



Australian Government

Department of Health, Disability and Ageing

REFORMS OF THE PRESCRIBED LIST OF MEDICAL DEVICES AND HUMAN TISSUE PRODUCTS (2021-2025) – A SUMMARY OF THE REFORM OBJECTIVES AND ACHIEVEMENTS

Why did the Reforms need to take place?

- Prescribed List (PL) reimbursement represents 14%* of health insurance expenditure. Increased costs and utilisation of these devices is being reflected in higher insurance premiums.
- Through reforms to the PL, we aimed to address this growth and improve the affordability of private health insurance for Australians.
- The reforms also focussed on opportunities to make the list more efficient, more transparent and better able to keep up with technological advances.

What did the Reforms involve?

- Approximately \$23 million was announced in the 2021-22 Budget to improve the affordability and value of private health insurance for Australians through Prescribed List reforms.
- The Reforms involved modernisation of the PL through a 4-year reform program with the following objectives:
 - Better align the price set for medical devices on the PL for private providers with those paid in the public hospital system.
 - Maintain no additional out-of-pocket costs for consumers associated with PL devices.
 - Maintain clinician choice.
 - Clarify the scope of the PL.
 - Improve the affordability and value of Private Health Insurance for privately insured Australians.
 - Clarify the purpose, definition and scope of the PL in legislation.
 - Regroup the items on the PL to better align devices with similar intended use or health outcomes.
 - Streamline the listing of new devices including assessment pathways and reviewing the functions of the advisory committees/groups
 - Improve the post-listing activities, including reviews and compliance activities.
 - Ensure ongoing financial stability of the PL by updating the existing cost recovery arrangements.

When were the Reforms implemented?

- The Department of Health, Disability and Ageing commenced the reform program on 1 July 2021.
- The department implemented these reforms in a staged manner over 4 years.
- The program of reforms ended on 30 June 2025.

What did the Reforms achieve?

- Benefit reductions for Part A medical devices:
 - Reduced the gap between the benefit paid in the private health system and the price paid in the public health system.

- The Independent Health and Aged Care Pricing Authority (IHACPA) calculated the benchmark price for medical devices provided in the public health sector in line with the [Memorandum of Understanding \(MoU\) with MTAA](#).
- PL benefits for Part A were reduced by 80% of the gap in 3 sequential reductions:
 - 1 July 2022 - 40% reduction of the gap
 - 1 July 2023 - 20% of the gap
 - 1 July 2024 - final 20% of the gap¹
- PL benefits for Part D were reduced by 100% of the gap in 3 sequential reductions:
 - 1 July 2022 – 40% reduction of the gap
 - 1 March 2023 – 40% reduction of the gap
 - 1 July 2023 – 20% reduction of the gap
- At this time, there are no more benefit reductions scheduled for medical devices.
- Achieved savings of approximately:
 - \$195.9 million in 2023-24
 - \$105.7 million in 2022-23
 - savings for the final year of the reforms (2024-25) will be calculated by IHACPA in October 2025
- Legislative changes:
 - Established definitions of medical devices and human tissue products.
 - Changed the name of the legislative instrument to better reflect its scope and purpose to regulate minimum benefits for the provision of medical devices and human tissue products (Prescribed List).
 - Included listing criteria for Parts A, B C and D in the legislative instrument.
 - Implemented revised cost-recovery arrangements to ensure ongoing financial sustainability of the PL administration that are compliant with the Australian Government Charging Framework.
- Governance arrangements:
 - The Medical Devices and Human Tissue Advisory Committee (MDHTAC) and its subcommittees, the Expert Clinical Advisory Groups (ECAGs), reflect a modernised application process. They replaced the former PLAC and the former CAGs.
 - Implemented 3 alternative listing pathways that reflect the complexity of the assessment required:
 - Tier 1: Departmental Assessment for well-established technologies that are like-for-like with other products already listed on the PL.
 - Tier 2: Clinical / Focused HTA Assessment for devices that require clinical assessment by the respective ECAG, and in some cases HTA. All applications are considered by MDHTAC.
 - Tier 3: Full HTA Assessment Pathway which includes consideration by MDHTAC and the Medical Services Advisory Committee (MSAC).
 - Commenced replacement of Prostheses List Management System (PLMS) with the Health Products Portal (HPP) to provide a single digital channel for industry to interact with us about regulated and reimbursed health-related products and services.²
 - The governance structures were supported by the development of guidance and education documents for stakeholders.
- Ongoing stability and safeguarding of the PL:

¹ PL benefit reductions for Cardiac Implantable Devices (CIEDs) were delayed 1 year.

² While this was a business-as-usual activity initiated across the department's HTA areas (PBS, MBS, PL and TGA) to reduce red tape rather than part of the reforms, the introduction of HPP has influenced the reform process.

- Where appropriate, the department will continue to address errors and inconsistencies in the current PL grouping scheme that are identified on a case-by-case basis to improve the integrity of the PL.
- The department will continue to work to rectify issues identified with the HPP and modify the system appropriately.
- Establish a Post-Listing Review capability that provides a purposeful and transparent approach to evaluate listings on the PL and implement measures to address issues identified by either the department or stakeholders.
- Design of a compliance framework aimed at maintaining the integrity of the PL and to provide assurance that policy outcomes are being met and to outline compliance obligations of applicants and device sponsors as well as the steps the department may take where there are concerns about non-compliant activities.
- A formal evaluation of the reform project activities is ongoing and the final report will be delivered by 30 June 2026. Baseline and Interim reports 1 and 2 for the evaluation are available on the [Department's website](#).

What were the Reforms unable to achieve?

- Regrouping items on the PL:
 - The department conducted an exercise to revise the grouping structure of the PL that is aligned to clinical outcomes, independent of benefit, is transparent and practical to navigate.
 - Detailed work was undertaken with clinical advice and input to group PL items by clinical outcome. However, this element of the Reforms came across several challenges and complexities which resulted in a lack of consensus from stakeholders (particularly in the context of perceived additional savings as a result of the regrouping which was inconsistent with the requirements of the MoU with MTAA).
 - Following further exploration of options to complete the PL regrouping, it was decided that the exercise would not be achievable unless the department and the MDHTAC undertook a Health Technology Assessment (HTA) for each listing on the PL to set a consistent benefit for each new group.
 - Given the time and resources required to conduct HTAs and the lack of agreement from stakeholders, the Government agreed to cease pursuit of the regrouping measure in the final year of the reforms.
- Removal of ineligible PL items:
 - A key component of the Reforms was to clarify the scope of the PL and remove items that do not meet the eligibility criteria such as the General Use Items (GUIs) – not originally intended for the PL as they are mostly not specific purpose such as consumables such as surgical glues and staples and tackers.
 - Part D contains 475 GUIs that were due to be removed from the PL on 1 July 2024.
 - The Government engaged the Independent Health and Aged Care Pricing Authority (IHCPA) to provide advice about an alternative funding arrangement to the PL for these devices that would result in bundling of the benefits. However, this was rejected by the key stakeholders as they said it did not provide suitable funding certainty.
 - On 1 May 2024, the Minister for Health and Aged Care announced GUIs would remain on the PL.
 - A total of 26 billing codes in Part D (for medicines and accessories to medicines) were removed from the PL. These billing codes are regulated by the Therapeutic Goods Administration (TGA) as medicines or accessories to medicines and therefore do not meet the PL eligibility requirements.