

Paxlovid® (nirmatrelvir and ritonavir)

Pharmaceutical Benefits Scheme Factsheet – Updated July 2022

Paxlovid® (nirmatrelvir and ritonavir) Pharmaceutical Benefits Scheme listing

Paxlovid was added to the Pharmaceutical Benefits Scheme (PBS) from 1 May 2022 as a treatment for COVID-19.

Vaccines are proven to provide the best protection against COVID-19, however there are some individuals who are at higher risk for severe disease if they become infected with COVID-19.

Risk factors include older age, certain medical conditions and being moderately or severely immunocompromised.

Paxlovid is an oral anti-viral medicine which can be used by patients with mild-moderate COVID-19 who have a high risk for developing severe disease, reducing the need for admission to hospital.

Paxlovid is a prescription only medicine which must be started as soon as possible after a diagnosis of COVID-19. From the onset of COVID-19 symptoms, a course of Paxlovid must be started within the first 5 days (more detail is provided below). The two active substances of the medicine, nirmatrelvir and ritonavir, which are given as separate tablets, must be taken together twice a day for 5 days.

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.

It is important that patients continue to follow local health guidance to isolate if they test positive for COVID-19, including seeing their doctor and asking their pharmacy to arrange for Paxlovid to be delivered at home, if necessary.

The recommendation to add Paxlovid to the PBS was made by the independent, expert Pharmaceutical Benefits Advisory Committee (PBAC).

Access to PBS subsidised treatment with Paxlovid

The PBAC has recommended changes to eligibility for access to Paxlovid on the PBS, which take effect from 11 July 2022. From this date:

Adults 70 years of age or older, with mild to moderate COVID-19 confirmed by a PCR or medically verified RAT, can be prescribed PBS-subsidised Paxlovid by their doctor or authorised nurse practitioner where:

- treatment is commenced within 5 days of the onset of symptoms, or
- treatment is initiated as soon as possible after diagnosis is confirmed where asymptomatic

For adults 70 years of age or older, no further risk factors for progression to severe disease are required for PBS eligibility.

Also, adults with mild to moderate COVID-19 confirmed by a PCR or medically verified RAT can be prescribed PBS-subsidised Paxlovid by their doctor or authorised nurse practitioner if treatment is commenced within 5 days of the onset of symptoms for:

- People 50 years of age or older, with two additional risk factors for developing severe disease;
- People 30 years of age or older, identifying as Aboriginal or Torres Strait Islander, with two additional risk factors for developing severe disease; and
- People 18 years of age or older, with moderate to severe immunocompromise;

Aboriginal or Torres Strait Islander adults under age 30 and other adults under age 50 are not eligible for PBS subsidised treatment, unless they have a moderate to severe immunocompromising condition.

The following is a list of risk factors (conditions) contributing to the PBS definition of high risk for development of severe disease. This list has been updated on the recommendation of the PBAC, with effect from 11 July 2022.

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

For the purpose of PBS eligibility, “moderately to severely immunocompromise” patients are those with:

1. any primary or acquired immunodeficiency including:
 - a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders
 - b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
 - c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency OR
2. any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:
 - a. Chemotherapy or whole body radiotherapy,
 - b. High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
 - c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
 - d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus) OR

3. any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab
4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies OR
5. People with disability with multiple comorbidities and/or frailty

This list has been updated on the recommendation of the PBAC, with effect from 11 July 2022.

The independent, expert PBAC takes account of a range of factors including the effectiveness and cost of a medicine when considering it for PBS subsidy. The PBAC considered that the updated eligibility criteria for PBS access to Paxlovid strike an appropriate balance, given what is known about COVID-19, recent PBS utilisation patterns, and what is known about the mechanism of action of Paxlovid.

The PBAC will continue to monitor the conditions for PBS access to Paxlovid by considering new evidence for its effectiveness and safety and the epidemiology of COVID-19.

The PBS is an appropriate mechanism to provide timely and equitable access to oral COVID-19 treatments. The Department has worked closely with the PBAC to make this available on the PBS in recognition of the urgent public health need related to the prevention, management, and treatment of SARS-CoV-2 infections.

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. The Government has also provided Paxlovid to Aboriginal Controlled Community Health Organisations and the Royal Flying Doctor Service for use in people at risk.

Importance of Vaccination

- Paxlovid is not intended to be used as a substitute for vaccination against COVID-19.
- Vaccinations are the best way to protect individuals and the wider community from COVID-19.

TGA Provisional Approval

- 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.
- Australians can be confident that the TGA's review process of Paxlovid was rigorous. The decision to provisionally approve the medicine was informed by expert advice from the [Advisory Committee on Medicines](#), an independent committee with expertise in scientific, medical and clinical fields including consumer representation.
- Data was provided as a rolling submission. Under normal circumstances, the TGA's assessment (for both provisional and general registration) begins once all information to support registration is available. As part of the Department of Health's response to the pandemic, the TGA has agreed to accept rolling data for COVID-19 vaccines and medicines, to enable early evaluation of data as it comes to hand.
- Pharmaceutical companies are required to continue providing information to the TGA on longer-term efficacy and safety from ongoing clinical trials and post-market assessment, both in Australia and around the world.

Diagnosis for PBS eligibility

- The onus is on the prescriber to be satisfied that the COVID-19 test is valid and to record that in the patient records.

Condition: SARS-CoV-2 infection
Indication: SARS-CoV-2 infection
Clinical criteria:
Patient must have received a positive polymerase chain reaction (PCR) test result OR
Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner
Prescriber instructions:
Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record
Prescriber instructions:
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 (or, for asymptomatic adults 70 years of age or older, as soon as possible after diagnosis is confirmed). 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.
- A benefit of this treatment is that it can be taken orally, rather than as an injection or infusion in hospital. This makes the treatment easier to administer in the community, particularly for patients in rural and remote areas and in residential aged care and disability services.
- Pivotal safety data for Paxlovid is limited to results from a Phase 2/3 clinical trial. In this trial, the most frequently reported side effects occurring in subjects receiving Paxlovid were dysgeusia (5.6 % of participants), diarrhoea (3.1%); headache (1.4%); and vomiting (1.1%). Older people receiving Paxlovid should be closely monitored for side effects.
- Safety and efficacy of Paxlovid have not been established in patients less than 18 years of age, therefore use in paediatric patients is not recommended.

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.

- Paxlovid is also contraindicated 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 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 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.

Contraindications

- The use of Paxlovid is contraindicated with drugs that are highly dependent on CYP3A for clearance, or potent inducers of CYP3A. Please refer to 'Interactions with other medicines' above for more information.
- Paxlovid is contraindicated in patients with severe renal or hepatic impairment.

Listing of medicines on the PBS

- The PBS is the main mechanism through which the Government subsidises the cost of medicines for the treatment of Australian patients.
- The PBAC is an independent, expert, statutory body established under the *National Health Act 1953* to make recommendations and give advice to the Australian Government and the Minister for Health and Aged Care about which drugs and medicinal preparations should be subsidised on the PBS.
- Under legislation, a new medicine cannot be listed by the Government on the PBS unless the PBAC makes a recommendation in favour of listing.
- When the PBAC evaluates applications for PBS subsidy, it is legally required to take into account the clinical effectiveness (how well it works) and cost effectiveness (value for money) of the medicine compared to other available therapies. The PBAC also takes into account the approval of a product granted by the TGA.
- While assessing applications, the PBAC uses a rigorous health technology assessment methodology to evaluate a range of factors including the comparative effectiveness and cost of alternative treatments.

Further information

Further information is available from

The Department of Health website:

[Oral treatments for COVID-19 | Australian Government Department of Health](#)

www.pbs.gov.au/browse/publications

The TGA website:

[COVID-19 treatments: Provisional registrations | Therapeutic Goods Administration \(TGA\)](#)

The National COVID-19 Clinical Evidence Taskforce website:

[Home - National COVID-19 Clinical Evidence Taskforce \(covid19evidence.net.au\)](https://covid19evidence.net.au)

■ NIRMATRELVIR (&) RITONAVIR

Caution Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

13112

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must not require hospitalisation at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

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.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13110

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation at the time of prescribing, **AND**
- Patient must be moderately to severely immunocompromised, **AND**
- Patient must be at risk of progression to severe disease due to immunocompromised status, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

- a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
- b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
- c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

- a. Chemotherapy or whole body radiotherapy,
- b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
- c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
- d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

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.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13107

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

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.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

Authority required (STREAMLINED)

13108

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.
For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

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.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size.

Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1113.99	42.50	Paxlovid [HD]