# PAXLOVID Oral COVID-19 treatment available on the Pharmaceutical Benefits Scheme from 1 May

**EMBARGOED 29 April 2022 AEST**

- *PAXLOVID™ (nirmatrelvir tablets and ritonavir tablets) will be available on the Pharmaceutical Benefits Scheme (PBS) on 1 May 2022 for the treatment of COVID-19 in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.[1]*
- *PAXLOVID is the first oral treatment of its kind; it includes nirmatrelvir, a 3CL (or main) protease inhibitor that was specifically designed to combat SARS-CoV-2.*
- *PAXLOVID is intended to be given within five days of the onset of symptoms.[1]*

**SYDNEY, AUSTRALIA, 29 April 2022** – From 1 May 2022, PAXLOVID™ (*nirmatrelvir tablets and ritonavir tablets*) will be available on the Pharmaceutical Benefits Scheme (PBS).

PAXLOVID will be available on the PBS for certain high-risk patients with mild-moderate COVID-19 disease not requiring supplemental oxygen for their COVID-19 and where treatment is commenced within five days of the onset of symptoms.[1]

Pfizer Australia & New Zealand Managing Director, Anne Harris, said the listing was another important milestone in the fight against COVID-19.

“While vaccination remains the most effective way to help prevent COVID-19, we know we need to tackle the virus on many fronts. PAXLOVID provides an important second line of defence for those most at risk.

“Simpler access to PAXLOVID means patients can access this important oral treatment at home,” Ms Harris said.

Pfizer Australia and New Zealand Medical Director, Dr Krishan Thiru, said “PAXLOVID is a first-of-its-kind oral antiviral treatment for COVID-19 specifically designed to combat SARS-CoV-2.

“This antiviral treatment works by slowing or stopping the virus from replicating, which may help reduce the risk of significant health consequences seen more commonly in people at higher risk.

“It’s important to get tested for COVID-19 at the first sign of symptoms, especially for people at higher risk. If they are COVID-19 positive, they can seek medical advice quickly and find out what treatment may be appropriate for them,” Dr Thiru said.

PAXLOVID is an oral treatment taken twice-daily for five days. It should be taken as soon as possible after a diagnosis of COVID-19, and within five days of symptoms appearing.[1]

Adults who have mild to moderate COVID-19 – confirmed by a COVID-19 Polymerase Chain Reaction (PCR) test result or a verified Rapid Antigen Test (RAT)[2] – and who can start treatment within five days of symptoms appearing, can be prescribed PAXLOVID by their doctor or nurse practitioner if they are:

- 65 years of age or older, with two other risk factors for severe disease (as increasing age is a risk factor, patients who are 75 years of age or older only need to have one other risk factor),

- Aboriginal or Torres Strait Islander, and are 50 years of age or older with two other risk factors for severe disease, or
- moderately to severely immunocompromised.[2]

PAXLOVID was provisionally approved by the Therapeutic Goods Administration (TGA) on 18 January 2022, for the treatment of adults with COVID-19 who do not require initiation of oxygen and who are at increased risk of progression to hospitalisation or death.

**PBS Information:** Authority Required (STREAMLINED).
Category: GENERAL – General Schedule (Code GE).
For verified SARS-CoV-2 infection. Treatment must be initiated within 5 days of symptom onset.
**Refer to PBS Schedule for full authority information.**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Patients can help by reporting any side effects they may get. Patients can report side effects to their doctor, or directly at www.tga.gov.au/reporting-problems.

For more information on PAXLOVID, consult a healthcare professional.

The Consumer Medicines Information leaflet is available from: CMI: PAXLOVID™ (tga.gov.au).

**About PAXLOVID™ (nirmatrelvir tablets and ritonavir tablets)**
PAXLOVID is a SARS-CoV-2 main protease ($M^{pro}$) inhibitor (also known as SARS-CoV-2 3CL protease inhibitor) therapy. It was developed to be administered orally so that it can be prescribed at the first sign of infection or, pending clinical success of the rest of the EPIC development program and subject to regulatory authorisation, at first awareness of an exposure – potentially helping patients avoid severe illness (which can lead to hospitalisation and death) or avoid disease development following contact with a household member who contracts COVID-19. Nirmatrelvir, which was developed originated in Pfizer laboratories, is designed to block the activity of the $M^{pro}$, an enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir helps slow the metabolism, or breakdown, of nirmatrelvir in order for it to remain active in the body for longer periods of time at higher concentrations to help combat the virus.

Nirmatrelvir is designed to inhibit viral replication at a stage known as proteolysis, which occurs before viral RNA replication. In preclinical studies, nirmatrelvir did not demonstrate evidence of mutagenic DNA interactions.

Current variants of concern can be resistant to treatments that work by binding to the spike protein found on the surface of the SARS-CoV-2 virus. PAXLOVID, however, works intracellularly by binding to the highly conserved $M^{pro}$ of the SARS-CoV-2 virus to inhibit viral replication. Nirmatrelvir has shown consistent *in vitro* antiviral activity against earlier and current variants of concern (i.e., Alpha, Beta, Delta, Gamma, Lambda, Mu, and Omicron).

PAXLOVID is generally administered at a dose of 300 mg (two 150 mg tablets) of nirmatrelvir with one 100 mg tablet of ritonavir, given twice-daily for five days. One carton contains five blister packs of PAXLOVID, as co-packaged nirmatrelvir tablets with ritonavir tablets, providing all required doses for a full five-day treatment course.

**Our Commitment to Equitable Access**
Pfizer is committed to working toward equitable access to PAXLOVID for all people, aiming to deliver safe and effective antiviral therapeutics as soon as possible and at an affordable price. During the pandemic, Pfizer will offer its oral therapy through a tiered pricing approach, pending country authorisation or approval, based on the income level of each country to promote equity of access across the globe. High and upper-middle income countries will pay more than lower income countries.

Pfizer continues to invest to support the manufacturing and distribution of PAXLOVID, including exploring potential contract manufacturing options. As a result of these efforts, Pfizer has raised its production projections, with the ability to produce up to 120 million courses of treatment by the end of 2022, pending global demand.

The company has initiated bilateral outreach to more than 100 countries around the world and has entered into agreements with multiple countries. Additionally, Pfizer has signed a voluntary license agreement with the Medicines Patent Pool (MPP) for its oral treatment to help expand access, pending country regulatory authorisation or approval, in 95 low- and middle-income countries that account for approximately 53% of the world's population.

**About Pfizer: Breakthroughs That Change Patients' Lives™**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. For more information, please visit: www.pfizer.com.au

**Disclosure Notice**

The information contained in this release is as of 29 April 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This statement contains forward-looking information about Pfizer's efforts to combat COVID-19 and PAXLOVID (including a Phase 2/3 study in paediatric patients, a potential age-appropriate formulation for three additional planned cohorts of younger than 6 years old, qualitative assessments of available data, potential benefits, expectations for clinical trials, advance purchase agreements and an agreement with MPP, efforts toward equitable access, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorisations, potential to maintain antiviral activity against current variants of concern, planned investment and anticipated manufacturing, distribution and supply), involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the possibility of unfavourable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data, including the risk that final results from EPIC-SR could differ from the interim data; the ability to produce comparable clinical or other results including efficacy, safety and tolerability profile observed to date, in additional studies or in larger, more diverse populations following commercialisation; the ability of PAXLOVID to maintain efficacy against emerging virus variants; the risk that serious and unexpected adverse events may occur that have not been previously reported with PAXLOVID use; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any drug applications or submissions to request emergency use or conditional marketing authorisation for any potential indications for PAXLOVID may be filed in particular jurisdictions and if obtained, whether or when such emergency use authorisation or licenses will expire or terminate; whether and when regulatory authorities in any jurisdictions may approve any applications or submissions for PAXLOVID that may be pending or filed (including a potential new drug application submission in the U.S. and submissions in other jurisdictions), which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities

impacting labelling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PAXLOVID, including development of products or therapies by other companies; risks related to the availability of raw materials for PAXLOVID; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand, which would negatively impact our ability to supply the estimated numbers of courses of PAXLOVID within the projected time periods; whether and when additional purchase agreements will be reached; the risk that demand for any products may be reduced or no longer exist; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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**References**


1. PAXLOVID™. Product Information. Last updated January 2022.
2. PAXLOVID. Pharmaceutical Benefits Scheme Factsheet. Available at https://www.pbs.gov.au/news/2022/04/files/Factsheet%20Paxlovid.pdf [Accessed April 2022.]