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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Anti-Infective Agents	**Original Policy Date:**	January 7, 2022
Subject:	COVID-19 Oral Antiviral Agents	**Page:**	1 of 5

Last Review Date: June 11, 2026

COVID-19 Oral Antiviral Agents

Description

Paxlovid (nirmatrelvir and ritonavir)

Background

Coronavirus disease 2019 (COVID-19) is caused by the novel coronavirus SARS-CoV-2. SARS-CoV-2 is an RNA virus that is associated with acute respiratory tract illness in humans. Symptoms may be mild to severe and generally occur within 2 to 14 days of exposure to SARS-CoV-2. The clinical course of COVID-19 is variable, but severe outcomes, including death, have occurred. Between 20- 30% of patients hospitalized do require mechanical respiratory support (1).

The intent of this criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Paxlovid has full regular FDA-approval for use in adults 18 years and older, while use in pediatric patients 12 to 17 years of age is covered under the emergency use authorization (EUA). Paxlovid is a combination of nirmatrelvir and ritonavir. Nirmatrelvir targets the SARS-CoV-2 main protease (Mpro), inhibiting protein processing and leading to inhibition of replication. Ritonavir inhibits the metabolism of nirmatrelvir, allowing it to exert its therapeutic effect longer before being inactivated (2-3).

Regulatory Status

Indications granted by the FDA: (2-3)

1. Paxlovid

- FDA-approved 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.
    i. Limitations of use: Paxlovid is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Emergency Use Authorization: The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved Paxlovid which includes nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in pediatric patients (12 years of age and older weighing at least 40 kg) 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.
    i. Limitations of authorized use:
        1. Paxlovid is not authorized:
            a. For initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
            b. For pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
            c. For use longer than 5 consecutive days.

Paxlovid is approved for use in adults 18 years of age or older, while the EUA of Paxlovid does not allow use in pediatric patients less than 12 years of age and weighing less than 40 kg (2-3).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Paxlovid may be considered **medically necessary** if the conditions indicated below are met.

Paxlovid may be considered **investigational** for all other indications.

Prior-Approval Requirements

Paxlovid has a Pre-PA allowance, the quantity that can be filled without a prior authorization (PA). Pre-PA quantity limit allows one 5-day fill every 30 days.

Age 12 years of age or older

Diagnosis

Patient must have the following:

Coronavirus disease 2019 (COVID-19)

a. Diagnosis confirmed by direct SARS-CoV-2 viral testing
b. Patient is at high risk for progression to severe COVID-19

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre–PA Allowance

Age 12 years of age or older

Drug	Quantity Limit**	Additional Requirements
Paxlovid [nirmatrelvir 300 mg (2 x 150mg) tablet and ritonavir 100mg]	30 tablets per 30 days (1 carton contains 20 tablets of nirmatrelvir tablets and 10 tablets of ritonavir)	Max day supply of 5 days
Paxlovid (nirmatrelvir 150mg tablet and ritonavir 100mg)	20 tablets per 30 days (1 carton contains 10 tablets of nirmatrelvir and 10 tablets of ritonavir)	
Paxlovid (nirmatrelvir 150mg tablet and ritonavir 100mg)	11 tablets per 30 days (1 carton contains 6 tablets of nirmatrelvir and 5 tablets of ritonavir)	

Quantity sufficient to allow one 5-day fill every 30 days. If the request exceeds the Pre-PA

quantity limit, the claim will reject with a message indicating a PA is needed.

Prior–Approval Limits

Drug	Quantity Limit
Paxlovid [nirmatrelvir 300 mg (2 x 150mg) tablet and ritonavir 100mg]	Pre-PA allows for the FDA recommended maximum dosage
Paxlovid (nirmatrelvir 150mg tablet and ritonavir 100mg)	

Duration 30 days

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Paxlovid (nirmatrelvir and ritonavir) is an antiviral agent granted authorization under an FDA emergency use agreement and full FDA approval for the treatment of mild-to-moderate COVID-19. Paxlovid is not for use in patients that are hospitalized. The agent should be started within 5 days of symptom onset and taken for no longer than 5 consecutive days (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Paxlovid while maintaining optimal therapeutic outcomes.

References

1. National Institutes of Health COVID-19 Treatment Guidelines Panel: Perspectives and Lessons Learned. RM Gulick, AK Pau, E Daar et al. Ann Intern Medicine. 2025 Nov; 177(11):1547-1557. doi: 10.7326/ANNALS-24-00464
2. Paxlovid [package insert]. New York, NY: Pfizer Labs; February 2026.
3. Paxlovid [Emergency Use Authorization Fact Sheet for Health Care Providers]. New York, NY: Pfizer; April 2022.

Policy History

Date	Action
January 2022	Addition to PA
June 2022	Addition of Paxlovid new strength/carton (nirmatrelvir 150mg tablet and ritonavir 100mg)
September 2023	Annual review and reference update. Changed policy number to 5.01.074
March 2024	Annual review
March 2025	Annual review and reference update. Per SME, added requirement that patient be at risk of progression to severe COVID-19
May 2025	Addition of new Paxlovid package containing 11 tablets per carton/blister card
June 2025	Annual review
March 2026	Annual review
April 2026	Removal of molnupiravir from policy
June 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.