Priority Eligibility Criteria and Prescribing for Paxlovid™

Prescribers **must comply** with requirements of the US Food and Drug Administration's <u>Factsheet for Healthcare Providers Emergency Use Authorization for Paxlovid™</u> 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 mgTablets: 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.