Draft Proposed Approach for Targeted Prostheses Reviews

This draft approach for targeted reviews of prostheses listings was developed by the Prostheses List Advisory Committee (PLAC) to support consistency and equity in conduct of reviews, the recommendation process, and implementation steps.

Transparency in conducting the reviews and stakeholders participation including the provision of data are key success factors for the PLAC.

Stakeholders are welcome to provide comments and feedback on this draft approach, emailed to Prostheses Reform by 2 June 2017.

Introduction

The PLAC Reform Work Plan includes development of a process for systematic reviews of targeted categories, sub-categories and benefits paid for prostheses, while the new benefit setting framework is being developed.

Most categories of prostheses and their benefits have not undergone major review since they were established in 2005 and 2006. Prostheses that were grandfathered from the former Schedule 5 have not undergone any form of formal review process.

The PLAC will establish a program of systematic reviews as a matter of good practice.

Desired Outcomes

Desired outcomes from the targeted reviews are that:

- the Prostheses List (PL) only provides benefits for medical devices that are clinically effective and cost effective;
- privately insured patients are left with minimised out-of-pocket expenses;
- private hospitals and medical device sponsors receive fair and equitable remuneration for their goods and services; and
- private health insurers are not required to pay more in benefits for prostheses and associated services than is fair and reasonable.

Scope

The scope of each review can include:

- categorisation of prostheses;
- appropriateness of criteria for listing;
- evidence and data requirements;
- examination of whether the Prostheses List is an appropriate mechanism for reimbursement for specific devices; and
- Prostheses List benefits accurately reflecting the combined aspects of: market value, indirect costs involved in supplying the device and value to patients.

Methodology

For each review, the methodology can include:

- reviewing grouping structures and prostheses within groupings (to identify price points);
- considering the issues noted by the Prostheses List Advisory Committee (PLAC) either at the time of listing, or thereafter;
- considering issues noted by the Medical Services Advisory Committee and/or the Therapeutic Goods Administration in relation to the prostheses under review;

- reviewing the comparative clinical effectiveness of prostheses, in light of current evidence and any advancements in technology or clinical practice;
- using pricing data from a variety of available sources to inform the level of benefit;
- incorporating the views, evidence, and advice from PLAC sub-committees, sponsors and other stakeholders; and
- ensuring appropriate transition periods to implement changes are provided.

Guiding principles for reviews

Guiding principles for reviews aim to ensure consistent approaches and outcomes across Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (Panel) and stakeholders. The key guiding principle of these reviews is that grouping of prostheses is based on comparative clinical outcomes for patients. Differences in materials and/or design will only be considered if they result in different outcomes.

Processes

It is proposed that each review consider nine components, although all may not be required for every review:

[1] Health Economics Sub-Committee, [2] Medical Services Advisory Committee, [3] Therapeutic Goods Administration, [4] Eg., the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

Consideration of reviews within a category and determination of clinical effectiveness

Consideration to be given to drivers for each review and what requires review within categories. These include:

- timeframe for completing the review
- grouping schemes
- reviews of comparative clinical effectiveness assessment
- definition of "clinical effectiveness" for the category
- review of benefits
- previously raised issues about prosthesis listing within the group
- anomalies between benefits on the Prostheses List and cost effectiveness assessment by the Medical Services Advisory Committee (MSAC) and/or Evaluation Sub Committee (ESC)

Review of grouping structure and/or comparative clinical effectiveness of prostheses

Clinicians with appropriate expertise selected from CAGs, Panel, PLAC or other complimentary HTA bodies will be reviewing the grouping structures and, where necessary, the comparative clinical effectiveness of prostheses.

Where the reviews might require resources that are not available in the current PLAC structure, the MSAC and/or external HTA experts may be approached for assistance.

Where necessary, the Secretariat will assist clinicians with accessing relevant clinical evidence or other information to assist in the assessment of the comparative clinical effectiveness of prostheses. After reviewing the clinical evidence and other information, the clinicians are to provide advice on possible revisions to the grouping scheme.

Collecting information on pricing, supply and reimbursement arrangements

Depending on the needs of the review, the Secretariat is able to collect information from a variety of reliable sources including: Hospital Casemix Protocol (HCP), the Independent Hospital Pricing Authority (IHPA), data from international markets, and other sources.

The Secretariat may also seek information from State and Territory authorities and hospitals and stakeholders on supply and reimbursement arrangements for prostheses to measure the extent to which they impact on prostheses benefits.

Analysis of cost and utilisation changes over time to inform group benefit setting

The Secretariat and PLAC will propose benefits for prostheses based on advice from clinicians on comparative clinical outcomes of prostheses as reflected by revised groupings and pricing and utilization data.

Notification to stakeholders of review and ongoing consultation throughout

Stakeholders including medical device sponsors, hospitals, private health insurers and consumers are to be actively engaged and communicated with throughout the review process. Opportunities for consultation include requests for submissions and consultation on proposed draft documents.

Reviews may be referred back to clinicians and the HESC in light of feedback from these consultations.

Consultation with HESC, MSAC, TGA and Registries

The HESC would be consulted where health economics expertise is required in proposing group benefits. Similarly MSAC, TGA and various medical device Registries would be consulted for information and data relating to their specific expertise.

Presentation to and discussion by PLAC

The PLAC reviews proposals and implementation plans for each review, as well as taking into consideration the views of stakeholders when preparing its advice to the Minister.

Recommendation to the Minister

The PLAC's recommendations from each review are submitted to the Minister for decision on the outcomes.

Advice to stakeholders

The PLAC and Secretariat provides timely advice to affected stakeholders and liaise with them as required on the implementation strategy for the review outcomes.

Critical success factors

Previous exercises to review listings and benefits have highlighted critical success factors for the reviews:

- there must be documented processes with clear line of sight between: the reasons for the reviews, the legislation, and the desired outcomes;
- opportunities for consultation or input from stakeholders should clearly communicated;
- issues raised by stakeholders are to be addressed, and outcomes communicated back to them;
- transparency of deliberations and outcomes, including sources of data and information, are essential; and
- conflicts of interest are to be managed quickly and effectively.

Risks and sensitivities

The various stakeholders will engage in the review processes in different ways. Consideration will need to be given to the needs and expectations of the stakeholders when engaging with them to ensure effective participation and outcomes.

The outcomes of the targeted prostheses reviews will have different impacts for the various stakeholder groups. Consideration will need to be given to the potential impacts on each stakeholder group.