

PBAC - WEB OUTCOME STATEMENT

MOLNUPIRAVIR,
Capsule 200mg, Lagevrio®,
Merck Sharp & Dohme Australia Pty Ltd

The Pharmaceutical Benefits Advisory Committee (PBAC) undertook an expedited consideration of a sponsor submission to add molnupiravir (Lagevrio®) to the Pharmaceutical Benefits Scheme (PBS) for use in treating patients with mild to moderate COVID-19 who are at risk of developing severe disease requiring hospitalisation. The expedited consideration by PBAC recognises the urgent public health need related to the prevention, management, or treatment of SARS-CoV-2 infections.

The PBAC recommended the listing on the PBS of molnupiravir as a General Schedule, Authority Required (Streamlined) benefit.

The PBAC recommended PBS-subsidised treatment initially be provided for the following groups of patients with mild-moderate COVID-19 disease not requiring supplemental oxygen for their COVID-19 and where treatment is commenced within 5 days of the onset of symptoms:

- People 65 years or older with two additional high-risk factors for developing severe disease,
- People 75 years or older with one additional high-risk factor for developing severe disease,
- Moderately to severely immunocompromised people irrespective of vaccination status, and
- Aboriginal and Torres Strait Islander people aged 50 years or older with two additional high-risk factors for developing severe disease.

The PBAC recommended the age-based PBS listing restrictions list several conditions that PBAC considered risk factors for patients with mild-moderate COVID-19 progressing to severe disease. Receipt of 0 or 1 vaccination doses was considered by the PBAC to be a risk factor. The PBAC acknowledged true vaccine protection against COVID-19 infection wanes and while vaccination is not fully protective against severe COVID-19 disease, at the moment the greatest risk of severe infection is in those who have had 0 or 1 vaccine doses.

The PBAC also recommended the PBS listing for immunocompromised people list several conditions for eligibility.

In making this recommendation, the PBAC noted the PBS is an established mechanism for providing subsidised access to medicines for patients in the community. It utilises a network of over 6000 community pharmacies, Aboriginal Health Services, and other dispensing

settings. The reach of the PBS and its integration with General Practice prescribing processes means all eligible Australian will be able to access treatment in a timely and equitable way.

The PBAC also noted that most antiviral agents for COVID-19 have only been evaluated in unvaccinated people, and currently most recommendations for their use are confined to unvaccinated or single dose vaccinated individuals, and for those with a high risk of primary vaccine failure.

The PBAC considered extending PBS subsidy to allow vaccinated older people to access therapy if they have multiple other risk factors strikes an appropriate balance, given what is known about vaccine protection against COVID-19, and what is known about the mechanism of action of molnupiravir.

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

The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of molnupiravir at the price proposed by the sponsor would be acceptable. In making this recommendation, the PBAC is satisfied that molnupiravir is likely to provide, for some patients, a significant improvement in efficacy over standard of care in terms of a reduction in the risk of developing severe disease requiring admission to hospital.