cardiovascular disease (e.g., HTN, valvular disease, CVA, PAD, CHF)

Diabetes

Patient Order

Medication: molnupiravir 200mg capsules

Instructions: Take 4 capsules by mouth every 12 hours for 5 days, with or without food

Dispense: #40 molnupiravir capsules

Refills: No Refills

Prescriber Name

Prescriber Signature

Prescriber Phone Number:

Pharmacy Fax Number:



Prescriber should fax to closest dispensing pharmacy with available supply