

Prostheses List Advisory Committee (PLAC)

Terms of Reference

Purpose:

The Prostheses List Advisory Committee (PLAC) is a committee composed of an independent Chair and individuals with expertise in health technology assessment, specialist surgery/interventional work, health economics and consumer issues, and representatives of stakeholders in private health insurance.

Its primary role is to make recommendations to the Minister for Health and advise the Department of Health about the listing of medical devices and their benefits on the Prostheses List. The PLAC's recommendations and advice are to be based on assessment of comparative clinical effectiveness and cost effectiveness of medical devices using the best available evidence. This process ensures that privately insured Australians have access to a range of medical devices that have been shown to be clinically effective and represent value for money.

Roles and function:

The role of the PLAC is to make recommendations and provide advice to enable the Minister to exercise his or her powers under the *Private Health Insurance Act 2007*. This includes:

- making recommendations to the Minister on whether applications to list medical devices should be granted or not and if any conditions of listing are appropriate;
- advising the Minister about the benefits for medical devices to be listed on the Prostheses List;
- advising the Minister on requests to amend current listings on the Prostheses List; and
- reviewing the listing and/or benefits of listed medical devices as appropriate and make recommendations to the Minister.

The PLAC will also:

1. develop options for improving application and assessment processes as recommended by the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) to drive improved cost effectiveness of new and current medical devices;
2. revise its governance structure including its sub-committees to ensure alignment with the purpose of the Committee and reform directions outlined by Government;
3. make recommendations to the Minister on moving to a benefit setting mechanism that reflects real market dynamics for medical devices, such as price disclosure and/or reference to pricing in other markets; and
4. assist the Department of Health to advise the Minister on any other policy matters pertaining to the medical device listing arrangements.

The PLAC will refer applications to the Medical Services Advisory Committee (MSAC) either via the Evaluation Sub Committee (ESC) of MSAC or directly to MSAC:

- where the new medical device employs a medical service that is not currently covered in the Medicare Benefits Schedule (MBS), or
- where the new medical device might be used in a medical service that is currently described in the MBS, but potentially extends the range of indications/patients beyond the original intent of the MBS item/s; or
- where the applicant claims use of a medical device delivers superior health outcomes relative to existing alternative devices, and seeks a higher benefit; or

- Where the application is for a first in class medical device; or
- Where the application is for an innovative medical device where an appropriate comparator listed on the Prostheses List cannot be easily identified. This may relate to the device itself, the patient population or the circumstances of use of the device.

To ensure listing of medical devices does not have an unintended impact on MSAC determinations, the PLAC will refer items to MSAC in advance of recommendations to the Minister of Health where there is doubt about the impact of PLAC recommendations on the cost effectiveness or budget impact of current or future MBS listings.

The PLAC will refer any concerns about safety of medical devices that arise during assessment of applications to list medical devices to the Therapeutic Goods Administration (TGA) for investigation and appropriate action.

The PLAC should liaise with the Pharmaceutical Benefits Advisory Committee (PBAC) and/or its subcommittees for advice on comparative clinical effectiveness and cost effectiveness of a new medical device incorporating a medicine.

The PLAC should liaise with the MSAC, the TGA and PBAC to develop assessment processes that maximise the use of the clinical and technical expertise of each body and reduce duplication of assessment.

The PLAC may establish subcommittees, comprising members or co-opted individuals with appropriate expertise, to assist the PLAC to perform its role under these terms of reference. Each subcommittee will operate according to terms of reference approved by the PLAC.

The PLAC is not bound to accept the advice of its subcommittees in making recommendations to the Minister.

Composition:

The PLAC's size and composition is determined in consultation with the Minister.

The PLAC will include an independent Chair, appointed by the Minister.

The PLAC's composition is drawn from a wide range of experts and stakeholder advisers and constituted from time to time to address the types of applications presented for consideration and recommendation.

Clinical and technical expert members of the PLAC are appointed by the Department in consultation with the Minister. The Department, in consultation with the Minister, can terminate an expert member's appointment at any time at its discretion.

The Minister will consult with stakeholder organisations on nominations for *advisory members*, and will appoint advisory members at the Minister's discretion.

The Minister can terminate a member's appointment to the PLAC at any time at his or her discretion.

Members may serve on the PLAC and any of its subcommittees. The PLAC may also co-opt non-members to its sub-committees or working groups as required.

Members sign a Deed of Undertaking in Relation to Confidentiality and Conflict of Interest upon appointment, and are required to declare potential, perceived or actual conflicts for each meeting/matter being considered.

Membership appointments are generally for a two year term, unless specified otherwise by the Minister. Appointments may be staggered to allow for continuity of the PLAC.