Australian Government

Department of Health

Consultation Paper: Options for reforms and improvements to the Prostheses List

December 2020

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INTRODUCTION

The Australian healthcare system operates under a mixed model of private and public health and hospital services. Australians with private health insurance may choose to receive treatment as private patients in either private or public hospitals. For privately insured patients with appropriate health cover, private health insurers are required to pay set benefits for prostheses (medical devices) when they are provided in prescribed circumstances. Prostheses include surgically implanted prostheses, human tissue items and other medical devices.

The Private Health Insurance (Prostheses) Rules (as made from time-to-time) is a legislative instrument made under the *Private Health Insurance Act 2007*. The Schedule of the Private Health Insurance (Prostheses) Rules is known as the Prostheses List (PL).

The PL specifies a set benefit amount for listed prostheses. The PL benefit applies to appropriately covered privately insured patients that receive a prostheses as part of treatment, where there is a Medicare benefit payable for the service as part of their treatment. The treatment can be delivered in a private or public hospital, or in a hospital-substitute setting. The PL benefit is used to determine the sum private health insurers are required to pay to hospital providers.

The Australian Government (the Government) is committed to ensuring consumers have access to safe, clinically effective and cost effective prosthetic items, chosen by their clinicians. The Therapeutic Goods Administration (TGA) is responsible for regulating the safety of medical devices, including prostheses, in Australia. The Minister for Health and the Department take advice on the clinical and cost-effectiveness of prostheses from the Prostheses List Advisory Committee (PLAC). The arrangements for including products on the PL help to ensure that benefits paid by insurers are relative to clinical effectiveness. The purpose of clinical assessment for the PL is reimbursement, not regulation.

The PL has undergone a number of changes since it was introduced in 1985. The current reform considerations were initiated in 2017, when the Australian Government entered into a Strategic Agreement with the Medical Technology Association of Australia (MTAA). Through the Agreement, each party agreed to:

- promote the sustainability of privately insured health care through rebalancing the costs of medical devices to privately insured patients, to help keep private health insurance affordable for all Australians;
- support a viable, innovative and diverse medical technology sector in Australia and local jobs; and
- improve the value of private health insurance for consumers by reducing benefits for prostheses on the PL.

The Government subsequently commissioned a number of Reviews and constituted a number of Industry Working Groups to inform options for improving the PL. The Revised Benefit Setting and Review Framework Industry Working Group (BSR IWG), was tasked to develop a revised framework for setting and reviewing benefits for devices on the PL. The BSR IWG report was published on 16 December 2020. The work of the BSR IWG provides an important contribution for the Department of Health to develop detailed reform options for the Government to consider, in collaboration with stakeholders.

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PURPOSE

This aim of this paper is to inform Government considerations around the direction and implementation of options for PL reform.

This consultation document is not a Regulatory Impact Statement but is intended to solicit information for the development and implementation of policy decisions. Genuine and timely consultation is an Australian Government requirement contained in Principle 4 of the Australian Government Guide to Regulatory Impact Analysis.

A number of related documents have also been made available publicly. These may be of interest for anyone seeking to understand the broader context for reforms to Private Health Insurance and the PL.
Consultation paper: Private health insurance reforms – second wave
Options for a Revised Framework for Setting and Reviewing Benefits for the Prostheses List
Review of the General Miscellaneous Category of the Prostheses List

HOW TO LODGE A SUBMISSION

Feedback on this paper is requested over the coming nine week period and by no later than close of business on 15 February 2021 by email to the Prostheses Reform mailbox: prosthesesreform@health.gov.au. Please note that feedback received after this date may not receive consideration.

The Department is seeking information and comment on any issues that respondents consider relevant to the proposed reform options. Respondents are free to comment on issues in addition to the specific matters raised in this consultation paper. The Department welcomes all feedback, including additional measures to address issues detailed in this paper.

Submissions may range from a brief comment or short letter outlining your views on a particular topic to a much more substantial document covering a range of issues. Respondents should support their submission with evidence.

Each submission and comment, except where supplied in confidence, will be considered for publication on the Department's website, and if published, remain indefinitely as a public document.

If respondents would like their feedback to remain confidential, please mark it as such, or indicate which sections should be confidential, and which are appropriate for publication. It is important to be aware that confidential feedback may still be subject to access under freedom of information laws. The freedom of information process usually includes consultation with the respondents prior to a decision about the release of information.

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OVERVIEW – CHALLENGES AND OPPORTUNITIES

Increasing medical costs, increasing utilisation of health services (particularly by older people and people with chronic disease) and declining participation rates (particularly by younger Australians) is challenging the affordability and long-term sustainability of the PHI sector.[1]

The Government recognises the important role that medical devices play in the overall health of Australian patients and the need to maintain a stable, sustainable and innovative medical device sector.

In 2019-20, over 3.1 million prostheses on the PL were supplied at a cost to private health insurers of approximately $2.1 billion.[2] Expenditure on prostheses accounts for 14 per cent of private health insurance hospital benefits paid annually. The cost of prostheses on the PL has been identified as a factor in the rising price of health insurance premiums for consumers.

Reform and improvement to the prostheses listing arrangements could put downward pressure on private health insurance premiums for consumers. Engagement across the health sector throughout the 2017-20 review period confirms there is broad agreement that the PL can, and should, be reformed. Whilst there is less consensus on the method of achieving reform, three key areas been identified as priorities:

- Price (particularly relative to the public hospital sector)
- Scope and definition
- Consolidation of the list

The key aim of any reform is to create a more transparent basis for purchase and reimbursement of medical devices and better relate the benefits paid by private health insurers for prostheses to actual public and private sector prices. This is intended to reduce pressure on private health insurance premiums for consumers, and in turn improve the affordability and attractiveness of private health insurance for consumers.

The main policy levers available to effect change in the private health setting include encouraging competition and deciding which health care interventions will be publicly funded. Within that context, two broad concepts for reform have emerged:

1. Consolidate the PL using Diagnosis Related Groups (DRGs) prostheses subcomponents, and revise benefit setting, with administration of benefit setting moved to the Independent Hospital Pricing Authority (IHPA).
2. Consolidate and redesign the PL with extensive changes to pre- and post-listing assessment and benefit setting processes, with administration maintained by the Department of Health.

Implementation for any reform would occur following the scheduled cessation of the Agreement with MTAA on 31 January 2022, in an appropriately staged manner.

[1] Commonwealth Ombudsman, Health Insurance Premium Increases Fact Sheet
[2] APRA Statistic, *Private health insurance prostheses report*, June 2020 (released 18 August 2020)

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UNDERSTANDING THE CHALLENGES

Addressing price disparity between the private and public hospital sectors

Benefits paid through the PL are generally inflated when compared to average prices paid for equivalent devices in other settings. Multiple reviews (Doyle 2007; HTA 2009; Sansom 2015; Clarke 2017) have found that the PL framework has led to higher average prices for devices used in the private sector compared with public hospital and international prices. IHPA's December 2019 report *Prostheses Costs in the private and public sector* estimates that for 2017-18 this gap was 130 per cent.

A likely cause of the disparity in pricing is that the minimum benefits set through the PL act as a floor price. There is little incentive for price negotiation between hospitals and device companies. Instead, there is incentive to move as many items on to the PL as possible because of the mandated benefits for listed items. This can lead to a number of market distortions including preferential use of PL items over equally effective and lower cost non-PL items or equipment. The very complexity of the PL with over 11,000 billing codes and 1,700 price groupings exacerbates these distortions.

In February 2017, the Government reduced minimum benefits by 7.5% to 10% for some high cost, high use device categories (cardiac, intra-ocular lens, hip and knee prostheses). In October 2017, the agreement with the MTAA included a series of further benefit reductions across the PL between February 2018 and February 2020. These were estimated to reduce outlays by a total of $1.1 billion over four years.

Whilst significant savings have been achieved, due to the impact of COVID-19 it is not clear if the total savings target has been met. However, the reduction in benefit payments by private health insurers have been smaller than expected because of higher utilisation growth (8.6% in the 2018 premium year versus forecast 5.7%). A significant proportion of the above-average utilisation can be attributed to the General Miscellaneous category, where annual use increased by 18.4 per cent in 2018-19.

The combined impact of reduced benefits and changing patterns of use is reflected in the changes to the annual average benefit. The average benefit per device reduced from $775 in 2017-18 to $670 in 2018-19, but subsequently increased slightly to $673 in 2019-20.

The ability to predict the timing and savings impact are some of the advantages of this approach to price control. However, the outcome has differential impacts on the medical technology sector, noting that the benefit reductions agreed with MTAA applied to all medical technology companies, MTAA members or not. Without changes to the underlying system for setting and reviewing PL benefits, one-off reductions are likely to be eroded over time. Relevant factors that continue to drive above trend growth include: the increasing scope of the PL; and increased per item pricing for mature technologies, enabled by the PL's complex classification system.

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As well as setting benefits, it is important to continually review the benefits to ensure they are appropriately pegged to the prices used in comparable settings. In general, once items are listed on the PL there is no structured mechanism for regularly reviewing the benefits paid for these items. The PL has been criticised as having a 'set and forget mode'[3]. Without sustainable reform, there will continue to be higher prices paid in the private sector versus the public sector and internationally.

Improving scope and definition: which items should qualify for a benefit

It has never been intended that the PL should be a mechanism for private health insurance funding for all medical devices or medical consumables used in an episode of hospital care.

However, there is growing concern that the scope for the PL is not well understood, meaning there are no obvious limits on what is included in the PL. The lack of a legislated definition of a 'prosthesis' potentially allows items to be placed on the PL which could be better funded by other avenues, or are already funded through other means ('double funded'). Indeed, the use of the word "prosthesis" to describe a medical device implanted during a medical procedure, seems at odds with the dictionary definition. This highlights the need to improve the current definition, without narrowing the scope such that the PL excludes clinically valuable innovations that are best funded through this mechanism.

The table below (see pages 9 and 10) outlines the range of current definitions in use across the various programs which have a medical device component, including the definitions applied to the PL.

While there is no legislated definition of prosthesis, the guidance documents that underpin the administration of the PL arrangements make clear that the products that are listed on Part A (the main part of the PL) should have the following features;

(i) they must be implanted or remain within the body, *and*
(ii) they must have a therapeutic purpose.

The eligibility for some items, such as joint replacements, pacemakers and cardiac stents, is well understood. Similarly, it is also well understood that devices such as external limb prosthetics, external breast prostheses, or implants used solely for cosmetic purposes are not eligible for the PL. In many cases these items are funded through other programs, such as the National Disability Insurance Scheme.

Advancements in technology mean that the PL has expanded over time to accommodate a wide range of devices, not all of which are permanently implanted. These exceptional products are listed on Part C of the PL and include insulin infusion pumps and cardiac home/remote monitoring systems.

However, there is evidence of items being included on the PL which arguably do not meet the criteria that the product be implanted (a term which itself has been variably interpreted). One example is topical skin adhesive products used to close wounds.

[3] Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017)

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The BSR IWG reviewed current PL arrangements and reform options over eight meetings held between April 2018 and February 2020. Although the BSR IWG did not reach agreement on the scope of the PL going forward, it did agree the factors which should be considered as important matters to take into account when making listing decisions for the PL. These include:

1. The current scope of general cover under private health insurance (hospital versus hospital-substitute care)
2. Demonstration of clinical effectiveness and cost-effectiveness as a precursor to listing and benefit setting
3. Avoidance of duplicated payments (e.g. medical services that include diagnostics that are funded through the MBS and/or medicines that are funded through the PBS)
4. Recognition that the PL is not the only mechanism for funding medical devices (and other therapeutic products) that are used in hospital care, but the PL should complement other hospital funding so as to avoid gaps in funding.
5. Avoidance of perverse behaviours prompted by access to PHI benefits rather than pursuing more efficient care (e.g. hospital admission for diagnostic tests which are more appropriately rendered in the community).
6. Ensuring that privately insured patients are not exposed to out-of-pocket expenses for use of a device listed on the PL. [4]

[4]Report by The University of Sydney reflecting discussions of the Revised Benefit Setting & Review Framework Industry Working Group, pg. 14

Medical Device and Prostheses Definitions	
Ordinary Dictionary Meaning	The ordinary meaning of 'prostheses', as given by the *Macquarie Dictionary*, is: 1. the addition of an artificial part to supply a defect of the body. 2. such a part, as an artificial limb.
Therapeutic Goods Administration	TGA defines a medical device as: (a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; (iv) control or support of conception; (v) in vitro examination of a specimen derived from the human body for a specific medical purpose; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or (aa) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection (2B); or (b) an accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a), (aa) or (ab); or (c) a system or procedure pack. *Therapeutic Goods Act 1989*, s41BD TGA defines an implantable medical devices as a medical device (other than an active implantable medical device) that is intended by the manufacturer: (a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or (b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or (c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure. *Therapeutic Goods (Medical Devices) Regulations 2002*
Independent Hospital Pricing Authority (Prostheses)	*For cost purposes:* Prostheses costs are defined within IHPA's National Hospital Cost Data Collection (both public and private collections) to cover goods and services used in the provision of services to implant prostheses, human tissue item and other medical devices that are: • specified on the Prostheses List; or • assessed as being comparable in function to devices of on the Prostheses List. *For intervention purposes:* Specific types of prostheses can be identified with individual episodes of care through their encoding as interventions using the Australian Classification of Health Interventions (ACHI). For example, the ACHI Code 41617-00 identifies 'Implantation of cochlear prosthetic device'.

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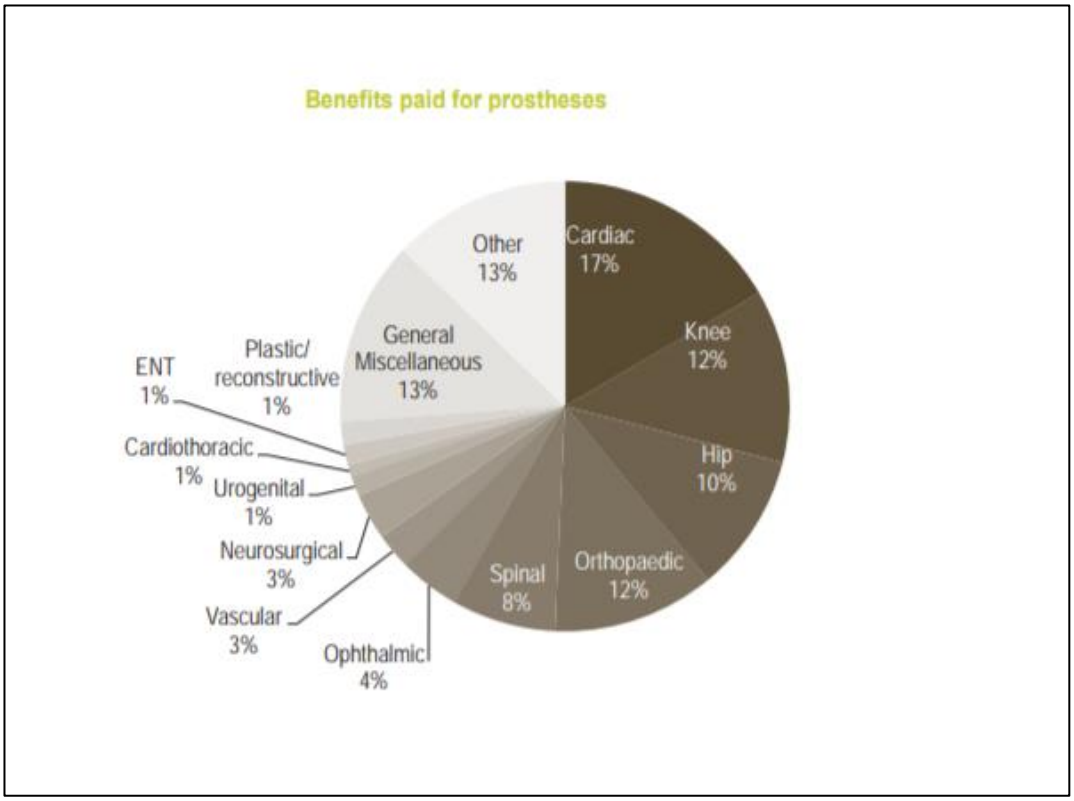
Medical Device and Prostheses Definitions	
PL Legislation	No specific definition of prosthesis Part B – Human tissue prosthesis means: a product that is substantially derived from human tissue where the tissue has been subjected to processing or treatments and the supply (however described, including trade, sell, give or gift) of which is governed by State or Territory law. *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018,* Definitions Part C – the listing criterion is that the kind of prosthesis is: (i) an insulin infusion pump; (ii) an implantable cardiac event recorder; (iii) a cardiac home/remote monitoring system; (iv) a cardiac ablation catheter; (v) a mapping catheter for catheter cardiac ablation; (vi) a patch for cardiac ablation; (vii) a monopolar device for surgical cardiac ablation; (viii) a bipolar device for surgical cardiac ablation; (ix) a system for surgical cardiac ablation; or (x) a probe for surgical cardiac ablation.
PL Guide ('Criteria for Listing')	1. The product must be entered and current on the Australian Register of Therapeutic Goods 2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment 3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist) 4. The product should: a. be surgically implanted in the patient and be purposely designed in order to i. replace an anatomical body part; or ii. combat a pathological process; or iii. modulate a physiological process; or b. be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted or c. be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and 5. The product has been compared to alternative products on the Prostheses List or alternative treatments and i. assessed as being, at least, noninferior in terms of clinical effectiveness; and ii. the cost of the product is relative to its clinical effectiveness.

Consolidation to improve efficiency and transparency

The current PL includes a complex and opaque classification system. The complexity is exacerbated by the continual growth of the PL. Since 1997 the number of items on the PL has expanded nearly tenfold. The most recent PL (November 2020) consists of 11,300 billing codes that are allocated to one of 1,700 groupings. Each billing code may have multiple distinct items listed underneath it.

	Number of Billing Codes	Number of Unique Groupings
Part A	10,484	1,683
Part B	759	4
Part C	62	37
Total Prostheses List	**11,305**	**1,724**



The current process results in a significant administration burden. Considerable resources are required to maintain the current list with its myriad of interdependencies, as well as managing the increasing flow of new requests. There is little opportunity for enhancements, such as digitisation, or compliance. The outcome is an assessment process that does not meet sponsors' needs for timely and efficient processes, nor the insurers' needs for applications to undergo sufficient scrutiny to ensure high quality and consistent decision-making.

The key issues which arise again and again in relation to the administration of the system are the lack of transparency in how decisions are made, and limited integration between health regulation and funding systems. These issues persist despite a number of reviews, over an extensive period, which have recommended greater transparency and better coordination and integration of health systems.

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In addition, there is no consistent approach to setting benefits for listed devices. Minor differences between devices, without demonstrated health impact, are recognised and differentially priced. For many devices, rather than paying benefits for the whole device, each of the component parts attract a benefit. For instance there are 38 price points for orthopaedic screws (ranging from $60-$474) in one category, with little or no evidence of differing performance or patient outcomes.

Case study
There are a number of external fixation systems used in complex fracture management.

Each system can involve use of multiple components (screws, bolts, struts, rings etc.). For one company's system, the components are classified under 16 billing codes with PL benefits ranging from $45 to over $2000 per code. In turn, each code has under it up to a dozen items or 'catalogue numbers' (e.g. different bolts), each of which can be billed multiple times.

Data from two comparable external fixation systems indicates there is a difference in the median benefit paid by insurers of more than 40 per cent:

Product A
The median number of billing codes billed per patient is 44 with PHI benefits paid of $31,816. The public hospital price is $15,900.

Product B
The median benefit per patient is $13,608.

The *Review of the General Miscellaneous Category of the Prostheses List* found evidence to suggest some products were being reclassified into different groupings (largely adding or changing suffixes) without any evident change to the product itself or the benefit to the patient. In some instances, this has resulted in the minimum benefit amount for the item increasing by up to 400 per cent.[5]

UNDERSTANDING THE OPPORTUNITIES

It has been broadly agreed by stakeholders who participated in reform discussions through industry working groups that the overall purpose of the PL should be to provide privately insured patients with access to beneficial and cost effective medical devices (prostheses) used in a medical procedure as part of an episode of hospital or hospital-substitute care.

As well as maintaining this purpose, a key objective of PL reform is to close the gap between public hospital and private hospital pricing for prostheses. A secondary aim is to streamline the arrangements to reduce complexity and the associated administrative burden of managing well over one thousand PL applications, amendments and listings each year.

Two options are presented below but both have some common elements, as follows.

[5] Review of the General Miscellaneous Category, pg. 30

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Improved Definition of Purpose and Scope

It is proposed that the following prerequisites for mandating payment of a private health insurance benefit for a funded prostheses be retained:

- The prostheses must be approved by TGA and listed on the Australian Register of Therapeutic Goods.
- The prostheses must be provided to an appropriately insured patient during an episode of hospital or hospital-substitute care.
- The prostheses must be provided during a medical procedure for which a Medicare benefit is available.

In addition, it is proposed that benefits be payable for specific purpose medical devices where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device (e.g. hip replacement, stent, balloon angioplasty). The device should not be one that is used as an adjunct to the procedure (e.g. sutures, haemostatic agents, adhesives).

It should be noted that this definition no longer requires that the device be implanted but retains the requirement that the device be therapeutic. The focus is on the device being one that is intended to remedy a medical condition.

A consequence of confining scope as proposed would be that most general use medical devices and consumables would no longer be funded through the PL, but would continue to be funded through other mechanisms, such as contracts between insurers and hospitals.

Appropriate use

No changes are proposed to the Medicare Benefits Schedule or medical payments by insurers with either option.

These reforms will not impact on the regulation of medical devices by TGA. However, both options contemplate better use of post market review to identify and address concerns about unexpected growth and variation in the use of devices.

Medical device registries, in particular the National Joint Replacement Registry for joint replacement prostheses, will continue to be important tools for addressing safety issues and prompting appropriate clinical use.

QUESTIONS

What, if any, general use products should continue to be funded though the PL and why?

Should there be an "exceptional circumstances" list (akin to the current Part C)? If so, what types of products should be listed and why?

How should general use items be transitioned to other payment arrangements in a phased manner? What time period and should some items continue to be listed for longer than others? If so why?

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OPTION 1: Consolidate the Prostheses List using the Diagnosis Related Groups (DRGs) model and set benefits with reference to the prostheses price components of relevant DRGs, with administration moved to the Independent Hospital Pricing Authority (IHPA).

Overview

IHPA would take over responsibility for setting and revising private prostheses benefits, within the current (or modified) DRG classification system.

Currently there are over 1,700 device groupings for the PL. In contrast, public hospital funding is based on grouping services into one of about 700 DRGs, with about half involving use of prostheses. Using these existing groupings (and any additional private sector DRGs), IHPA could set a private health insurance benefit for the prostheses component of each DRG initially based on reference pricing against the current public hospital prostheses cost for that DRG. IHPA would have the ability to develop specific private sector DRGs and to adjust the benefit to take account of any significant disparity between the current private and public hospital prostheses DRG cost, caused by reasonable differences in usage patterns.

It would also be possible to include an additional premium in the benefit to recognise the additional costs of providing a larger range of prostheses for choice by private patients, and to recognise different approaches to device purchasing between public and private hospitals.

Private health insurers would be required to pay PL benefits set by IHPA for use of in-scope prostheses. However, insurers and hospitals would continue to negotiate payments for the non-prostheses component of the episode of care.

Medical costs are not impacted by this reform.

Following the initial price setting exercise, IHPA, would review and reset benefits using its existing system for collecting hospital level pricing data. Private hospitals would negotiate prices with device sponsors to supply necessary medical devices and costs data would be periodically reported to IHPA.

For novel, high cost medical devices not readily accommodated in existing DRGs, IHPA could determine the need for health technology assessment (HTA) and a new DRG (current process). Concerns about access to these novel technologies could be addressed by creating a special time-limited list with the initial benefit set through HTA, conducted by the Medical Services Advisory Committee (MSAC). MSAC would continue to evaluate new medical services that use novel devices and hence provide advice about benefit setting.

For most medical devices used in medical procedures, once TGA approved, the device could be used by clinicians and hospitals without further assessment, with DRG defined benefits payable.

IHPA would monitor patterns of use (utilisation and expenditure) and could undertake post market reviews (with or without the involvement of MSAC) if there were identified concerns. TGA would retain its responsibility for managing safety concerns.

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It is anticipated that the gap between public hospital and private hospital prostheses costs would be closed over some years, through staggered annual 'benefit per DRG' reductions.

How this option addresses the key aims for reform

The DRG infrastructure provides a ready-made mechanism for simplifying administration. The 700 DRG groups (about half of which already have a device component) would replace the 1,700 PL groupings that currently exist. The ongoing IHPA data collection cycle, which also captures costs, ensures a sustainable approach (setting and reviewing the benefit) for managing pricing.

Anticipated stakeholder impact

The reform aims to close the gap between public and private hospital prices with consumers benefitting from moderation of private health insurance premiums and faster access to new devices on TGA registration, without the need for an additional reimbursement assessment process. Otherwise consumers and clinicians should be unaffected by these changes provided there continues to be reasonable choice of devices and the reform does not lead to higher out of pocket expenses. As the reform aims to reduce costs, there may be adverse impacts on device companies, offset by the ability to bring new products to market faster for private patients without the need for separate PLAC assessment. Private health insurers will need to ensure that appropriate funding to hospitals continues for necessary medical devices and consumables that may no longer be funded through the PL or this model.

Regulatory Burden Estimate

This option reduces red tape through dismantling current assessment and listing processes. It encourages hospitals and device companies to negotiate on price. Access to new medical devices will occur sooner.

What are the longer term opportunities

This reform could be a stepping stone to the private sector wholly moving to a DRG payment system. This wider reform could only be developed in the context of overall private health insurance and hospital funding reform and is outside the scope of this paper.

QUESTIONS

Should the public/private gap be closed completely or instead allow for relativity that favours the private sector? If so why?

What evidence is there that choice of prostheses in the public sector is more limited than the private hospital sector? Is there any evidence of difference in outcomes in the public and private settings?

How should concerns about maintaining choice be addressed?

What safeguards should be adopted to prevent patients being exposed to out of pocket expenses for prostheses?

What market distortions would be continued or created by this proposal and how can they be addressed?

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OPTION 2: Consolidate and redesign the Prostheses List with extensive changes to pre- and post-listing assessment and benefit setting processes, with administration of benefit setting supported by the Department of Health.

Overview

The PL would be redesigned but continue to be administered by the Department of Health. The objective of the reform would be similar to option one with the gap between prostheses pricing in the public and private sectors progressively closed. This would be achieved through consolidating the list into a smaller number of pricing groups, with new groups requiring justification supported by clinical evidence, generally assessed by MSAC. The new arrangements would also include much-enhanced assessment of applications through increased cost-recovered resourcing and better use of health technology assessment; as well as an ongoing review of benefits, potentially through regular approaches to market.

At a minimum, redesign could entail:

- revising the legislated definition of a prostheses and refining the listing criteria to reflect the scope discussed above. A more confined scope would mean that most general use items including medical consumables would no longer be funded through the PL.
- redeveloping and enhancing the HTA process for assessment and benefit setting, including continuing with recent reforms that mean that MSAC has a greater role in evaluating novel devices or incremental changes to existing devices where price premiums are sought.
- introducing ongoing review and benefit setting using a combination of reference pricing (principally to the public sector), mandated price reductions and tendering.
- monitoring trends in PL usage and expenditure and undertaking post market reviews as necessary, akin to those undertaken for pharmaceuticals and medical services.
- developing a compliance program to enable proper scrutiny of disputed and anomalous claims.

These reforms could be introduced in a staged manner from February 2022, with the consolidation and initial benefit setting processes occurring during 2021.

Enhanced administration and the necessary increase in Departmental resourcing would be funded though re-based cost recovery fees.

How this option addresses the key aims for reform

The DRG infrastructure described in option one provides a ready-made mechanism for consolidating groups on the PL and simplifying administration. Option two has the same objectives as option one and achieves this through similar means but by building a new system that in many respects, mirrors what is done by IHPA already. Both options require a new approach to grouping and benefit setting.

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Anticipated stakeholder impact

Consumers and clinicians may favour option two because it appears familiar and builds on the status quo. However, following benefit setting reform, the same issues around potential choice and patient out of pocket expense may emerge. Hence, like option one, there is need to adopt safeguards for patients. Currently the very high PL benefits mean that there are no patient out of pockets. Medical device companies will be most impacted by the reform if it is effective in reducing the disparity between public and private sector pricing. Hospitals may be concerned that general use items will no longer be funded though the PL and hence private health insurers would need to ensure that clinically necessary devices and consumables are adequately funded.

Regulatory Burden Estimate

It is expected that there would be increased cost for medical device companies and perhaps other industry stakeholders through increased cost recovered fees. With more HTA and new compliance processes there is likely to be increased administrative burden and cost for medical device companies.

QUESTIONS

What advantages or disadvantages does option two have over option one?

What groups structure should be used and why? Examples include grouping by episode of care, procedure or device?

Would it be possible to use IHPA's DRG grouping structure as part of reforming the PL under this option?

If benefits are set through commercial tenders (for existing products and categories), how frequently should those tenders occur?

If benefits are set through reference pricing, should this include public hospital prices and international prices? Which countries should be referenced, how and why? For public hospitals, how would reference pricing be supported outside the IHPA framework, and should this include averaging?

How should compliance be supported to ensure companies accurately identify referenced prices?

CONCLUSION

It is accepted that no stakeholder will be supportive of every element of any reform option. These proposals have been developed following extensive review of the existing system through Industry Working Groups set up under the 2017 Agreement between the Government and MTAA. In addition to the specific questions outlined, stakeholders are invited to indicate their support for or disagreement with specific elements of the reform options (with reasons and evidence) and suggest ways that the option can be improved. It is recognised that through this public consultation, a hybrid reform model may emerge.