COVID-19 Oral Antiviral Treatments Key Points

Oral Agent	**Nirmatrelvir/Ritonavir tablets (Paxlovid™)**	**Molnupiravir capsules**
Authorization Date	12/22/2021	12/23/2021
Manufacturer	Pfizer	Merck
Mechanisms of Action	Protease inhibitor targeting viral RNA polymerase	Induces errors in viral RNA
Duration of Treatment	**5 days** (Completing regimen is an important counseling point) in ambulatory patients	
Indication for Treatment	Mild-moderate COVID-19 for patients **12 years of age and older** weighing at least 40 kg with positive SARS-COV-2 diagnostic test who are at high risk for disease progression	Mild-moderate COVID-19 in **adults** with positive SARS-COV-2 diagnostic test who are at high risk for disease progression
When to Initiate Treatment	Initiate treatment soon after diagnosis of COVID-19 and **within 5 days of symptom onset** [Early treatment depends on access to early testing]	
How Supplied	150 mg nirmatrelvir tablets AND 100 mg ritonavir tablets	200 mg capsules
Dosing Instructions	• eGFR ≥ 60 mL/min: 300 mg nirmatrelvir (2 tablets) with 100 mg ritonavir (1 tablet), with all 3 tablets taken together twice daily for 5 days. • eGFR ≥ 30 to < 60 mL/min: 150 mg nirmatrelvir (1 tablet) with 100 mg ritonavir (1 tablet), both tablets taken together twice daily for 5 days	800 mg (4 capsules) twice daily for 5 days
Inclusion/Exclusion Criteria	For study inclusion/exclusion criteria from pivotal study, visit EPIC-HR study link	For study inclusion/exclusion criteria from pivotal study, visit MOVe-OUT study link
Key counseling Points	• Thoroughly screen each patient to be treated with Paxlovid for potential drug-drug interactions utilizing a tertiary drug resource (https://www.covid19-druginteractions.org/) • If on cobicistat and ritonavir products, continue as indicated with no dose adjustment • Renal dose adjustment labels can be ordered at C19therapies@amerisourcebergen.com if needed. See Paxlovid Renal Impairment Dispensing Information • Ritonavir can decrease efficacy of hormonal contraceptives and an additional non-hormonal method should be considered	• Completion of 5-day treatment course especially important to maximize viral clearance • Males of reproductive potential who are sexually active with females of reproductive potential: Use reliable contraception during treatment and for at least 3 months after last dose • Females of reproductive potential: Use reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose
Special Populations Considerations	• Renal impairment: Not recommended in patients with **eGFR < 30 mL/min** or receiving dialysis • Hepatic impairment: Not recommended in patients with **Child-Pugh Class C** hepatic impairment • Pregnancy/Lactation: Not studied in pregnant or breastfeeding patients	• Lactation: Advise patients to **avoid breastfeeding** during treatment and for 4 days after last dose • Pregnancy/Lactation: **Not** recommended
Key Warnings, Precautions and Contraindications	✓ eGFR < 30 mL/min or receiving dialysis ✓ History of clinically significant hypersensitivity reactions to either active component ✓ Co-administration with drugs highly dependent on **CYP3A or drugs that are potent CYP3A inducers** ✓ Hepatotoxicity: Ritonavir may cause hepatic transaminase elevations, clinical hepatitis, and jaundice ✓ HIV-1 Drug Resistance: Risk of HIV-1 resistance developing to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection	✓ No renal or hepatic dose adjustments (not studied in eGFR < 30 mL/min) ✓ Bone and Cartilage Toxicity: Not authorized in patients under 18 due to potential effects on bone and cartilage growth ✓ Potential embryo-fetal toxicity
	✓ Use of effective contraception methods required in both males and females	
Adverse Reactions	Most common adverse reactions were dysgeusia, diarrhea, hypertension, and myalgia	Most common adverse reactions were diarrhea, nausea, and dizziness
Other Resources	Paxlovid Fact Sheet for Healthcare Providers Paxlovid Fact Sheet for Patients/Caregivers Paxlovid Renal Impairment Dispensing Information CPS Paxlovid New Drug Summary	Molnupiravir Fact Sheet for Healthcare Providers Molnupiravir Fact Sheet for Patients/Caregivers Molnupiravir Checklist Tool for Prescribers CPS Molnupiravir New Drug Summary

CYP3A4= Cytochrome P450 Family 3 Subfamily A Member 4; eGFR= estimated glomerular filtration rate; RNA= ribonucleic acid