

# Lagevrio® (molnupiravir)

## PBS Factsheet

### **Lagevrio® (molnupiravir) PBS listing**

Lagevrio is being added to the Pharmaceutical Benefits Scheme (PBS) from 1 March 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.

High risk factors include age and other medical conditions or being moderately or severely immunocompromised.

Lagevrio 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.

Lagevrio is a prescription only medicine which must be started as soon as possible after a diagnosis of COVID-19 and within 5 days of developing symptoms.

A PBS listing for Lagevrio means eligible patients can access this medicine from their local community pharmacy on a prescription from their doctor.

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

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

### **Access to PBS subsidised treatment with Lagevrio**

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 Lagevrio by their doctor 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); 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.

The criteria for accessing PBS-subsidised treatment with Lagevrio are well aligned with the National COVID-19 Clinical Evidence Taskforce recommendations for treatment with a disease modifying medicine:

- the age threshold is the same (50 years of age and older for Aboriginal or Torres Strait Islanders and 65 years of age and older for all others);
- both require older patients to have other risk factors. The list of risk factors in the PBS eligibility criteria has been expanded to include cirrhosis; neurological conditions, including stroke and dementia; and patient is in residential aged care or residential disability care.

- both include adult patients who are moderately to severely immunocompromised regardless of immunisation status. The list of eligible immunocompromising conditions in the PBS eligibility criteria has been expanded to include rituximab in past 12 months; very high-risk conditions including cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies and severe physical or intellectual disabilities requiring residential care.

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 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 the eligibility criteria for PBS access to Lagevrio strike an appropriate balance, given what is known about COVID-19, and what is known about the mechanism of action of Lagevrio.

The PBAC will continue to monitor the conditions for PBS access to Lagevrio 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 been working closely with the sponsor and the PBAC to expedite PBS availability in recognition of the urgent public health need related to the prevention, management, and treatment of SARS-CoV-2 infections.

The Department has also worked with the sponsor, distributors, and peak medical and pharmacy organisations to prioritise Lagevrio for those patients at highest risk of developing severe COVID-19 as reflected in the PBS eligibility criteria, and to discourage private prescriptions.

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 Lagevrio 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 Lagevrio to Aboriginal Controlled Community Health Organisations and the Royal Flying Doctor Service for use in people at risk.

### **Importance of Vaccination**

- Lagevrio is not intended to be used as a substitute for vaccination against COVID-19.
- Vaccinations are the best way to protect yourself, your loved ones and the wider community from COVID-19.

### **TGA Provisional Approval**

- Lagevrio 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 Lagevrio was rigorous. The decision to provisionally approve the medicine was informed by expert advice from the [Advisory Committee on Medicines](#) (ACM), 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 treatments, 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 prescriber to be satisfied that the test for COVID-19 is valid and to record that in the patient records. See below extract from the PBS eligibility criteria.

<b>PBS Indication</b>	SARS-CoV-2 infection
<b>Clinical criteria</b>	<p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner</p>
<b>Prescriber Instructions</b>	<p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p>

### Treatment Administration

- Treatment with Lagevrio should be commenced as soon as possible after a diagnosis of COVID-19 and within 5 days of symptom onset. It is taken as 4 capsules 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 Lagevrio is limited to results from a single Phase 3 clinical trial. In this trial, the most frequently reported side effects occurring in  $\geq 1\%$  of subjects receiving were diarrhoea (2% of participants); nausea (1%); and dizziness (1%). All these reactions were classified as either mild or moderate in severity. Older people receiving Lagevrio should be closely monitored for side effects.
- Based on the limited available data, there have been no drug interactions identified.

### Pregnancy, breastfeeding and contraception

- The use of Lagevrio is not recommended during pregnancy and breastfeeding. It is recommended that sexually active women of childbearing potential use contraception during and for 4 days after treatment with molnupiravir. There is no data available in relation to whether molnupiravir affects sperm. It is recommended that men who are sexually active with a

partner of childbearing potential use an adequate form of contraception during and 3 months after treatment with molnupiravir.

#### **Paediatric use**

- Safety and efficacy of Lagevrio have not been established in patients less than 18 years of age, therefore use in paediatric patients is not recommended.

#### **Listing of medicines on the Pharmaceutical Benefits Scheme (PBS)**

- The Pharmaceutical Benefits Scheme (PBS) is the main mechanism through which the Government subsidises the cost of medicines for the treatment of Australian patients.
- The Pharmaceutical Benefits Advisory Committee (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 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. The Government does not interfere with the PBAC's considerations or process to develop recommendations to Government.
- The PBAC's consideration is generally initiated by the pharmaceutical company responsible for a medicine applying for the medicine to be considered for PBS listing. The pharmaceutical company usually holds the scientific data and other information necessary to inform the PBAC's consideration. Pharmaceutical companies are private entities that make their own decisions on the availability of their medicines.
- 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 NPS MedicineWise website at

[Oral antivirals and sotrovimab for adults with mild-to-moderate COVID-19 who do not require oxygen - NPS MedicineWise](#)

The Department of Health website at

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

The TGA website at

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

The National Clinical Evidence Taskforce website at

[FLOWCHART-2-MANAGEMENT-OF-MILD.pdf \(covid19evidence.net.au\)](#) and

[FLOWCHART-12-DMT-FOR-ADULTS.pdf \(covid19evidence.net.au\)](#)