

## OUTCOME STATEMENT

### COVID-19 ORAL TREATMENT RESTRICTIONS

**MOLNUIRAVIR, Capsule 200 mg, Lagevrio<sup>®</sup>, Merck Sharp & Dohme Australia Pty Ltd**

**NIRMATRELVIR AND RITONAVIR, Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5, Paxlovid<sup>®</sup>, Department of Health (Commonwealth)**

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended changes to the Pharmaceutical Benefits Scheme (PBS) eligibility criteria for both molnupiravir (Lagevrio<sup>®</sup>) and nirmatrelvir and ritonavir (Paxlovid<sup>®</sup>), in the light of current understanding of the evidence for effectiveness and safety of these medicines, recent PBS utilisation patterns, and the changing epidemiology of COVID-19.

The PBAC recommended that treatment be provided as a General Schedule, Authority Required (Streamlined) benefit for the following groups of patients with COVID-19 disease not requiring supplemental oxygen for their COVID-19 and where treatment is commenced within 5 days of the onset of signs/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;

and 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:

- People 70 years of age or older.

The PBAC recommended changes to the list of conditions that define high risk for developing severe disease, including clarification and/or expansion of eligibility in relation to respiratory, cardiac, and neurological co-morbidity. The PBAC acknowledged that a large majority of Australian adults have received more than one COVID-19 vaccination, and recommended that the current condition 'patient has received less than 2 doses of SARS-CoV-2 vaccine' no longer need be included in the list.

The PBAC recommended changes to the definition of 'moderate to severe immunocompromise,' noting correspondence received from the Australian Rheumatology Association in relation to immunosuppression with use of methotrexate, azathioprine and abatacept.

In considering the need for changes to PBS eligibility for these medicines, the PBAC also noted correspondence from the Advisory Committee for the COVID-19 Response for People with Disability, and from the Australian Health Protection Principal Committee Aged Care Advisory Group.

The PBAC will continue to monitor the conditions for PBS access considering new evidence for the effectiveness and safety of these medicines and the epidemiology of COVID-19. The PBAC's recommendation for listing was based on, among other matters, its understanding of the commitments the Commonwealth has already made regarding the procurement or funding of these medicines, and the expected utilisation of these medicines after recommendations for changes to eligibility are implemented.