Private Healthcare Australia
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Prostheses List Reforms – Consultation Paper 3 – A modernised fit-for-purpose listing process

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About PHA

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body that currently has 22 registered health fund members across Australia and collectively represents 97% of people covered by private health insurance. PHA member funds today provide healthcare benefits for over 14 million Australians.

About medical device funding

The most important issue facing private health insurance from consumers' point of view is simply the cost. Research repeatedly shows that affordability is top of mind among consumers when discussing health care. The cost of medical devices is too high, and the largest contributing factor to premium increases.

The 2021-22 Budget included modest proposals to gradually reduce the cost of generic medical devices, which are among the most expensive in the world. The existing program of reform will still leave Australians paying the highest prices for medical devices in the world in four years' time.

In determining the best policy settings for medical device funding, the Australian Government should seek to maximise public value for Australians. The Prostheses List is not a subsidy system for large multinational companies, but a way to ensure Australians have access to high quality medical devices at a reasonable cost.

Current listing pathway issues

The existing pathway for listing items on the Prostheses List is fatally flawed. It is a system that supports manufacturer profits over quality, efficacy, efficiency and safety, and puts very little importance on value for money for the Australian consumer.

Error rates are too high. As manufacturers determine their preferred comparator, they are incentivised to choose a comparator that provides higher remuneration. Items are placed in the wrong categories due to pricing anomalies, which has a "knock on" effect for other similar devices to also gain the higher benefits. Consumer benefit has been placed well behind a system designed to suit the manufacturers.

Transparency is appallingly low. The funders only access restricted to vague descriptors of products, rather than catalogue numbers that clearly identify all elements of the product and intended use. The system is designed to allow manufacturers to assert their product is covered by the Prostheses List, rather than facilitate open and transparent challenge and audit processes. This has resulted in instances where devices are misnamed to seek higher benefits, for example, a manufacturer billing over $1000 for a bolt identified as a pin clamp assembly, and after an investigation found to not even be listed in the Prostheses List Management System (see Appendix).

Manufacturers can seek to have their product assessed for one use, and if deemed suitable for that use, the law requires funders to subsidise any use. A product deemed safe and cost-effective for a specific spinal surgery when used with a cage cost consumers tens of millions of dollars being

used all over the body without the cage (the product is currently subject to legal action). This compromises safety as well as being economically irresponsible.

When mistakes are discovered, the nature of the current listing process means it takes months or years to rectify. In the meantime, there is a continued legal requirement to fund, compounding the error, increasing healthcare costs unnecessarily and allowing manufacturers to continue to profit.

Currently, some sponsors appear to take the approach they should see what they can get away with, rather than take a sustainable approach of providing value to the consumer. A minority of sponsors have sought to manipulate the holes in the current system to maximise profit. There are scores of examples each year of companies claiming features for their products that do not exist, and some examples where sponsors have provided misleading information to the government to seek a benefit.

With no penalties for making errors (deliberate or otherwise) and significant upside to providing incorrect information, the high rate of errors in the Prostheses List is not unexpected. Consumers would benefit immediately from introducing a range of penalties similar to those in place for the Australian Register of Therapeutic Goods (ARTG) in ss9G and 9H of the T*herapeutic Goods Act 1989.*

A self-regulatory system based on self-declaration and trust does not serve the community interest. Additional consumer protections are required to protect all stakeholders, including manufacturers who themselves will at times become be adversely affected by the actions of their competitors.

PHA welcomes competition and notes the inherent anti-competitive features of the Prostheses List. There is no competition on price, and consumers miss out on the benefits of competition (higher quality devices delivered at a lower price, with better service).

Transparency

The current process is not transparent, with funders often having no idea of the actual product they are meant to be funding. The listing process must be more transparent, both to ensure payment integrity and to assure the community that the medical devices being funded have been assessed as being safe, effective and cost-efficient for the intended and actual use.

All sponsors that seek funding for their devices should be required to outline, at a minimum:

- Links to the Australian Register of Therapeutic Goods reference, or if still in the application phase, a copy of the application
- The catalogue numbers of the device(s) in the application
- A picture of each device in the application
- Links to information guides and surgical technique documents
- The product group(s) the device is seeking benefits for
- The MBS items (or group of items) that the device is seeking benefits for
- A declaration which includes:
    - that the device is eligible for the Prostheses List

- whether the device is a direct competitor for an existing device or a new product or a product likely to add to costs (see below)
    - If the device is additive, an estimate of sales volume over each of the first four years
- that the device has not been previously assessed, or details of previous assessments by MSAC, PLAC or other bodies.

For most applications, these details will add less than ten minutes to the application process and provide a permanent record to assist the community and funders identify items on the Prostheses List. It will also allow scrutiny and reduce errors in the list.

Key issue – will a new product add to costs?

A fundamental issue for private health insurers is the cost of providing care. These costs contribute directly to premiums paid by Australian consumers. Clarity on whether a new or amended listing will add to costs is a key issue for future listing pathways.

Added costs for medical devices is not necessarily a detriment to consumers. Many devices, through technical advancements, add significantly to the public good. Where costs do increase for private health insurers paying for medical devices, benefits can flow to the insurer, to hospitals or medical practitioners, and to the patient, in addition to the sponsor of the device.
Most new or amended listings do not add to costs and are simply a new version of a product that is already on the list. A new orthopaedic plate will not add to costs if used in place of another sponsor's plate. In these cases of direct substitution, PHA supports changes to speed the process and provide more choice for clinicians and their patients, while noting the current and proposed system does not allow consumers to capture the benefits of greater competition due to price fixing.

Some new or amended listings may add to costs. This occurs where:

- A new or innovative product comes to market
- A product at a higher price is substituted for a lower priced product

Adding costs – Example of a new or innovative product

TAVI (Transcatheter Aortic Valve Implantation) adds to the device cost of the operation compared to existing valves, however the minimally invasive technique is shown to have better long-term efficacy, and results in a shorter hospital stay. Costs for TAVI have grown to approximately $47 million over four years, but in theory should result in longer term savings for

Adding costs – Example of higher priced product substituting for a lower priced product

In the November 2019 the price for the Baxter Infusor BX237 was changed from $79 to $241 with the inclusion of the word "set", even though nothing changed. There are no discernible differences between the systems at lower priced products (now priced) at $73 and those at $224.

This product was listed at the lower price for more than five years (presumedly with some level of profit), then simply tripled in price with no assessment of consumer value, costing $2 million

Adding costs – A product adding to the cost of a procedure

Evicel should be used as an adjunct to haemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical technique (such as suture, ligature or cautery) is ineffective or impractical. However, it is predominantly used as in orthopaedic operations, where standard surgical techniques such as suturing have been used for decades. Despite known to be low value care, using Evicel has added more than $1000 to the cost of thousands of standard hip and knee replacements, costing consumers over $10 million in the last two years.

- A product is added to the list which is used in addition to an existing device
- A greater volume of a product is used than the comparator
- The product is used in a different manner than the comparator (for example, in a different part of the body)

It is important for payors to understand any potential for increased costs (along with any associated benefits). Where there are not going to be additional consumer costs, a simple declaration from sponsors will allow more items to be assessed quickly and effectively.

Adding costs – Example of a product used in greater volume

Several biomodel and surgical guide manufacturers use multiple models per operation, with invoices over $50,000 being received for plastic models that are not inserted into the patient. This has contributed to the product group cost to the consumer increasing by more than $21 million in just five years.

Adding costs – Example of a product used in a different manner

There has been a four-fold increase in the use of liquid sealant for dura defect repairs over the last five years. This is because the product is now most commonly used for sleeve gastrectomy operations rather than in neurosurgery. It has never been assessed for cost-effectiveness for this use.

Pathways

PHA supports different pathways depending on the risk to the community, with the proviso of additional accountability and transparency mechanisms. Any pathway that does not improve the scrutiny of payors is wholly unacceptable.

There are over 100 known errors in the Prostheses List, costing consumers millions of dollars each year. The error rate from sponsors in applications to PLAC is currently around 20%. Without scrutiny, nearly all these errors would result in consumers paying more for medical devices. Many more mistakes in the existing system are avoided by being caught late in the process by PLAC scrutiny. Reducing payor scrutiny would allow for millions of dollars of low value or wasted spending.

Each pathway should include a basic question – will approving funding for this device provide a community benefit? Currently, clinical advisory groups and the Prostheses List Advisory Group are asked to consider a series of technical questions for assessment, with no explicit view sought on whether adding a device to the Prostheses List at the nominated price will improve community welfare (such as improved outcomes or lower costs of care). It is a legalistic system of precedent and comparison that benefits manufacturers. The question of consumer benefit should be put and considered for each pathway option.

Abbreviated pathway

PHA is conditionally supportive of an abbreviated pathway where payor scrutiny is assured. An abbreviated pathway that reduces transparency is wholly unacceptable and will lead to further abuse.

To ensure transparency, PHA recommends an additional step in the abbreviated pathway to ensure that the process is sound, plus a new declaration from sponsors to ensure that the community is protected from predatory behaviour.

A key addition should be a declaration from the sponsor that the product seeking approval through the abbreviated pathway is an alternative to an existing product, and thus will not add to the cost of providing care. (See below for recommendations on making a false or misleading declaration.) This will provide assurance to the community that the abbreviated pathway is being used correctly.

A new step 3A would have each of the applications published on the department's website, with the delegate not making a decision until at least 28 days have passed from publication. This would ensure that payors, competitors, clinicians and other interested parties could present information for the delegate's consideration.

Such a process would ensure that mistakes are avoided and protect consumers' interests. Over the past year, several items that were missed through the existing processes were picked up by PLAC members, with PHA representatives discovering several issues that the department and PLAC agreed were errors in assessment.

Examples include incorrect categorisations where the device did not have the features attracting higher benefits, devices that were not eligible mixed in with others in amendment applications, and in one instance, an attempt to use an amendment to get a device onto the Prostheses List after it had been rejected by MSAC (see box).

The most likely outcome of a payor or competitor providing additional information to the delegate is either the department seeking an amended application (as issues are corrected) or the department electing to assess the product through a more rigorous pathway.

Allowing public scrutiny of applications through the abbreviated pathway also opens the possibility of more regular updates to the Prostheses List. Ideally, items could be added monthly to ensure products can get to market as quickly as possible.

Case study – Trying to get listing for a product rejected by MSAC

Recently, a product applied to be listed on the Prostheses List was knocked back as it was very expensive, and the potential market was very large. The Prostheses List Advisory Committee (PLAC) rejected the application and referred the product to the Medical Services Advisory Committee (MSAC) for health technology assessment.

After a rigorous health technology assessment review, MSAC found the product did not meet the threshold for funding as it did not demonstrate effectiveness.

Two months after the MSAC decision, the sponsor included a new listing on the Australian Register of Therapeutic Goods (ARTG) for small plastic components used exclusively with the product which had been rejected by PLAC and MSAC. The components are also included in the ARTG entry for the primary product, so this second ARTG listing was redundant.

In 2021, PLAC was asked to consider adding a handful of new product codes to the sponsor's listing for another product. The catalogue number for the small plastic components was included with a number of other amendments. The sponsor did not disclose that the components were part of the primary product (they serve no other purpose); nor did they disclose that PLAC and MSAC have previously rejected funding for the product; nor did they mention that approving the amendment would increase costs to the consumer.

While not seeking to ascribe motive to the sponsor, the effect of approving this application would have allowed for the product which had been rejected by PLAC and MSAC to be rebated at roughly two thirds of the original asking price.

While the application did make it through initial assessments, PLAC and the Department of Health caught the application before it was approved, and the sponsor failed in their bid to list the components on the Prostheses List.

Focused pathway

Transparency

Again, in the interests of transparency, a new step would have each of the applications subject to scrutiny, with the focussed review not starting until at least 28 days have passed from publication. Unlike the "me-too" products subject to the abbreviated pathway, there are commercial in confidence considerations that suggest a more limited process should be adopted.

New applications should be scrutinised by a panel consisting of payors (PHA, Members Health Fund Alliance plus a panel of fund representatives), consumers nominated by the department, and clinical advisers (some of whom would be asked to examine the proposals in detail, consistent with the existing CAG panels). All potential reviewers would need to abide by commercial in confidence protocols.

The advantages of payors and others considering applications prior to assessment include problems being identified earlier in the process. Currently, sponsors may spend many months or years developing an application, with PLAC rejecting the application very late in the process. Earlier identification of issues will lead to better applications and more efficiency for sponsors.

If clinical advisers, consumer representatives and payors are comfortable with an application, PHA would expect that the focussed pathway would be more efficient, providing quicker and less costly processes prior to assessment. In effect, insurers would be bearing some of the time and cost of assessment at the start of the process, rather than halting the application late in the piece.

Class III devices

PHA supports the focussed pathway as the minimum level of assessment for Class III devices. These devices have been assessed by the TGA as constituting a greater risk to the community (and most likely, greater benefit), so a focussed pathway is most appropriate.

With the panel scrutiny outlined above, many of the assessments of Class III devices would be quick and efficient.

HTA pathway

The existing HTA pathways are reasonable. Similar to the pathway for focussed HTA above, a panel of payors, consumers and clinicians should be allowed to present information for the review's consideration within a 28-day period.

Addressing errors in pathway selection

PHA notes that many products over the years have been nominated by the sponsor as not meeting the threshold for a full HTA pathway yet have ended up being very high cost to the consumer and the health system. There is a clear incentive for sponsors to self-select the path of least scrutiny. In some cases, this will be a genuine error, and in some cases, it will be a calculation that there are no penalties and many commercial benefits for nominating the incorrect pathway. PHA recommends that there be penalties for false declarations (see below) to discourage such behaviour.

PHA also recommends that where a product increases the cost in any particular product group by more than $1 million or 10% (whichever is the higher), an automatic price-volume adjustment be made to the group, followed by the group going through the HTA pathway.

The price-volume adjustment should be a percentage reduction of half the volume increase (adjusted for surgery volumes and the estimated outcomes of HTA processes). For example, an increase of 10% in volume should result in a 5% reduction in price, until an HTA determines if the price should be adjusted.

Penalties for false declarations

The integrity of the Prostheses List process has been challenged by a minority of sponsors providing information to the department which has proven not to be correct. The lack of scrutiny, the volume of applications and the lack of transparency has resulted in an environment where errors in applications have been overlooked. Several of these errors have resulted in sponsors making significant excess revenue. When errors are discovered, it can take years for them to be corrected, and in the meantime, the sponsor continues to obtain excessive benefits at the expense of consumers.

There are clear financial incentives for sponsors to provide incorrect or misleading information when listing medical devices, which may lead some actors to display a lack of scrutiny to information provided. The incentives for doing the wrong thing may have led to some actors making a deliberate decision to provide incorrect or misleading information. There are no penalties or sanctions for incorrect, misleading or false statements.

Given the potential for significant consumer harm, the government should introduce legislative sanctions into the system. PHA would be very surprised if such sanctions were ever used, but the existence of penalties provides a counter to the existing incentives and improves the integrity of the system.

The *Therapeutic Goods Act 1989* (ss. 9G and 9H) contains a series of criminal and civil penalties for providing false or misleading information to the ARTG, which should be replicated for the Prostheses List.

Addressing errors

The pathway to address errors proposed in the discussion paper is weak and does not serve the community interest. Allowing companies right of reply with no timeframe invites delay, which may result in monies continued to be incorrectly paid by consumers (through private health insurance premiums) for significantly longer than necessary.

PHA has notified the department of a range of errors in the Prostheses List which cost consumers over $10 million per annum. For one product that was incorrectly listed, every month of delay resulted in consumers paying over $150,000 incorrectly. It took more than a year for the product to be delisted. For knee replacement parts listed for revision procedures but used for primary procedures, consumers have been penalised with more than $15 million of inappropriate spending since the issue was notified to the government and the sponsors. The sponsors have refused to modify their listings, preferring to wait until they are forced to do so by the government.

Case study – the $1023 bolt

These devices described by the manufacturer as a 'pin clamp assembly.' Between 12 and 36 of these devices are used to hold together a frame for very complex leg fractures (pictured). Pin clamp assemblies are on the Prostheses List at $1023 each.

When PHA suggested that these devices were bolts (which should be charged at $45 each), the department discovered that the catalogue numbers were not listed on the Prostheses List Management System, and they did not have record of the manufacturer applying to have the devices on the list. (The manufacturer asserts there was an application that included these bolts, and they were assessed). Thus, the manufacturer's claims for over $2 million in benefits for these bolts were simply an assertion that the devices were on the Prostheses List at $1023 each.

As the Prostheses List does not publicly disclose catalogue numbers and the law requires private health insurance funds to pay the list price, funds had no way of knowing that their customers were being charged for devices that did not appear on the list until they investigated very high prices for this manufacturer's system (over $50,000) compared to another system on the market (around $15,000).

As at the time of writing, the manufacturer has refused requests to refund customers.

Despite notifications from PHA and from government, sponsors with incorrect listings have continued to delay changes and/or refuse to change their listings relying on legal loopholes. The MTAA Agreement, which expired on 1 February 2022, gave companies the right to refuse delisting requests, and some sponsors took advantage of those provisions at the expense of consumers.

The department should remove items immediately where:

- The device is clearly ineligible (for example, where there is no current ARTG listing), or
- There are safety concerns.

In these instances, the device may be immediately relisted if the issues identified are addressed.

In other cases where the concern is around the type of listing rather than eligibility or safety, the department should initiate a 'show cause' process, with the department providing a draft decision to the sponsor to delist, reprice or change a device's categorisation. The sponsor should be given

28 days to respond, and the department has a further 28 days to affirm their decision, withdraw the action, or send the issue for review. If the issue is sent for review, the eventual decision should be deemed to have been made at the point of review, ensuring delays in the process do not financially disadvantage consumers. Funders should be required to suspend potential benefits, with monies released once a decision is made, unless the decision is that the item is not eligible for benefits (so no monies are paid) or partial benefits are paid if the item is reclassified.