Advice to prescribers and dispensers of Paxlovid®

28 April 2022

Dear colleagues

Paxlovid® for the treatment of COVID-19

I am writing to provide further details about Pharmaceutical Benefits Scheme (PBS) access to the oral COVID-19 treatment Paxlovid® (nirmatrelvir + ritonavir) manufactured by Pfizer Australia Pty Ltd, which was provisionally approved by the Therapeutic Goods Administration (TGA) on 18 January 2022. A PBS listing for Paxlovid® means eligible patients can access this medicine from their local community pharmacy on a prescription from their doctor or nurse practitioner.

Access to Pharmaceutical Benefits Scheme subsidised treatment with Paxlovid®

Paxlovid® will be listed on the PBS from 1 May 2022 as a treatment for COVID-19. Paxlovid® will be made available to all Community Service Obligation (CSO) Distributors, prior to 1 May 2022, to distribute to community pharmacies as per normal supply arrangements and will be subject to the CSO obligations, ensuring supply of Paxlovid® to community pharmacies within 24 hours of the regular order cut off times.

Paxlovid® is being supplied to community pharmacy for the purpose of supply through the PBS. To prioritise Paxlovid® for patients at highest risk of developing severe COVID-19, prescribers are requested to prescribe Paxlovid® only in accordance with the PBS eligibility criteria; and prescribers and dispensers are strongly discouraged from providing it via private prescription.

State and territory hospital systems provide complementary mechanisms for access where the prescriber considers treatment is clinically indicated but the patient is not eligible under the PBS. The Government has provided Paxlovid® and a range of other COVID-19 treatments to state and territory health departments via the National Medical Stockpile for use in people at risk. Distribution of that non-PBS stock of Paxlovid® within a jurisdiction is the responsibility of each state or territory based on their COVID care arrangements, also informed by the recommendations from the National COVID-19 Clinical Evidence Taskforce.

Patients eligible for Pharmaceutical Benefits Scheme subsidised Paxlovid®

The Pharmaceutical Benefits Advisory Committee (PBAC) has advised that this medicine should be listed on the PBS for adults who have mild to moderate COVID-19 confirmed by a PCR or medically verified RAT and who can start treatment within 5 days of symptom onset, can be prescribed PBS-subsidised 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 of older only need to have one other risk factor); or
- they identify as Aboriginal or Torres Strait Islander origin, and are 50 years of age or older with two other risk factors for severe disease, or
- they are moderately to severely immunocompromised.

Paxlovid® is not recommended for use in pregnant or breastfeeding women and in women of childbearing potential not using contraception. For further information, please refer to the TGA product information.

The criteria for accessing PBS-subsidised treatment with Paxlovid® are the same as those for accessing Lagevrio® (molnupiravir) and are well aligned with the National COVID-19 Clinical Evidence Taskforce recommendations for treatment with a disease modifying medicine.

The PBS eligibility criteria also allow vaccinated older patients access to treatment if they have multiple other risk factors for developing severe COVID-19.

Unvaccinated Aboriginal or Torres Strait Islander adults under age 50 and other unvaccinated adults under age 65 are not eligible for PBS-subsidised treatment, unless they have a moderate to severe immunocompromising condition.

The PBAC outcome statement is at pbac-web-outcome-nirmatrelvir-and-ritonavir-march-2022.pdf (pbs.gov.au).

Diagnosis for Pharmaceutical Benefits Scheme eligibility

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

Treatment Administration

Treatment with Paxlovid® should be commenced as soon as possible after a diagnosis of COVID-19 and within 5 days of symptom onset. The standard dosage for most people is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) taken together orally every 12 hours for 5 days. Patients with moderately reduced kidney function may be prescribed a dose of 150 mg of nirmatrelvir (one 150mg tablet) with 100 mg of ritonavir (one 100mg tablet), every 12 hours for 5 days.

Interactions with other medicines

Paxlovid® interacts with many different medicines, including herbal supplements. These may lead to clinically significant adverse reactions, potentially leading to severe, life-threatening or fatal events from greater exposures of concomitant medications. They may also lead to a loss of therapeutic effect of Paxlovid® (due to reduced exposure to Paxlovid®). Paxlovid® is contraindicated:

- with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- with drugs that are 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. Paxlovid® cannot be started immediately after discontinuation of a potent CYP3A inducer, due to the delayed offset of the recently discontinued CYP3A inducer.
- in patients with severe renal or hepatic impairment

In addition to the above contraindications, careful monitoring is recommended when Paxlovid® is used with a wide range of other medicines. For complete details of drug interactions, including medicines for which concomitant use of Paxlovid® is contraindicated, please refer to section 4.3 of the Paxlovid® Product Information approved by the TGA. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drug before prescribing or dispensing Paxlovid®.

Further Information

Please see the TGA website for supporting regulatory documents including the Product Information and Consumer Medicine Information, which provide details on dosage, side effects, contraindications and other essential prescribing information.

The National COVID-19 Clinical Evidence Taskforce guidelines on use of Paxlovid® for the treatment of COVID-19 can be found at https://covid19evidence.net.au/.

Further information, including a PBS factsheet can be found at Pharmaceutical Benefits Scheme (PBS) | Paxlovid® (nirmatrelvir and ritonavir) PBS listing.

Thank you for your ongoing commitment to supporting your patients and your community throughout the COVID-19 pandemic. While Paxlovid® will not be suitable for everyone, and prescribers will need to work with individual patients to determine whether they are suitable, this medicine offers us another tool to use in our response to COVID-19.

As always, please continue to remind patients where necessary that vaccinations are the best way to protect individuals and the wider community from COVID-19 and COVID-19 oral treatments are not intended to be an alternative for vaccination against COVID-19.

Professor Michael Kidd AM
Deputy Chief Medical Officer
Australian Government Department of Health