Private Healthcare Australia
Better Cover. Better Access. Better Care.

Prostheses List

Purpose, definition and scope

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We collectively represent 97% of people covered by private health insurance. PHA member funds today provide healthcare benefits for over 14 million Australians.

Introduction

The Australian Government has pursued a range of private health insurance reforms over many years, seeking to simplify arrangements and ensure the 14 million Australians with private health insurance are not paying too much for their premiums. Australians with private health insurance are generally older, and their median income is lower than the Australian average.

Private health insurance funds have a primary responsibility to their members. Those who are lucky enough not to need to use their insurance pay for devices through their premiums, and those who do need services need access. Australia's health system – both public and private – rely on a strong network of people willing to contribute to their own care, a network of doctors and other health professionals providing services in the private sector, and private providers willing to invest in hospitals and equipment to provide that care. We need access to medical devices, but at a reasonable cost. The massive profits of multinational medtech goliaths at the expense of Australian consumers are not a priority, and the reforms proposed by the Australian Government leave plenty of funding on the table for Australia to remain an attractive market for medical technology.

The Australian Government decided in the 2021-22 Federal Budget to remove consumable items from the Prostheses List. Consumable items on the Prostheses List, including those identified by the Ernst & Young report, are generally high-quality medical items that provide benefits to patients. Consumable items which are removed from the Prostheses List from 1 February 2022 will continue to be funded by private health insurance. The benefits of reform will be shared by consumers and hospitals. Private health insurers have committed to pass on savings to their customers.

This consultation paper follows several years of consideration, consultation and observation by government and stakeholders in the private health insurance industry. It is now time to act. The COVID-19 pandemic makes the need for reform even more urgent as severe constraints on the provision of elective surgery in the public system will mean increased pressure to keep private elective surgery affordable and accessible for as many people as possible.

This consultation paper does not seek a debate on the merits of items used by medical practitioners in treating their patients. The debate is simply how these items will be paid for – as part of a government-controlled mandated price list or through market mechanisms.

Is the proposed approach to the definition of a kind of prosthesis flexible enough to anticipate future technologies while providing sufficient clarity on the scope of PL?

Generally, yes, subject to the implementation issues detailed below.

At present, the operation of the Prostheses List encourages use of medical devices and human tissue in a manner that is not cost-effective. PHA notes the distortion caused in the market by the Prostheses List and supports in principle an approach that is cost-neutral with respect to the type of therapy. PHA's initial proposal to use procedure group benefits would have addressed this issue and may still be an option for a select group of procedures.

The department's proposal to allow some single-use surgically invasive medical devices, if they meet other Part A criteria for listing, is an attempt to address this market distortion by creating another distortion. The proposal as presented is vague and holds significant financial risk across the entire episode of care for insurers and could lead to higher premiums for 14 million Australians.

This appears to be a solution in search of a problem. If an alternate procedure is cost-effective, then there is a clear incentive for providers and insurers to come to a commercial arrangement to improve outcomes and reduce costs. Reducing the very high margins on some devices (such as drug eluting stents) will improve the opportunities to come to such arrangements. Government expanding the scope of the Prostheses List violates many of the Australian Government's Principles for Best Practice Regulation.[1]

Further, there is a fundamental flaw in the proposal to price alternate treatments up to the higher prostheses price, rather than reduce the cost of the prostheses to a more cost-effective option. This flaw would lead to higher costs for consumers through inflationary pressures. There is no strong reasoning behind using a 'most expensive option' approach rather than a best value approach to benefit consumers. All new items considered for the Prostheses List must meet a value assessment (through HTA) rather than simply referencing an already inflated price for the incumbent device.

Assuming this flaw is addressed, the proposal could work through offsetting distortions by limiting the reimbursement of single use items, if they meet other Part A criteria, to specified MBS items (to avoid the issues of single use items being used in circumstances where value has not been established). PHA notes transient items will not be eligible for the Protheses List, and the definitions of transient items and single use items in this context will be important.

Single use items must be cost-effective, which generally would result in the alternate item(s) on the Prostheses List being reduced to a matching price. The rules would also need to specify that only one treatment will be funded – there should not be the opportunity to claim for both a balloon and a stent, for example. The most effective way of managing this risk would be to nominate a price for the procedure, rather than for each individual item. Further protections for consumers, such as price-volume agreements, should also be considered.

This proposal would also require adjustments to contracts, procedure banding and other payment mechanisms where funds currently pay for items proposed to be added to the list. For example, the cost of balloons is included in the procedure band.

Does aligning terms with established terms used by TGA (such as medical devices and biologicals) improve clarity?

Yes.

[1] Available at https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation

Are the proposed listing criteria for Part A fit-for-purpose? If not, what changes are needed?

The proposed listing criteria are generally fit for purpose but miss several opportunities to improve public benefit and provide safer, more efficient, and efficacious care for the community.

Conditions on listing

There should be a clear, positive obligation that devices should only be automatically reimbursed where the use of the device matches that assessed by the Therapeutic Goods Administration (TGA), generally as described in the indications for use (IFU) documentation. There is a common misperception that if the TGA approves an item, it is safe and efficacious. However, the TGA only assesses safety for the intended use. Implying that the item is therefore safe for all uses is incorrect. Items on the Prostheses List should be listed against specified procedures, and reimbursement should only be required where an item is used for that purpose.

The issue of patient safety should be paramount. The Prostheses List has required private health insurers to fund devices used off label where significant harm has come to patients, including hernia mesh used in the treatment of pelvic organ prolapse. There are a range of other items where funding outside the intended purpose has been required by legislation, leading to medicolegal risk for providers and funders.

Items are priced (deemed to be cost-effective) based on reference to other similar items or health technology assessment based on the intended use. There are several examples through the Prostheses List of items approved for one purpose then reimbursed for one or more different purpose. Examples include INFUSE bone graft, revision knee components, dura sealants, hip screws, and many others. In some cases, these usages may be unsafe (as they have never been tested), and in each of these cases, no cost-effectiveness assessment has been made for the alternate uses.

In addition to the conditional listing, PHA recommends items also be reimbursed where the treating medical practitioner declares that the use of the item outside indication is reasonable and necessary. The treating practitioner would be expected to meet their obligations to adequately document the reasons for their decision, and ensure the patient provides consent.

If more than 10% of usage occurs outside the intended use, the item should be reassessed for safety, efficacy, efficiency, quality and safety.

Removing listings

The legislative arrangements must include the capacity to remove or amend listings based on public benefit criteria. PHA has highlighted more than 80 items on the Prostheses List which are clearly incorrect, with over $10 million in additional benefits being paid annually. These are monies that could be used to reduce pressure on premiums.

The current practice of removing listings only with the permission of the sponsor is seriously flawed and does not meet any reasonable public interest test.

Regular review

There are no triggers for reviews of items on the Prostheses List. Listing should be reviewed regularly (at least every ten years), or when circumstances change. A simple trigger to reassess cost-effectiveness should be when an item's usage increases more than 10% in a single year (moving to 5% from 2024).

In most cases, any additional usage will be clinically necessary. For the product groups with over 10% increases in usage last year, around half were matched by increases in the number of relevant procedures. For others, there was an increase in usage per procedure, which should trigger a review to determine if the price per unit needs to be adjusted to ensure cost-effectiveness.

For example, the use of artificial skin has increased dramatically in recent years due to changes in clinical guidelines. However, the cost-effective price was set when the usage per procedure was significantly lower. The price per unit of artificial skin should be reduced to maintain cost-effectiveness.

Bundled listings

PHA supports the proposal that devices that are essential and specifically designed as a single-use aid for implanting a prosthesis, or are critical for maintaining ongoing-function of the surgically implanted prosthesis, should be bundled into the price of the device.

There are several examples on the Prostheses List of tools and accessories to implanted devices that do not meet the test of common sense. For example, there are $140 screwdrivers, $342 plastic clips, as well as extension leads costing over $1000. There are spinal cages where consumers are required to pay for each half, and many other examples.

PHA looks forward to working with the department to identify egregious examples of add-on devices, and we also recommend analysis of HCP1 data to identify where Prostheses List codes are billed together or in multiples per procedure.

These are plastic ID clips that go on a frame for people who have had a very serious leg injury. According to Australia's Prostheses List system, these are described as "Frame Component - Circular Coupling Devices" and the law requires private health insurers to pay $342 for the set.

In many cases, bundling items will involve summing of the current reimbursement, but in many other cases, bundling will in effect remove items and simply change the description of the main device. For example, the $342 Frame Component - Circular Coupling Devices pictures could be included in the description of the rods they attach to with no additional charge to consumers.

Splitting devices to maximise revenue is a blight on the current system. It disadvantages consumers, who pay more than necessary, and it disadvantages manufacturers who do the right thing. Any future medical device reimbursement system must stamp out this insidious practice.

Clinical effectiveness and cost effectiveness

The criterion that the device is to be at least, of similar clinical effectiveness and cost effectiveness compared to alternative prostheses on the PL or alternative treatments should remain. However, additional "me-too" devices should be encouraged to set a new price below the existing price to reset the market for the benefit of consumers.

The Prostheses List sets a floor price, and new entrants should reset the floor. High prices attract new entrants to the market without the benefit of price competition, particularly where the benefit levels are too high (spinal fusion cages are a clear example). This is a clear signal that the price is too

high and should prompt a review of the category to ensure that the advantages of competition accrue to the consumer. There should be trigger points to reassess benefit levels.

A process where the price of a new product is set by referring to another similar item on the list fails to capture benefits for consumers. For direct comparators, there is no price competition between brands, no opportunity to offer a lower price to attract market share, and no advantage to members of health funds if technological improvements reduce the manufacturing cost. This scenario favours incumbents, and stifles innovation.

Should the scope of products eligible for listing on Part B remain unchanged?

The operation of Part B of the Prostheses List is prone to the same vulnerabilities as the rest of the list. Many items are significantly overpriced, and there is evidence of some usage creep.

For example, the significant increase in the use of human tissue products (up 37% in one year) has occurred without review of the safety, efficacy or cost-effectiveness of this additional usage.

Should the PL retain an option for the Minister to list items in exceptional circumstances on Part C? Are there any other exceptional circumstances factors that Part C should accommodate?

The operation of Part C of the Prostheses List is prone to the same vulnerabilities as the rest of the list. Many items are significantly overpriced, and there is evidence of some usage creep.

The danger is that Part C of the Prostheses List expands to any item that the government of day thinks is a good idea, rather than relying on rigorous processes that protect the public interest as a whole – including the premium prices paid by 14 million Australians with private health insurance. Decisions by the Minister must be based on rigorous, transparent advice on the evidence of cost-effectiveness, where there is no other solution to ensure patient access. All decisions for Part C need to be regularly evaluated and reviewed.

For example, insulin pumps were added to Part C of the Prostheses List, and now cost almost double what patients pay in New Zealand. There is no mechanism for review to ensure the public interest is maintained.

Please consider the tables at Attachment B and explain which products meet the future criteria for listing and the reasons why?

The items in appendix B are a mixture of items that should not be on the Prostheses List on some which should remain.

Femur – proximal (human tissue) should be listed in Part B.

Hip femoral stems and cardiac pacemakers meet the criteria and should be listed in Part A.

Knee hinge ancillary products and cardiac pacemaker leads should be bundled into the relevant primary items listed in Part A.

Catheters and ablation devices should not be on the Prostheses List. There is no evidence that listing these items in Part C has improved access, but strong evidence that consumers are paying more for these items. Placing these items on the Prostheses List was solving a problem that did not exist. Listing these items has removed competition and has increased inflationary pressures.

Cardiac monitoring is a valued service that should be paid for as a service rendered. Currently, device companies are paid for a box or software regardless of whether it is used or not. These items should not be on the Prostheses List and a reasonable price for the service to the treating medical practitioner and patient should be supported by private health insurance.

Insulin pumps are valued devices, but currently consumers (through their private health insurance) are paying almost double the price paid by New Zealanders. Listing these items on the Prostheses List destroys competitive pressure and delivers a windfall to manufacturers. These items should be procured for their patients by health funds directly or through the National Diabetes Services Scheme to promote competition on price and service.

Surgical guides and biomodels are among the most abused part of the Prostheses List, and do not satisfy the existing or proposed criteria for listing.

Consumables and surgical instruments such as intraocular dyes, pressure wires, stent retrievers and catheters are generally included in the existing pricing for procedures, through banding or bundled payments. They should not be included on the Prostheses List.

Should the name of the list be modernised and, if so, what should it be called?

PHA recommends the name be changed to the Implantable Medical Devices List.

Does the list of items at Attachment A flagged for inclusion and removal accurately reflect the proposed future criteria for listing?

Yes, this list accords with the proposed criteria. The Ernst and Young report is very clear the items identified in the discussion paper should not be paid through the Prostheses List, rather through the ordinary arrangements between hospitals and health insurers. The other items proposed for removal at appendix A are similar and should be included.

The removal of items identified at Attachment A is scheduled to commence from February 2022. If a decision is taken to remove these items in tranches, is there a logical bundling of the items at Attachment A that would make staged implementation over time possible? Is the proposed staged removal aligned with PL updates workable? What is the most appropriate timing?

Each of these items should be removed in February 2022. This reform has been flagged for many years, and each month of delay will simply fail to provide the benefits of reform to consumers. There are no administrative difficulties in a one-step approach for each the items in attachment A.

PHA has proposed a generous and staged support package for hospitals based on each of the items being removed on schedule. In part, this was to allow hospitals more time and opportunity to seek the best prices available in the market. There would be reduced need to stage the support package if the implementation of the policy is done in stages.

Further, delays to implementing this policy would result in higher pressure on premiums for 14 million Australians with private health insurance.