Response ID ANON-3GBU-RQWU-Z

Submitted to **Review of the General Miscellaneous Category of the Prostheses List**
Submitted on **2020-03-03 09:50:14**

Introduction

1 What is your name?

Name:
s 47F

2 What is your email address?

Email:
s 47F

3 What is your organisation?

Organisation:
Private Healthcare Australia

Questions

4 Are there any sub-categories or product groups/sub-groups within the General Miscellaneous Category that should not be included on the Prostheses List?a. If so, why?b. If not, why not?

Q1 - Products that should not be included on the Prostheses List:
Private Healthcare Australia RECOMMENDS that:
• all items in the General and Miscellaneous category of the Prostheses List should be removed,
• the Prostheses List should only be for items that:
o have a permanent and ongoing function in the body,
o are required for a specified procedure, and
o cannot be adequately funded through other mechanisms such as bundled payments,
• consumable items elsewhere on the Prostheses List, such as ocular fluids and software, should also be reviewed.
• all Prostheses List items should be conditionally listed, so they may only be used in accordance with:
• TGA approved indications, and
• the purpose for which the item was approved by the Prostheses List Advisory Committee (in most cases, linked to MBS item(s)).

The general and miscellaneous category of the Prostheses List is driving significant cost increases for Australian families paying private health insurance premiums, in the absence of associated improvements in patient care or outcomes. The increase in usage of items on the Prostheses List is growing significantly faster than the growth in procedures. APRA reported a 275,000 unit growth increase on Prostheses List items funded with 0.3% surgical growth in 2018/19.

The Australian Prudential Regulatory Authority (APRA) has recently warned that excessive costs in the industry are threatening the survival of health funds. While Private Healthcare Australia is not convinced that APRA's warnings on mass consolidation in the industry will occur, APRA is correct to note the threats of excessive costs to the industry.

Supernormal profits on prostheses are a simple transfer of wealth from millions of Australian families who struggle to pay their bills to multinational device companies and their shareholders.

The extension of the Prostheses List to include non-prostheses that combat a pathological process or modulate a physical process has led to many of the problems observed in rapid growth of utilisation at a time of flat surgical growth. The Prostheses List should only for be implants that have a permanent and ongoing function in the body, and not associated consumables that already have an existing funding mechanism.

Many of the items in the general and miscellaneous category do not meet the common-sense definition of a prostheses and should be removed.

Other devices, which are technically prostheses, can also be more efficiently funded through other mechanisms.

Items that are not prostheses should be, and in most cases already are, funded through bundled payments made by insurers to hospitals. Private health insurers use a combination of DRGs, case payments and procedural banding to fund private hospitals for consumables utilised during surgical procedures (these are multi-year commercial agreements). This effectively results in a double billing to funds who are mandated to cover the cost of items on the Prostheses List under the Private Health Insurance Act of 2007 as well as the surgery payment agreements in place with Private Hospitals. Dermabond is a clear example – see attached case study.

Most health financing systems in Australia and overseas use bundled payments for procedures that include payments for general use items. Australia is alone is using a model such as the Prostheses List which is used to fund small, itemised components of surgical prostheses kits including consumables. Bundled

payments for procedures are the most common and most efficient way to fund medical care, although an exception for high-cost individual prostheses (or bundled prostheses where there are multiple components) can be efficient if the funding mechanism is sound. (In Australia, we overpay for many common prostheses.)

For high-volume, low-cost prostheses such as Ligating Devices, Staples and Tackers, the Prostheses List is a very inefficient funding mechanism. Thousands of these items are used in surgical procedures, most of which cost under $1000 (and some under $100). There are a number of suppliers of these products and intellectual property costs for which the costs are already sunk; this is an area ripe to capture the benefits of competition to improve public benefit.

Bundled payments by procedure are be a much more efficient way to fund Ligating Devices, Staples and Tackers. Such arrangements are already negotiated between health funds and hospitals, providing an incentive for hospitals to get the best poss ble price from suppliers. The benefits are predominantly captured by hospitals, with fund members also benefitting as hospitals pass on lower prices. Government administrative costs would fall significantly.

Bundled payment mechanisms provide accountability between payers and providers. Currently, the granting of a Prostheses List listing becomes an unrestricted license to sell items into as many procedures as possible and with no restrictions on volume of use and no requirement to have an evidence base for the item's use.

There is no ability for insurers to promote cost-effective treatment; there is no incentive for the surgeon or the hospital to consider cost-effectiveness for consumable items; and strong incentives for manufacturers to promote items of limited additional value to the patient knowing the bill is being sent to the insurer. Further, the insurer is not currently permitted by law to refuse to fund an item on the list – even if the insurer has a reasonable belief that the item may be doing harm to a patient (for example, the case of INFUSE).

To illustrate the example of poor public value, the use of Evicel as a sealant in joint replacements adds at least $1,443 to the cost of the procedure, with no cost-benefit analysis. Evicel was developed for high risk bloody vascular operation such as sealing the aorta – the accepted sealant for a joint replacement is a $15 suture foil. PHA has isolated an example where more than $10,000 was billed for Evicel for a single patient having a knee replacement.

Our expectation is that items on the Prostheses List should be there for a specific function. Many items on the Prostheses List in the general and miscellaneous section are used outside their intended purpose (for example, beyond the manufacturer's recommendation), the purpose for which they have been assigned to the Prostheses List (for example, used for procedures not listed in the manufacturer's application) and in some cases, outside the Therapeutic Goods Administration's (TGA) approved indications. The unrestricted nature of the Prostheses List means once an item is listed, it may be used for any purpose regardless of the evidence base for that use and with no cost-benefit analysis, and the community (through insurers) must pay for it. This is contrary to all public value theory and does not serve the community interest.

Consistent language about the clinical indications for which products may be used and funded is vital. There needs to be a direct line of sight from TGA approved indications, through health technology assessment processes, Medicare funding and prostheses use. Where products are used for purposes other than which approvals are sought, medicolegal and safety risks increase for all concerned.

The methodology for this current review should be extended to other consumable items on the Prostheses List, including but not limited to; ocular fluids, gasses and oils (many of which are able to be used outside the operating room) as well as bio-models that are not critical to implanting devices (these are simply software that form part of the production process, and ithey are adequately covered commercially in the higher priced plate) as well as bone graft substitute.

Returning to the specific items covered by the general and miscellaneous category of the Prostheses List, our recommendations by subcategory are listed below.

Brachytherapy

No items in this category should be retained. Brachytherapy is a delivery mechanism rather than a true prosthesis. While we endorse Brachytherapy as a treatment modality it should be funded under diagnostic reference group (DRG) payments. The radioactive seeds should not be listed as devices. The seeds play no role in replacing a bodily function or ongoing modulation of a physiological process.

Drug delivery devices

No items in this category should be retained, these are delivery mechanisms rather than true prostheses.

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None of the above are implanted devices. For example, the "intuitive, full colour touch screen interface" offered by one product is not implanted into the patient.

03.02.06 - Pharmaceutical Beads should not be retained

This alternate method of delivering pharmaceuticals should be funded through pharmaceutical pricing mechanisms if cost-effective.

Enteral tubes

No items in this category should be retained; while these are implanted devices, they are not permanent.

Gastric bands

All items in this category are permanent prostheses but should be banded or contracted rather than on the PL given their price and competition in the market.

Haemostatic devices

No items in this category should be retained. These items are not permanent and do not have an ongoing function.

Luminal stents

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03.07.03 - Drainage Shunts, Peritineovenous are permanent and have ongoing function but should be banded or contracted rather than on the PL given their price and competition in the market.

Closure devices

Anything that is not permanent and ongoing in its function should be removed, such as glues and other temporary consumable items.

This includes all items in the following categories:
03.08.01 - Adhesion Barriers
03.08.02 - Internal Adhesives

Items which are permanent and ongoing but should be banded or contracted rather than on the PL given their price and competition in the market. These items include:

03.08.03 - Ligating Devices
03.08.04 - Staples & Tackers
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03.08.07 - Complete Biomaterial Mesh
03.08.08 - PTFE/ePTFE Mesh
03.08.09 - Plugs

PHA has previously expressed concerns around reimbursement rates for Ligating Devices, Staples and Tackers. There is a strong administrative efficiency argument that low cost (under $1000) items should be excluded from the Prostheses List and funded through other mechanisms. These items are common, there is significant competition in the market, and funding through the Prostheses List is inflationary and distorts the market.

Q1 - Products that should not be included on the Prostheses List:
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5 Would any of the sub-categories (or groups or sub-groups) within the General Miscellaneous Category of the Prostheses List be better listed elsewhere in the Prostheses List?a. If so, where and why?

Q2 - Products Better Listed Elsewhere:
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No.

Private Healthcare Australia and its member funds welcome suppliers with positive health technology assessments for new technologies to present these for consideration. The funding of these devices should be managed through high quality clinical and costed models via a direct payment agreement/DRG, or through a procedures list that has been assessed and recommended by the Medical Services Advisory Committee.

6 Are there any General Miscellaneous Category items that were funded through non-Prostheses List arrangements prior to being listed on the Prostheses List?a. Were patients left out-of-pocket through this non-Prostheses List arrangement?b. Where patients were not previously out-of-pocket through a non-Prostheses List arrangement, what advantage did patients receive from the inclusion of such a product on the Prostheses List?c. Were there any other effects that have been identified as a result of listing this product?

Q3 - Alternative Funding Arrangements:
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3. Are there any General Miscellaneous category items that were funded through non-Prostheses List arrangements prior to being listed on the Prostheses List?

Yes. Many of the items on the consumable list were and continue to be funded under existing case payment models. New MBS items are considered by the National Procedure Banding Committee, the outcomes of which are published by the Australian Private Hospitals Association. All consumables are included in the band.

Consumable items are used by hospitals and clinicians where it is cost-effective to do so. If a new product is introduced to the market, hospitals and clinicians determine if it is more effective than the incumbent process. Placing an item on the Prostheses List that is not an implantable item distorts this assessment, leading to cost inflation.

For example, Dermabond is a skin glue which was first launched in Australia in the late 1990s. It is not a prosthesis. The skin glue lasts a week (falling off in the shower) and is listed as an internal closure device. Dermabond was submitted for the Prostheses List in February 2018. The product has and continues to be funded in hospital DRG and case payments.

In the space of two years funding for Dermabond on the Prostheses List has grown from nothing to $13.8 million. Private health insurers are paying a second time for this product, as for nearly 20 years they were covered under DRG and case payments.

Consumable items on the Prostheses List that have a history in the market prior to being listed are captured by banding or other bundled payment arrangements. In addition to Dermabond, examples include Nasopore, Brachytherapy and Oxiplex.

Were patients left out of pocket through these non-Prostheses List arrangements?

No.

a. Where patients were not previously out-of-pocket through a non-Prostheses List arrangement, what advantage did the patients receive from the inclusion of such a product on the Prostheses List?
None.

b. Were there any other effects that have been identified as a result of listing this product?

There has been a significant transfer of wealth from Australians paying private health insurance premiums to device manufacturers and their shareholders, most of whom reside outside Australia.

Manufacturers who are doing the right thing are disadvantaged. The Prostheses List Advisory Committee has seen correspondence from manufacturers directly disadvantaged by a competitor listing a consumable product on the Prostheses List. (There are currently no penalties for misleading the Prostheses List Advisory Committee, and many incentives to do so.)

In addition to answering the above questions you may wish to provide specific examples of where you believe there are anomalies or inconsistencies in the General Miscellaneous Category, including examples to support your claims.

Nasopore

• NasoPore is a sponge. It is not a prosthesis.
• In 2010, the indications for the Prostheses List expanded to a device that combated a pathological or physiological process. This expansion was designed to support expensive pacemakers and nerve stimulators that permanently functioned for the life of the device. NasoPore was listing because it stops bleeding (a physiological process)
• Nasopore was introduced in Australia before 2009 and placed on the Prostheses List in 2017
• The impact of adding items such as sponges to the Prostheses List has cost Australian families paying private health insurance premiums millions of dollars annually
• Like many miscellaneous items, sponges are also funded through DRG and case payments
• Sponges can be used inside and outside the operating room. For example, NasoPore is a common sight on football fields
• A box (8) of these absorbable sponges costs $1,136 on the Prostheses List. Compared to $143 per unit in Australia, NasoPore is listed through the NHS at £25.65 on the NHS, and members of the public can buy a box of eight through esutures.com for $US99.

Sapphire Infusion System

• The Sapphire Infusion System is an infusion pump designed for the volumetric delivery of medications to patients at a programmable rate.
• The listing on the Prostheses List notes that “Sapphire is the first pump to offer an intuitive, full colour touch screen interface in an ambulatory package”
• This is not implanted into the patient; it is not a prosthesis.
• The device is a capital item and may be used for multiple patients

Ligaclip Endoscopic Multiclip Applier

• This is an example of a range of devices for inserting stapes. It is not implanted into the patient; it is not a prosthesis.
• Appliers existed before their entry on the Prostheses List and were paid for through existing mechanisms such as bundled payments where they added value to the surgery.
• The addition of appliers on the Prostheses List has meant that value is no longer a factor in the decision to use a device – the entire cost is transferred to people paying private health insurance premiums, and the entire benefit of time savings accrues to the provider.

Spongostan Absorbable Haemostat

• This is a sponge. It is not implanted into the patient; it is not a prosthesis.
• Sponges have been used in surgery for a long time prior to the introduction of this item on the Prostheses List and covered by other funding mechanisms. Adding sponges to the Prostheses List has resulted in funds paying twice for these products.
• With a list price of $9, the Prostheses List is a very poor mechanism for funding a low-cost, high use item.

7 Other comments.

If you would like to expand or explain any of your previous answers, or you have any further comments or feedback, please enter details here::
Word version attached

Select 'Choose File' to navigate to the file on your computer, then select 'Open' to upload. Word, Excel or PDF files only please.:
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INPUT TO THE REVIEW OF THE GENERAL MISCELLANEOUS CATEGORY OF THE PROSTHESES LIST

1. **Are there any sub-categories or product groups/ sub-groups with the General Miscellaneous Category that should not be included on the Protheses List.**
    a. **If so, why?**
    b. **If not, why not?**

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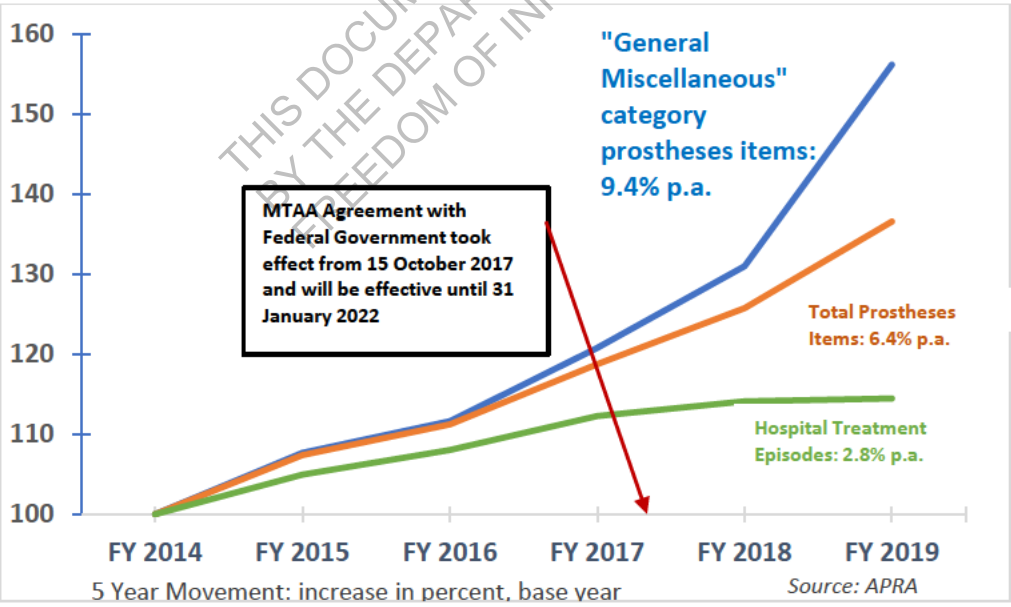

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2. **Would any of the sub-categories (or groups of sub groups) within the General Miscellaneous Category of the Prostheses List be better listed elsewhere in the Prostheses List?**
    a. **A. If so, where and why?**

No.

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Were patients left out of pocket through these non-Prostheses List arrangements?

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- The addition of appliers on the Prostheses List has meant that value is no longer a factor in the decision to use a device – the entire cost is transferred to people paying private health insurance premiums, and the entire benefit of time savings accrues to the provider.

Spongostan Absorbable Haemostat

- This is a sponge. It is not implanted into the patient; it is not a prosthesis.
- Sponges have been used in surgery for a long time prior to the introduction of this item on the Prostheses List and covered by other funding mechanisms. Adding sponges to the Prostheses List has resulted in funds paying twice for these products.
- With a list price of $9, the Prostheses List is a very poor mechanism for funding a low-cost, high use item.