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Department of Health and Aged Care

Reforms to the Prostheses List Part B

May 2023

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Contents

1 Background

The Prostheses List

The Prostheses List (PL) is the primary mechanism for reimbursement of medical device and human tissue products in the private health system. It specifies a set benefit amount for listed prostheses, which private health insurance funds are required to pay on behalf of insured patients. The legislative instrument under the Private Health Insurance Act is the *Private Health Insurance (Prostheses) Rules*, which provide the requirements in relation to the provision of a minimum price for products listed. For human tissue products listed under Part B of the PL, the benefit amount also sets a de facto price for public hospitals who also purchase human tissues products listed.

Reforms to the Prostheses List

In the 2021-22 Federal Budget, the Australia Government committed $22 million over four years to the *Modernising and Improving the Private Health Insurance Prostheses List* Budget measure, instigating a multi-year reform process by the Department of Health and Aged Care (the Department). Prostheses List improvements were proposed with the aim of improving transparency, increasing consumer protection, and addressing the sustainability of the system of reimbursement.

The Prostheses List Reform Taskforce published two consultation papers, regarding the proposed modern listing pathways to be adopted for the PL:

- Consultation Paper 2(a) – Modernisation of Part B of the Prostheses List.
- Consultation Paper 3 – Prostheses List: A modernised fit-for-purpose listing process.

These papers reflect the design of the reforms, including the proposal to establish the separate pathways to list existing products and technology, variations and novel technology. Feedback was collated and published to provide an opportunity for the sector to consult and contribute to the reform process. In 2022, changes were made to Part A (Medical Devices) and Part C (Other Devices) of the PL including the listing pathways, groupings and benefits payable.

Given the complex policy and ethical issues, changes to Part B (Human Tissue) have not been finalised. While reform of Part B of the PL was intended to follow a similar path to Part A and Part C, there are additional complexities surrounding benefit setting in the context of cost recovery limitations on products in Part B and the need to ensure alignment with other national policy priorities. These include promoting a self-sufficient and sustainable tissue sector in Australia and ensuring ethical safeguards for tissue donation remain in place.

The tissue sector in Australia

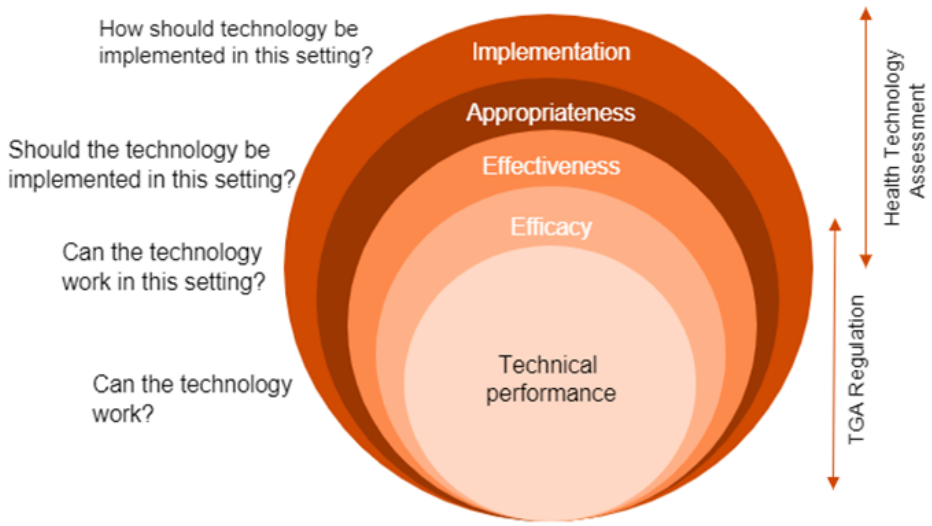
Human tissue products in Australia have a clearly defined regulatory pathway through the Therapeutics Goods Administration (TGA) under the Biologicals Framework. All products approved for use in Australia are listed on the Australian Register of Therapeutic Goods (ARTG). The Biologicals Framework classifies biologicals based on risk. This is influenced by the level of processing applied to the biological and the intended use of the product, but also the level of external governance and clinical oversight. Most biologicals on the PL are Class 2 biologicals (low risk), but it is likely that more highly processed biologicals i.e. Class 3 (medium risk) or Class 4 (high risk) will be listed in the future.

The TGA also regulates areas such as donor suitability, infectious disease testing requirements, labelling requirements and shelf life through Therapeutic Goods Orders (TGOs). All manufacturers of tissue products must hold a TGA manufacturing licence and comply with the relevant Code of Good Manufacturing Practice.

The tissue sector in Australia is fragmented, with differing models for collection, processing, pricing, and distribution of tissues. Various state-based legislation regulates the collection of human tissue for transplantation and other research purposes. In Australia, it is illegal to profit from the collection or retrieval of human tissues in their natural form. However, the situation is more nuanced once human tissue has been subject to manufacturing processes. Most state and territory legislation contain exceptions to prohibitions on trading in human tissue that has been processed. A summary of relevant legislation is provided at Appendix A.

While the TGA assesses the quality, safety and efficacy of a product prior to approval to list on the ARTG, the assessment process for the PL is focussed on comparative clinical effectiveness and cost-effectiveness. Applications are assessed by the Department with relevant clinical experts providing recommendations to the Prostheses List Advisory Committee (PLAC). Under the current parallel assessment process, stakeholders can concurrently submit an application on the Prostheses List with evidence that a valid application to TGA has been submitted. However, PL approval will not be granted until the item has a valid ARTG entry. While there are some overlapping evidentiary requirements, these are separate and distinct processes (see Figure 1 below).

Figure 1: Purpose of TGA and HTA processes



Relevant supporting frameworks

In 2007, the National Health and Medical Research Council (NHMRC) released ethical guidelines *Organ and tissue donation after death, for transplantation: Guidelines for ethical practice for health professionals* (NHMRC guidelines). The NHMRC guidelines noted 'it is essential that commercial imperatives do not overtake the ethical principles on which donation and tissue banking are based'. The ethical principles identified in the report include consent issues, need to protect the spirit of altruism, effect on public perception of organ and tissue donation, conflicts of interest, and need to protect recipients from harm. The NHMRC is currently undertaking work to review and update these guidelines.

The National Eye and Tissue Sector Framework (the Framework), released by the Department in 2022, provides the strategic direction for the eye and tissue sector in Australia. The Framework outlines the national objectives and high-level principles for providing Australians with safe, equitable and ethical access to tissue transplantation. In relation to tissue supply costs, the Framework states that reform changes to Part B should align with state and territory legislation, NHMRC ethical guidance, and 'further support the sustainability of the sector through improved benefit setting arrangements

2 Methodology

PwC was engaged by the Department to consult with stakeholders and develop a proposed way forward for reform to Part B of the PL. PwC undertook a series of internal meetings with the Department, analysed materials and consultation responses, and facilitated two stakeholder workshops to inform the recommendations contained within this final report. A timeline of key activities and deliverables is shown in Figure 2 below.

Figure 2: Timeline of key activities and deliverables

Kick-off meeting

A kick-off meeting was held with the Department to discuss the key objectives of this project in progressing reforms to Part B of the PL:

- Discussing with stakeholders the proposed assessment pathways consistent with the reforms to Part A and Part C of the PL.
- Progressing work on the groupings.

While consistent costing of Part B products was noted as an ongoing challenge, this was acknowledged to be out of scope for this engagement.

In 2019, hereco had undertaken significant work on grouping and had previously provided the Department with a technical paper. The Department requested that PwC subcontract hereco to provide technical advice and answer questions in the stakeholder consultation workshops.

Project plan and methodology

A project plan and methodology were developed in conjunction with the Department and provided in a final format to the Department on 30 January 2023 (*see separate attachments provided*).

Summary of Consultation Paper 2(a)

A summary of Consultation Paper 2(a) was undertaken which included identification of key themes and analysis of each of the seven proposal questions. The report was provided to the Department in a final format on the 30 January 2023 (*see separate attachments provided*).

Stakeholder workshop 1

A stakeholder workshop was held with the sponsors of Part B products, including not-for-profit tissue banks, commercial tissue banks, industry representatives and staff from hereco. The workshop focused on:

- Validating the responses to Consultation Paper 2(a).
- Exploring areas of concern with stakeholders.
- Discussing the proposed new groupings as outlined in the 2019 hereco technical paper.

There was significant discussion regarding the need for a revised ethical framework to safeguard the operation of the sector, and guide decision making around reimbursement for both not-profit and commercial entities. It was noted that National Health and Medical Research Council (NHMRC) is currently updating the NHMRC guidelines.

Actions arising from the workshop were to:

- Provide a definition of a Part B product.
- Meet with the TGA to discuss issues raised in the workshop and the consultation paper.
- Provide further information on when each of the three assessment pathways would be used.
- Provide stakeholders with a further opportunity to comment on the proposed groupings.
- Obtain an update of the status of the NHMRC guidelines.

A short summary of the meeting was distributed to stakeholders. The proposed groupings were also circulated with stakeholders, who were given two weeks to provide feedback. A copy of the slides presented is included at Appendix C.

Meeting with TGA

PwC and the Department met with the TGA to discuss issues which arose during the first stakeholder consultation workshop including:

- The level of evidence and data required to support applications under the Biologicals Framework.
- The structure of the ARTG and whether there was any opportunity to align this with Part B of the PL.
- Whether the Special Access Scheme (SAS) impacted listing of Part B products on the PL.
- How risk is determined for biologicals.
- How the TGA recognises claims for increased performance e.g., osteoinductivity.

Feedback from the TGA was presented to the stakeholder group in stakeholder workshop 2.

Collation of grouping feedback

Following Workshop 1, stakeholders were invited to submit further written feedback regarding the proposed grouping structures based on the detailed materials which were made available by the Department. PwC collated this feedback on behalf of the Department. A summary of the feedback received can be found at Appendix B**.**

Stakeholder workshop 2

A second workshop was held with stakeholders to present solutions to the proposals and themes outlined in the first stakeholder workshop, and progress discussion on groupings including:

- A recommendation not to pursue restricting the use Part B products to specific MBS items.
- Feedback from the TGA.
- Definitions for a 'Part B product' and 'benefits'.
- A process map outlining the operation of the proposed three assessment pathways.
- A summary of stakeholder feedback on groupings.

Recommendations and next steps coming out of the second stakeholder workshop include:

- The Department to consult with stakeholders regarding the definition for a Part B product.
- The Department to share with stakeholders more detailed advice on the proposed assessment pathways and provide a final opportunity for comment prior to implementation.
- Undertaking additional work to refine and update the grouping work commenced by hereco in 2019.

A copy of the slides presented is included at Appendix D.

Final report

This final report collates the key inputs from Consultation Paper 2(a), the stakeholder workshops, and meetings with the Department and other internal stakeholders, including the TGA. The four areas central to reform of Part B and associated recommendations are explored in further detail in the report below:

- Definition of a Part B product.
- Groupings.
- Assessment pathways.
- Costing.

The report also contains recommendations or resolutions to the proposals contained within Consultation Paper 2(a).

3 Definition of Part B products

A key consideration for the Department is to determine and establish a definition for Part B products. Part B products have traditionally been limited to tissues that have been minimally processed (such as corneal tissue) and mostly provided by not-for-profit entities. However, commercial manufacturers are increasingly developing and listing more sophisticated and highly processed (biotech) products on Part B.

In line with the TGA and the Office of Best Practice Legislation, the proposed definition of Part B products is:

> *Human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law).* [1]

Some stakeholders expressed ethical concerns regarding the definition of Part B products, with some indicating a strong preference that highly processed tissue products be included in Part A or in a new separate section of the PL. This desire appears to be driven by ethical considerations, and to reflect the not-for-profit status of most state-based tissue banks which operate using cost-recovery models. It should be noted that highly developed biotech products will continue to be manufactured regardless of where they are listed on the PL. Part A listings may in fact be more favourable for manufacturers of these products as the benefits payable in Part A are not constrained by the cost-recovery limitation which currently exists within Part B.

All Sponsors of Part B products are also currently exempt from application fees, initial listing fees, and ongoing listing fees which apply to other parts of the PL.[2] When Part B of the PL was established, Sponsors were mainly not-for-profit entities supplying low risk tissue products which had been minimally manipulated (Class 2 biologicals). However, as more highly processed tissues appear on the PL and there is increasing involvement by commercial Sponsors, the appropriateness of this exemption should be reconsidered. Commercial manufacturers or Sponsors will usually have the resources to pay the appropriate listing fees and assessment of applications for highly processed tissues can be time intensive. If these more highly processed products remain in Part B, a delineation could be made between:

- Commercial Sponsors and not-for-profit Sponsors (as registered with the Australian Taxation Office (ATO)); or
- Sponsors of Class 2 biologicals, and Sponsors of Class 3 and Class 4 biologicals.

Key considerations for the Department include:

- The importance stakeholders place in relation to nuances of language, including terms like ‘manufacture’ and ‘benefit’, particularly in the context of the ethical issues associated with altruistically donated tissue.
- The need for decision-making surrounding highly processed Part B products, and where they belong on the PL.
- Whether it is appropriate for the exemption of Part B fees to remain for commercial providers and/or manufacturers of highly processed Part B products.

Recommendation 1: that the Department offer stakeholders the opportunity to provide feedback on a proposed definition for Part B products.

Recommendation 2: that the Department consider whether the exemption from fees associated with Part B of the PL be restricted to Sponsors of Class 2 biologicals or Sponsors who are registered as a not-for-profit entity with the ATO.

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[1] *Prostheses List – Guide to listing and setting benefits for prostheses*, Australian Government, Department of Health, February 2017.

[2] The TGA does not exempt Sponsors of biologicals (i.e. human tissues) from fees which are factored into cost recovery models.

4 Groupings

Previous research conducted by PwC in our 2016 report for the Organ and Tissue Authority, *'Analysis of the Australian Tissue Sector'*, as well as consultations with stakeholders outlined that Part B required significant reforms to acknowledge the changes in use, supply, and clinical utilisation of products over time. The Department proposed a revised classification structure for the following reasons:

- To extend on reform work done to Part A and bring appropriate and rationalised clinical logic to groupings across the entire PL list.
- To bring confidence and clarity to both stakeholders and the Department as to where Part B products belong.
- To determine the appropriate assessment pathway of products and track substantially similar products.
- To use as a reference point for future work that will be done on determining benefits.
- For ease and efficiency in lodging product applications, considering the imminent roll-out of the Health Products Portal (HPP).

In 2019, hereco was commissioned to produce proposed groupings for Part B, providing the Department with the rationale and analyses to support the chosen categorisations. The four existing categories of the current PL Part B (Cardiothoracic, Ophthalmic, Orthopaedic and Dermatologic) have been retained in the proposed revision of the groupings, with the Part B Dermatologic Category renamed to Plastic and Reconstructive. In the proposed structure, three levels of categorisation have been created – Subcategories, Groups and Subgroups.

Through consultation workshops and submissions, general and specific feedback from stakeholders has been collated and can be found in detail in Appendix B. There are core concerns raised, and it is evident that further work is required to update and amend the grouping proposed by hereco in 2019 for Part B products.

Table 1: Feedback on Groupings

Groupings section	Feedback
01 - Cardiothoracic	• Feedback on Category 1 indicated that the grouping structure is confusing and not well aligned, in comparison to other categories. Stakeholders collaborated to propose a structure outlined below in Table 2.
02 – Ophthalmic: Sclera (02.02)	• Stakeholders suggest that Whole and Patch groups, as is the case for cornea, should be included for the sclera subgroup.
03 – Orthopaedic: Fascia Lata (03.02.02)	• Stakeholders suggest that Fascia Lata is a specific anatomical entity, in comparison with the other groups for non-osseus tissues. Therefore this would be more appropriate as 'Fibrous Sheaths', where Fascia Lata is a sub-group.
03 – Orthopaedic: Hemipelvis, Whole or Part (03.01.01.02)	• Suggested that this would be better reflected as two (2) separate subgroups.
03 – Orthopaedic: Long Bone, Distal, Proximal and Proximal with Soft Tissue (03.01.01.03.05)	• Suggested that this is better reflected as Long Bone, Whole, Half and Third, as three (3) separate subgroups. All groups should be plus or minus soft tissue (or this may form a processing sub-group).
03 – Orthopaedic: Ligament, Medial (03.02.03.01)	• Suggested that this is not required as a subgroup. Ligament may be a single listing, or with subgroups based on size (i.e., length, width, and thickness), which may be more indicative of processing complexity as well as a more useful descriptor for users of the list.
04 – Plastic and Reconstructive: Split Skin (04.01.01)	• Stakeholders suggest that subgroups for differing thicknesses (i.e., retrieval or processing approach), size or number of patches is likely to be a more useful indicator for users and reflect different processing costs. This may also form a process sub-group if more appropriate at this level.

Groupings section	Feedback
04 – Plastic and Reconstructive: Biological Scaffolds (04.02)	• Many stakeholders are concerned that this is the only sub-group organised by clinical indication. Acellular dermal matrix is listed twice despite being the same product and it suggested that this group be restructured consistent with other groups. Products should only occur once on the PL.

As noted in the table above, manufacturers of cardiothoracic products met to discuss a proposed grouping structure outlined in Table 2 below.

Table 3: Proposed Cardiothoracic grouping structure

Subcategory	Types included	Current corresponding billing code (where available)
Valve	Aortic Valve, Pulmonary Valve, Mitral Valve, Tricuspid Valve	SHV01, QHV01, SHV02
Conduit	Aortic Conduit, Pulmonary Conduit, Thoracic Aorta conduit	QHV11, QHV07, TBV56, TBV03, SHV03
Valved Conduit	Aortic Valved Conduit, Pulmonary Valved Conduit	QHV09
Patch	Aortic Patch, Pulmonary Patch	SHV03
Pericardium	Pericardial Patch	TBV50, QHV05, SHV03
Vascular Graft	Descending Aorta, Iliac artery, Femoral Artery, IVC, Femoral vein	SHV03

A summary of key themes and considerations for the Department include:

- Sub-groupings in the proposed grouping structure require further consultative effort to refine and distinguish levels of processing and treatment, size and volume, particularly in the Orthopaedic category.
- There are some categories i.e. Ophthalmic and Cardiothoracic, where the sector has proposed changes which appear relatively straightforward to action. These groups have fewer items and are therefore less complex.
- Stakeholders are concerned about a reliance on grouping products based on clinical utilisation, with the default assumption that one product is used for one indication.
- There are some new items that will need to be included in the grouping structure that were included on the PL after 2019.
- Some items have been included in the revised groupings twice based on different indications.

There is an opportunity for the Department to design and develop an updated grouping structure that reflects Part B products and stakeholder supply more accurately, through further consultative work and seeking specific feedback from stakeholders. Once the feedback is collated, the groupings list can be updated and provide a sound foundation for benefit-setting and costing arrangements.

Recommendation 3: that the Department update and refine the groupings proposed by hereco, incorporating the stakeholder feedback contained in Table 1 and Table 2.

Recommendation 4: that the Department establish a regular review process for Part B groupings.

5 Assessment Pathways

The Department's original proposal was that the assessment pathways for Part B should mirror the assessment pathways used for Part A and C.[3] These pathways included a newly developed Departmental Assessment Pathway, the Clinical/Focused HTA Pathway and a Full HTA (MSAC) Pathway of assessment. A description of each pathway as it applies to Part B is provided in Table 3 below, and the filtering of pathways is illustrated in the accompanying flow chart (Figure 3).

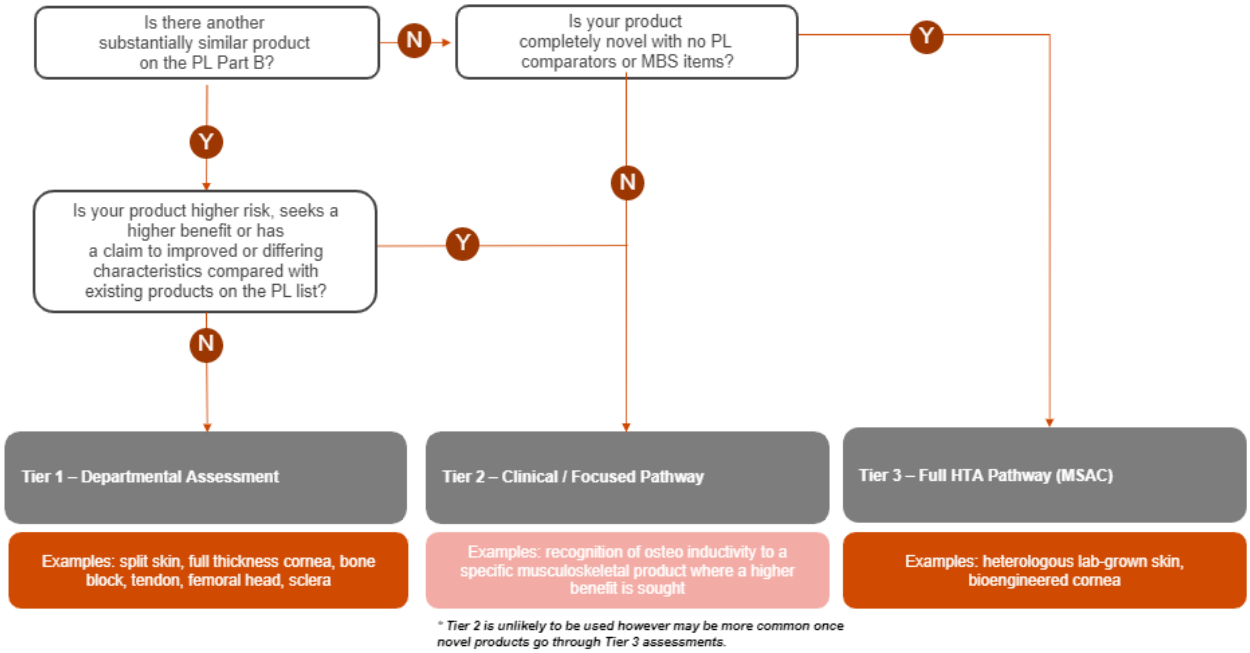
Table 3: Description of HTA Pathways

Tiered pathways	Description
Tier 1 - Departmental Assessment Pathway	• A pathway for products with a valid ARTG that do not require clinical or cost-effectiveness assessments. • Product is medium or lower risk, is a well-established product and is substantially similar in characteristics, intended use and clinical effectiveness to other devices listed on the PL in the existing grouping with the benefit set up based on the reference pricing. • Assessments will largely be undertaken by staff in the Department with relevant expertise and knowledge of human tissue products. • Aims to reduce time for assessment and eliminate red tape, with the majority of Part B products going through this pathway.
Tier 2 - Clinical / Focused HTA Pathway	• A pathway evolving from the existing PL assessment pathway for products with a valid ARTG that are requested to have a higher PL benefit based on claimed superior clinical performance. • Product is of higher risk and/or is not a well-established product, and/or claims for improved/different characteristics/manufacturing/processing requirements compared with the existing devices listed on the PL. • Clinical/Focused assessments will include comparative clinical effectiveness and/or cost effectiveness assessments with inputs from the relevant experts.
Tier 3 - Full HTA (MSAC) Pathway	• A pathway incorporating the MSAC processes on comparative safety, effectiveness and cost-effectiveness of a product with a valid ARTG for listing. • Product has no MBS items relevant to its use and/or the product is a novel technology/process with no comparators on the PL list. • Full HTA (MSAC) assessments would include the full clinical and cost-effectiveness assessments undertaken by MSAC with inputs from relevant experts as required.

Stakeholders were provided with an overview of the operation of this pathway (Figure 3 below) which was focussed on identification of similar products already listed (Tier 1) or improved products which may justify increased benefit (Tier 2). New or novel products would require a full HTA (Tier 3).

[3] Prostheses List Reforms – Consultation Paper No. 3, Prostheses List – A modernised fit-for-purpose listing process, Australian Government, Department of Health

Figure 3: Proposed assessment pathways



Through consultation workshops and feedback, several challenges and considerations were identified:

- There is a need to develop tailored processes to account for the differences in Part B products compared to products listed on Part A and C.
- There are limitations regarding published evidence available to support assessment of clinical efficacy and cost benefit of Part B products whereas Part A and Part C products usually require successful clinical trials to support TGA and PL applications.
- Stakeholders are concerned regarding their capability and capacity to navigate the more complex Tier 2 and Tier 3 assessment pathways. Not-for-profit providers also noted their resource constraints relative to commercial providers who often have a dedicated section of the company to navigate regulatory and reimbursement processes.
- The provision of additional benefits available through the Tier 2 pathway did not appear to be as relevant for Part B products as the benefit able to be obtained is limited by cost recovery. It is also noted that while improved performance may be the result of increased investment in manufacturing or testing requiring an increased benefit to recover costs, this is not always the case.
- Balancing both the need for insurers to have assurance in appropriate stakeholder product usage and the need for future proofing the PL list with stakeholder needs.

The evidence requirements for the Health Technology Assessment (HTA) process and engagement with the Medical Services Advisory Committee (MSAC) are clearly defined.[4] When introducing new products into the Australian market, many Sponsors undertake the TGA registration process and the PL process in parallel. While the outcomes and purpose of each is separate and distinct, the same evidence base is used to justify claims around clinical efficacy, usually but not always obtained through clinical trials. The TGA evidence requirements for each class of biological is shown in Table 4 below.

[4] Medical Services Advisory Committee, *Documents for Applicants and Assessment Groups*, 3 February 2023, Department of Health and Aged Care

Table 4: Classification of biologicals

Class & Risk	Approach to classification	Definition	Evidence requirements
Class 2 Low risk	Method of preparation and intended use.	Class 2 biologicals are restricted to those that: • have been subjected to only minimal manipulation; AND • are only for homologous use.	Sponsors must provide a brief summary of evidence to support the intended use. This is usually evidence drawn from scientific literature, including appropriate reviews or reference to standard texts or clinical usage guidelines. **While clinical data may be included, this is not required.**
Class 3 Medium risk	Method of preparation and intended use.	Class 3 biologicals cover those that are either: • for homologous use but have been prepared using more than minimal manipulation; or • for non-homologous use, regardless of whether they have been prepared using minimal manipulation or more than minimal manipulation.	Sponsors must provide evidence regarding non-clinical development and clinical development. Evidence may be obtained through *in vitro* testing and animal studies, prior to undertaking human clinical trials. Where relevant, evidence may be required for: • Biodynamics • Biokinetics • Dose finding studies • **Clinical efficacy (including clinical trial data)** • Clinical safety • Biovigilance and risk management plan

Class 4
High risk
	Specified in Schedule 16 of TGO.	Class 4 biologicals are high risk products that are currently defined in Schedule 16 as:
		• biologicals that comprise or contain live animal cells, live animal tissues, or live animal organs;
		• biologicals to which both of the following paragraphs apply:
		  • the biologicals comprise, contain or are derived from human cells or human tissues that have been modified to artificially introduce a function or functions of the cells or tissues;
		  • the artificially introduced function or functions were not intrinsic to the cells or tissues when they were collected from the donor;
		• pluripotent stem cells;
		• biologicals derived from pluripotent stem cells	

Source: *Dossier requirements for Class 2, 3 and 4 biologicals, Australian Regulatory Guidelines for Biologicals (ARGB) v 1.1,* TGA, November 2021

For Class 3 and Class 4 biologicals, which are highly processed, Sponsors are very likely to be able to provide the evidence required for both the Tier 2 and Tier 3 HTA pathways as the TGA requires significant evidence to support registration of these products, including data on clinical effectiveness from clinical trials. However, TGA evidence requirements for Class 2 biologicals generally rely only on literature, and in some instances expert clinical opinion. Apart from corneal tissue, which is tracked through the Australian Corneal Graft Registry, most manufacturers of Class 2 biologicals do not collect objective long-term evidence as to the clinical effectiveness of their products including through registries.

Most not-for-profit stakeholders who manufacture Class 2 biologicals will use the Tier 1 pathway or rarely the Tier 3 pathway. Engagement with the Office of Health Technology Assessment is suggested to determine whether the evidence requirements for Class 2 products could be relaxed in the event the Tier 3 pathway is required to be used. It is possible that the Tier 2 pathway will be used by commercial providers to seek additional benefits. In the event this occurs, the Sponsor will likely have the internal capability to navigate the use of this pathway.

Recommendation 5: that the Department proceed with implementing the three assessment pathways which mirror the pathways in Parts A and C of the PL.

Recommendation 6: that the Department provide additional support and guidance for Sponsors of Class 2 biologicals to navigate HTA pathways.

6 Costing

Part B of the PL determines the rebate provided by private health insurers for use of human tissue products and currently operates on cost-recovery principles. Cost-recovery in the context of Part B products is defined as costs associated with Part B applications, staffing, assessments and reviews reimbursed by the Commonwealth Government.

The PL rebate also acts as the de facto cost of the product used by the sector to determine the price charged to public hospitals and uninsured individuals. While costing and benchmarking work was out-of-scope, the relationship between the HTA pathways, groupings and costing processes meant PwC was able to collate feedback that was received as part of the consultation processes.

Throughout the consultations it was identified that:

- The evidence and costings provided to the Department by Sponsors are highly inconsistent. Current cost-recovery arrangements are not determined by a thorough study of stakeholders' financial statements or cost.
- Stakeholders currently have very limited guidance in seeking imbursements and prices, due to the lack of costing standards across the industry in Australia.
- Some tissue banks have undertaken detailed work on costing with consultants or employed staff with appropriate expertise. NSW Tissue Bank and Queensland Tissue Bank are both amenable to sharing the work they have completed to date with the Department.

There is an opportunity for the Department to lead the development of costing standards, tailored to Part B products, once grouping structures are finalised. This would be the first step to determining a reference for benefit setting and benchmarking (if this is pursued). This will also provide not-for-profit tissue banks with guidance to set prices on their products and delineate other costs such as overheads, storage, staff payments etc.

Key feedback and considerations for the Department when pursing benefit setting include:

- Creating flexible but fit-for-purpose costing standards and benefit setting processes that account for the variations of each tissue bank including donation rates, geographic location, operating model, state variability in key input costs etc.
- Identifying that benchmarking can only follow key policy decisions and discussions such as:
    - The impact of state and territory tissue legislation which prohibits trading in human tissue; and
    - Whether the operation of Part B of the PL should continue to be restricted by cost recovery principles.

Recommendation 7: that the Department undertake further work on the methodology for pricing including the development of costing standards.

Recommendation 8: that the Department undertake a review of state and federal legislative requirements which prohibit trading in human tissue and its application to determining benefits for Part B.

7 Other outcomes

There were seven proposals put forward in the Consultation Paper 2(a). Clear outcomes and/or recommendations were developed over the course of this engagement and are summarised in Table 4 below.

Table 5: Issue raised in Consultation Paper 2(a)

#	Proposal/Issue	Outcome/Recommendation
1	The PL Guide should clarify whether autologous products are eligible for listing and, if ineligible, that skull flaps and autologous femoral heads are removed from the list.	Stakeholders strongly supported the retention of autologous products on Part B, noting the importance of the PL to price setting and that there were instances in which the item would be used. **Recommendation 9: that the Department retain the PL items for autologous skull flaps and femoral heads.**
2	That further work is undertaken to develop guidance on an ethical framework for human tissue and human tissue products used for medical treatment, possibly in consultation with the NHMRC.	The National Eye and Tissue Framework was released in August 2022. The Department has taken an action to determine the status of the work being undertaken by the NHMRC on an ethical framework.
3	That the number and nature of ARTG listings for human tissue products is discussed with the TGA to explore the feasibility of greater specificity of ARTG listings for these.	PwC and the Prostheses List Reform Branch discussed the structure of the ARTG with representatives from the TGA. It was determined that aligning the PL with the ARTG is not currently feasible as the number of PL items is significantly greater than the items listed on the ARTG, and it would increase regulatory burden for sponsors.
4	That the application and assessment pathways for human tissue products mirror the three proposed application and assessment pathways (i.e., Departmental Assessment, Clinical/Focused HTA Pathway, and Full HTA pathway (MSAC)) for medical devices.	As above.
5	That advice is sought from the TGA regarding whether a Class 3 biological has an equivalent risk level to a Class 3 medical device.	The TGA has advised that the risk profile of a Class 3 biological is not equivalent to a Class 3 medical device. The risk profile of biologicals is based on the extent to which to the original tissue product is manipulated (minimal manipulation or more than this), and the intended use (homologous or non-homologous).
6	That Part B products undergoing HTA assessment have an agreed list of appropriate MBS items assigned to them to enable their use to be restricted to specific clinical indications.	Extensive stakeholder consultation was undertaken in Workshop 1 in relation to this proposal with concerns raised regarding limiting clinician choice and how this change would work in practice. Discussion with the Department indicated that restricting the use of Part B products to specific MBS items would not be consistent with Part A and C of the Prostheses List. **Recommendation 10: that the Department does not pursue restricting the use of Part B items to specific MBS items at this time.**

#	Proposal/Issue	Outcome/Recommendation
7	That there is a clear understanding of the nature of the assessments undertaken by the TGA for different groupings of tissue products before the Departmental Assessment Pathway is used to determine benefits for tissue products.	The TGA advised that they rely on literature reviews and expert clinical advice to assess applications for Class II biologicals. Data from clinical trials or registry data regarding clinical effectiveness is not required for Part B products.

8 Recommendations and next steps

Key recommendations

A summary of the key recommendations made by PwC to the Department, outlining practical and tangible steps forward to support the reforms to Part B of the Prostheses List, is outlined below:

Recommendation 1: that the Department offer stakeholders the opportunity to provide feedback on the proposed definition for Part B products.

Recommendation 2: that the Department consider whether the exemption from fees associated with Part B of the PL be restricted to Sponsors of Class 2 biologicals or Sponsors who are registered as a not-for-profit entity with the ATO.

Recommendation 3: that the Department update and refine the groupings proposed by hereco, incorporating the stakeholder feedback contained in Table 1 and Table 2.

Recommendation 4: that the Department establish a regular review process of the Part B groupings.

Recommendation 5: that the Department proceed with implementing the three assessment pathways which mirror the pathways for Parts A and C of the PL.

Recommendation 6: that the Department provide additional support and guidance for Sponsors of Class 2 biologicals to navigate HTA pathways.

Recommendation 7: that the Department undertake further work on the methodology for pricing including the development of costing standards.

Recommendation 8: that the Department undertake a review of state and federal legislative requirements which prohibit trading in human tissue and its application to determining benefits for Part B.

Recommendation 9: that the Department retain the PL items for autologous skull flaps and femoral heads.

Recommendation 10: that the Department does not pursue restricting the use of Part B items to specific MBS items at this time.

To support stakeholders, reform of Part B should occur incrementally, gaining in momentum across the multi-year investment towards consistency. This will allow for ongoing consultation and policy support to continue to build capability and capacity within the sector.

Glossary

Abbreviation	Term
ARTG	Australian Register of Therapeutic Goods
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
NHMRC	National Health and Medical Research Council
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
TGA	Therapeutic Goods Administration

To allow for a level of standardisation in the issues summary, our definitions and terminology references are listed below. These have been sourced from Consultation Paper N.3 and the TGA classification tool.[5; 6]

Term	Definition
Departmental Assessment pathway	A refined pathway for listings that are medium or lower risk, are a well-established technology and are substantially similar in characteristics, intended use and clinical effectiveness to other devices based on PL in the existing grouping with the benefit set up based on the reference pricing. Assessments are largely undertaken by the Department with relevant expertise and knowledge.
Allograft	The transplant of tissue from one individual to another individual of the same species
Autograft or Autologous product	The graft of person's own human tissue either from one point to another of the same individual's body, or after the tissue is removed and stored for reimplantation at the same site later (e.g. a skull flap)
Classification structure for biologicals	Classification refers to the TGA regulatory approval structure of human tissue products, according to the level of harm they may pose to users or patients. This will be influenced by the level of processing applied to the biological and the intended use of the product, but also the level of external governance and clinical oversight. • Class 1 biologicals are low risk and have an appropriate level of external governance and oversight • Class 2 biologicals are low risk, and have been subjected to only minimal manipulation and are only for homologous use • Class 3 biologicals are medium risk and have subjected to more than minimal manipulation and are f homologous use or are for non-homologous use regardless of manipulation. • Class 4 biologicals are high risk, and are comprising or containing live animal cells, tissues or organs and/or have been modified to artificially introduce a function of the cells or tissues, or not intrinsic to the cells or tissues when they were collected from the donor.
Cost-recovery system	Cost-recovery involves government entities charging individuals or non-government organisations some or all the efficient costs of a specific government activity. This may include goods, services or regulatory activities, or a combination of them. An individual tissue bank or commercial supplier may determine a cost-recovery price by considering the aggregated costs of tissue recovery, processing, preserving, product development, quality assurance and supply distributed across all the tissue and tissue products supplied by that organisation in a year.
Clinical/Focused HTA pathway	This pathway is suitable for higher risk products that are not a well-established technology, and/or has claims for improved/different characteristics compared with existing devices listed on PL. Assessments include comparative clinical effectiveness and/or cost effectiveness assessments with inputs from the relevant experts.
Full HTA pathway (MSAC)	This pathway incorporates the MSAC processes where there are no MBS items relevant for the use of the products and/or the product is a novel technology and/or there are no comparators on PL. Assessments include the full clinical and cost-effectiveness assessments undertaken by MSAC with inputs from relevant experts as required.

[5] Prostheses List Reforms – Consultation Paper N.3, 'A modernised fit-for-purpose listing process', Australian Government Department of Health, 2022.

[6] 'Classification of biologicals', Australian Government Department of Health, Therapeutic Goods Administration, 2020.

List of stakeholders

Submissions to Consultation Paper 2(a)

The following stakeholders **made submissions** to consultation paper 2(a):

Stakeholder	Abbreviation
Names have been removed for privacy reasons	

Stakeholders workshop attendance

The following stakeholders indicated acceptance to the stakeholder workshops:

Workshop 1 – 7 February 2023	Workshop 2 – 15 March 2023
Names have been removed for privacy reasons	**Names have been removed for privacy reasons**

Appendix A

Table 6: Summary of state and territory legislation

State / Territory	Legislation:	Legislation requirements
Queensland	Transplantation and Anatomy Act 1979	42A Person who owns a prescribed tissue bank may charge amount to recover certain costs etc. (1) They may: (a) Cost recovery amount to recover the persons reasonable costs associated with removing, evaluating, processing, storing or distribution donated tissue or (b) sell, agree to sell, offer to sell or hold himself or herself out as being willing to sell donated tissue for a cost-recovery amount; or (c) inquire whether a person is willing to buy from the person or another person donated tissue for a cost-recovery amount (4) A regulation may regulate the charging of a cost-recovery amount. (5) An amount charged contrary to the regulation is taken not to be a cost-recovery amount. Sections 40, 41 and 42 (prohibition) do not apply to the trading of tissue if— (a) the tissue has been subjected to processing or treatment; and (b) the trading of the tissue is for a therapeutic purpose, medical purpose or scientific purpose; and (c) the tissue is— (i) a biological or a medical device included in the register under the Therapeutic Goods Act 1989 (Cwlth); or (ii) a registered good under the Therapeutic Goods Act 1989 (Cwlth); or (iii) any exempt material derived wholly or in part from tissue; and (d) the tissue is not relevant tissue.
Australian Capital Territory	Transplantation and Anatomy Act 1978	Part 7 44(2) Subsection (1 – prohibitions)) does not apply to or in relation to the sale or supply of tissue other than blood or any of its constituents if the tissue has been subjected to processing or treatment and the sale or supply is made for use, in accordance with the directions of a doctor, for therapeutic or scientific purposes. Part 44(3) Subsection (1 - prohibitions) does not apply to or in relation to a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act.
Victoria	Human Tissue Act 1982	39A Recovery of certain costs of tissue banks 1. A person who owns or controls a tissue bank prescribed by the regulations may charge an amount to recover the reasonable costs associated with the removal, evaluation, storage, processing at the tissue bank and distribution from the tissue bank of tissue removed in accordance with this Act. 2. Section 38(1 – prohibition of buying) does not apply to a person who only charges an amount in accordance with subsection (1). 3. Section 39(1 – prohibition of selling) does not apply to a person who only pays an amount charged in accordance with subsection (1).

State / Territory	Legislation:	Legislation requirements
Tasmania	Human Tissue Act 1985	Part IV Prohibition of Trading in Tissue (2) Subsection (1 – prohibition of sale) does not apply to or in relation to the sale or supply of tissue other than blood or any of its constituents if the tissue has been subjected to processing or treatment and the sale or supply is made for use, in accordance with the directions of a medical practitioner, for therapeutic or scientific purposes. (3) Subsection (1 – prohibition of sale) does not apply to or in relation to a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act.
Northern Territory	Transplantation and Anatomy Act 1979: As in force at 2 Nov 2022	Part 5 Prohibition of trading in tissue 22E (2) However, subsection (1 - prohibition) does not apply if the contract or arrangement: (a) is entered into in accordance with an authorisation under section 22F; or (b) provides only for the reimbursement of expenses necessarily incurred by the person for the removal of tissue under this Act. (3) Also, subsection (1- prohibition) does not apply in relation to the supply of tissue if: (a) the tissue is obtained under a contract or arrangement authorised under section 22F; and (b) the tissue has been subjected to processing or treatment; and (c) the tissue is supplied for use, in accordance with the directions of a medical practitioner, for therapeutic or scientific purposes.
South Australia	Transplantation and Anatomy Act 1983	Part 7: Prohibition of trading in tissue 35 – Certain contracts to be void 3. Subsection (1 - prohibition) does not apply to or in relation to the sale or supply of tissue (not being tissue obtained under a contract or arrangement that is by subsection (1) void) if the tissue has been subjected to processing or treatment and the sale or supply is made for use, in accordance with the directions of a medical practitioner, for therapeutic, medical or scientific purposes. 4. Subsection (1 - prohibition) does not apply to or in relation to a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act.
Western Australia	Human Tissue and Transplantation Act 1982	Part 5 – Trading in tissue 29 – Trading in tissue, legal consequences (3) Subsection (1 - prohibition) does not apply to or in relation to a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act. (4) The Governor may, by Order in Council published in the Gazette, declare that subsection (1 - prohibition) does not apply to the sale or supply of a specified class or classes of product derived from tissue that has been subjected to processing or treatment.
New South Wales	Human Tissue Act 1983 (NSW)	32 Trading in tissue prohibited (1) A person must not enter into, or offer to enter into, a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person— (a) to the sale or supply of tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person, as the case may be, or (b) to the post-mortem examination of any such person's body after that person's death or of the body of any other person after the death of that other person.

State / Territory	Legislation:	Legislation requirements
		Maximum penalty—40 penalty units or imprisonment for 6 months, or both. (2) Subsection (1) does not apply to or in respect of the sale or supply of tissue if the tissue has been subjected to processing or treatment and the sale or supply is made for the purpose of enabling the tissue to be used for therapeutic purposes, medical purposes or scientific purposes. (3) Subsection (1) does not apply to or in respect of a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act. (4) Where the Minister considers it desirable by reason of special circumstances so to do, the Minister may, by instrument in writing, approve the entering into of a contract or arrangement that would, but for the approval, be void by virtue of subsection (5), and nothing in subsection (1) or (5) applies to or in respect of a contract or arrangement entered into in accordance with such an approval. (5) A contract or arrangement entered into in contravention of this section is void.

Appendix B

Table 7: Feedback on Groupings

Date Received	Format received	Stakeholder	Feedback / Question
2/24/2023	Written Submission	[redacted]	Human tissue items may fall under Multiple Groupings within the listing. i.e. requiring listing in Part B more than once – but the benefit should be reasonably consistent between groupings (otherwise it may contravene the meaning of "reasonable costs" withing the various Human Tissue Acts). For example – Human amnion would be listed under both Ocular for ocular surface disease and elsewhere as a Wound dressing (under Skin?). The service fee may vary depending on supplier and on volume, but there needs to be a degree of benchmarking between the groupings on this item.
2/24/2023	Written Submission	[redacted]	Need for specific product and process review at a sub-group level, to identify further grouping based on processing and/or testing methods (referred to in our letter as 'process subgroups'), relevant to all categories, comprising: a. identification and confirmation of the required balance of process detail where a notable cost or specification difference exists (and is relevant to users) or where this is not relevant, and b. identification of sub-group product naming conventions and size/volume measures, and changes by Sponsor. There is significant opportunity to align product names and descriptions across Sponsors, where existing variability is not material or useful for users.
2/24/2023	Written Submission	[redacted]	01 - Cardiothoracic: Overall, grouping structure is confusing and not well aligned, in comparison to other categories. Suggest adjustments were attached in the document.
2/24/2023	Written Submission	[redacted]	02 – Ophthalmic: Sclera (02.02) – [redacted], Sclera - Patch as a product on the Prostheses List – Part B ([redacted]), having identified the variability in cost-structure for sclera allograft. Whole and Patch groups, as is the case for cornea, should be included for the sclera subcategory.

Date Received	Format received	Stakeholder	Feedback / Question
2/24/2023	Written Submission	[redacted]	03 - Orthopaedic: - Fascia Lata (03.02.02) – this is a specific anatomical entity, in comparison with the other groups for non-osseus tissues, this would be more appropriate as 'Fibrous Sheaths', where fascia lata is a sub-group. - Hemipelvis, Whole or Part (03.01.01.02) – better reflected as two (2) separate subgroups. - Long Bone (Distal, Proximal, and Proximal with Soft Tissue) (03.01.01.03-05) – better reflected as Long Bone, Whole, Half and Third, as three (3) separate subgroups. All groups should be plus or minus soft tissue (or this may form a processing sub-group). - Ligament, Medial (03.02.03.01) – Not required as a subgroup. This is meaningless unless linked to the relevant joint. Ligament may be a single listing, or with subgroups based on size (i.e., length, width, and thickness), which may be more indicative of processing complexity as well as a more useful descriptor for users of the list.
2/24/2023	Written Submission	[redacted]	04 - Plastic and reconstructive: - Split Skin (04.01.01) – subgroups for differing thicknesses (i.e., retrieval or processing approach), size or number of patches is likely to be a more useful indicator for users and reflect different processing costs. This may also form a process sub-group if more appropriate at this level. - Biological Scaffolds (04.02) – These are the only sub-groups by clinical indication. Clinical indication should not reflect wholesale differences in the product, and any approach where products are separated in this way has the potential to impact equitable supply of tissue. Furthermore, where they are used across multiple indications this is will be determined by the surgeon based on patient need. Rather, as with split skin sub-groups may reflect size or number of patches.
2/24/2023	Written Submission	[redacted]	Groupings are outdated and done with minimal consultation, with very limited timeframe to respond to this information.
2/24/2023	Written Submission	[redacted]	No indication or reasoning behind groupings.
2/24/2023	Written Submission	[redacted]	Current grouping is based on Part A model of utilisation of a product rather than a service provided.

Date Received	Format received	Stakeholder	Feedback / Question
2/24/2023	Written Submission	[redacted]	4.2.1-1 Breast Reconstruction. We agree with the proposal from hereco to list the human tissue dermal matrix according to its clinical use. Currently [redacted] billing codes proposed to be separated and defined in sub-group 4.2.1-1 Breast Reconstruction. We would like to understand that with this sub-group listed as proposed, will this restrict surgeons clinical use? If so, we do not agree with restricting clinical access as an unforeseen consequence of listing. We have three questions we would like confirmation and understanding advised in writing to be informed of consequences in the healthcare system for all stakeholders if the proposed listing is used: 1. If listing as proposed is confirmed, will surgeons be guaranteed PHI reimbursement if used in non-breast reconstruction? 2. If so, is the sub-grouping needed to be duplicated as clinical indications for dermal matrix may expand to address surgeon treatment need? Or will it be legislated that PHI must rebate as per the current legislation that PL listing reflects clinical efficacy? 3. Should the listing reflect available published clinical use?
2/24/2023	Written Submission	[redacted]	These sub-groupings do not appear to distinguish between the levels of processing or manufacturing required for each product, yet this is directly related to the value requiring recuperation under a cost recovery model. There is significant opportunity to align product names and descriptions across sponsors, where existing variability is not material or useful for users. Naming conventions and size/volume measures could be sought from sponsors.
2/24/2023	Written Submission	[redacted]	Further work is required to clarify whether: - The Category 4 subgroups would be expanded to include every potential application for fresh/ frozen amnion? - The product would be added to the ophthalmic and other discipline specific groupings. - The application be responsible for identifying each of the clinical uses for listing? - A request for amnion for a non-listed application would attract the benefit? What process would be applied, and by whom? If it does not attract any benefit will supply revert to user pays as with the current ARTG listing?
2/24/2023	Written Submission	[redacted]	The proposed grouping structure is informed by the PHI Part B listings as of 2019. The information may have become outdated and not reflective of all currently listed / distributed products via PHI List.

Date Received	Format received	Stakeholder	Feedback / Question
2/24/2023	Written Submission	[redacted]	Although the logic in the grouping Categories/ sub-categories suggested by hereco supposedly follow those set in Part A which tends to link the medical device to a specific clinical utilization and essentially linked to a clinical field and medical procedure (and its MBS), this default assumption of "one medical device being used to a single indication, by a single surgical specialty" may not be applicable to human tissue transplants / products where same tissue transplants / products may be utilized by different surgical specialties and for different indications.
2/24/2023	Written Submission	[redacted]	The proposed grouping structure is informed by the PHI Part B listings as of 2019 and were put together with minimal stakeholder engagement. The information is very likely to have become outdated and not reflective of all currently listed / distributed products via PHI List. For example, some groupings appear too fragmented to be functional in current state, while others not separated enough to ensure similar products are grouped together. Additional consultation is required to ensure the groupings are fit for purpose.
2/24/2023	Written Submission	[redacted]	The logic in the grouping Categories/ sub-categories suggested by hereco supposedly follow those set in Part A- which links the medical device to a specific clinical utilization within a clinical field and medical procedure (and its MBS. The default assumption of "one medical device being used for a single indication, by a single surgical specialty" may not be applicable to human tissue transplants / products where same tissue transplants / products may be utilized by different surgical specialties and for different indications. Examples: - Category 03 – Orthopaedic / Subcategory Osseous – these tissue transplants can be used by different specialties such as Orthopaedic, Neurologic (Spinal) and Plastic Surgery in multiple indications. - Category 04 – Plastic and Reconstructive / Subcategory Biological Scaffold – where the product may be used in multiple indications.

Appendix C

Reform of Part B of the Prostheses List

Stakeholder Workshop

Presentation by PwC
7 February 2023

Acknowledgement of Country

We acknowledge and pay our respects to Aboriginal and Torres Strait Islander peoples as the First Peoples of Australia, whose ancestral lands and waters we work and live on throughout Australia. We honour the wisdom of Elders past and present and acknowledge the cultural authority of all Aboriginal and Torres Strait Islander peoples.

Prostheses List Part B Stakeholder Consultation Agenda

Item	Item title	Content	Duration	Lead
1	**Welcome**	• Acknowledgement of Country	5 mins	DHAC
Part A – Workshop Opening and Scene Setting				
2	**Workshop Opening**	• Introductions • Department address • Session overview • Scope, objectives and givens	15 mins	PwC and DHAC
Part B – Consultation on proposals				
3	Proposals not for discussion today	• Proposals 1,2,3,5	20 mins	PwC
4	Assessment pathways	• Departmental Assessment, Clinical/Focused Assessment, Full HTA Assessment (MSAC) • Concerns heard by stakeholders	1 hour	PwC
5	Groupings	• Grouping structure • Benchmarking Analysis	1 hour	PwC
6	MBS Item Numbers	• Proposal to restrict the use of Part B products to specified MBS item numbers	30 mins	PwC
7	**Session close**		10 mins	DHAC

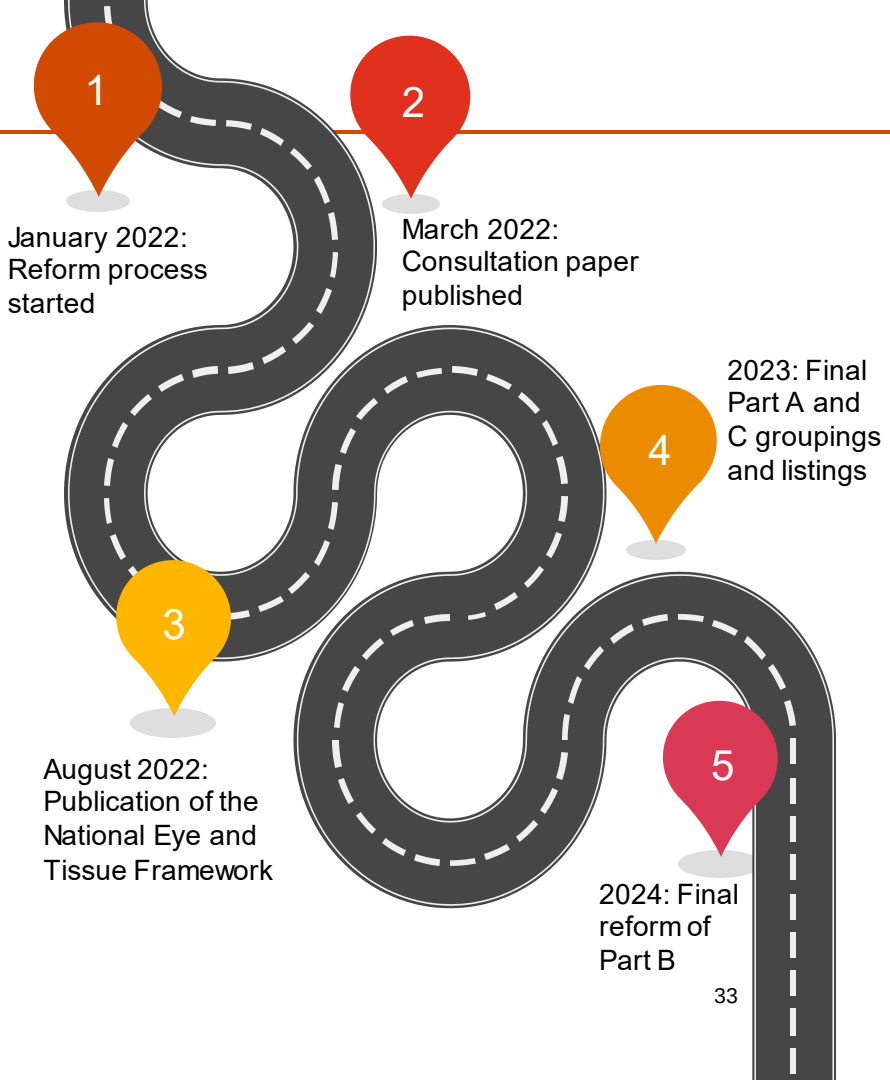
Workshop Opening

The Prostheses List reform journey

The schedule to the Private Health Insurance Prostheses Rules, under the Private Health Insurance Act 2007, is known as the Prostheses List (PL) and requires private health insurers to pay benefits for products listed under the PL and provided to patients. Products currently eligible under the PL include surgically implanted medical devices (Part A), human tissue items (Part B) and other specified items (Part C).

The Department has engaged in extensive consultation after the commitment of $22 million by the Australian Government for the *Modernising and Improving the Private Health Insurance Prostheses List* Budget measure. As part of this consultation, the Department invited stakeholders to respond to seven proposed improvements to Part B of the Prostheses List outlined in consultation paper 2(a). These proposals aim to revise the classifications structure of human tissue products, introduce health technology assessments for greater transparency, improve sustainability of the sector, streamline processes, and increase consumer protection.

PwC has been engaged to provide key recommendations for the next steps of the PL Part B reforms, through facilitating discussion and consultation with sponsors and stakeholders.



Objectives, Scope and Givens

Objectives

Together we will:

- validate our understanding of the key concerns and issues raised by stakeholders in response to Consultation Paper 2(a).
- identify solutions and further actions required to a path forward for reform.

Scope

In scope:

- *Health Technology Assessments*
- *Groupings and listings*

Out of scope:

- *Deregulation*
- *Governance (PLAC, CAGs, PoCE)*
- *Cost recovery arrangements*
- *Monitoring post-listing*
- *National Eye and Tissue Framework*

Givens

- A second workshop will be convened in 3-4 weeks to present the proposed solutions and timeframes for stakeholder feedback.
- Decisions will be made by the Department of Health and Aged Care.

Proposals not requiring discussion today

The following proposals are either awaiting further action or were not contested and require no further discussion in this consultation. The progress of these proposals will be communicated at our next consultation.

Proposal #	Proposal	Rationale for non-discussion
1	The PL Guide should clarify whether autologous products are eligible for listing and, if ineligible, that skull flaps and autologous femoral heads are removed from the list	The Department will retain autologous products on the list
2	That further work is undertaken to develop guidance on an ethical framework for human tissue and human tissue products used for medical treatment, possibly in consultation with the NHMRC	This proposal was widely supported by stakeholders
3	That the number and nature of ARTG listings for human tissue products is discussed with the TGA to explore the feasibility of greater specificity of ARTG listings for these products	TGA discussions are yet to take place
5	That advice is sought from the TGA regarding whether a Class 3 biological has an equivalent risk level to a Class 3 medical device	TGA discussions are yet to take place

Assessment pathways

HTA assessment processes differ to TGA assessment processes

A key outcome of the PL listing process is a decision regarding reimbursement. It is critical that both comparative clinical and cost-effectiveness are key inputs for any assessment.

The modern listing process will re-introduce rigorous methods for assessing cost-effectiveness, enhance post-market monitoring of reimbursement decisions and clarify processes for delisting (dis-investment) of some devices as required.

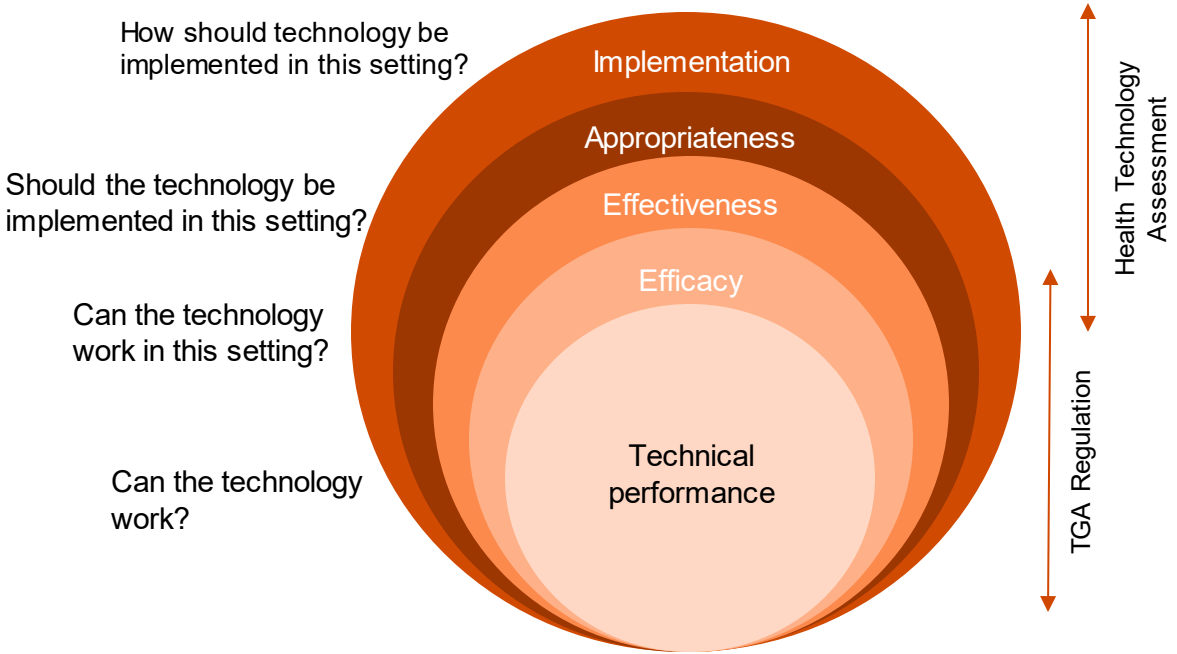


Diagram source: Consultation Paper N° 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

The current PL listing pathway process requires modernising and reforming to fit the needs of stakeholders

A consulting firm was engaged to conduct broad consultations on the PL pathways with a range of stakeholders, including sponsors, private hospitals, private health insurance funds, and the Department of Health PL Secretariat. The following findings relating to the current PL listing pathways were found:

- Sponsors claim inconsistency and inadequacy of feedback, evidence requirements and decision making from CAGs
- Errors in the list and coding/naming conventions pose significant financial risk for private hospitals
- Roles in the assessment process lack clarity and purpose, which makes providing feedback difficult
- Changes and amendments to the list are not adequately communicated to funds and hospitals, which poses significant financial risk
- Delays in the list being published and multiple amendments make it difficult for private hospitals to prepare for list effective dates
- Manual handling of information reduces the efficiency of the process

Source: Consultation Paper N° 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

Health Technology Assessments contribute to streamlining and regulating the PL listing process

Health Technology Assessments use scientific evidence to evaluate the quality, safety, effectiveness and cost-effectiveness of health services and health technology. Efficient and effective HTA process processes are crucial to supporting sustainable management of subsidised health technologies. This process is undertaken by key advisory and regulatory bodies in Australia such as the Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC).

Tier 1 **Departmental Pathway**	• a **new pathway** • device is medium or lower-risk, is a well-established technology, and is substantially similar in characteristics, intended use and clinical effectiveness to other devices listed on PL in the existing grouping with the benefit set up based on the reference pricing • assessments are largely undertaken by the Department with the relevant expertise and knowledge in medical devices.
Tier 2 **Clinical/Focused HTA Pathway**	• the **pathway evolving from the existing PL assessments** • device is of higher risk and/or is not a well-established technology (e.g. has a comparator that is a novel device/undergone HTA) and/or has claims for the improved/different characteristics compared with the existing devices listed on PL • assessments include comparative clinical effectiveness and/or cost effectiveness assessments with inputs from the relevant experts.
Tier 3 **Full HTA Pathway (MSAC)**	• the **pathway incorporating the MSAC processes** • there are no MBS items relevant for the use of the device and/or the device is a novel technology and/or there are no comparators on PL • assessments include the full clinical and cost effectiveness assessments undertaken by MSAC with inputs from relevant experts as required.

 Table source: Consultation Paper Nº 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

Departmental Assessment Pathway

The Departmental Assessment pathway is a new PL listing process that is intended to be more efficient, reflecting the nature of the product and information the sponsor provides. The assessments are performed by the Department and do not require clinical or cost-effectiveness assessments. **Most Part B products will utilise this pathway**.

Aims to:

- Eliminate red-tape for eligible applications
- Potentially reduce the time for an application to be assessed and the product to be listed on the PL

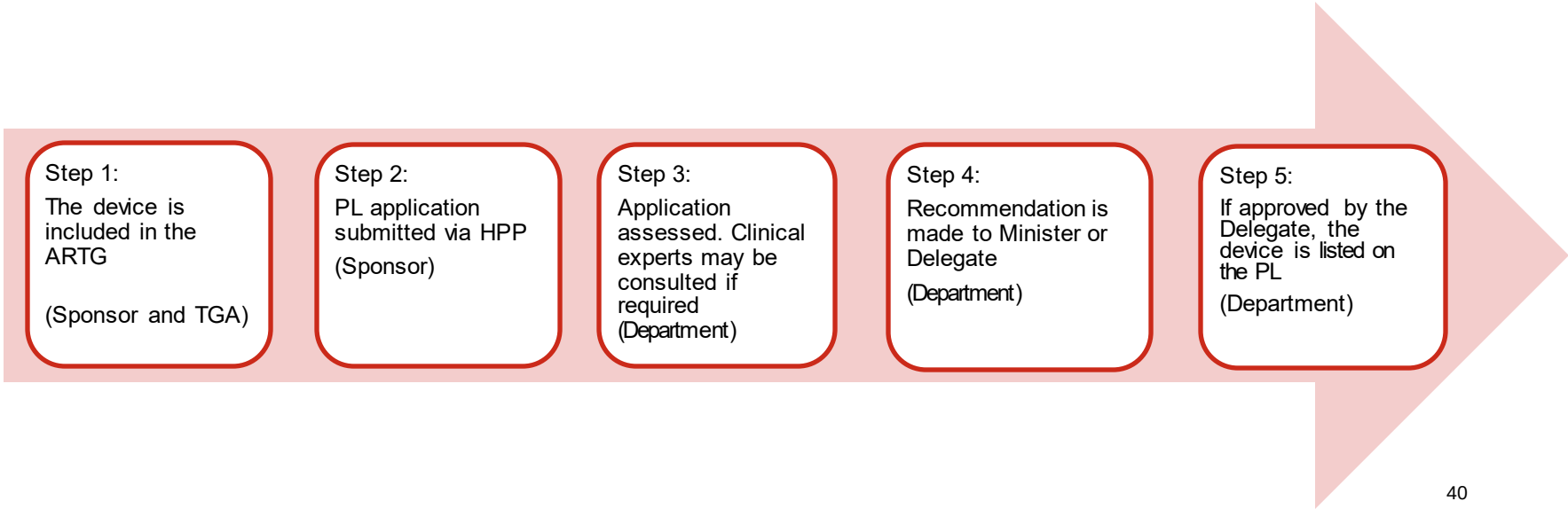
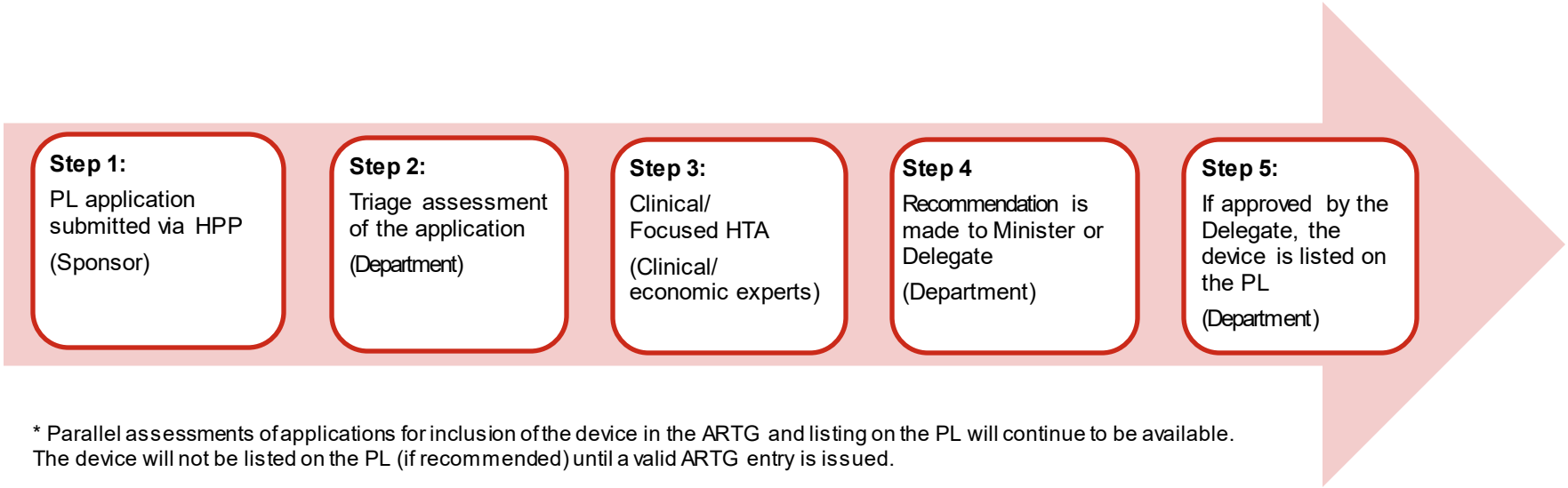


Diagram source: Consultation Paper N° 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

Clinical / Focused HTA Pathway

A Clinical/Focused HTA Pathway will be used for applications that require either a comparative clinical effectiveness assessment or a focused cost-effectiveness assessment. This pathway is similar to existing assessments for Part A and Part B and will include assessments by clinical experts and HTA evaluators as required for products that do not require a comprehensive assessment by the MSAC. Examples of applications that will be considered under this pathway include:

- Any Class III device risk equivalent human tissue product
- New technology or products with significantly different characteristics compared with the devices listed on the PL
- Products that are requested to have a higher PL benefit on the basis of claimed superior clinical performance



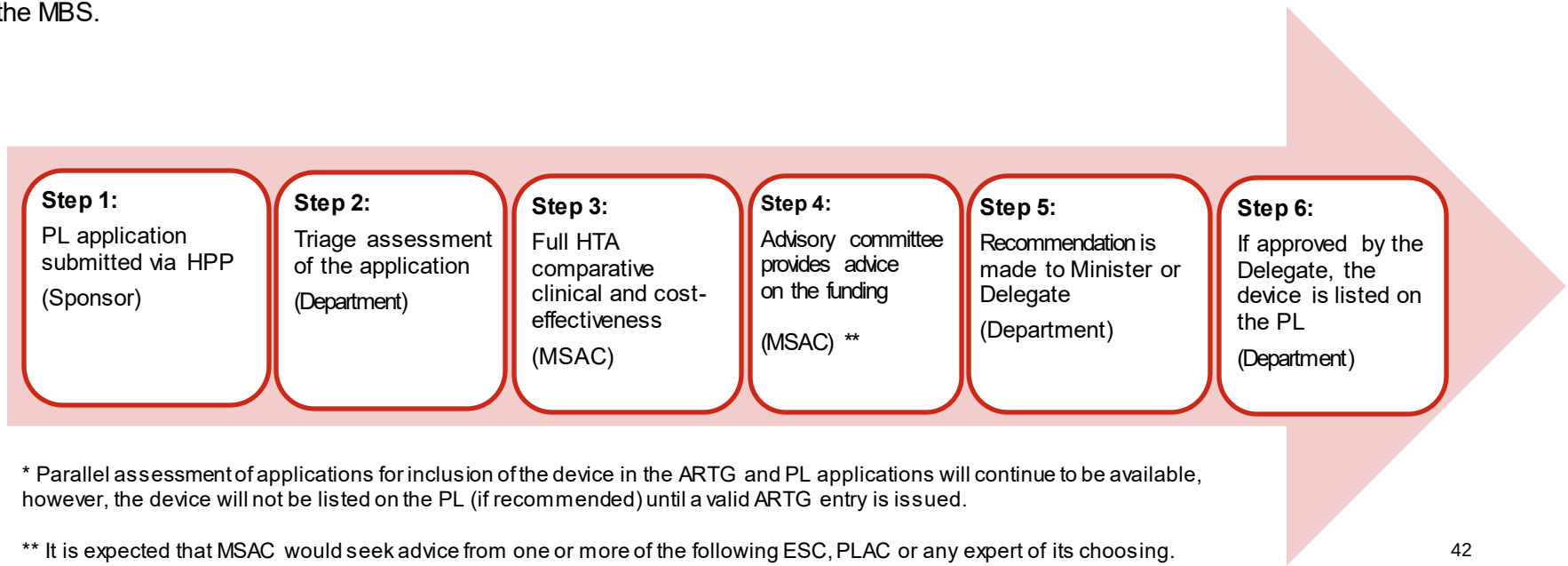
* Parallel assessments of applications for inclusion of the device in the ARTG and listing on the PL will continue to be available. The device will not be listed on the PL (if recommended) until a valid ARTG entry is issued.

Diagram source: Consultation Paper Nº 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

Full HTA Pathway (MSAC)

The Full HTA Pathway (MSAC) will apply for novel/first in class/breakthrough technology, or a new technology with a significant financial impact on the health system, or where there are no comparators already listed on the PL and may or may not require the establishment or modification of an MBS item.

The Medical Services Advisory Committee (MSAC) will provide advice on the comparative **safety, effectiveness and cost-effectiveness** of a product for listing on the PL and may also provide advice to the Department on the listing of an associated service on the MBS.



* Parallel assessment of applications for inclusion of the device in the ARTG and PL applications will continue to be available, however, the device will not be listed on the PL (if recommended) until a valid ARTG entry is issued.

** It is expected that MSAC would seek advice from one or more of the following ESC, PLAC or any expert of its choosing.

Diagram source: Consultation Paper N° 3 – Prostheses List – A modernised fit-for-purpose listing process, The Australian Government Department of Health, 2022.

HTA Assessment Pathway Concerns

Following the call for submissions from stakeholders, there were a number of key concerns and issues about the introduction of HTA's for Part B of the PL. Our aim is to validate and discuss with you whether these concerns remain, if they are accurate and their order of priority.

Concern

The cost (financial and resourcing) of undertaking HTA's will threaten the viability of the sector and increase patient cost

Concern

Mirroring the proposed pathways for Part A and C for Part B is not appropriate due to differences between human tissues and devices

Concern

The TGA already requires a rigorous assessment process and proposed process is duplicative

Concern

Suppliers will choose to import human tissue to Australia, and we will lose our existing diversity of suppliers

1. Have we accurately captured the key concerns and issues you have about the introduction of HTA assessments?
2. Of those we have identified, how would you prioritise these in terms of how they impact and relate to your organisation?
3. Have we sufficiently clarified the process of HTAs and does this alleviate some of the notable concerns?

Groupings

Proposed Part B Grouping Structure

In the proposed structure, three levels of categorisation have been created – Subcategories, Groups and Subgroups. The existing Dermatologic Category has been renamed 'Plastic and Reconstructive'. This aligns with the current categorisation structure of Part A of the Prostheses List.

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clinical evidence for the real world

Grouping 1

- **01 Cardiothoracic**
  - 01.01 Conduit
  - 01.02 Valve
  - 01.03 Patch
    - 01.03.01 Valve patch
  - 01.04 Pericardium

Grouping 2

- **02 Ophthalmic**
  - 02.01 Cornea
    - 02.01.01 Cornea, Full Thickness
    - 02.01.02 Cornea, Precut
    - 02.01.03 Cornea, Patch graft
  - 02.02 Sclera

Proposed Part B Grouping Structure (cont.)

Grouping 3

03 Orthopaedic

- 03.01 Osseous
  - 03.01.01 Intact Bone, Whole or Part
  - 03.01.02 Manufactured, Structural
  - 03.01.03 Manufactured, Non-structural
  - 03.01.04 Manufactured, Non-structural with Inert Carrier
- 03.02 Non-osseous
  - 03.02.01 Cartilage
  - 03.02.02 Fascia Lata
  - 03.02.03 Ligaments
  - 03.02.03 Tendons

Sub-groups relating to orthopaedic are provided in a separate table.

Grouping 4

04 Plastic and Reconstructive

- 04.01 Skin Graft
  - 04.01.01 Split Skin
- 04.02 Biological Scaffold
  - 04.02.01 Acellular Dermal Matrix
    - 04.02.01.01 Breast Reconstruction
    - 04.02.01.02 Joint Repair

Benchmarking Analysis

In establishing a Benchmark benefit for items in groupings, analyses was performed to explore benefits by quantity (including surface area, weight or volume). Through a process of consultation with stakeholders, there are a number of challenges that has arisen from the benchmarking methodology. The main challenges in the grouping work included:

Part B items use either of two alternative measures of quantity (weight and volume). This inconsistency inherently places limitations on benchmarking.

Many Part B items are used for multiple products of various size, and it is not possible to accurately estimate benefits in the absence of product-specific information.

It is proposed that benchmarking take place at the **lowest level of grouping**, recognising that this will fall at different levels for different types of product. For example, it was considered necessary to group down to the level of Subgroup for all items in the Orthopaedic Category, so benchmarking would take place at the Subgroup level for orthopaedic items.

Hereco suggest it may be necessary to create a **tailored approach** for each product type and potentially for each stakeholder within a Sub-group before benchmarking can take place

MBS item numbers

Increasing use of Part B items

Private health insurers have noted that they are experiencing a rapid rise in utilisation of billing of human tissue products, in the context of a declining number of surgeries. In recent years, there has been an increase in commercial suppliers listing Part B products, which are using more sophisticated and complex processing techniques.

Responses to the consultation paper suggested potential ways to address the increased use of tissue products, particularly from commercial suppliers, to ensure that use of human tissue products is sustainable, ethical and consistent with the experience of other countries.

Potential responses we have heard from you

Implementing an ethical framework for the supply of tissue products

Increased quality assurance mechanisms

Examine and compare data sources with international sources

Examine incentives that exist for clinicians using allograft tissues

Establish registry data for Part B products

Increased literature availability

Linking MBS items to Part B items

For items to be eligible for listing on the Prostheses List and to be reimbursed, the sponsor must nominate one or more applicable MBS items. However, the Department notes that MBS items do not always specifically correlate to the use of the Part B product and there is no current restriction on the use of Part B items once they are listed.

Proposal 6 suggests that the use of Part B human tissue products that have undergone an HTA process could be restricted to specific and appropriate MBS items, in order for their suitability to be assessed as part of their listing application.

Viewpoint

The proposal improves product tracking and transparency, curbs excess use and increases consumer safety

Viewpoint

There is concern about the feasibility of linking specific items, as it would be limiting product use

1. Have we accurately captured the key viewpoints you have on the proposal to link MBS items?

2. How would the linking of MBS items impact and relate to your organisation?

Next steps

Next steps

The next steps in the reform process for Part B include:

1. PwC to draft proposed solutions based on the consultation today
2. Solutions to be validated with the Department
3. Second workshop with stakeholders to present solutions
4. Final report provided to the Department

Thank you

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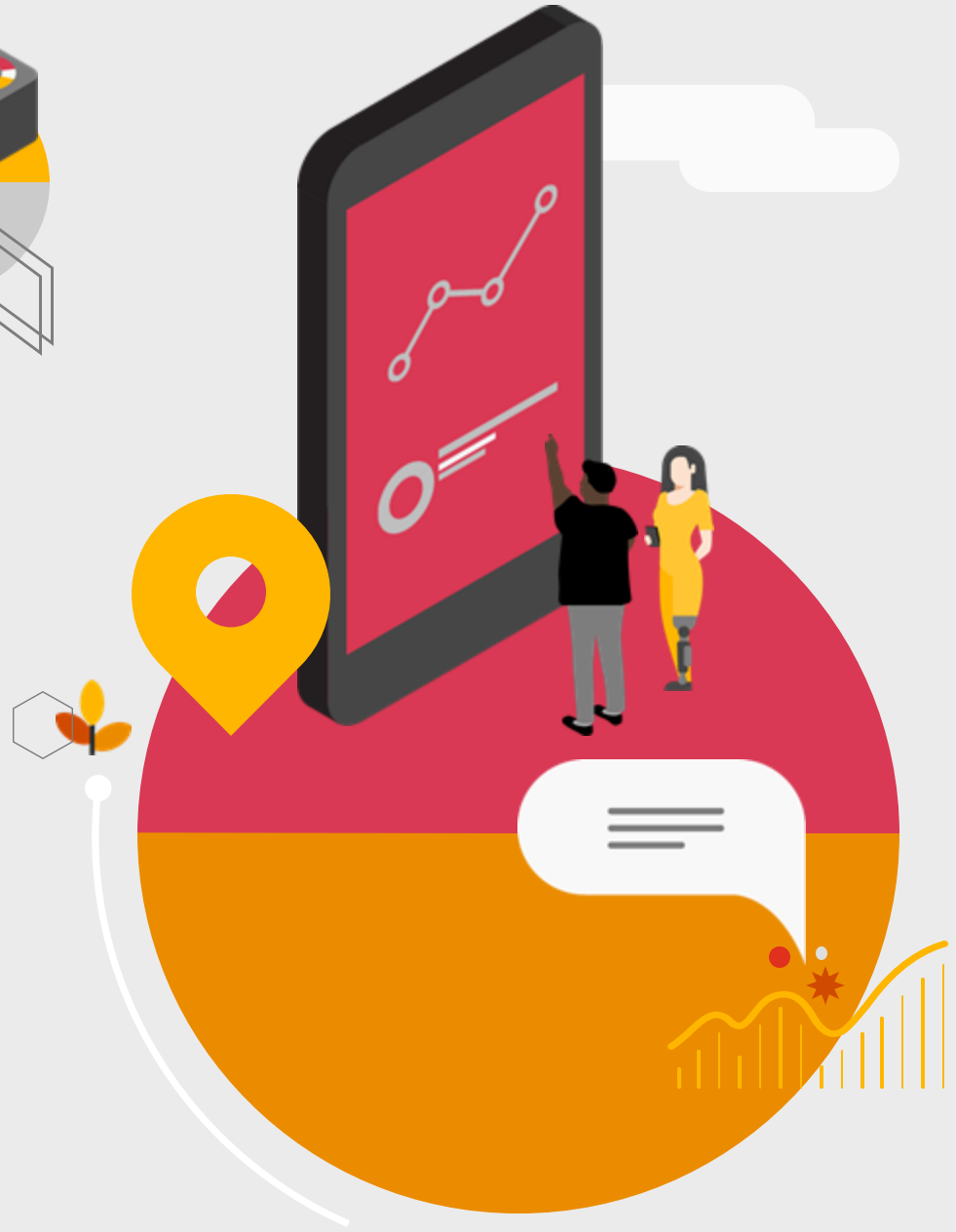
Appendix D

Reform of Part B of the Prostheses List

Stakeholder Workshop 2

Presentation by PwC
15 March 2023



Acknowledgement of Country

We acknowledge and pay our respects to Aboriginal and Torres Strait Islander peoples as the First Peoples of Australia, whose ancestral lands and waters we work and live on throughout Australia. We honour the wisdom of Elders past and present and acknowledge the cultural authority of all Aboriginal and Torres Strait Islander peoples.

Prostheses List Part B Stakeholder Consultation Agenda

Item	Item title	Content	Duration	Lead
1	**Welcome**	• Acknowledgement of Country	5 min	DHAC
Part A – Workshop Opening and Scene Setting				
2	**Workshop Opening**	• PwC and Department address • Session overview • Scope, objectives and givens	10 mins	PwC and DHAC
3	**Recap of previous workshop**	• Recap of issues and actions by PwC and DHAC	15 mins	PwC
Part B – Consultation on proposals				
4	Part B Definitions	• Definition of Part B product • Definition of benefit	20 mins	PwC
5	HTA Processes	• HTA Process Flow Chart • Scenario tests	20 mins	PwC
6	Groupings feedback	• Feedback heard from written and email submissions	30 mins	PwC
7	**Session close**		10 mins	DHAC

Workshop Opening

Objectives, Scope and Givens

Objectives

Together we will:

- validate our understanding of the key feedback heard from submissions provided and Workshop #1.
- identify solutions and further actions required to a path forward for reform.

Scope

In scope:

- *Health Technology Assessments*
- *Groupings and listings*

Out of scope:

- *Deregulation*
- *Governance (PLAC, CAGs, PoCE)*
- *Cost recovery arrangements*
- *Monitoring post-listing*
- *National Eye and Tissue Framework*

Givens

- Decisions will be made by the Department of Health and Aged Care.

Recap of our previous workshop

Table: Issues and Actions from Workshop #1				
	Issues raised	PwC Actions	DHAC Actions	Recommendations (if applicable)
1	**Overarching Issues** • Differing legislation • Ethical framework • Highly processed tissue being considered under Part B	• PwC to advise a clear definition of a Part B product.	• DHAC to seek a timeline for the revision of the ethical framework.	
2	**HTA Assessment Pathways**	• PwC to liaise with DHAC to create a process flow chart for Part B listings that outlines the relevant assessment pathway, and the evidence and information needed to support the application. • PwC to define the meaning of 'benefit' in relation to price and product.	• DHAC to liaise with TGA on requirements of the Special Access Scheme products (complete).	We recommend that the Department give clear guidance for all biologicals (as defined by the TGA) to determine whether they are eligible for the Tier 1/Departmental assessment pathway.
3	**Groupings**	• PwC to receive and collate written feedback within 2 weeks of Workshop 1 on the proposed groupings, including specific requirements for each stakeholder. *Note: following receipt of stakeholder feedback, additional work will be required around groupings to update the Hereco technical paper and address issues raised by stakeholders.*	• DHAC to clarify the use of tissue products in two listings.	

Recap of our previous workshop (cont.)

Table: Issues and Actions from Workshop #1				
	Issues raised	PwC Actions	DHAC Actions	Recommendations (if applicable)
4	**Pricing**	N/A	N/A	We recommend that the Department undertake further work on the methodology for benchmarking/pricing. To support this work and address stakeholder concerns, it would be of benefit to engage with the policy section regarding: • The development of costing standards: and • Undertaking a review of state and federal legislative requirements which prohibit trading in human tissue and its application to determining benefits for Part B.
5	**Listing of MBS items**	N/A	N/A	We recommend that the Department does not pursue restricting the use of Part B products to specified MBS item numbers.

Purpose of each stage of the PL process

Groupings	How can we best organise the PL to group similar products?	The structure of the list is important for two reasons: 1. To determine the assessment pathway. 2. As reference point for determining benefits. Further work is required to update the groupings proposed by Hereco in 2019.
Assessment process	Should private health insurers pay a benefit for this product? (Y/N)	The proposed cost of a product is relevant for assessing cost effectiveness. The HTA process is **not intended** to determine the benefit paid, this is determined as part of the costing process.
Costing	How much should the benefit be?	This issue is out of scope for discussion. It is noted: • The maximum benefit which can be paid is currently limited to cost recovery. • There is a need for sector specific costing standards. • Further work will be undertaken to determine whether it is possible to benchmark or better align benefits.

Feedback from TGA

DHAC and PwC met with the TGA on 28 February for further clarification and guidance on existing proposals and evidence. The following concerns were discussed:

Level of evidence provided for dossiers

The TGA has provided advice that literature reviews are sufficient to support registration of products on the ARTG. Clinical opinion as to the efficacy of the products is relied on during the assessment process.

Is the risk associated with Class III biologicals equivalent to Class III medical devices?

The risk for a class III biological **is not equivalent** to the risk for a Class III medical device.

The way in which risk is considered for biologicals is different than for medical devices. Risk is determined for biologicals with reference to the tissue and the level of processing and manipulation, which does not apply for medical devices.

Aligning ARTG groupings with PL groupings

The TGA has confirmed that the ARTG groupings are more general than the PL, and that it would be administratively burdensome to expand these groupings to align with the prostheses list.

Impact of the Special Access Scheme (SAS)

The SAS should only be used where there isn't an equivalent locally available product listed on the ARTG. For products that are currently being supplied via the SAS, once a local equivalent is listed, then medical professionals should use the ARTG listed product. The SAS should not adversely impact the ability of a Sponsor to obtain a Part B listing, and there is currently no interaction between the two processes.

Part B Definitions

Definitions

Part B – Human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law).[1]

Benefit (price) : The monetary amount claimable from an insurer for a specific service or product.

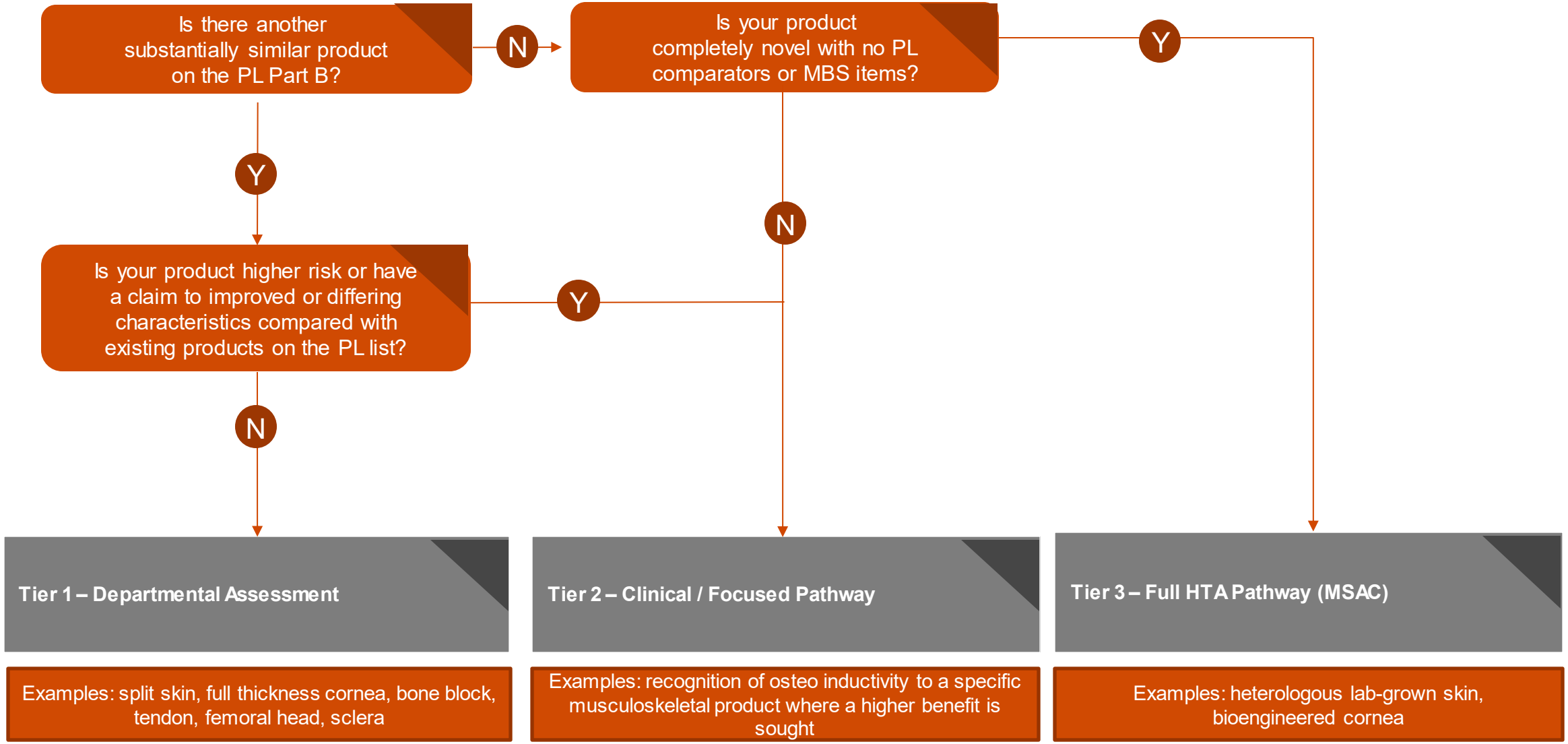
Benefit (product) : The positive impact that a product has on the patient receiving it.

1 Regulation Impact Statement (RIS), Improving the Private Health Insurance Prostheses List, Office of Best Practice Regulation, Department of Health (Federal).

HTA processes

HTA decision process flow chart

**Flowchart made with the assumption that the existing PL Part B list will be grandfathered.*



Examples

Example 1 – Departmental Assessment Pathway

[redacted] has recently been established. [redacted] has registered their full thickness cornea on the ARTG and now wish to include the product on Part B of the Prostheses List. [redacted] match the product to the 'Cornea, Full Thickness' group in the Ocular Tissue category of the PL. They use the departmental assessment pathway by providing evidence, including referencing their ARTG listing and providing processing procedures, that the product is substantially similar to the other products in that group. The Department approves the inclusion of the product on the list.

Example 2 – Departmental Assessment Pathway

A tissue bank notices that smaller quantities of milled bone are currently being imported by dentists via the Special Access Scheme (SAS). While they already manufacture packets of milled bone in larger quantities, they decide to start manufacturing the product in smaller quantities. To list this product on Part B of the PL, they use the departmental assessment pathway as the product is the same. The Department approves the listing, and the benefit payable is then recalculated based on the smaller quantity. The TGA removes the product from Category C of the SAS as there is now a locally available product.

Example 3 – Full HTA Pathway (MSAC)

A consortium of tissue banks and research groups develop a heterologous, lab-grown skin graft 'BioSkin'. The consortium believe BioSkin has superior performance to autologous skin grafts or the split skin products currently listed on the PL. As BioSkin is a novel product, they are unable to match it to an existing product on the PL. A full HTA is undertaken to determine whether BioSkin should be included on Part B of the PL.

Groupings feedback

Groupings feedback

General feedback:

Listings link products to specific clinical utilisation, with the default assumption that one product can be used for one indication by a single surgical specialty, which is not applicable for Part B. Human tissue items may fall under multiple groupings within the list, requiring reasonably consistent benefits between groupings.

There is a need to update the proposed groupings to ensure they are reflective of all products current listed or distributed. Further consultation with stakeholders is required.

There has been limited communication on the reasoning behind the current proposed groupings.

There is concern regarding the impact the proposed listing will have on surgeons and their reimbursement.

Sub-groups do not distinguish between the levels of processing or manufacturing required. Further refinement and alignment is needed where subgroups could be based upon:

- Process
- Existing tissue bank naming conventions
- Size and volume measures.

It is unclear how benchmarking will be used with this model of grouping.

Groupings feedback

Specific feedback:

01 - Cardiothoracic

Suggested groupings:
- Valve (Aortic Valve, Pulmonary Valve, Mitral Valve, Tricuspid Valve)
- Arterial Conduit (Aortic Conduit, Pulmonary Conduit, Thoracic Aorta Conduit)
- Valved Conduit (Aortic Valved Conduit, Pulmonary Valved Conduit)
- Patch (Aortic Patch, Pulmonary Patch, Mitral Patch, Tricuspid Patch)
- Pericardium (Pericardial Patch)
- Vascular Graft (Desc Aorta, Iliac Artery, Femoral Artery, IVC, Femoral vein)

02 - Ophthalmic

Whole and patch groups should be included for Sclera (02.02) subcategory

03 - Orthopaedic

Long Bone (Distal, Proximal and Proximal with Soft Tissue) (03.01.01.02) - this is better reflected as 3 subgroups which are Long Bone, Whole, Half and Third +/- soft tissue.

Hemipelvis, Whole or Part (03.01.01.02) – better reflected as two separate subgroups.

Fascia Lata (03.02.02) – this is a specific anatomical entity which would be more appropriate as Fibrous Sheaths and Fascia Lata as a subgroup.

Ligament, Medial (03.02.03.01) – this is not required as a subgroup.

Subcategory Osseous – these tissue transplants can be used by different specialties such as Orthopaedic, Neurologic (Spinal) and Plastic Surgery in multiple indications.

04 – Plastic and Reconstructive

Split Skin (04.01.01) – subgroups for differing thicknesses, size or number of patches would be more useful indicators for users.

Biological Scaffolds (04.02) – Only sub-groups by clinical indication which is not effective.

Breast Reconstruction (04.02.01.01) Agreement from JJM to list human tissue dermal matrix according to clinical use without limiting surgical clinical use.

Next steps

Next steps

The next steps in the reform process for Part B include:

1. PwC to draft proposed solutions based on the consultations to date
2. Solutions to be validated with the Department
3. Final report provided to the Department

Thank you

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