# PBAC - WEB OUTCOME STATEMENT

# NIRMATRELVIR AND RITONAVIR,

# Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5, Paxlovid®,

# Department of Health (Commonwealth)

The Pharmaceutical Benefits Advisory Committee (PBAC) undertook an expedited consideration of a submission to add the combination product, nirmatrelvir and ritonavir (Paxlovid®) 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 nirmatrelvir and ritonavir as a General Schedule, Authority Required (STREAMLINED) benefit.

The PBAC recommended that nirmatrelvir and ritonavir should be PBS subsidised 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 noted its recommended eligibility criteria for accessing PBS subsidised treatment with nirmatrelvir and ritonavir are the same as the current molnupiravir (Lagevrio®) PBS criteria.

The PBAC considered whether any updates should be made to the risk factors for eligibility to PBS subsidised oral anti-viral treatments for mild-moderate COVID-19. In particular, the PBAC noted the Australian Technical Advisory Group on Immunisation (ATAGI) has updated its vaccine recommendations. The PBAC considered the evidence continues to show the highest risk for hospitalisation and death in older patients infected with COVID-19 is associated with no or one vaccine doses. The PBAC decided not to make any changes to the risk factors at this time.

The PBAC recalled its advice at the March 2022 meeting that molnupiravir is suitable for prescribing by nurse practitioners. The PBAC advised that nirmatrelvir and ritonavir is also suitable for prescribing by nurse practitioners.

The PBAC requested the listing for nirmatrelvir and ritonavir include a caution to alert prescribers and dispensers to the potential for serious drug-drug interactions with nirmatrelvir and ritonavir.

The PBAC will continue to monitor the conditions for PBS access considering new evidence for the effectiveness and safety of nirmatrelvir and ritonavir 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 nirmatrelvir and ritonavir at the proposed price would be acceptable. In making this recommendation, the PBAC is satisfied that nirmatrelvir and ritonavir 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.