Billing and Coding Guide for PAXLOVID

INDICATION

PAXLOVID is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitations of Use

PAXLOVID is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

IMPORTANT SAFETY INFORMATION

WARNING: SIGNIFICANT DRUG INTERACTIONS WITH PAXLOVID

- **PAXLOVID includes ritonavir, a strong CYP3A inhibitor, which may lead to greater exposure of certain concomitant medications, resulting in potentially severe, life-threatening, and/or fatal events**
- **Prior to prescribing PAXLOVID: 1) Review all medications taken by the patient to assess for potential drug-drug interactions with a strong CYP3A inhibitor like PAXLOVID and 2) Determine if concomitant medications require a dose adjustment, interruption, and/or additional monitoring**
- **Consider the benefit of PAXLOVID treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed**

Please see complete Important Safety Information, as well as Full Prescribing Information, including BOXED WARNING and Patient Information.

Pfizer

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Paxlovid™

(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)

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Disclaimer

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for COVID-19 testing, PAXLOVID, or PAXLOVID prescription dispensing, assessment, and consultation fees. Coding and coverage policies change periodically, and often without warning. The healthcare provider (HCP) is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for PAXLOVID or PAXLOVID prescription dispensing, assessment, and consultation fees.

This information is not meant to be comprehensive, and customers should refer to the full list of codes on the PAXLOVID Prescribing Information, the FDA website, and/or the CMS website.

IMPORTANT SAFETY INFORMATION (CONT'D)

PAXLOVID is **contraindicated in patients with a history of clinically significant hypersensitivity reactions** (eg, toxic epidermal necrolysis or Stevens-Johnson syndrome) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue PAXLOVID and initiate appropriate medications and/or supportive care.

PAXLOVID is **contraindicated with drugs that are primarily metabolized by CYP3A and for which elevated concentrations are associated with serious and/or life-threatening reactions and drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.**

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COVID-19 testing codes[1]

HCPs and pharmacists are responsible for determining appropriate codes based upon actual patient circumstances. The following codes may be appropriate when submitting a claim for COVID-19 testing.

CPT code	Short descriptor
U0001	2019-Ncov Diagnostic P
U0002	Covid-19 Lab Test Non-CDC
87635	SarsCov2 Covid19 Amp Prb
87636	SarsCov2 & Inf A&B Amp Prb
87637	SarsCov2 & Inf A&B&RSV Amp Prb
0240U	Nfct DS Vir Resp RNA 3 Trgt
0241U	Nfct DS Vir Resp RNA 4 Trgt
87426	SarsCov Coronavirus AG IA
87428	SarsCov & Inf Vir A&B AG IA
87811	SarsCov2 Covid19 W/Optic
86328	Ia Nfct A&B SarsCov2 Covid19
86408	Neutrlzg Antb SarsCov2 Scr
86409	Neutrlzg Antb SarsCov2 Titer
86413	SarsCov2 Antb Quantative
86769	SarsCov2 Covid19 Antibody
0224U	Antibody SarsCov2 Titer(s)
0226U	Svnt SarsCov2 Elisa Plsm Srm

CPT=Current Procedural Terminology; HCP=healthcare provider.

IMPORTANT SAFETY INFORMATION (CONT'D)

There are certain other drugs for which concomitant use with PAXLOVID should be avoided and/or dose adjustment, interruption, or therapeutic monitoring is recommended. Drugs listed here are a guide and not considered a comprehensive list of all drugs that may be contraindicated with PAXLOVID. The healthcare provider should consult other appropriate resources such as the prescribing information for the interacting drug for comprehensive information on dosing or monitoring with concomitant use of a strong CYP3A inhibitor like PAXLOVID.

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Diagnosis coding for COVID-19

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, as appropriate, to report the patient-specific diagnosis.

ICD-10-CM codes may include, but are not limited to, the code listed below[2]:

ICD-10-CM code	Descriptor
U07.1	COVID-19

Pharmacist-specific codes for patient evaluation and management[3]

The following codes may be appropriate for pharmacists to use when evaluating a patient for COVID-19. Pharmacists are responsible for determining appropriate codes based upon actual patient circumstances.

New patient	Time spent
99202	15-29 minutes
99203	30-44 minutes

Established patient	Time spent
99211	<10 minutes
99212	10-19 minutes
99213	20-29 minutes

IMPORTANT SAFETY INFORMATION (CONT'D)

Drugs that are primarily metabolized by CYP3A for which elevated concentrations are associated with serious and/or life-threatening reactions: Alpha 1-adrenoreceptor antagonist: alfuzosin; Antianginal: ranolazine; Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine; Anti-gout: colchicine (in patients with renal and/or hepatic impairment); Antipsychotics: lurasidone, pimozide; Benign prostatic hyperplasia agents: silodosin; Cardiovascular agents: eplerenone, ivabradine; Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine; HMG-CoA reductase inhibitors: lovastatin, simvastatin (these drugs can be temporarily discontinued to allow PAXLOVID use); Immunosuppressants: voclosporin; Microsomal triglyceride transfer protein inhibitor: lomitapide; Migraine medications: eletriptan, ubrogepant; Mineralocorticoid receptor antagonists: finerenone; Opioid antagonists: naloxegol; PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension; Sedative/hypnotics: triazolam, oral midazolam; Serotonin receptor 1A agonist/serotonin receptor 2A antagonist: flibanserin; Vasopressin receptor antagonists: tolvaptan.

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PAXLOVID coding overview for commercial supply[4]

The following NDCs for PAXLOVID prescription are typically included on claim forms for commercially insured patients:

Dose	Carton NDC	Blister card NDC
Standard dose: 300 mg nirmatrelvir; 100 mg ritonavir	0-0069-5321-30	0-0069-5321-03
Reduced dose: 150 mg nirmatrelvir; 100 mg ritonavir	0-0069-5317-20	0-0069-5317-02

NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (CONT'D)

Drugs that are strong CYP3A inducers: PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer: Anticancer drugs: apalutamide; Anticonvulsant: carbamazepine, phenobarbital, primidone, phenytoin; Antimycobacterials: rifampin, rifapentine; Cystic fibrosis transmembrane conductance regulator potentiators: lumacaftor/ivacaftor; Herbal Products: St. John's Wort (*hypericum perforatum*).

Risk of Serious Adverse Reactions Due to Drug Interactions: Initiation of PAXLOVID, which contains ritonavir, a strong CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving PAXLOVID, may increase plasma concentrations of medications metabolized by CYP3A. Medications that induce CYP3A may decrease concentrations of PAXLOVID. These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications
- Loss of therapeutic effect of PAXLOVID and possible development of viral resistance

Severe, life-threatening, and/or fatal adverse reactions due to drug interactions have been reported in patients treated with PAXLOVID. The most commonly reported concomitant medications resulting in serious adverse reactions were calcineurin inhibitors (eg, tacrolimus, cyclosporine), followed by calcium channel blockers.

Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. Therefore, caution should be exercised when administering PAXLOVID to patients with **pre-existing liver diseases, liver enzyme abnormalities, or hepatitis**.

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PAXCESS™ Patient Support Program

The PAXCESS Patient Support Program offers insurance coverage information and provides financial assistance resources to eligible patients who are 18 years of age and older who have been prescribed PAXLOVID. Available resources include:

Insurance benefits verification

Help with identifying financial assistance options

Your patients may be eligible for financial assistance, including the Co-Pay Savings Program

Live PAXCESS representatives

Our team can provide help with understanding insurance coverage and program eligibility

With the PAXCESS Co-Pay Savings Program,

Patients may pay as little as $0* for PAXLOVID

Shown in image: the PAXLOVID PAXCESS™ Co-Pay Card, front and back.

The PAXCESS Co-Pay Savings Program is for eligible prescribed patients with commercial insurance.

Patients enrolled in federal programs such as Medicare, Medicaid, and Veterans Affairs healthcare are not eligible for the PAXCESS Co-Pay Savings Program. However, they may qualify for other financial assistance resources for PAXLOVID. Please visit PAXCESSpatientportal.com to learn more.

PAXCESS representatives can verify your patient's health insurance coverage to determine what financial assistance resources they may be eligible for.

*Eligible commercially insured patients can save up to $1,250 per prescription. Annual savings up to $1,250. Federal and state healthcare insurance beneficiaries are not eligible. Terms and conditions apply.

IMPORTANT SAFETY INFORMATION (CONT'D)

Because nirmatrelvir is coadministered with ritonavir, there may be a **risk of HIV-1 developing resistance to HIV protease inhibitors** in individuals with uncontrolled or undiagnosed HIV-1 infection.

The most common **adverse reactions** in the PAXLOVID group (≥1%) that occurred at a greater frequency than in the placebo group were dysgeusia (5% and <1%, respectively) and diarrhea (3% and 2%, respectively).

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IMPORTANT SAFETY INFORMATION (CONT'D)

The following adverse reactions have been identified during use of PAXLOVID under Emergency Use Authorization:

Immune System Disorders: Anaphylaxis, hypersensitivity reactions

Skin and Subcutaneous Tissue Disorders: Toxic epidermal necrolysis, Stevens-Johnson syndrome

Nervous System Disorders: Headache

Vascular Disorders: Hypertension

Gastrointestinal Disorders: Abdominal pain, nausea, vomiting

General Disorders and Administration Site Conditions: Malaise

PAXLOVID is a strong inhibitor of CYP3A, and an inhibitor of CYP2D6, P-gp, and OATP1B1. Coadministration of PAXLOVID with drugs that are primarily metabolized by CYP3A and CYP2D6 or are transported by P-gp or OATP1B1 may result in increased plasma concentrations of such drugs and increase the risk of adverse events. Coadministration with other CYP3A substrates may require a dose adjustment or additional monitoring.

Pregnancy: Available data on the use of nirmatrelvir during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Published observational studies on ritonavir use in pregnant women have not identified an increase in the risk of major birth defects. Published studies with ritonavir are insufficient to identify a drug-associated risk of miscarriage. There are maternal and fetal risks associated with untreated COVID-19 in pregnancy.

Lactation: There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production. A transient decrease in body weight was observed in the nursing offspring of rats administered nirmatrelvir. Limited published data report that ritonavir is present in human milk. There is no information on the effects of ritonavir on the breastfed infant or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAXLOVID and any potential adverse effects on the breastfed infant from PAXLOVID or from the underlying maternal condition.

Contraception: Use of ritonavir may reduce the efficacy of combined hormonal contraceptives. Advise patients using combined hormonal contraceptives to use an effective alternative contraceptive method or an additional barrier method of contraception.

Pediatrics: The optimal dose of PAXLOVID has not been established in pediatric patients.

Systemic exposure of nirmatrelvir increases in renally impaired patients with increase in the severity of renal impairment. No dosage adjustment is recommended in patients with mild renal impairment. **Reduce the dose of PAXLOVID in patients with moderate renal impairment** (eGFR ≥30 to <60 mL/min). **PAXLOVID is not recommended in patients with severe renal impairment** (eGFR <30 mL/min) **or in patients with end-stage renal disease** (eGFR <15 mL/min).

PAXLOVID is not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C).

References: 1. Centers for Medicare & Medicaid Services. Medicare administrative contractor (MAC) COVID-19 test pricing. Published January 25, 2021. Accessed September 12, 2023. https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf **2.** Centers for Disease Control and Prevention. National Center for Health Statistics--ICD-10-CM: index to diseases and injuries. Accessed August 11, 2023. https://icd10cmtool.cdc.gov/?fy=FY2023&query=U07.1 **3.** Arkansas Pharmacists Association/University of Arkansas for Medical Sciences (UAMS) College of Pharmacy. 2023 pharmacist prescribing & medical billing resource guide. V1.06.2023. Published June 2023. **4.** Paxlovid. Prescribing information. Pfizer Inc.; 2023.

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