Improving access to medicines – New medicines added to the Pharmaceutical Benefits Scheme

The Australian Government is investing $2.4 billion in new and amended listings for the Pharmaceutical Benefits Scheme (PBS), including treatments for cancer, cystic fibrosis, severe eczema, asthma, Human Immunodeficiency Virus (HIV) infection and heart failure.

These listings demonstrate the strength of the strategic agreements between the Australian Government with Medicines Australia and the Generic and Biosimilar Medicines Association and the commitment of the *New Medicines Funding Guarantee* in the 2020–21 Budget to meet the cost of future new and amended medicines listings.

Since 2013, the Australian Government has approved more than 2,800 new or amended listings on the PBS. This represents an average of around 30 listings or amendments per month - or one each day - at an overall investment by the Government of around $15 billion from 2013–14 to 2022–23.

Over the past decade significant developments in delivering access to important medicines through the PBS include:

* More than $1 billion for listing new antiviral medicines to treat and cure hepatitis C in 2016
* Over $200 million for the listing of immuno-oncology medicines to treat patients with malignant mesothelioma (nivolumab and ipilimumab) in 2021, and
* Over $180 million for the listing of evolocumab in 2020 to treat patients with high risk cardiovascular disease caused by high cholesterol.

The Government has rapidly approved and funded important new medicine listings for the PBS which have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC).

For the first time, from May 2022 –

* Ofev® (nintedanib) will be included on the PBS for use in the treatment of progressive fibrosing interstitial lung disease, which will save more than
1,400 Australian patients $40,000 a year.
* Zolgensma® (onasemnogene abeparvovec) will also be listed for the treatment of spinal muscular atrophy, which, each year, will save around 20 patient families more than $2.5 million for the treatment.
* Trodelvy® (sacituzumab govitecan) will be included for the treatment of triple negative breast cancer, which will save an average of 580 patients each year $80,000 per course of treatment.

From April 2022 –

* Trikafta®, the combination product of elexacaftor/tezacaftor/ivacaftor and ivacaftor will be listed on the PBS for the treatment of cystic fibrosis,
helping an average of 1,900 patients reduce their out of pocket costs by around $250,000 a year.

Instead of paying thousands of dollars to access these treatments, Australians will pay a reduced $42.50 per script, or as little as $6.80 with a concession card.

Other new and amended PBS listings include:

From March 2022 –

* Lagevrio® (molnupiravir) will be available until 31 January 2024 in line with the provisional registration by the Therapeutic Goods Administration for Australians with mild-moderate COVID-19 who have a high risk for developing severe disease, reducing the need for admission to hospital. This includes adults aged 65 or older, with two other risk factors for severe disease, people identifying as of Aboriginal or Torres Strait Islander origin, who are 50 years of age or older with two other risk factors for severe disease, or the moderately to severely immunocompromised.
* Uvadex® (methoxsalen) for the treatment of chronic graft versus host disease, and for around 180 patients would otherwise cost $9,200 per course of treatment.
* Mylotarg® (gemtuzumab ozogamicin) to help patients with acute myeloid leukaemia, which means they will no longer need to pay $18,000 per course
of treatment.
* Ultomiris® (ravulizumab) to benefit people with paroxysmal nocturnal haemoglobinuria (PNH), saving 160 Australians a year from paying
$550,000 per year for treatment.
* Soliris® (eculizumab), also used for the treatment of paroxysmal nocturnal haemoglobinuria (PNH), previously available through the Life Savings Drug Program, and would otherwise cost each patient $440,000 per year of treatment.

From February 2022 –

* Calquence® (acalabrutinib), for the treatment of approximately 350 patients with mantle cell lymphoma, which means they will no longer have costs of $8,200 per script.
* Rinvoq® (upadacitinib) to assist people with severe atopic dermatitis, saving around 3,600 patients a year from facing an out of pocket bill of $27,000 per year for their medication.

From January 2022 –

* Braftovi® (encorafenib) in combination with PBS-listed cetuximab, for which around 340 patients battling colorectal cancer (bowel cancer), they will no longer have costs of more than $33,600 per course of treatment.
* An expanded listing of Forxiga® (dapagliflozin) for the treatment of symptomatic heart failure, which for around 75,000 patients would otherwise cost $630 per year.

# Why is this important?

Listing medicines on the PBS saves and protects lives. The PBS New Medicines
Funding Guarantee safeguards the listing of innovative, life-saving and life-changing medicines on the PBS.

Ongoing investment in the PBS means that Australians can access the medicines they need at an affordable price – these medicines can be prohibitively expensive if not subsidised through the PBS.

# Who will benefit?

Australian patients will benefit from the addition of new, innovative, life-saving medicines to the PBS. They can also have confidence that the New Medicines Funding Guarantee means adding new medicines to the PBS will be done quickly and will be protected from funding pressures.

The listing of new medications means the Australian Government will subsidise the cost of more life-saving medicines for patients.

Alongside these listings, the Government has continued to work with the medicines and pharmacy sector to strengthen current PBS policy settings with a focus on:

* guaranteeing the supply of life changing medicines already listed on the PBS
* improving the quality use of medicines through community pharmacy
* providing timely patient access to emerging high cost treatments where there is evidence to support Government subsidy, and
* ensuring value for money for the Australian tax payer.

# How much will this cost?

The Australian Government is investing $2.4 billion over five years, from 2021–22 to 2025–26.