Prescribing Oral Antivirals Paxlovid and Molnupiravir for COVID-19

In December 2021, the Food and Drug Administration granted emergency use authorization (EUA) for oral COVID-19 antivirals, Paxlovid and Monupiravir. The EUA was specific to outpatient treatment of mild to moderate COVID-19 for persons at **high risk for progression to severe COVID-19**, including hospitalization or death. HAP supports access to these highly effective treatments, therefore, **there is no member copay or cost share and there is no prior authorization criteria.** Due to limited supply, the State of Michigan has created a narrow prioritization framework for eligibility, but it is anticipated that eligibility will broaden as supply increases. Below is important information for prescribing these medications.

Prescriber Requirements

Due to limited availability of these medications, prescribers must meet the requirements below to ensure persons at highest risk have access to these medications. As quantities of medication increase, prescribing requirements are likely to change to increase access for more patient populations.

- Provide a Fact Sheet prior to prescribing
- Determine the closest confirmed availability of the product prior to prescribing
- Fax the State's authorized form or electronic prescription (no telephone orders)
- Specify high-risk condition that meets priority eligibility criteria **and** date of symptom onset

Please see the tables on the next page for criteria to help meet the above requirements.

Exclusions

Oral COVID antivirals are not for:

- Initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19
- Pre-exposure or post-exposure prophylaxis of COVID-19
- Use longer than five consecutive days

Monoclonal Antibody Therapy

Treatment with Sotrovimab (mAb) continues to be an important therapy for mild to moderate COVID-19 infection. It's 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)
- Are beyond five days (but within 10 days) of symptom onset

Treatment with mAb should be considered for patients who are in eligible lower risk tiers.

For more information, please visit:

- https://www.michigan.gov/coronavirus/0,9753,7-406-98163-575198--,00.html
- https://www.michigan.gov/documents/coronavirus/Priority_Eligibility_Criteria_for_COVID-19_Outpatient_Therapy_745091_7.pdf

We are committed to partnering with you to improve the health of our communities.

Paxlovid

Michigan Priority Eligibility	CDC Definition of Moderately or Severely Immunocompromised
• Patients 12 or older (at least 40 kg) with moderate to severe immunocompromise regardless of vaccination status • 75 or older and not maximally vaccinated (including booster)	• Active cancer treatment for tumors or cancers of the blood • Organ transplant and are taking medicine to suppress the immune system • Stem cell transplant within the last 2 years or are taking medicine to suppress the immune system • Moderate or severe primary immunodeficiency • Advanced or untreated HIV infection • Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response
Dosing	**Contraindications/warnings/precautions**
• 300 mg nirmatrelvir (two 150 mg tablets) • 100 mg ritonavir (one 100 mg tablet) • 3 tablets taken together twice daily for 5 days [30 tablets]	• Hypersensitivity to components • Co-administration with CYP3A4 substrates/inducers • Abundant, complex & clinically significant drug-drug interactions** • Hepatotoxicity – LFT elevations, clinical hepatitis and jaundice have occurred; Not recommended in severe liver impairment [Child-Pugh Class C] • Kidney disease – Dose reduction in eGFR 30 to <60 ml/min [reduce each nirmatrelvir dose by 150 mg, 1 tablet]. Not recommended in eGFR<30 ml/min; • HIV-1 drug resistance
• Treatment should be initiated as soon as possible after confirmed diagnosis and within 5 days of symptom onset. • Product availability must be confirmed here https://rx.meijer.com/covid19/therapeuticprogram	

Molnupiravir

Michigan Priority Eligibility	Michigan Priority Risk Factors
• Alternative for nonpregnant patients 18 and older unable to access other FDA authorized treatments including mAb therapy or Paxlovid • Alternative for patients aged 65-74 not maximally vaccinated (including booster) with Michigan priority risk factors	• 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) • Cardiovascular disease (e.g., HTN, valvular disease, CVA, PAD, CHF) • Diabetes
Dosing	**Contraindications/Warnings/Precautions**
• 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days. [40 capsules]	• Embryo-Fetal Toxicity: Molnupiravir is not recommended for use during pregnancy or lactation – Contraception during and 4 days after last dose. Discard breastmilk during and 4 days after last dose. • Bone and Cartilage Toxicity: not authorized for use in patients <18 years, may affect bone and cartilage growth
• Treatment should be initiated as soon as possible after confirmed diagnosis and within 5 days of symptom onset.	