

SCHEDULE OF PHARMACEUTICAL BENEFITS EFFECTIVE 11 JULY 2022

ADDENDUM

(1) This Addendum updates the restrictions for **MOLNUPIRAVIR, molnupiravir 200 mg capsule, 40, (Lagevrio®)**, and **NIRMATRELVIR (&) RITONAVIR, nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6, (Paxlovid®)**, to include the following groups of patients with COVID-19 disease not requiring supplemental oxygen:

- 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; where treatment is commenced within 5 days of the onset of signs/symptoms.

- People 70 years of age or older, where treatment is commenced within 5 days of the onset of symptoms, or where asymptomatic, treatment is initiated as soon as possible after diagnosis is confirmed.

▪ **MOLNUPIRAVIR**

NoteNo increase in the maximum quantity or number of units may be authorised.

NoteNo 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.

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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.

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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,
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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.

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molnupiravir 200 mg capsule, 40

12910L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1101.39	42.50	Lagevrio [MK]

▪ 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.

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

Authority required (STREAMLINED)

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- 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.

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

- a. Chemotherapy or whole body radiotherapy,
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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]