PROSTHESES LIST CONSULTATION: DEFINITION, PURPOSE AND SCOPE

PREPARED FOR THE DEPARTMENT OF HEALTH

BY MTAA

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Contents

Executive Summary

For over 30 years the Prostheses List has guaranteed patient access to clinically proven medical devices in the private health system.

This access will be threatened if proposals to reduce its scope and role are accepted without guaranteed alternative funding arrangements.

The Prostheses List was established to ensure privately insured patients have access to TGA registered and clinically effective medical technologies used in hospital treatment or hospital-substitution treatment.

Any proposed changes to the Prostheses List need to be measured against this aim.

MTAA supports clarifying the scope of the Prostheses List in order to reflect technological innovation and changing clinical practices. However, this needs to be a clinically led and patient-centered process, informed by appropriate input from manufacturers and sponsors.

When a clinical review process recommends an item for removal from the Prostheses List, MTAA stresses the need for a guaranteed and transparent funding pathway to be established prior to removal.

Without an agreed funding pathway, removal could result in reduced patient access to many devices, with the following potential adverse impacts:

- Poorer health outcomes
- Higher out-of-pocket costs
- Increased pressure on the public hospital system

MTAA does not support the Department's assumption that market arrangements between insurers and hospitals will cover any products removed from the Protheses List.

We are concerned that unless a funding pathway is guaranteed, hospitals will be constrained by insurers' refusal to fund devices removed from the Prostheses List. This would mean clinicians will not get equitable access to the devices they need to treat their patients.

MTAA does not believe that hospitals and patients should have to take on the financial risk of ensuring access to medical technologies.

The proposal by Private Healthcare Australia for funding of removed products is fundamentally flawed in that it is not binding on any insurers, leaving hospitals and patients will no certainty and exposing them to risk. It also bases its pricing assumptions on a flawed methodology which does not reflect market realities.

The only stakeholder who believes that insurers will pay hospitals a fair price for medical devices is insurers themselves.

MTAA's modified public private referencing model provides a sustainable funding mechanism for medical devices and will save insurers at least $750 million over four years without compromising patient access or clinical freedom.

MTAA has also recommended other reforms to the Prostheses List to improve administrative efficiency and utilisation.

These changes will strengthen the Prostheses List as a sustainable funding mechanism for medical devices while also guaranteeing clinical freedom and patient access.

MTAA urges the government to work with the medical technology sector, clinicians, consumers, private hospitals, and the insurance sector to implement these proposals.

Introduction

MTAA welcomes the opportunity to build on its contribution to Prostheses List (PL) reform through its February 2021 submission to the Department's consultation on the future of the PL through responding to this paper. MTAA has proposed a modified public price referencing system that will save insurers at least $750m over four years in the most radical reform of the PL in its history. MTAA has also recommended other reforms to the PL to improve administrative efficiency and utilisation.

The Consultation Paper released by the Department, and the questions asked, seem predicated on the assumption that the Government has already taken the decision to remove general use items by altering the scope of the PL to cover only 'specific purpose medical devices' that are not 'adjunct to the procedure'. However, the Budget announcement appears focused on ensuring that the scope and purpose of the PL are better defined and that products would only be removed if they are 'better funded through direct contractual engagement between parties'. In MTAA's view it is not a given that this is the case for 'general use' or 'adjunct' items.

Changing the scope of the PL necessarily requires removals of numerous items from the Prostheses List. MTAA's comments about the PL scope are predicated on no removals occurring without the necessary funding to enable hospitals and clinicians to make choices in the best interest of patient care, rather than an arbitrary budget constraint.

MTAA's position is that removals should require:

- A thorough clinical review; and
- A guaranteed funding pathway that will ensure patients can access clinically necessary devices chosen by their surgeon; and
- Ensuring there is no competitive disadvantage across products/technologies

MTAA has low confidence that the Department's current approach - to assume market arrangements between insurers and hospitals will cover these products - will provide this guaranteed funding pathway. There is a real risk that clinicians will not get equitable access to the devices they need to treat their patients as some hospitals act to manage their financial position due to lack of funding by insurers. The current 'offer' by PHA to hospitals does not provide this certainty because it is not binding on its members, overstates expected price reductions, and provides no continuity beyond year four.

The Department's proposal to narrow the scope to include only devices 'where the intention of the medical procedure is to remedy disease or dysfunction through use of the specific medical device', and its interpretation/application of this criteria in the Consultation Paper, will remove many devices that are critical to a safe and successful procedure. This underscores the need for proper funding arrangements for any removals.

Any products that remain on the PL through this process will still be included in the public price reference mechanism announced by the Government. Therefore, whether removals do or do not occur, savings will be achieved on these product groups, unless they already have a competitive benefit level.

At present MTAA sees too much risk in narrowing the scope because of the lack of confirmed funding arrangements for removed products and so does not support it.

Improving current definitions

MTAA supports the Government's stated Budget objective to 'better define and clarify the scope of the PL to provide greater clarity and certainty about which items are eligible for inclusion'[1]. Under the current definition, with appropriate clarity of definitions, there will likely be some removals of products previously listed that do not/no longer qualify, meaning some simplification and potentially a modest amount of savings could be achieved. However, this needs to go through the clinical review process with opportunity for comment by sponsors which provides clarity & transparency on the process and clear communication on the final outcome. Even for these products, a guaranteed and transparent funding pathway is needed.

The Purpose of the Prostheses List

MTAA recommends returning to the question of the purpose of the PL, which is not explicitly addressed in the Consultation Paper. The purpose of the PL is to ensure privately insured patients who have made the choice to purchase private health insurance have access to TGA registered and clinically effective medical technologies used in hospital treatment or hospital-substitution treatment. Patient access is the primary test of its function, which is why MTAA welcomes the Government's decision to reject payment by DRGs and why proposed removals would be of significant concern if not appropriately managed.

There are devices routinely used in private hospital theatres for which there is no access risk for patients if they aren't specifically and individually funded. However, given the nature of the private hospital system, which is financed by individual payments for procedures initiated and undertaken by independent clinicians, there will be many devices with real access risk. Generally, private hospitals provide a service with costs that need to be passed through, and their operation is predicated on the basis that the risk is largely assumed by the insurer. Therefore, the purpose of the PL – patient access - is inseparable from the nature of the private healthcare system itself because this determines the circumstances under which patient access is likely to be at risk.

Given the nature of the private healthcare system, and its generally limited ability to take on financial risk, dictate to surgeons or manage inventory, the PL has generally been 'fit-for-purpose' in what has been listed on it, providing the necessary patient access. Narrowing the scope and removing large numbers of products seems predicated on the idea that insurers will pay fairly and private hospitals will be able to either shift their model to carry the cost of any device that is not the specific interventional device or find a risk-free alternative.

Only one stakeholder group, insurers, seems to hold this view universally and it seems this view has some genuine risk for the purpose of the PL – patient access. It is clear from the submission by Private Healthcare Australia (PHA) to this consultation, and its other public statements, that they place no value on any mechanism to provide consumer protections for access to devices and see this as a hinderance to their business model.

In completing the Review of the General Miscellaneous category, Ernst and Young warned that there is inherent risk in removals that needs to be mitigated through careful testing of case based payments to ensure there weren't adverse consequences for patients. The report states:

> *[I]t would be an adverse outcome if removal from the PL led to an increased cost burden for clinically essential items and/or a reduction in usage to the extent that clinical outcomes for patients were compromised… Most importantly, the processes and contractual mechanisms for including these items within case based or bundled payments will need to be developed and tested so that there are no short-term adverse impacts on clinical outcomes and the cost of services.*[2][emphasis added]

[1] Budget 2021-22 Factsheet 'Private Health Insurance – Modernising and improving the private health insurance Prostheses List'

[2] Ernst and Young 'Review of the General Miscellaneous Category of the Prostheses List' 31 July 2020 p.9

There is no apparent intention on the part of the Department or insurers to develop and test these contractual mechanisms to avoid the impacts Ernst and Young describes.

Process to guarantee funding for removals

Given this, the Government should broker an agreement between the insurers and the hospitals that enables secure funding to be achieved for removals in every insurer-hospital contract without breaching competition law. This funding should be in perpetuity, adjusted based on agreed factors over time. The collective group of items to be funded needs to be clearly documented, understood and agreed by clinicians, hospitals, health funds and sponsors so that the current lack of clarity, which insurers have used to claim 'double-dipping', is avoided and clinicians are aware of the reasonable expectations they should have for hospital provision of these devices in the future.

Without this guarantee, the potential for patient out-of-pocket gaps following removals of PL items remains significant, as the utilisation per procedure will vary by patient characteristics, by surgical procedure, and by surgeon technique and experience. For example, a surgeon may appropriately use a substantial number of haemostatic devices well beyond the typical level to save a patient's life due to a coagulation issue. The expenditure on the haemostatic devices in this situation can be thousands of dollars. Such usage would exhaust an allocation a hospital would have for that procedure and they may need to address this type of situation through various strategies to remain viable. Out-of-pocket costs for patients and pushing patients to the public sector are two ways this may occur.

Private Healthcare Australia (PHA) has made a proposal for funding of removed products[3]. This proposal has the inherent problem that it is not binding on any insurer. It is also flawed in its pricing assumptions. It inconsistently compares products across the world and selects the prices that best suit them without reference to the costs of respective healthcare systems. Furthermore, some prices have been sourced via on-seller sites. In addition to not reflecting Australian market conditions, the comparison of such pricing is misleading as they don't provide training and services for products, may not even be able to supply at the advertised price or may be temporarily moving short-dated stock.

MTAA data shows that the differences between benefits paid on the PL and prices paid in the competitive public market, which represents the best comparison, are much lower than what PHA assumes. Moreover, Ernst and Young in their Review of the General Miscellaneous Category, which benchmarked PL benefits against public prices in two Australian jurisdictions, did not suggest that these products on the PL had significantly higher prices than in the public system. The proposal further has no meaningful longevity beyond 2025 given the very low rates for the support package for uncontracted services. Therefore, it appears unlikely to achieve a resolution that would guarantee market access.

The PHA proposal certainly does not meet the qualification for a 'developed and tested' process and contractual mechanism recommended by Ernst and Young.

Monitoring and assessment of impact of removals

Where removals do occur, there needs to be a process overseen by the Department of Health to monitor this to ensure there are no unintended adverse consequences. For example, the impact of removal of haemostats and sealants on the rate of bleeding complications, increased rates of transfusions, surgical procedure changes and any changes in patient type being treated in private hospitals.

[3] Private Healthcare Australia 'Paying for consumable items that are coming off the Prostheses List in February 2022' Revised Version August 2021

The Department should undertake a comprehensive survey of clinicians annually to monitor whether access to products has changed and what impact it has had on clinical outcomes. This will provide some level of measurement to assess the impact to patients who have private health insurance. This could be combined or substituted with other existing tracking processes such as registries

Answers to questions in the consultation paper

It is only in the context of the above comments that MTAA provides responses to the specific questions, which, as noted, appear to assume that narrowing of the scope and consequent removals will not result in reduction in patient access, an assumption which is not well founded if purely left to individual negotiations. However, to help inform the Government's understanding of how the proposed definition would work in practice, aside from the question of funding removals, MTAA provides the following responses.

Note on limiting price to the PL Benefit

In the Context section of the Consultation Paper the Department flags that in a future consultation they will propose introducing for new applications a declaration by companies that there will not be extra charges for the products beyond the PL price. MTAA will address this issue when raised in the future consultation. However, our members would have significant concerns with any limitations on the freedom of pricing of company devices, including potential consequences for access in the private sector.

Definition & Scope

Q1: 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?

Anticipating new technologies and technology 'discrimination'

Any new single use device, no matter how innovative or critical to patient care, that is considered 'adjunct', for example for haemostasis, arterial closure or internal wound closure, would fall outside this definition unless listed on Part C as an exception. In that sense, the new definition would not account for some potential new technologies.

The main upside of the new definition is that it no longer discriminates based on the implantable definition which, in isolation, may distort funding in favour of certain device types and not others. MTAA supports the proposal to extend eligibility for listing on Part A of the new PL to non-implantable devices. As noted in the Consultation Paper, drug coated balloons and drug coated stents can both be used for percutaneous coronary intervention (PCI) and the treatment of peripheral artery disease but only the stents are eligible under the current definition because they are implanted, whereas the drug coated balloons are not. In general, the bias in development in new devices will often be toward achieving the therapeutic effect without an implant if possible, because leaving an artificial device in a patient's body is never entirely risk free.

Therefore, it makes sense to remove this distinction in the case of single use devices used in a hospital procedure. It also resolves any questions about whether the duration of the time in patient's body, or its absorbability, qualifies as an 'implant' or not. Clinicians are therefore assured of a range of solutions being available, all other things being equal.

However, the inclusion of non-implantable, single-use devices can still occur without large scale removal of many clinically valuable items now on the PL if a Criterion 4d) is added to the existing Criteria 4a-c) for Part A that

specifically allows for this. If the government wanted to restrict this to 'specific purpose' devices only, that could be added without changing the definition of Criteria 4a-c).

Clarity of definitions

The Department's proposed definition is likely to resolve some existing ambiguities but at the same time create others, so it is unlikely to be *clearer* than existing definitions are, or could be, if they were sufficiently fleshed out. The Department's definition seems drawn from a perception about paradigm cases of what should be covered by the PL, for example a hip implant or a pacemaker, where the point of the procedure is to implant a device or combination of devices working together to achieve a specific therapeutic effect. Under the Department's definition this would extend to single-use invasive devices that are not implanted, but still are the primary means of achieving the intended effect of the procedure.

There are however many procedures where the paradigm case does not apply and this is likely to increase as new technologies become available that work interactively or concomitantly. Scenarios include:

- Two or more completely different devices or device systems are used in the same procedure to achieve the same intended therapeutic effect, where one in isolation would be insufficient or sub-optimal, but the second or third devices are not 'unique and specific' to the other main device to qualify under current Criterion 4b)
- Procedures where the intervention is specifically to achieve an outcome that might ordinarily be considered adjunct to a procedure e.g. abdominal closure after laparotomy
- Procedures where there is intensive surgical intervention not delivered primarily by means of a device but still a device(s) must be used to complete the surgery and make that surgical intervention possible. For example, either a haemostat or a sealant is usually essential to the success of coronary artery bypass surgery or aortic surgery.

Specific examples include:

- Hernia fixation technology (including tacks & tackers) is specific to hernia surgery whereby they are used for securing mesh in the laparoscopic repair of ventral and inguinal hernia. This technology performs a therapeutic role and is essential to performing the laparoscopic approach.

- Use of advanced surgical stapling products in Product Group 03.08.04 - Staples & Tackers includes resection (removing part of an organ), transection (cutting through an organ or tissue), and anastomosis (joining divided structures to create a connection). These products are the main device specifically required for procedures involving resections of the lung, gastrointestinal tract, bowel, pancreas, and liver and in bariatric surgery. For a lung resection, the surgical removal of all or part of the lung, because of lung cancer or other lung disease, the advanced stapling product is the main device required to perform that procedure – it's use is clearly not general purpose in that case.

There is such a diversity of procedures with different clinical contexts that ambiguity will be unavoidable and there may be no gain in clarity on the current definitions. Therefore, the justification needs to be something other than mere clarity, for example, removing discrimination of technologies as noted above.

Furthermore, there will be kinds of devices, possibly used in scenarios above, where some uses will meet a definition of 'specific purpose' while others may not. It would need to be resolved whether the device should remain on the PL or not, or remain with a conditional listing, with the additional administration burden that brings for hospitals, clinicians and insurers. This would add a new complexity that doesn't presently exist.

If clarity were the goal of this change, it could equally be achieved through focused attention on fleshing out the current definitions now applied under Criteria 4a-c) of Part A. This would include attention on the definition of

'implantable', 'consumable', 'unique and specific' or even the term 'suture'. Based on the list of PL groups proposed for removal in Attachment A of the Consultation Paper, there is a requirement for this anyway, since groups such as 04.02.05 Liquid Sealants are proposed for removal when these clearly meet the specific purpose criteria in their indicated use.

The term 'consumable' is defined in the paper as 'devices that are used and replaced regularly (removable sutures, needles, tubing, topical adhesives, and sealants for wound dressing)'. While the concept that devices used very regularly being made part of case payments is intuitive, there is a question about the definition of 'regular' and whether it is meant to apply to all types of surgery, specific types of surgery or even specific types of procedures that may be done in some hospitals and not others.

Many of the past ambiguities around interpretation of current criteria have already been resolved through assessment and discussions by the Prostheses List Advisory Committee (PLAC), Clinical Advisory Groups (CAGs) and the Department of Health and these could easily be formalised or, if the Government preferred, legislated. However, there is an inherent danger in removing all flexibility from the process, remembering that patient access is the primary goal. For example, certain mapping catheters for cardiac ablation are in theory interchangeable with ablation catheters supplied by other companies. However, it would not advance patient access if they were excluded on the grounds that they did not have a 'unique and direct connection' to the ablation device. Another example of the problem of inflexibility is the distinction between a registered medicine and a registered medical device discussed below.

Treatment of 'accessories'

The Consultation Paper defines 'accessories' as 'devices designed and intended by the manufacturer to always be used together with another implantable or surgically invasive device for therapy, to enable that device to be used as the manufacturer intended.' It proposes that 'some of these devices (accessories) will no longer be separately funded through the PL, but instead it is anticipated that their cost will be bundled into the cost of the device they are intended to be used with or funded under a different funding mechanism).' It is unclear whether the proposal is only to treat products in this way if they are registered as a system or procedure pack (see next question).

It is very important to be clear that many devices on the PL now categorised as 'accessories' are not accessories in the above definition but critical components of specific surgical procedures e.g. use of intraocular fluids in cataract surgery, or that form part of an overall construct created by the clinician (particularly true in orthopaedic categories).

Furthermore, some devices on the PL such as neuromodulation items are listed and funded separately due to the variation in the clinical scenarios which would require different mix of components (accessories, external components, different types of leads or lead extensions). Some products e.g., in the Neurostimulation therapy group for pain management (04.05), the leads, implantation tools or accessories are supplied separately and can be used with multiple different neurostimulators from the same manufacturer. Therefore, it would not be practical to list it as a system.

The problems of bundling based on clinical scenarios are illustrated below.

Under 04.05 Neurostimulation therapy group, there can be 12 different clinical scenarios corresponding to different PL item configurations:

1. Temporary Stim Trial
2. Permanent Stim Trial
3. Permanent Implant without leads and extensions (patient has had a permanent trial prior)

4. Permanent implant with leads without extensions
5. Permanent IPG implant with leads and with extensions
6. Permanent IPG implant without leads and with extensions (patient has had a permanent trial prior)
7. Lead Revision without leads and without extensions: Using all single items
8. Lead Revision with leads and without extensions: Only certain single items needed
9. Lead Revision with leads and with extensions: Only certain single items needed
10. Lead Revision without leads and with extensions: Using all single items.
11. Implant Swap / reposition
12. Implant Swap / reposition with extensions

Some of the cases (Trials and Permanent Implants) are predictable and generally use the same devices each time and bundling may work in those cases. However, there are also a wide variety of uses for neuromodulation products to meet the needs of individual patients and their clinical situations.

Considering this example, descriptions may not necessarily be sufficient to uncover whether it would be appropriate to exclude or include accessories on the PL. It would be essential to have a clinical review of each category to ensure patient specific clinical requirements are captured and patient access is not compromised.

Bundling may have adverse consequences for insurer costs as well. Based on the scenarios presented above, if bundling were to occur, when single items only of that bundle are needed in individual case circumstances, the bundled cost may well exceed the cost of the single item.

Q2: Does aligning terms with established terms used by TGA (such as medical devices and biologicals) improve clarity?

Aligning PL terms with established terms used by the TGA may help in some cases to define what should be included on the PL, and how they should be listed, but this needs to be applied with caution because TGA terms are driven by issues specific to registration that may not apply to reimbursement. In particular, MTAA would like to highlight the need for further consideration for medicines, diagnostic devices, system and procedure packs, and personalised medical devices. These are described in more detail below.

Medicine vs device distinction

Very recently the Department has begun ruling out registered medicines as being eligible for the PL under the current criteria, despite registered medicines being on the PL since its inception in 2005, and likely on Schedule 5 prior to that. While it may satisfy the desire to remove as many products as possible from the PL and provide a certain delineation, it is factitious distinction when it comes to reimbursement through the PL. The distinction made by the TGA is only for the purposes of regulatory assessment and in fact products that are very close to each other in nature and may even be used interchangeably, can easily be classified as one or the other. There are certain products registered as medicines that are used in the medical device environment. In these cases, the medicinal products may not be eligible for reimbursement through the PBS. In order to ensure a mechanism of reimbursement, in these instances, products that are ineligible for inclusion on the PBS for hospital use but meet the criteria for listing should be included in the PL.

For instance, a tissue adhesive containing fibrin is classified as a medical device purely because it has 'shape' whereas a haemostatic product also containing fibrin is listed as a medicine because it does not have 'shape'[4]. Nonetheless the haemostatic may also be indicated as a sealant, adhesive or mesh fixation agent like other medical devices on the PL. In this case if the product is removed, the alternative to the guaranteed funding arrangement on the PL is to apply for PBS listing, but all the comparators would be medical devices and neither S.85 nor s.100 listing would seem appropriate to this kind of product. Therefore, access would be compromised on the grounds of a legalistic definition rather than patient need.

Therapeutic vs Diagnostic

The Department is proposing that the meaning of a medical device will be consistent with the definitions used in the Therapeutic Goods Act and Regulations for the purposes of improving clarity and transparency:

Section 41BD of the Therapeutic Goods Act states that a medical device is:

"any instrument, apparatus, appliance, software, implant, reagent, material or other article…intended…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

The paper states that a medical device intended to be used for therapy, defining therapy as including "monitoring, treatment or alleviation of disease or compensation for an injury or disability".

The Consultation Paper specifically excludes diagnosis, prevention, and prediction, while these are included in the TGA's definition of a medical device alongside monitoring, treatment, and alleviation of disease/injury/disability.

Therefore, even though the proposal states that the definition of medical device "aligns" with that in the TG Act, this is not entirely a true statement.

System and procedure packs

The Consultation Paper states that '[i]f a product is a system or procedure pack under the TG Act (e.g. a kit containing multiple components), it is a kind of prosthesis for the purposes of the PL.' For clarification, we would like to highlight that in the most recent update to the regulations, system or procedure pack is already included as part of the definition of a medical device.

Furthermore, systems and procedure packs are defined in s41BF of the Act as:

41BF System or procedure packs
Two or more goods (including at least one medical device) are a system or procedure pack if:

a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or
b) all of the goods are packaged together for use in a medical or surgical procedure.

In order to register a product as a system/procedure pack, a special declaration of conformity (Clause 7.5) needs to be signed by the manufacturer declaring that the product is a System/Procedure Pack. It is therefore the responsibility of the manufacturer to determine if a medical device is a system/procedure pack.

In addition, while the new definitions have been added into the regulations, further changes to regulatory requirements for system or procedure packs will be occurring at a later date and we understand targeted workshops will commence on 25 November 2021 which will be followed by a detailed guidance document.

[4] Therapeutic Goods Administration Australian medical devices guidance document number 35 Device – medicine boundary products 2005 [under review]

The Department should be aware of this and not seek through PL reform to impose an arbitrary system designation on PL devices that does not line up with the manufacturer's listings on the ARTG. This includes in the group consolidation work now underway commissioned by the Department.

Custom-made devices (TGA proposed refinement)

While not specified in this consultation paper, it is our understanding that patient-matched medical devices included on the ARTG, are eligible to be included in the PL if they meet the criteria for listing.

The Department does not consider custom-made medical devices in the medical device eligibility criteria of inclusion on the PL because they are not registered on the ARTG. There is no reason in legislation why they can't be listed. Custom-made medical devices meet the TGA's definition of a medical device, although it is supplied under the new framework of Personalised Medical Devices. Given that there is currently no mechanism for reimbursement in the private setting (other than ex gratia), if the custom device otherwise meets the criteria for listing specified in the Schedule of the Prostheses Rules, we propose that there be consideration of the custom-made devices as a 'kind of prostheses'.

ARTG and PL alignment

The Department is proposing that the criterion that a medical device or biological is included in the ARTG will be clarified so that the information that appears on the ARTG certificate such as the intended purpose, and where applicable, functional description of the device or indication is aligned with the information captured in the PL (product name, description, purpose and grouping). The Department's apparent intent with this clarification is to be able to ensure that the items on the PL are approved for supply under a valid ARTG. Whilst the Department's intention of validating catalogue numbers in this manner makes sense in theory, there are specific nuances in the information included in the ARTG that will be make this process difficult practically.

Intended purpose:

Regarding the intended purpose of a medical device on an ARTG certificate, there may be many cases where this statement will not be comparable to the information found on the PL, for the following reasons:

1. The TGA does not specify the requirements for the intended purpose statement on the ARTG, therefore there can be a lot of variability in this statement between sponsors/ARTGs for similar devices. In addition, indication for use may or may not be included in this intended purpose statement.

2. According to section 41BE of the Therapeutic Goods Act, a medical device is taken to be of the same kind as another medical device if they:
   (a) have the same sponsor; and
   (b) have the same manufacturer; and
   (c) have the same device nomenclature system code (see subsection (3)); and
   (d) have the same medical device classification; and
   (e) are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question

   Therefore, under section 41BE of the Therapeutic Goods Act, kinds of devices can be approved for supply under one ARTG entry (Class I-IIb) and therefore the intended purpose statement on the ARTG certificate can be quite broad in some cases and inconsistent between sponsors for the same kind of devices, making it difficult to make a meaningful comparison to the PL entry.

3. While product names are included on the PL, product names for products that are lower than Class III are unlikely to be included in the intended purpose statement of an ARTG entry.

4. The ARTG certificate does not capture catalogue numbers especially for class I-IIb as the sponsor is required to hold the Australian Declaration of Conformity which may or may not contain catalogue numbers. Therefore, information on the PL will not be comparable to the ARTG certificate.

Functional description

Currently, sponsors provide functional description as part of the new PL application regardless of the classification of the medical device. Functional description is only published on the ARTG for Class III devices. Therefore, there is a large subset of devices on the PL that will not have this information on the ARTG certificate to be comparable to information on the PL.

Also, similar to the intended purpose statement, there is no regulatory requirement for what information is included in the functional description. As there is no guidance from the TGA about the standardisation of this part of the ARTG, there is great variance. For example, some sponsors may not include brand names or sizes in the functional description. This will not be conducive to aligning the details on the PL to the information about the product on the ARTG certificate.

Definition of an implantable device

For the case that the definition of 'implantable' continues to be relevant, the Dictionary of the Therapeutic Goods (Medical Devices) Regulations 2002 offers a useful definition about the length of time which a device needs to be in place before being considered 'implantable'.

An implantable medical device means 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.

This clarifies that, except in the case of partial introduction, a device only needs to be in the patient at the end of the procedure. This should mean that absorbable devices also qualify. Whether or not they are short term or long term, as defined by TGA, is not the issue.

Criteria

Q3: Are the proposed listing criteria for Part A fit-for-purpose? If not, what changes are needed?

Based on the proposed approach to funding removals of products and the operation of the private market, MTAA's view is that the proposed change overall is not fit-for-purpose, notwithstanding the welcome addition of specific non-implantable devices. Essentially the hospital would take on all funding and management responsibilities for devices that are not the main intervention. Without significant recalibration of the funding arrangements this would certainly undermine patient access and also threaten hospital viability.

Please note comments already included in the Introduction and under Question 1. To restate the main points:

- It is impossible to divorce assessment of the criteria from their practical impact in private hospital funding arrangements – and the proposed criteria create significant risk for patient access
- There has already been significant tightening of current definitions and this work could be continued and codified, if there is still room for appropriate flexibility
- The 'specific purpose' criterion does not offer more clarity than the current criteria – it helps solve some problems but creates others
- The main upside of the 'specific purpose' criterion for patient access is that it allows non-implantable technology to be included – but this could also be achieved with an additional alternative criterion under Criterion 4 that allows single use surgically invasive devices that meet the 'special purpose' criterion

In its submission PHA makes a number of assertions under this question about the need for 'cost-effectiveness reviews', bundling of existing listings or resetting prices for 'me-toos' that show a basic lack of understanding of the new benefit review methodology that the Government is proposing. Public price referencing with any appropriate modifications will determine the PL benefit level. Overlaying complex review processes would just consume resources unnecessarily. Bundling groups of products into a single code will result in it being compared to exactly the same bundle in the public sector and have no material difference on the price paid overall. The only possible gain would be administrative efficiency. Likewise, it is the public price, not new entrants on the PL, that should set the benefit level for a group. MTAA's has made a proposal for more than $750 million in savings to insurers. The Government has adopted the underlying methodology, if not all its important features. PHA appears to want to circumvent this methodology with all kinds of incongruous additions which MTAA rejects.

Q4: Should the scope of products eligible for listing on Part B remain unchanged?

Yes.

Q5: Should the PL retain an option for the Minister to list items in exceptional circumstances on Part C?

Yes, any criteria that are established for Part A are likely to exclude some possible devices that should be funded for patient access. Part C can operate as an appropriate mechanism for this situation. Removing Part C would entail removing existing important devices such as insulin pumps that are integral to the private health insurance offering.

While the Minister can retain final authority to approve listings on Part C it is important that submissions can still be made and reviewed through an HTA without an express invitation from the government as has happened in the past. Not all circumstances require clinical and cost-effectiveness assessed by the MSAC, although that may be informative for many decisions. The technology should have initial triage to determine whether a full MSAC assessment is appropriate or whether a more pragmatic or focussed review of the relevant information may be more useful for decision making.

Q6: Are there any other exceptional circumstances factors that Part C should accommodate?

The current proposal in the Consultation Paper is that products could only be listed on Part C if they 'demonstrated cost saving to the health system in comparison to current treatments'. Medical innovations may be more expensive than existing options right across the health system but also provide better patient outcomes. It would seem strange to exclude these by insisting on cost saving to the health system.

Using the example of coronary pressure wires for fractional flow reserve, which MTAA believes should be listed on the PL, criteria could be established for including a limited number of diagnostics on Part C or even Part A. In particular, they should be single use diagnostics used in an in-patient setting to inform whether or how an imminent procedure should be performed in that facility. In this example, coronary pressure wires have the advantage of both being indicated for a procedure on the MBS and are associated with improved patient outcomes and demonstrated cost savings to the Australian healthcare system.

PHA's submission to this consultation makes some bizarre assertions about the listing of cardiac ablation catheters, asserting that somehow consumers are paying more and that access is no better than it was. In fact, prior to being included on the PL there was significant patient concern about inconsistent access to these products in the private system. There are a number of media articles from that time containing patient stories where access to ablation catheters was denied despite the fact that the patients were insured. See for example, "Private health fund members stuck with outdated treatments" and "Why health funds are prevented from paying for this lifesaving device". In welcoming the inclusion of these devices on the PL, the patient group, Hearts4heart, noted that '[u]ntil now, the refusal of many health funds to cover the full expense of catheter ablation…saw thousands of patients join blown-out public waiting lists, a delay which often precluded them from treatment during the narrow window of time associated with highest rates of success'. This access issue has now been resolved due to the inclusion of these products on the PL. They are now listed at a cost effective price and will by 2022 start to be benchmarked against competitive public prices.

It is exactly this disconnect between insurer rhetoric and the real world experience of patients which highlights why the PL is so important as a consumer protection.

Q7: Please consider the tables at Attachment B and explain which products meet the future criteria for listing and the reasons why?

The following is provided as an indicative assessment only. Full clinical review including clinicians using the products would be required to make a proper assessment.

Kinds of products	Therapy / diagnosis Implantable / Surgically invasive / Not invasive	Part A / B / C	MTAA assessment
Femur – Proximal	Human tissue product / Therapy / Implantable	Part B	Agree – no change
Hip Femoral Stem	Medical device / Therapy / Implantable	Part A	Agree – no change
Knee hinge ancillary implants (augments, plates, wedges, etc)	Medical device / Therapy / Implantable	Part A	Agree – no change
Cardiac pacemaker	Medical device / Therapy / Implantable	Part A	Agree – no change
Cardiac leads for pacemakers	Medical device / Therapy / Implantable	Part A	Agree – no change
Cardiac ablation catheter	Medical device / Therapy / Surgically invasive	Part A (?)	Agree - Part A if proposed criterion were applied. The device is being used to achieve the therapeutic effect intended by the surgery
Mapping catheter for catheter cardiac ablation	Medical device / Diagnosis / Surgically invasive	Part A (?)	Part A for those that are 'unique and specific' to the interventional device under Criterion 4b). Part C if proposed criterion were applied if do not meet the 'unique and specific criterion' for the ablation catheter because they are diagnostic. The latter would result in a cumbersome split between the mapping catheter on Part C and the ablation catheter on Part A
Other cardiac ablation devices (assume referring to patches)	Medical device / Diagnosis / Surgically invasive (in the case of the main device)	Part A (?)	Part A for those that are 'unique and specific' to the interventional device under Criterion 4b). Otherwise Part C because may not meet the strict definition of 'unique and specific' under Criterion 4b)

Cardiac remote monitor (i.e. the bedside monitor)	Medical device / Therapy / Not invasive	Part C	Part C or could be Part A because unique and specific under Criterion 4b), but not affected by criterion change
Insulin pump	Medical device / Therapy / Not invasive	Part C	Agree – no change
Surgical guide or biomodel	Medical device / Therapy / Surgically invasive	Part A (?)	Part A if unique and specific to the main (usually custom) implant; Otherwise Part C because may not meet the strict definition of 'unique and specific' under Criterion 4b)
Intraocular dye	Medical device / Therapy / Surgically invasive	Part A (?)	Likely Part C because may not meet the strict definition of 'unique and specific' under Criterion 4b) and likely not considered to the device used to specifically achieve the therapeutic effect
Coronary pressure wire	Medical device / Diagnosis-measurement / Surgically invasive	Part C (?)	Agree – single use diagnostics used in hospital to inform imminent surgery should be eligible for Part C
Drug eluting vascular balloon catheters	Medical device / Therapy / Surgically invasive	Part A (?)	Agree - Part A if proposed criterion were applied as it is device being used to achieve the therapeutic effect intended by the surgery
Mechanical thrombectomy catheter and stent retriever	Medical device / Therapy / Surgically invasive	Part A (?)	Agree - Part A if proposed criterion were applied as it is device being used to achieve the therapeutic effect intended by the surgery
Microcatheter (small diameter catheter)	Medical device / Therapy / Surgically invasive	Part A (?)	Whether it is eligible could vary widely on the procedure. If the microcatheter is delivering the main therapeutic device or medicine it may not be considered eligible. If it is being used to actually perform the surgical intervention it may be eligible
Ophthalmology microcatheter	Medical device / Therapy / Surgically invasive	Part A (?)	Agree - Part A if proposed criterion were applied as it is device being used to achieve the therapeutic effect intended by the surgery

Name

Q8: Should the name of the list be modernised and, if so, what should it be called?

There is a good reason to change the name as it does create a misapprehension in the public mind and even occasionally confusion amongst stakeholders about the role of the PL. While some other names such as the Medical Technology List could be more suitable they are also broad. One option to consider is the Private Health Insurance Medical Device List or Medical Device – Guaranteed Access Program. However, all names have some ability to be misinterpreted. The name should be reconsidered once the final criteria are determined.

Renaming should also be considered for particular categories of the PL. The General Miscellaneous Category and the Product Groups within it should also be renamed to more appropriately represent the specific therapy areas these medical devices are used for.

Consequence of Changes

Q9: Does the list of items at Attachment A flagged for inclusion and removal accurately reflect the proposed future criteria for listing?

The products listed in Attachment A require a comprehensive review, particularly by clinicians regularly using the products, to make a proper assessment. It is also highly dependent on the interpretation of the criteria. However multiple devices in the listed groups would in some or all circumstances be the specific devices used to perform the intervention to achieve the therapeutic effect.

There are many examples of these which would need to be carefully considered by relevant clinical societies but three examples are the following:

Example 1: Resolution 360 Ultra Clip BS379

The Resolution 360 ULTRA Clip BS379 is categorised on the PL in *03.08.03 - Ligating Devices.*

It is indicated for clip placement within the Gastro-intestinal (GI) tract for the purpose of:

- Endoscopic marking, (precise location of bleeding ulcers)
- Hemostasis for: Mucosal/sub-mucosal defects < 3 cm, Bleeding ulcers, Arteries < 2 mm, Polyps < 1.5 cm in diameter, Diverticula in the colon, Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection;
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
- As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

The therapeutic use is reflected in MBS items where these products are specifically identified to be used in GI procedures. For example, MBS item 30478 - Oesophagoscopy (other than a service to which item 41816, 41822 or 41825 applies), gastroscopy, duodenoscopy, panendoscopy or push enteroscopy, one or more such procedures, if:

a) the procedures are performed using one or more of the following endoscopic procedures:
    i. polypectomy;
    ii. sclerosing or adrenalin injections;

iii. banding
iv. **endoscopic clips;** [emphasis added]

Product Group *03.08.10 - Anastomosis Clip* is listed in the Consultation Paper 'Table 3: Part A - General Miscellaneous Items Proposed to be Retained and 2018-19 Prices Paid'. Product Group *03.08.03 Ligating Devices* should be retained on the PL for the same reason anastomosis clips have been identified to be retained on the PL. Anastomosis clips and ligation devices have the following similarities:

- Both product groups are for products that provide therapy i.e. treatment or alleviation of disease
- They are not intended for general purpose to support a range of different types of surgical procedures
- They are not consumables
- They are not accessories

Example 2: THD Slide MS056

THD Slide MS056 is categorised on the PL in *03.08.03 - Ligating Devices*.

It utilises the Transanal Haemorrhoidal Dearterialization (THD) technique to locate and ligate rectal arteries and to repair rectal prolapse (rectopexy). The product replaces / returns the prolapsed rectal tissue to the correct anatomical position and removes haemorrhoids. The specific procedural intention of the device has been widely published in the clinical literature, with particular by Ratto, C. (2013) THD Doppler procedure for hemorrhoids: the surgical technique (attached). THD Slide is not used as an adjunct to the procedure.

The device is particularly designed for the use by physicians specialised in colorectal procedures (as compared to other items which may have more generalised use cases). The MBS codes commonly used with THD Slide (MS056) are within Category 3, Group T8, Subgroup 2 (Colorectal). The codes are:

- 32120 (Rectal Prolapse, perineal repair of)
- 32138 (Haemorrhoidectomy, including excision of anal skin tags when performed)
- 32139 (Haemorrhoidectomy, involving 3rd or 4th degree haemorrhoids, including excision of anal skin tags when performed).

Example 3: Nasopore HW582

Nasopore HW582 is categorised on the PL as *03.05.06 – Haemostatic Devices.*

While it is a wound dressing it is specifically used to for patients following nasal or sinus surgery to prevent common complications. While it remains for around 30 days it is clearly implanted.

These examples illustrate the need for careful clinical review of various cases.

As far as MTAA is aware, the product groups listed for removal in Table 2 of Consultation Paper have not been flagged by the Department in any previous public document as being outside the Prostheses List criteria. Many of these product groups have been listed on the PL since its inception. The Consultation Paper does not provide the reasons why they have been listed for removal. These will require further consideration and consultation.

Q10: 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?

As already flagged by MTAA, the most fundamental question for removals is whether there is adequate funding in place. However, if the decision is made to proceed with removals and to do this in tranches, it is critical that groups with overlapping utilisation are treated the same, so that there is not a technology bias toward devices that happen to have remained on the PL as against those that are removed.

An uneven playing field created by technology bias does not only affect the sponsors disadvantaged. It has the potential to result in suboptimal patient outcomes by elevating financial over clinical considerations, or even increasing costs to insurers as technologies that remain on the PL may be more expensive to use overall than those which are removed.

The most obvious example here is across the closure device category where there are multiple technologies that may be used. These may be used concomitantly but also substituted for one another in some cases if the financial drivers are sufficient, whether or not that is the best outcome for the patient, or the most efficient and lowest cost for the clinician and hospital.

Likewise, similar products in the neurosurgery category for dura repair-liquid sealants and self-adhesive sealing devices that achieve the outcome of closure, sealing or haemostasis should also be treated the same to ensure a level playing field.

From a timing perspective, consideration should also be given to the current COVID-19 pandemic where the hospital system is under increasing pressure, private hospitals are being co-opted to support the public system, elective surgeries are being cancelled and costs of insurers are likely to be falling again.