Australian Government
Department of Health and Aged Care

Prostheses List Reforms – Consultation Paper No 3(b) –

Pathways for Applications to the Prostheses List

Contents

Summary

In January 2022, the Department of Health and Aged Care (the Department) released *Consultation Paper 3(a) – Prostheses List – A modernised fit-for-purpose listing process*. The aim of the Paper was to canvas stakeholder views on the proposed three-tiered approach to the assessment of Prostheses List (PL) applications for Part A and Part C applications.

The PL is the schedule to the *Private Health Insurance (Prostheses) Rules* and is split into four parts.

- Part A – prostheses that satisfy the criteria for listing agreed by the Prostheses List Advisory Committee (PLAC) and approved by the Minister for Health and Aged Care. This includes devices that are:
    - surgically implantable prostheses, or
    - an integral single use aid for implanting a surgically implantable prosthesis, or
    - required for the ongoing function of a surgically implanted prosthesis, and
    - at least, of similar clinical effectiveness as other devices listed on the PL and the cost of the device is relative to its clinical effectiveness.
- 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).
- Part C – groups of prostheses that are stated in the Prostheses Rules as satisfying the criteria for listing on Part C i.e. an insulin infusion pump, a cardiac home/remote monitoring system etc.
- Part D – General Use Items (noting that these items will be removed from the PL on 1 July 2023).

The consultation period was open from 11 January to 4 March 2022, with 34 submissions received from stakeholders representing the medical technology sector, private hospitals, private health insurers, clinical societies and individual consultants.

The Adelaide Health Technology Assessment (AHTA), within the School of Population Health at the University of Adelaide, were engaged to develop Options for a Reformed Prostheses List Pre-Listing Assessment Framework and Governance Structure which align with the other health technology assessment processes carried out by the Department. The report is currently out for consultation.

In addition, the Department engaged AHTA to facilitate a series of workshops with key stakeholders (including a variety of sponsors) and present the findings in a *Final Report, Co-design of Pathways for Applications to the Prostheses List* (Attachment A). The Final Report outlines the refined pathways for pre-listing on the PL and was informed by the discussion from the workshops, feedback from submissions received via *Consultation Paper 3(a)* and engagement from the PLAC Chair and Departmental representatives.

Modernising the pathways is key to improving the administration of the PL by reducing red tape, ensuring all medical devices are listed on the PL in line with current health technology assessment guidelines, and ensuring the application assessment process is fit for purpose.

Three pathways for the pre-listing assessment of PL applications (new, amendment, expansion, and compression applications) were proposed in *Consultation Paper 3(a)* as:

- Abbreviated HTA Pathway
- Clinical/Focused HTA Pathway
- Full HTA Pathway (MSAC).

To reflect the feedback of stakeholders, refinements have been made to better meet the purpose and process of each pathway. The pathways are now named:

- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical/Focused HTA Pathway
- Tier 3: Full HTA Pathway (Medical Services Advisory Committee (MSAC))

The Tier 2 Pathway is further separated into two components to reflect the varying levels of HTA involvement of external expertise. All Tier 2 Pathway applications require a clinical assessment however, in some instances a health economic evaluation may also be required. Therefore, the two components of Tier 2 applications are:

- 2a – a clinical assessment only
- 2b – a clinical assessment plus health economic evaluation.

The Department acknowledges some submissions provided feedback out-of-scope to *Consultation Paper 3(a)* however, where relevant, they will be used to inform additional elements of the reforms. Feedback included:

- sustaining and strengthening the PLAC (or equivalent committee)
- removing industry from decision-making committees due to perceived conflicts of interest
- adding consultation to the pathways
- eliminating unnecessary committee deliberation on ineligible or substandard applications
- providing guidelines and templates for the production of better-quality products to review.

Existing Arrangements

Currently sponsors (or in some cases agents acting on the sponsors' behalf) submit applications online via the Prostheses List Management System (PLMS) for Departmental vetting and/or assessment. This includes all applications, including Part A and Part C, which will be subject to the new pathway arrangements when implemented (noting that the assessment processes for applications for listing on Part B are considered separately).

The types of applications received include:

- new applications for listing a prosthesis on the PL,
- amendment applications asking to change the PL billing code details, expansion or compression applications asking to combine or separate the devices listed under the existing billing code,
- sponsors' transfer applications,
- duplication or applications asking to delete the existing billing code.

All new, amendment, expansion and compression applications are currently assessed by either one of the Clinical Advisory Groups (CAGs) or the Panel of Clinical Experts (PoCE) before being considered by the PLAC.

The CAGs and PLAC meet 3 times per year, with the updates to the PL occurring on 1 March, 1 July, and 1 November. Although the PLAC advise whether a product is to be listed or not listed on the PL, the final decision on the application rests with the Minister or the Minister's Departmental Delegate.

This process has been deemed to be not fit-for-purpose with feedback suggesting it is inefficient, ineffective, and requires improvements.

Departmental Response to AHTA Report

The Department has considered the Final Report from AHTA and supports the outcomes reached through the co-design consultation process on the three-tiered approach to the assessment of PL applications. The Department thanks all stakeholders and sponsors who provided written submissions and attended the workshops, and notes that although there were divergent views on occasion, all supported the need to have applications considered via an appropriate pathway.

The PL Reforms Taskforce recognises the pathways presented represent a sizeable shift away from existing processes, however, considers it the best option moving forward as it will improve the efficiency of the current process, particularly when supported by the revised guidance materials for sponsors and stakeholders, and the expansion of the Health Products Portal (HPP) to include PL applications.

Separating the pre-listing application process into three tiers provides clarification for sponsors on the eligibility and evidentiary requirements for each pathway. This ensures that applications which require more resource intensive assessment can be considered with appropriate scrutiny, compared to those that are appropriate to be assessed by the Department.

Escalation from Tier 2 to Tier 3

The Department anticipates there will be times where it is unclear whether a device requires a Tier 2 or Tier 3 assessment, with this distinction often made once a CAG assessment has been completed or a PLAC meeting has occurred. Based on advice from the Department, CAGS or the PLAC, or even by the request of a sponsor, a referral to the MSAC to undergo assessment via the Tier 3 pathway, can occur at any point in the Tier 2 pathway. Although the Department, CAGS or PLAC may provide this advice to the sponsor, it is the responsibility of the sponsor to make this decision. It is in the best interests of a sponsor to accept advice from the Department, CAGS or PLAC due to the possibility their application is declined by the PLAC resulting in additional costs to the sponsor and timeframes being expanded for their application being considered down Tier 3.

Parallel process

Throughout the consultation process, feedback from stakeholders indicated that it was essential that parallel assessment process for applications undergoing assessment by the Therapeutic Goods Administration (TGA) and PL applications be allowed for Tier 1.

Under the parallel assessment process, sponsors can submit a new PL application for the device before they receive an Australian Register of Therapeutic Goods (ARTG) entry, however, they

must provide appropriate evidence of a valid effective conformity assessment application or evidence that an ARTG inclusion application has been submitted to the TGA [for the meaning of an effective application, refer the TGA legislation] as part of the information provided with the PL application.

In response, the Department has agreed that parallel assessment will also continue to be available, however, the device will not be listed on the PL (if recommended) until a valid ARTG entry is issued. This is consistent with the current processes. For Tier 3 applications MSAC cannot finalise its appraisal until there is confirmation of inclusion of the device on the ARTG.

If at any time during the assessment, it becomes apparent that the application with the TGA is no longer valid (withdrawn or rejected), the PL application will be considered to be invalid as well and removed from the assessment process.

Class III devices

The Department can confirm Class III devices will continue to be assessed under the Tier 2 Pathway as these items are deemed high risk and should be subject to significant scrutiny. Although the TGA assesses safety, quality and performance, the Department expects a device that will be privately funded will be assessed by the PLAC (or equivalent) and its relevant subcommittee for their comparative clinical and cost-effectiveness.

The Department acknowledges some stakeholders may be disappointed with this outcome and will monitor the impacts of this decision before potentially reviewing it. However, sponsors need to take responsibility for assuring the quality of their applications before the Department would consider Class III devices under Tier 1.

Public consultation

Protracted public consultation periods and the sharing of information during the assessment of devices is of concern to some stakeholders. The Department recognises there is commercially sensitive information contained in an application, and for this reason, will not circulate applications for comment. It is the intention of the Department that key industry stakeholders will be kept abreast of outcomes or any issues through regular key industry stakeholder forums and would also have a role in the post-listing review process to ensure products are regularly reviewed to address any post-listing issues, as required. For Tier 3 applications, standard MSAC consultation processes apply, including public consultation on applications noting that applicants are given the opportunity to identify commercially sensitive information which should be redacted from the application form prior to consultation.

Timeframes for listing

Stakeholders also expressed concern regarding timelines, specifically relating to PLAC frequency and PL updates. At present, there is no intention to increase the number of PL updates from three updates a year (March, July and November) and therefore it is unlikely that any of the pathway tiers will be “faster” or “slower” than the current process. This is due to the Department receiving over 700 applications per cycle and the requirement of health insurers and hospitals to update their systems which is resource intensive. The Department reiterates that the single most important factor for an application to be processed in a timely manner is for the application to be complete with all required information and the correct pathway selected. In addition, the

Department intends to support Sponsors to improve their applications with the development of thorough guidance documents and workshops to support sponsors.

Cost Recovery

The Department notes stakeholder feedback regarding risks associated with the cost recovery arrangements under the new listing pathways. There may be applications where a small amount of evidence is to be assessed by a clinical expert, the Department notes that under new pathways, all Tier 2 applications will be reviewed by CAGs and PLAC. The associated effort and timing associated with CAGs and PLAC are appropriate to include in the cost recovery fees as per the Australian Government Cost Recovery Guidelines.

There may be additional MSAC cost recovery considerations for Tier 3 applications. MSAC cost recovery arrangements are out of scope for this consultation. The associated effort and timing associated for Tier 3 Prostheses List applications has taken into account and excluded any processes that are duplicated with any proposed MSAC cost recovery process.

What we invite you to do

The Department is seeking to engage with a diverse range of stakeholders, and we invite you to consider the proposed options detailed in the Final Report at Attachment A.

This AHTA Paper will be out for consultation until COB 26 October 2022.

The AHTA Paper does not explore the following issues:

- revised guidance material and improved application forms for the new pathways (including any more detailed criteria for each proposed pathway)
- consolidation of the existing and proposed grouping structure, including the benefits payable of devices on the PL by private health insurers
- legislative amendments on the PL definition and compliance provisions
- revised cost recovery arrangements to reflect the modern listing pathways and ensure compliance with the Australian Government Charging Framework. **The work undertaken to co-design the pathways has informed the development of a cost recovery proposal including a summary of indicative fees. Information on the cost recovery proposal and indicative fees is detailed at Attachment B; questions relating to the cost recovery proposal are outlined below**
- the review of governance arrangements associated with the PL listing process, including the future of the PLAC, Clinical Advisory Groups and their membership.

Please consider the questions below and provide your responses via the Consultation Hub. To ensure all feedback is received, submissions will not be accepted outside of this process (i.e. email). This feedback will be used to inform the finalisation of the pathways, noting some concepts may change based on feedback the Department receives through this consultation process. Feedback or issues presented which are out of scope will be used to inform other aspects of the reform work, where appropriate.

Questions

Pathways for Applications

1. Do you have any significant concerns with the proposed pathways for assessing Prostheses List applications? If you do, please advise how they could be improved.

2. Are the terms in the glossary clearly defined? If not, please advise which terms require further clarification.

3. Have all the characteristics been captured in Table 2 (comparison table) to demonstrate interchangeability and identify differences between the subject device and the proposed comparator? If not, what additional characteristics are required?

Cost Recovery Proposal and Indicative Fees

4. Overall, what positive impact will the cost recovery of Prostheses List applications have for the sector? What will be the scale of this positive impact?

5. Overall, what negative impact will the cost recovery of Prostheses List applications have for the sector? What will be the scale of this negative impact?

6. Do you have any further comments on the cost recovery proposal?

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All information in this publication is correct as at September 2022

THE UNIVERSITY of ADELAIDE

CO-DESIGN OF PATHWAYS FOR APPLICATIONS TO THE PROSTHESES LIST

FINAL REPORT

JULY 2022

make history.

This report was written by:

David Tamblyn

Jacqueline Parsons

Klara Salinger

Tracy Merlin

Adelaide Health Technology Assessment (AHTA)

School of Public Health, University of Adelaide

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Acronyms

Acronym	Full name
ADAR	Applicant developed assessment report (MSAC process)
AIMD	Active implantable medical devices
ARTG	Australian Register of Therapeutic Goods
DCAR	Department contracted assessment report (MSAC process)
HPP	Health Products Portal
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
PASC	PICO confirmation Advisory Sub-Committee
PBS	Pharmaceutical Benefits Scheme
PICO	Population Intervention Comparator Outcome
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
RCT	Randomised Controlled Trial
TGA	Therapeutic Goods Administration

Glossary

Term	Definition
Assessment Group	An independent consultancy group with expertise in health technology assessment that is contracted by the Department of Health and Aged Care to review applications for the funding of health technologies.
Comparator	Another device currently included on the PL or non device comparator against which clinical effectiveness will be compared and cost-effectiveness will be established.
Interchangeability	The principle that one device can be substituted for another device. This concept is pivotal to a number of pathways in this report, and is explained in depth alongside the pathway principles.
Predicate (device)	Previous iteration of a medical device (within the same lineage of devices, with the same intended purpose and from the same manufacturer) that may include changes to characteristics such as design, composition, indication, packaging, or size range.
Subject Device	The device(s) which is the subject of: • an application for listing on the Prostheses List, or • an amendment to an existing Prostheses List billing code.
Novel device	A new type of device. *"Novelty typically means that there is a lack of experience in regard to the safety and performance of the device or specific features of the device or related clinical procedure, and there are no similar devices or insufficient experience with similar devices to enable straightforward appraisal of its future real-world safety and performance"* (European Union Medical Device Regulation).
Well-established technology	A device with safety and performance characteristics that are proven and well-known. *"The common features of the devices which are well-established technologies are that they all have:* • *relatively simple, common and stable designs with little evolution;* • *their generic device group has well-known safety and has not been associated with safety issues in the past;* • *well-known clinical performance characteristics and their generic device group are standard of care devices*

Term	Definition
	where there is little evolution in indications and the state of the art; • *a long history on the market"* (Medical Device Coordination Group Document, MDCG 2020-6)
Medical device classification	As defined in section 41DB of the *Therapeutic Goods Act 1989* and Division 3.1 of the Therapeutic Goods (Medical Devices) Regulations 2002

1 Introduction

The Australian Government committed $22 million in the 2021-22 Federal Budget to improve the Prostheses List (PL) and its arrangements. The Prostheses List Reform Taskforce, working with insurers, hospitals, manufacturers and clinicians, aims to ensure that the List will become more efficient, transparent and current.(1)

Adelaide Health Technology Assessment (AHTA) from the School of Public Health, University of Adelaide, were contracted by the Prostheses List Reform section of the Australian Government Department of Health and Aged Care ('the Department') to propose an assessment framework, pathways and governance options for a reformed PL application and determination process.

During the development of the governance structure and proposed assessment pathways, the scope of the project was changed to allow greater stakeholder involvement in the final development of the PL Assessment Pathways. This was in response to the signing of a Memorandum of Understanding (MoU), on 14 March 2022, between the former Minister for Health and Aged Care, the Hon Greg Hunt, and the Medical Technology Association of Australia (MTAA). This MoU set out the final policy parameters for the PL Reforms.(1)

This report describes the proposed pathways for assessing Prostheses List applications; this includes new applications for listing a device for the first time on the PL, and amendment, compression or expansion applications for changing the details of the existing PL billing codes. This report also details the processes undertaken to involve stakeholders in the development of these pathways. The report does not address applications to delete or transfer billing codes from one sponsor to another on the PL.

1.1 Objectives

The objectives of the project were to:

1. Develop pathways for the evaluation of an application for device listing, or amendment to an existing listing, on the PL with the following goals:
    a. Optimise the resources required for assessing applications
    b. Provide clarity around the eligibility for proposed pathways to reduce the likelihood of sponsors selecting the incorrect pathway
    c. Provide clarity around the evidence requirements for each pathway, and tailoring these to be responsive to the requested PL benefit group and to the degree of novelty of the subject device.
2. Capture the key concerns of the relevant stakeholders from written feedback, and during workshop consultation, including:
    a. Medical device sponsors or consultants acting on behalf of a sponsor
    b. Representatives of private health insurers
    c. Representatives of private hospitals and private health providers
    d. Representatives from the Department of Health and Aged Care including individuals from the Prostheses List Reform Taskforce

    e. The relevant committees, including the Prostheses List Advisory Committee (PLAC) and the Medical Services Advisory Committee (MSAC)
3. Describe additional challenges related to the development of the pathways, but that were out-of-scope for this current project.

2 Methodology

The development of the PL assessment pathways involved a review and synthesis of the materials provided by the Department (listed in Table 1), a review of the stakeholder feedback in response to *Consultation Paper 3(a)*, and a series of two-hour workshops with the Department, relevant Committee representatives and stakeholders. All of this information was collated and synthesised into an initial draft report submitted to the Department and, subsequently, this final report.

Table 1. Materials compiled and evaluated as part of desktop review of Prostheses List processes

Date	Authors	Title
December 2020	Menzies Centre for Health Policy, University of Sydney	Options for a revised framework for setting and reviewing benefits for the Prostheses List
2019	Department of Health	PLAC Terms of References and Operational Guidelines
June 2020	Department of Health	Prostheses List - Guide to Listing
December 2021	Prostheses List Advisory Committee	Meeting minutes of December 2021 meeting
2021, 2022	Department of Health	**Prostheses List Reforms Consultation papers:** No 1: Prostheses List - Purpose, Definitions and Scope (including stakeholder feedback report) No 2(a): Modernisation of Part B of the Prostheses List No 3(a): A modernised fit-for-purpose listing process *[Consultation paper 3(a)]* Responses to *Consultation Paper No 3(a)* (unpublished)

In addition to materials provided by the Department, the following sources were consulted:

- *Clinical evidence guidelines for medical devices, Therapeutic Goods Administration* (Version 3.0, November 2021)(2)
- *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (Version 5.0, September 2016)(3)
- *Guidelines for preparing assessments for the Medical Services Advisory Committee* (May 2021) (4)
- One meeting with the PLAC Chair, representatives from the Prostheses List Reform Taskforce and Departmental representatives from MSAC to discuss the Assessment Framework.

Workshops and format

Between the 10th of May and the 1st of June 2022, the Department arranged five stakeholder workshops, each with a duration of 2 hours. Workshops were undertaken via video conference. A list of the workshops, and attendees is provided in Appendix 1. After an introduction by Departmental staff, the consultants from AHTA facilitated the workshops with industry sponsors, health insurers,

industry representatives and private healthcare providers (workshops 3, 4 and 5). Internal workshops (1 and 2) with the Department were more informal, taking a more direct question and answer format.

The purpose of the workshops was to present proposed pathways (as outlined in *Consultation Paper 3(a)*) to stakeholders, and to elicit feedback relating to the proposed eligibility and evidence requirements for each pathway. The *Consultation Paper 3(a)*, which outlined the three tiers of proposed assessment for applications to the PL, provided the basis for these discussions.

During the three workshops involving sponsors, health insurers, private healthcare providers and industry representatives, pathways were discussed and amended and accounted for the feedback and input provided during the workshops.

Input provided during the workshops also included broader feedback relating to the reform of the PL. Some of these issues were directly related to the governance arrangements to support the proposed pathways, or to consequences relating to the implementation of the pathways. This report has captured this feedback (Appendix 2).

The final workshop, provided on the 1st of June 2022, sought to establish consensus among stakeholders for the finalised assessment pathways.

Feedback during the workshops was conceptual and provided clear options for alternative design features. This input was frequently provided by way of examples of historical applications and precedents. Over the duration of the workshops, the pathways were iteratively altered to capture suggestions from the stakeholders, and to ensure that they were applicable to the examples that had been provided. A summary of the key issues discussed at the workshops is provided in Appendix 2.

The pathways that have been developed on the basis of this consultation are presented below, by Tier.

3 Background to the Prostheses List Assessment Pathways

This report describes three pathways for the assessment of PL applications (including for new, amendment, expansion, and compression applications).

The pathways represent an evolution of the pathways presented in the *Prostheses List Reforms - Consultation Paper 3(a) - A modernised fit-for-purpose listing process*. Changes and refinements have been made to the pathways to reflect the feedback of stakeholders and to better meet the stated aims of the project.

In the initial *Consultation Paper 3(a)*, the pathways were described as follows:

- Abbreviated Health Technology Assessment (HTA) Pathway
- Clinical/Focused HTA Pathway
- Full HTA Pathway (MSAC)

The naming of these pathways has been amended to better reflect the purpose and process of the pathways. The final names of the pathways are:

- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical/Focused HTA Pathway
- Tier 3: Full HTA Pathway (MSAC)

The consultation process explored the following key areas relating to the pathways:

- Key principles underpinning each of the pathways (Principles)
- Overarching characteristics of the assessment process for including devices on the PL (Characteristics)
- Criteria for eligibility for each of the pathways (Eligibility)
- Evidence requirements for each of the pathways (Evidence)

3.1 Principles underpinning PL reforms

The key purpose of the PL reforms, as set out in *Consultation Paper 3(a)*, is:

> *"to improve the administration of the PL to reduce red tape and ensure that all medical devices are listed on the Prostheses List (PL) in line with health technology assessment guidelines while streamlining the application and listing processes." (5)*

The Department has provided the following six core principles that should underpin a modernised listing process:

1. Form part of the Australian HTA system (with approaches that are consistent and not duplicative)
2. A single Departmental portal for Australian Government HTA processes

3. A process that is efficient for both sponsors and assessors (including the use of digital options to decrease the regulatory burden and cost recovery fees proportionate to the services provided)
4. Ensure globally accepted HTA principles underpin the Australian Government process
5. Balance transparency (for consumers, clinicians and payers) and confidentiality (respecting privacy and commercial information)
6. Develop a process that is collaborative and not compulsory - The Australian Government cannot compel a medical technology company to seek reimbursement of a device on the PL if it does not wish to do so.(5)

In addition, in 2019 the Quality of Information and Guidance Industry Working Group (the QIG) noted that a modernised process should be characterised by:

- Clear and specific evidence requirements
- Transparent decision making
- Efficient use of resources
- Predictable timelines
- Consistency of approach.

These principles have provided the basis for the development of each of the pathways.

It should also be noted that the *principle of providing the best available evidence* applies to all pathways no matter which pathway is used. It is recognised that the evidence base in the device space is not the same as in other types of HTA, such as for the assessment of medicines, with a scarcity of Randomised Controlled Trials (RCTs) and other clinical evidence. However it is important that all applications provide the best information available that is relevant to their claim. The presented pathways reflect the different types and levels of evidence likely to be available. The evidence requirements for each pathway have been tailored by appropriately linking the requirement for more or better-quality evidence with the concomitant risk associated with the device.

3.2 Key concepts

3.2.1 Subject device

A subject device is the device or devices applied to be listed under one application or already listed on the PL under one billing code. For the purposes of this report, a subject device refers to a device or multiple devices, and necessary components of a device. A subject device may be:

- A single device identified by one catalogue or part number that has no variations in sizes or any other characteristics, for example, one model/product code of the implantable cardioverter defibrillator
- Multiple devices that differ by physical size, such as surgical meshes or plates that are provided with varying sizes and shapes
- Composite devices that are always used in combination with other devices, for example, integral fixation spinal cages that are used in combination with the screws and the plate

- Devices used in combination with guides, such as a transcatheter heart valve and the delivery system used to insert it.

While some individual components of a subject device may already be included on the PL, the assessment of effectiveness of the device (and cost-effectiveness, if necessary) relates to the performance of the subject device as a whole (including all of the components) and how it is used in clinical practice.

3.2.2 Interchangeability

Interchangeability is a concept that describes how closely a subject device relates to a comparator device in terms of clinical indication, technical and biological characteristics. A subject device that is regarded as interchangeable with a comparator would usually be expected to substitute for the comparator, or other devices within the same PL group.

In general, interchangeability is intended to satisfy the following criteria:

- Physically comparable (using the images with the respective catalogue numbers identifying all devices in the application compared with the comparator).
- Identical clinical use – used in the same patient population and with the same indications for use.
- Similar technical and biological characteristics – same mechanism of action, similar materials and similar design.
- Technical evidence (such as bench data) to establish that small design differences do not affect the clinical effectiveness of the device (where applicable).
- If listed, the subject device would share the market with the comparators and is not expected to result in a marked change in aggregate utilisation.

For applications other than in Tier 1, clinical data are required to substantiate claims for interchangeability.

Demonstrating interchangeability is facilitated by completing a comparison table (Table 2). The comparison table is intended to clearly identify both the similarities and differences across the subject and comparator devices. Similarities are to be supported by technical documentation provided in the application. Differences require a reference (or multiple references) to supportive documentation that establishes that the differences will not negatively affect the clinical effectiveness of the subject device relative to the comparator device.

Incomplete comparison tables will impede the ability to successfully assess an application for inclusion on the PL and may result in rejection of the application at submission.

3.2.3 Guidelines and templates

While the evidentiary requirements associated with each of the proposed assessment pathways are described below and are implicit in the type of pathway selected, more detailed guidelines are needed to support sponsors with the development of their applications. Templates will need to be developed to ensure that applications are presented logically and consistently and include the types of

information that will facilitate an evidence-based assessment to be conducted. Some of the template requirements will be fulfilled by the application process through the Health Products Portal (HPP).

Table 2: Example comparison table for demonstrating interchangeability and identifying differences between the subject device and the proposed comparator

Characteristic	Subject device	Nominated Comparator	Analysis of similarities & differences	References[c]
Device description[a]				
PL billing code/Application ID				
Device name / UPIs			-	
Description				
Size				
Catalogue numbers				
Representative images for each device in the application and the billing code identified by catalogue numbers				
Specification as applicable (e.g. application is for a kit or system containing more than 1 component)				
Material				
Design characteristics				
PL grouping				
MBS item				
ARTG/TGA application ID				
Risk Classification				
GMDN Code/Term				
Clinical characteristics[b]				
Intended use				

Characteristic	Subject device	Nominated Comparator	Analysis of similarities & differences	References[c]
Intended indications/patient population				
Contraindications				
Adverse events (known and potential)				

[a]Device description:

The device description requested in the comparison table includes both technical / design characteristics and biological characteristics of the device. In general, the characteristics provided for the subject device and comparator device should be adequate to establish that the design, dimensions, available sizes, mechanical features, mechanisms of action, method of implantation and interaction with other devices are similar. Minor differences in technical characteristics can be discussed, and supported with technical documentation. The goal of such a discussion is to explain that minor differences (such as small differences in dimensions or methods of fixation etc.) will not have a negative impact on the comparative clinical effectiveness.

A comparison of the material(s) used for the subject device and comparator device is required. Differences in materials may affect both the technical characteristics (durability, strength, resorption rate etc.) and the interaction between the material and human tissue. Applications submitted to the Tier 1 Pathway should only include devices with material(s) that are commonly used for that type of device. If the material used in the subject device is likely to be regarded as novel for the proposed intended use, an application to the Tier 1 Pathway will be rejected.

[b]Clinical characteristics

Clinical characteristics refers to the intended use and clinical indications. These characteristics are drawn from the Australian Register of Therapeutic Goods (ARTG) entry or application for ARTG inclusion, and supported by the instructions for use (IFU) or surgical technique. These should be consistent with the ARTG inclusion. Where the intended use of a subject device is broader than that of the comparator device (ie, includes broader populations or different clinical indications), clinical evidence to support the performance of the subject device within these indications or populations will be required. Tier 1 applications are not appropriate for the treatment of new populations or indications and should be submitted to the Tier 2 Pathway.

[C] Provide references to the documentation that will verify the included information.

4 Tier 1: Departmental Assessment Pathway

4.1 Background

The Tier 1 Pathway was proposed in the *Consultation Paper 3(a)* report and was referred to as the "Abbreviated Pathway".

The pathway was described as suitable for new listings and amendments to listings that were:

- Medium or lower-risk devices that are well-established technology;
- Subject devices with substantially similar in characteristics, intended use and clinical effectiveness to other devices listed on the PL in the existing grouping;
- Assessments that could be largely undertaken by the Department.

4.2 Characteristics

The goal of the Tier 1 Pathway is to efficiently assess devices for inclusion into an existing PL benefit group if there is clear evidence that the device is a well-established technology, not high risk and interchangeable with other devices already listed in the nominated group/sub-group. This pathway is proposed to efficiently utilise Departmental resources, which is intended to be accurately reflected in cost-recovery measures. To ensure the viability of the pathway, applications are assessed on the completeness, eligibility and evidentiary basis supporting the claim of interchangeability. Sponsors using this pathway will have only one opportunity to provide clarifications or additional information, and incomplete or inappropriate applications will be rejected.

A device taking this pathway is expected to share the existing market with the proposed comparator (or other interchangeable devices in the same PL benefit group). It is expected that there will be no increase in utilisation in the nominated PL benefit group as a consequence of listing the device on the PL.

The Tier 1 pathway is suitable for applications for new listings and amendments to listing. Administrative type applications will be processed separately.

4.3 Eligibility

A list of eligible PL groups will be maintained by the Department and outlined in the proposed Guidelines (“PL Guide”). Devices that would potentially sit in one of these eligible PL groups must also have:

- A relevant MBS number (or numbers)
- A reputation as a well established technology, that is not high-risk, and interchangeable with other devices already listed in the same nominated group
- Confirmation of an ARTG entry, valid conformity assessment or ARTG inclusion application (i.e. parallel assessment process).

The types of devices eligible for the Tier 1 Pathway would be explained in the PL Guide, and the Guide would be updated as required.

4.4 Evidence requirements

A range of information will need to be provided by a sponsor in an application to the Tier 1 Pathway. This includes:

- A description of the subject device, including images with catalogue numbers, usually in the product brochures, surgical techniques, or other product material
- Additional device documentation if required (e.g. instructions for use, labels, etc.)
- Details of the nominated comparator, including PL billing code, product name, description, size and catalogue numbers, representative images of the comparator device
- Comparison table establishing similarities and differences in clinical indication and characteristics of the subject device and proposed comparator (Table 2)
- Additional evidence to support interchangeability, where minor differences have been identified in the comparison table
- Clear concise justification demonstrating that the subject device is no less clinically effective than the comparator, particularly if differences have been identified
- Estimate of utilisation of the subject device, if included on the PL.

It is the responsibility of the sponsor to ensure applications are complete and fulfil the evidentiary requirements. This will ensure expedience of the assessment process and reduce the likelihood of rejection of an application and the need for resubmission. Guidelines supporting applications to each of the pathways will be available ("PL Guide").

The key evidence requested to support a claim of interchangeability would be presented in a comprehensive comparison table. The table is intended to demonstrate that the subject device is similar enough to the comparator and, if listed, will be sharing the market with the comparator (or other comparators in the same PL group). An example of the information likely to be required in a comparison table can be found at Table 2.

Device documentation, including (but not limited to) product brochures, instructions for use and surgical technique documents are to be submitted to assist in the description of the subject device. Final versions of documents are required. If a parallel process is underway, then updated documentation is to be provided following inclusion on the ARTG with clear explanations of any differences between the documentation that was assessed for inclusion on the PL and the final versions approved by the TGA.

4.5 Departmental Assessment Pathway flowchart

The Tier 1 Pathway involves consideration of the claim of interchangeability. This process may involve up to one opportunity for correspondence with the sponsor for the purposes of clarification or to provide additional evidence as might be required for the assessment.

Risks with this pathway mainly relate to potential capacity constraints within the Department in terms of workforce and expertise in device assessment.

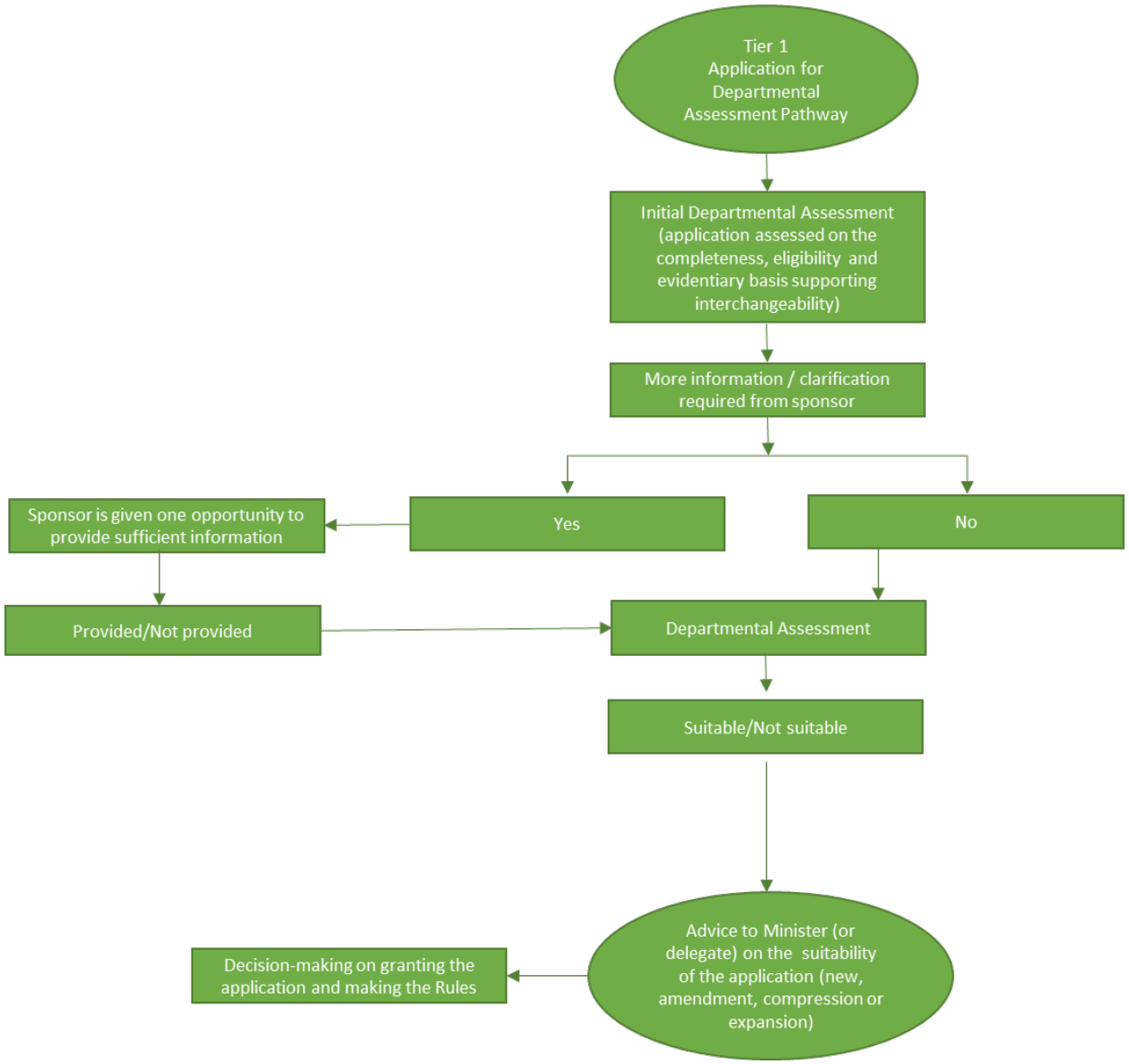

Figure 1: Application flow through the Tier 1 (Departmental Assessment) Pathway

5 Tier 2: Clinical/Focused HTA Pathway

5.1 Background

The Tier 2 Pathway was initially proposed in the *Consultation Paper No.3(a)* report. In this report, the Tier 2 Pathway was labelled as a "Clinical / Focused Health Technology Assessment (HTA) Pathway".

The pathway was described as suitable for:

- Higher risk devices, or devices that are not a well-established technology;
- Claims that the subject device has incremental improvements/some different characteristics compared with comparator devices on the PL;
- Assessments that would rely on comparative clinical effectiveness and/or cost effectiveness, with input from relevant experts.

5.2 Characteristics

The Tier 2 Pathway is intended for applications that require external expert advice to perform a partial HTA in regards to the clinical aspects of the device and its use and in some cases cost-effectiveness. Applications to the Tier 2 Pathway are not suitable for the Departmental Assessment Pathway (Tier 1) and, equally, do not require a Full HTA to be carried out to inform the Medical Services Advisory Committee (MSAC) (Tier 3). However, based on advice from the Department, Clinical Advisory Groups or the PLAC, or even by the request of a sponsor, a referral to the MSAC to undergo assessment via the Tier 3 pathway, can occur at any point in the Tier 2 pathway. Although the Department, CAGS or PLAC may provide this advice to the sponsor, it is the responsibility of the sponsor to make this decision.

External advice would be sought from clinical specialists in the CAGs (or their replacements) and HTA groups. In some circumstances, these HTA groups would be contracted to provide a commentary on the application that has been lodged. This commentary would review the clinical evidence and could feasibly include an economic evaluation if sufficient data are available. This would be an expense that would be cost-recovered from the sponsor. The role of the commentary would be to identify the strengths and uncertainties of the provided evidence and identify appropriate inputs for an economic evaluation. The type of external advice required for any particular application would be determined based on the needs of the Department.

The Tier 2 Pathway describes two components:

- A clinical assessment (only)
- A clinical assessment plus a health economic evaluation.

The clinical assessment (involving clinical evidence) is required for all applications in the Tier 2 Pathway. A health economic evaluation would only be required in some circumstances.

5.2.1 Clinical assessment

During consultation, it was the view of stakeholders that the amount and type of clinical evidence required for assessment is variable, and should be related to the novelty of the device and whether the subject device is proposed to be included in a current PL group or a new PL group. The relevant outcomes provided in the clinical evidence will vary by the type of device and nature of the claim:

- Clinical evidence reporting the use of the device in the proposed indicated population is required for subject devices that can demonstrate similarity or interchangeability with a comparator device. Non-comparative evidence may be adequate but should be supplemented with benchmark performance data for the class of devices (i.e., effectiveness outcomes expected for similar devices), if available.
- Evidence of comparative effectiveness is required for devices that are novel, and to support any claim for a greater clinical benefit.

The presentation and synthesis of clinical evidence must be relevant to the specific issue the application is seeking to address. This means that evidence is presented and interpreted with clear statements of how it informs the comparison between the subject device and the proposed comparator. The presentation of large amounts of evidence with questionable relevance to the sponsor's claim is unhelpful and may impede the assessment process or result in a request for resubmission.

Guidance regarding acceptable clinical evidence for a device would be provided by the “PL Guide”. Templates should be available to facilitate a consistent approach to the presentation of evidence in the applications.

The consultation identified an additional circumstance that might influence the type of evidence required for an assessment. Subject devices that are expected to substitute for multiple comparator devices should provide clinical evidence of equi- or superior effectiveness in addition to evidence that the subject device will function similarly to the comparator devices in the proposed indication. For complex devices, comparative clinical evidence is required to establish that patient health outcomes would be similar with the proposed new device.

5.2.2 Economic assessment

Whether an economic assessment is needed would be guided by the following principles.

5.2.2.1. No economic assessment required

An application for a subject device to be included in an existing PL benefit group (for the same benefit) is expected to establish either that the device is:

- Interchangeable (supported by a comparison table, and some clinical evidence)
- No less clinically effective (supported by clinical evidence demonstrating similar effectiveness)

A cost-effectiveness assessment is not generally required for subject devices that are requesting inclusion in an existing PL benefit group. It is expected that the subject device would be a substitute for the comparator or other devices in the proposed PL benefit group. While the financial impact of a single PL benefit group may vary based on changes to the population, clinical practice or number of services provided, the overall financial impact of listing a “like for like” subject device is expected to

be neutral. Substantial changes to the aggregate cost of the PL benefit group, related to a broadening of the population, or an increased use of the subject device during each procedure, may warrant a review of the substitution mechanism or decision.

5.2.2.2. Economic assessment required

The economic evidence required to support a proposed PL benefit will vary across devices. Economic evaluations are intended to introduce a value metric into the assessment of devices. The economic evaluation and commentary addressing the economic evaluation are intended to inform deliberations relating to benefit setting.

A subject device requiring a new PL group may have a similar performance to a comparator (but different mechanism of action), or it may be superior to a comparator. A comparator may be another device currently included on the PL or may be a non-device comparator. There are two forms of economic evaluation that may be relevant depending on the relationship between the subject device and the comparator.

Cost-comparison

For a PL application that claims the performance of a subject device is no less clinically effective than a comparator, a cost-comparison is required to ensure that the cost of the subject device is no greater than the cost of the comparator. Costings include pre-intervention costs, device costs, surgical costs and post-intervention costs. Applicants should justify the types of costs included.

A cost-comparison can also be used if a subject device is a substitute for an alternative device at a ratio that is not one-to-one. An example of this is if the use of one subject device is intended to replace the use of several comparator devices and is supported with clinical evidence that the subject device is no less clinically effective than the use of several comparator devices combined, and there are utilisation data of the ratio of substitution in clinical practice. The aim of the cost-comparison, in this case, is to establish the total cost of a procedure using the subject device and compare it with the total cost of a procedure using the comparator device. The cost-comparison is required for benefit setting.

A cost-comparison can also be used if the comparator is a non-device (such as a medicine or other standard of care).

Cost-effectiveness / cost-consequences

For a PL application requesting a new PL benefit group for a device that is superior to an existing device or superior to standard-of-care if no comparator device exists, a robust comparison of costs and likely patient health outcomes is required. A cost-consequences analysis reports the costs of an intervention and comparator (often disaggregated), and a range of disaggregated outcomes. This type of analysis can be helpful for decision makers to consider the source of additional costs and the types of additional benefits. A cost-effectiveness analysis, on the other hand, presents incremental costs and incremental outcomes for a subject device relative to the comparator. Presentations of disaggregated data for a cost-effectiveness analysis resemble a cost-consequences analysis, however the final analysis reports how much it costs to gain a single unit of health (this might be in terms of life years gained or quality adjusted life years).

The choice of economic evaluation should be consistent with the clinical evidence and commensurate with the proposed incremental cost of the device. The value of a device with a proposed small increase in PL benefit over a comparator may be supported by an estimated cost per reduction in adverse event, or cost per increase in short-term positive health outcome. A device that requests a larger incremental PL benefit may require longer-term cost and outcome data to support an estimate of value.

The sponsor must account for all the changes in costs, including costs realised in preparation for the use of the device (such as imaging), during the use of the device, and downstream costs (e.g. associated with adverse events) following the use of the device. Where costs are not expected to differ between the subject device and the comparator, this must be clearly stated and justified. Evidence of changes in costs are best collected alongside clinical studies or clinical practice. Clinical expertise may be used to inform likely costs, however for the most part, costs should be collected using objective and unbiased methods, and clearly documented.

5.2.3 Sponsor and clinical expert input during assessment

Some assessments may be informed by contracted Health Technology Assessment (HTA) groups. Clinical experts are essential to helping HTA groups to understand the risks and benefits of a subject device. This advice is likely to be sourced through the Clinical Advisory Groups (CAGs). In addition, mediated meetings between the HTA group and the sponsors may be required to clarify sections of the submission and to reduce the likelihood of resubmissions and of errors in the commentary.

5.2.4 Post commentary sponsor response

Due to the involvement of an HTA group, an additional step permitting a sponsor to respond to the commentary (on both the clinical and economic evidence) is included in the pathway. This 'natural justice' step occurs in other Departmental HTA processes. The sponsor's response is intended to include clarifications and (limited) additional evidence requested in the commentary, and an opportunity to identify errors in the commentary. This response would occur prior to, and be incorporated into, the committee deliberations and decision-making.

5.2.5 Public consultation option

The assessment of devices that are novel or could potentially result in marked impacts on patients may go through a period of public consultation. This consultation process would invite consumers and clinicians to provide comments, and these would be incorporated in deliberations by the decision-making committee. This consultation process is expected to be achievable within the timeframes of an assessment. Public consultation for novel or high impact devices in the Tier 2 Pathway is consistent with processes in the Tier 3 Pathway. Having this consultation step addresses the overarching principle of transparency and involvement of consumers and stakeholders. Thresholds for the triggering of public consultation will need to be determined by the Department and clinical experts.

5.3 Eligibility

Subject devices that would be ineligible for the Tier 1 Pathway are potentially eligible for the Tier 2 Pathway if they also have a:

- Relevant MBS number (or numbers)

- Clear justification for the proposed comparator
- Confirmation that the device has an ARTG entry, a valid conformity assessment or ARTG inclusion application (i.e. parallel assessment process).

5.4 Evidence requirements

The type of information that will need to be provided by a sponsor in an application to the Tier 2 Pathway includes:

- A description of the device, including images with catalogue numbers, usually in the product brochures, surgical techniques, or other product material
- Additional device documentation if required (e.g. instructions for use, labels, etc.)
- Details of the nominated comparator, including PL billing code, product name, description, size and catalogue numbers, representative images of the device
- A comparison table establishing similarities and differences in clinical indication and characteristics of the subject device and proposed comparator (Table 2)
- Additional evidence to support a relevant claim:
    - No less clinically effective – supported by evidence of interchangeability and additional supportive evidence where minor differences are identified in the comparison table
    - No less clinically effective – supported by clinical evidence
    - Superior – supported by comparative clinical evidence
- Economic evaluation consistent with the clinical claim and the proposed PL benefit
    - Cost-comparison to support a claim of no less clinically effective where the requested PL benefit is the same as the comparator
    - Cost-consequences to support a claim of superiority where the requested PL benefit is similar or minimally higher than the comparator
    - Cost-effectiveness to support a claim of superiority where the requested PL benefit is higher than that of the comparator
- Estimate of utilisation of the subject device, if included on the PL

5.5 Clinical/Focused HTA Assessment Pathway flowchart

A flowchart depicting the basic process for this pathway is given in Figure 2. Risks with this pathway mainly relate to availability of clinical expertise across all possible applications of subject devices.

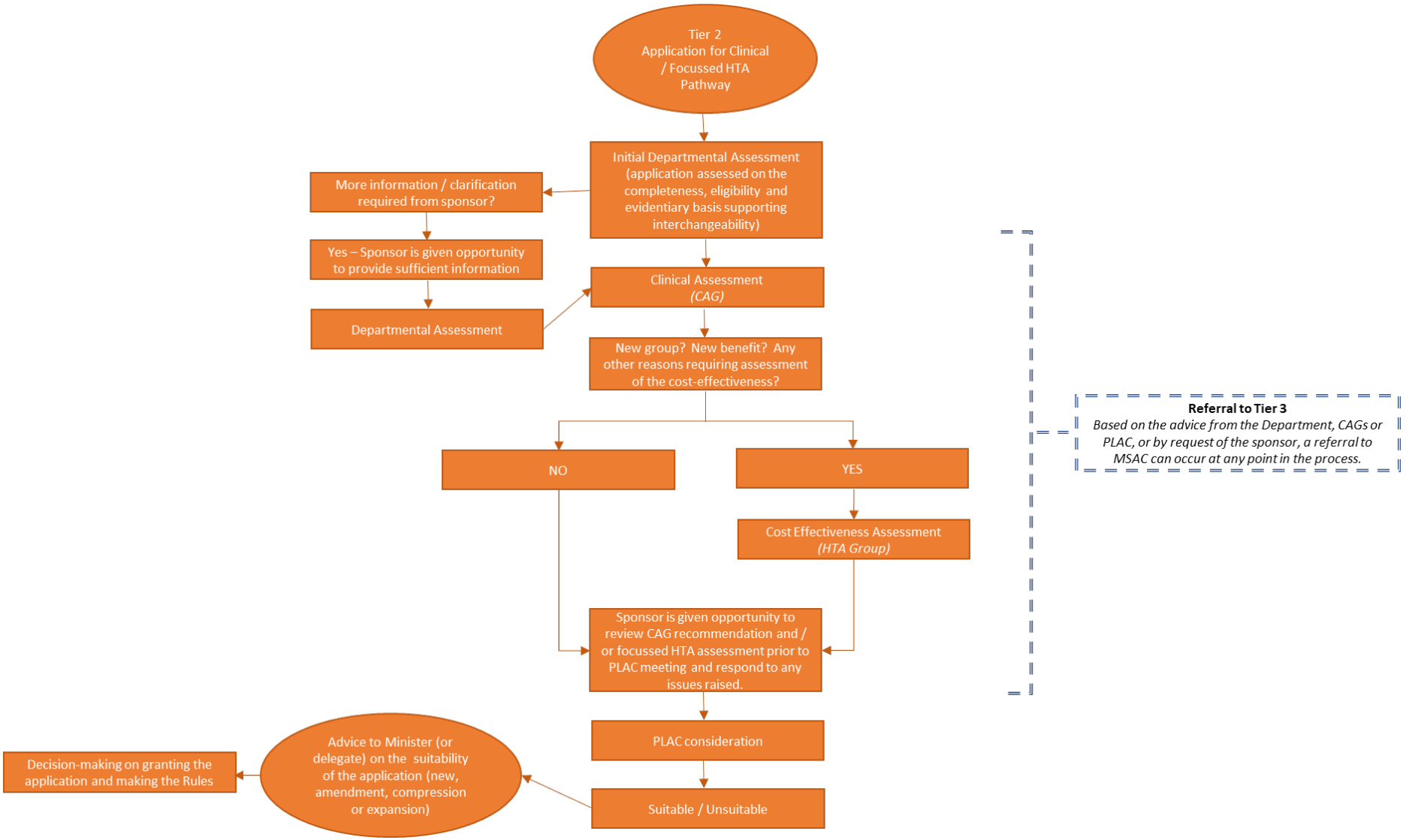

Figure 2: Application flow through the Tier 2 (Clinical/Focused HTA) pathway

*The economic assessment component, if required, occurs in parallel with the clinical assessment.

6 Tier 3: Full HTA (MSAC) Pathway

The Tier 3 Pathway represents an existing pathway and utilises the HTA processes currently undertaken to support MSAC consideration of funding of medical services.

6.1 Background

The Tier 3 Pathway was initially proposed in the *Consultation Paper 3(a)* report.

The pathway was described as suitable for:

- Applications for listing devices on the PL where there is no relevant MBS item number for the use of the device (a new MBS item number is required or an MBS item descriptor requires amendment for use); and/or,
- The device is a novel or "first in class" technology and/or there are no appropriate comparators on the PL.

The assessments were described as including comparative safety, clinical effectiveness, cost-effectiveness and total cost that would be considered by MSAC, with inputs from relevant experts as required.

6.2 Characteristics

The goal of the Tier 3 Pathway is to establish the effectiveness, safety and cost-effectiveness of the subject device when used for its intended purpose. The pathway is congruent with the existing MSAC assessment process. The outcome of the Tier 3 Pathway is the provision of a new or amended MBS item number (if required), and evidence to inform benefit setting for the subject device.

The comparative safety, clinical effectiveness, cost-effectiveness and total cost evaluation for this pathway follows the requirements outlined in the *Guidelines for preparing assessments for the Medical Services Advisory Committee*(4). The MSAC process is also supported by a preliminary step in which the relevant research questions and parameters for the evidence are established. This PICO Confirmation step involves input from applicants and public consultation, attempts to delineate the place of the medical device/service in clinical practice, and is considered by the PICO Advisory Sub-committee (PASC).

The MSAC application process and timelines are available on the Australian Government MSAC website. Guidelines and templates for preparing assessments for MSAC are also available for applicants to assist in the development of an assessment report for consideration by MSAC.

During the assessment and deliberations, MSAC and/or its subcommittees will liaise with the Prostheses List governance committee (currently the PLAC) to ensure device related concerns are addressed.

6.3 Eligibility

Subject devices that would be ineligible for the Tier 1 and Tier 2 Pathways would be eligible for the Tier 3 Pathway if they also have:

- No relevant MBS number or are a novel / first-in-class device requiring a full HTA to establish comparative safety, clinical effectiveness and cost-effectiveness and total cost
- Confirmation that the subject device has an ARTG entry, a valid conformity assessment or ARTG inclusion application (i.e. parallel assessment process).

It is expected that most completely novel devices will not have an eligible MBS item number for use. Therefore, the proportion of devices that require the Tier 3 Pathway that have an eligible MBS item number is expected to be small. Sponsors are encouraged to liaise with the Department via a pre-application meeting for guidance regarding the choice of pathway if there is uncertainty regarding the applicability of an MBS item number, or the interpretation of novelty.

6.4 Evidence requirements

The type of information that will need to be provided by a sponsor in an application to the Tier 3 Pathway are outlined in the *Guidelines for preparing assessments for the Medical Services Advisory Committee* ("MSAC Guidelines")(4).

Evidence requirements, and the approach taken to support an assessment report for MSAC consideration, are also defined during the PICO confirmation phase. During this phase, an HTA group will define the relevant population, intervention, comparator, and outcomes, and construct the research questions that need to be answered concerning the clinical safety, effectiveness and value for money of the subject device.

In addition to the evidence requirements outlined in the MSAC Guidelines, applicants would also provide similar information as for the Tier 2 Pathway, so that the Prostheses List categorisation can be determined by the departmental and clinical assessment.

6.5 Full HTA Pathway Flowchart

The flowchart for the Tier 3 Pathway, presenting three options, is simplified for the purposes of this report. There are three MSAC pathways (a standard pathway, comprehensive pathway and expedited pathway) that describe different requirements. The appropriate MSAC pathway is determined by the Department in consultation with the applicant, however, the applicant is able to determine if they prefer to:

- submit an application to MSAC and PLAC simultaneously (Option 1), or
- submit an application to MSAC first, clearly stating about their intent to submit a PL application, but applying to PL later [at any time throughout the process] (Option 2).

An additional pathway (Option 3) is for those applications which have been referred from the Tier 2 pathway which may or may not require further consideration by CAGs and / or PLAC. CAG and / or PLAC consideration is dependent on at what point the referral from Tier 2 occurred.

The pathway below (Figure 3) does not provide detail of these MSAC pathways. The detail for the MSAC processes can be found on the MSAC website:
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSAC-Guidelines

Risks with this pathway primarily relate to capacity within device companies to produce the clinical and economic evidence needed to satisfy evidence-based decision-making.

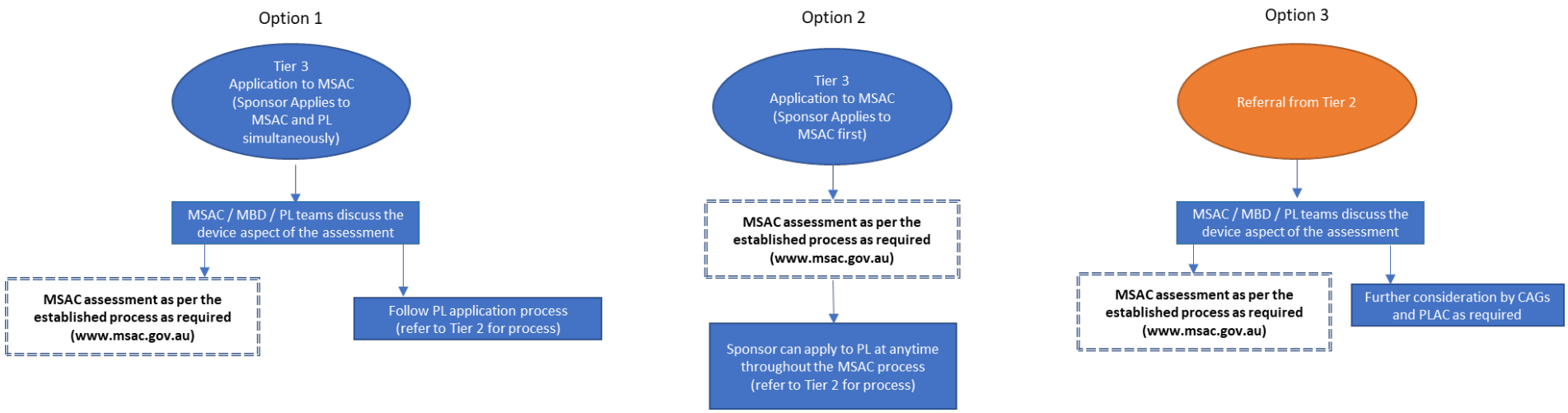

Figure 3: Simplified application flow through the Tier 3 (Full HTA (MSAC)) Pathway

7 Out of scope points raised during consultation

The Department informed stakeholders about the aims of the workshops prior to and during their presentation. It was made clear that some concerns related to new PL processes were out of scope for this part of the PL reforms. These out of scope issues included timeliness, cost recovery and post-listing review. Unsurprisingly, some of these issues did come up during the consultation process, and the discussion around these has been included for completeness.

7.1 Timeliness

Stakeholders raised concerns that the assessment of devices through the Tier 2 Pathway would result in a greater time to inclusion on the PL compared with assessment through Tier 1. Device companies are obviously interested in progressing their applications through to a PL listing as quickly as possible and expressed hope that the Tier 1 Pathway would expedite the process and permit a broader range of applications.

Some stakeholders suggested an increase in the number of PL updates per year, possibly shortening the time to listing. However, the Department advised during the workshops that given the processes involved in the updating of the PL for both the Department and other stakeholders (private hospitals and private health insurers) there will not be an increase in the number of PL updates each year.

Similar concerns were raised regarding the timeliness of the Tier 3 Pathway. It is noted that the Tier 3 Pathway is established and will not be impacted by the PL reforms, nor is there any suggestion that more applications will be directed to MSAC for consideration than there are currently.

7.2 Cost-recovery

Stakeholders noted that a cost-recovery based on Tier may be inequitable. This relates to devices that are ineligible for the Tier 1 Pathway (because of Departmental capacity) and therefore require the Tier 2 Pathway, but for which the effort of evaluation would be similar (i.e. a small amount of clinical evidence assessed by a clinical expert). This would compare, unfavourably, to a Tier 2 application for which a clinical and economic evaluation is required, and which would normally be expected to attract a higher cost. This issue will need to be worked through with the Departmental cost recovery section.

Departmental (MSAC) feedback also noted that devices that are first to market and need to go through a Tier 3 Pathway have a cost and evaluation burden placed on them which will not apply to their competitors once the device and MBS number are listed. Again, this is an issue for the Department to consider.

7.3 Post-listing safeguards

Payers (Private Health Insurers) reported examples of marked increases in costs associated with the listing of devices in PL benefit groups. This appears to be in conflict with a key goal of the PL pathways which are to ensure value to consumers and the broader health care system. It is expected that

demonstrating interchangeability and entry into an existing PL benefit group would have minimal impacts on overall expenditure within that PL group. Therefore, utilisation and related cost triggers in PL benefit groups with new or expensive device additions should be considered for automatic review.

7.4 MBS item numbers

During the first workshop it was suggested that relevant MBS item numbers are provided at the point of application for a device. Relevant MBS item numbers are those that may be associated with the use of the device. This ensures that the intended purpose of the device (as per TGA and PL applications) is consistent with the MBS item. This request has been applied to the eligibility criteria for Tier 1 and Tier 2 assessments.

An additional suggestion raised during a stakeholder discussion was the inclusion of eligible MBS items associated with a device on the PL entry. The aim of this is to limit the reimbursement to the use of the device in its intended clinical indication, thus preventing leakage.

The devices are assessed for their safety and performance based on the intended use, which is not necessary the same as descriptors of the MBS items. Further, it is recognised that clinicians often wish to have choice in how to use the devices for their patients.

If conditions are placed on the PL billing code, clinicians could still have the choice of using the device for the medicare service they consider appropriate for their patient, and claim the respective MBS item but they would need to explain why they used the device “outside the approved indication” when claiming for the device from the private health insurers. This would allow better monitoring of off-label use and could help in identifying any concerns post-listing. The Department may wish to consider this option for other aspects of the reform process.

8 Conclusions

This project aimed to incorporate the views of stakeholders across the PL process into the design of new application pathways for the PL. Stakeholders involved in this consultation included the Department of Health and Aged Care Prostheses List Reform Taskforce Branch, Prostheses List Administration section, MSAC Secretariat and HPP staff; and representatives of the Medical Technology Association of Australia, Private Healthcare Australia, Australian Medical Association, private hospitals, private insurance funds, AusBiotech and sponsor companies.

As indicated in the written feedback to the *Consultation Paper 3(a)*, there were divergent views on key aspects of the PL process. However, there was also a shared commitment to greater efficiency and transparency in processes for all stakeholders.

The proposed pathways that have been presented in this report are designed to accommodate, as much as possible, the requests of stakeholders. The pathways seek a balance between efficiency, transparency and consistency for sponsors and for payers, whilst acknowledging the parameters set by the Department in terms of available resourcing and capability. Importantly, the pathways reflect the principles of a reformed listing process set out at the beginning of the reform project:

- Clear and specific evidence requirements and eligibility criteria » pathways have been developed that include eligibility criteria, provide clarity on the type of evidence required and a recommendation for more detailed guidelines and templates
- Transparent decision making » the pathways incorporate payer scrutiny at an earlier stage of assessment, with public consultation in selected pathways; guidelines will provide further transparency about the basis of decision making
- Efficient use of resources » the pathways provide different levels of assessment consistent with the complexity of an application
- Predictable timelines » dates for submission and decision will be set in cycle with listing
- Consistency » all applications seeking the same pathway are treated the same

The pathways represent a shift away from the existing processes, and it is recognised that this will take some adjustment from all parties. Key to the transition will be clear guidelines and templates so that sponsors and other stakeholders understand what is required of them. Clear guidance for the application process is expected to be captured within the HPP.

The proposed pathways, importantly, align with HTA processes within the Department. The pathways, alongside the other activities being undertaken as part of the Prostheses List reforms, will help to improve transparency, increase consumer protection and address sustainability of the system of reimbursement through private health insurance.

9 References

1. Australian Government Department of Health. The Prostheses List reforms 2021 [April 2022]. Available from: https://www.health.gov.au/health-topics/private-health-insurance/the-prostheses-list/the-prostheses-list-reforms.
2. Australian Government Department of Health. Clinical evidence guidelines for medical devices 2021. Available from: https://www.tga.gov.au/resource/clinical-evidence-guidelines-medical-devices.
3. Commonwealth of Australia Department of Health. Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee (Version 5.0) 2016. Available from: https://pbac.pbs.gov.au/content/information/files/pbac-guidelines-version-5.pdf.
4. Australian Government Department of Health. Guidelines for preparing assessments for the Medical Services Advisory Committee 2021. Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/$File/MSAC%20Guidelines-complete-16-FINAL(18May21).pdf.
5. Australian Government Department of Health. Prostheses List Reforms - Consultation Paper No 3. Prostheses List - a modernised fit-for-purpose listing process. Canberra: Department of Health; 2022.

10 Appendix 1

Table 3: Participants in the workshops facilitated by AHTA

Workshop	Date	Participants
1	10 May 2022	Departmental only, including Prostheses Reform Taskforce, PL Administration staff
2	11 May 2022	Departmental only, including Prostheses Reform Taskforce, PL Administration staff, MSAC staff, HPP staff
3	18 May 2022	• Medical Technology Association of Australia • Private Healthcare Australia • Australian Medical Association • Australian Private Hospital Association • Catholic Healthcare Australia • Day Hospitals Australia • Australian Health Service Alliance • Members Health Fund Alliance • AusBiotech • Abbott Medical • Arthrex Australia • Biotronik Australia • Boston Scientific • BXTA • Cochlear • Johnson & Johnson Medical • LifeHealthcare • Medtronic • Rocket Medical • Stryker • Departmental staff
4	25 May 2022	• Abbott Medical • Arthrex Australia • Biotronik Australia • Boston Scientific • BXTA • Cochlear • Johnson & Johnson Medical • LifeHealthcare • Medtronic • Rocket Medical • Stryker • Medical Technology Association of Australia and Private Healthcare Australia as observers • Departmental staff
5	1 June 2022	• Medical Technology Association of Australia • Private Healthcare Australia • Australian Medical Association • Australian Private Hospital Association • Catholic Healthcare Australia • Day Hospitals Australia • Australian Health Service Alliance • Members Health Fund Alliance

Workshop	Date	Participants
		• AusBiotech • Abbott Medical • Arthrex Australia • Biotronik Australia • Boston Scientific • BXTA • Cochlear • Johnson & Johnson Medical • LifeHealthcare • Medtronic • Rocket Medical • Stryker • Departmental staff

11 Appendix 2

Summary of the key discussion points related to the pathways from the consultation workshops.

The eligibility of devices for the Tier 1 (Departmental Assessment) Pathway based on TGA medical device risk classification

Sponsor feedback, from both written consultation and through the workshops, indicated that a higher TGA risk classification should not make a device ineligible for the Tier 1 Pathway. In the consultation paper, the eligibility is defined as 'low clinical and financial risk' and could include '"me too" devices as they are a comparable / similar device to what is currently listed on the PL list'. Sponsors argued that Class of device was not a reasonable determinant of the ability to demonstrate interchangeability, nor an indication of how complex the assessment may be. Sponsors also noted that the TGA provide more scrutiny to Class III devices, so additional assessment through the PL application process reflects duplication of effort.

Other stakeholders were opposed to Class III devices being eligible for the Tier 1 Pathway, as they felt that the higher risk devices should receive more scrutiny.

It was noted that the TGA assessment has different objectives (regulatory) to the PL assessment (reimbursement), and contributes to, rather than comprises, the PL assessment, and therefore cannot substitute for PL assessment.

The Department further clarified that the Tier 1 Pathway could only include applications for devices that represent well-established technology with low or medium risk classifications, for which the Department has internal capacity (i.e. specialised knowledge and experience) to assess the claim for interchangeability. A list of devices (or types of devices) that will be eligible for this pathway will be provided in the "PL Guide" and will be subject to change as Departmental capacity changes.

Regulatory / Prostheses List parallel applications

Prostheses, like all medical devices, require regulatory approval in order for sponsors to be able to legally supply the device in Australia, i.e. the device must be included in the ARTG.

Initially, the proposed Tier 1 Pathway did not accommodate parallel processing with TGA.

Stakeholders raised concerns regarding the timeliness of sequential processing (i.e. ARTG registration must be received before PL application can begin), noting that if PL assessment does occur following receipt of an ARTG number, then there will be occasions where an application misses the cut-off for inclusion on the PL and must wait for an additional 4 months. It was unclear what proportion of devices would fall into this category.

During the workshops, it was agreed that parallel assessments would be permitted in the Tier 1 Pathway. It is noted that parallel assessments remain an option for the Tier 2 and Tier 3 Pathways.

Stakeholder scrutiny

Feedback was received around the opportunity for payers (and potentially private hospital representatives) to scrutinise applications to the PL. It was noted that in the existing process, there

was a very short period of time prior to the PLAC meeting for these stakeholders to scrutinise applications.

An opportunity for public consultation/notification was included in pathway examples in the initial stakeholder workshop. During the second sponsor-only workshop, sponsors expressed concerns around the concept of public consultation, citing that a public notification was not likely to be necessary if the eligibility criteria are clear, and a public notification process may interfere with the efficiency of the pathway. They were also concerned about potential commercial-in-confidence breaches.

The option for public notification was removed, however the lack of scrutiny was raised in Workshop #3 by payers as a concern. It became clear that the concept of 'public notification' as presented in the first workshop represented a misunderstanding on the purpose of this step, where it is intended that there would be payer scrutiny rather than broader public consultation. Further discussion involving a broad range of stakeholders resulted in a consensus that some form of scrutiny by payers (and other interested parties, such as the group representing the private hospitals) should be incorporated.

Several issues remain to be decided by the Department with regards to payer scrutiny, namely: the timing of access to applications by the payers; who would have access to the applications; and what information would be available.

Clarity regarding eligibility

Stakeholders identified the need for clear definitions of the terms used in eligibility criteria for each pathway. The intention of the Tier 1 Pathway is to include only applications for devices that are interchangeable with existing devices on the PL that represent mature technology, with a history of prior assessments and utilisation. A considerable amount of discussion in the workshops focused on what types of devices, and what types of claims, may be eligible for the Tier 1 Pathway.

The term "well-established technology" indicates that the devices in this group have a long history on the market, have relatively simple, common and stable designs with little evolution, have not been associated with safety issues in the past, have well-known clinical performance characteristics and are standard of care where there is little evolution in indications.

In the context of the PL, the above means that the subject device has multiple comparators from the same group listed on the PL for an extended time, and the subject device and the comparators have very similar characteristics, material, intended use and population, and do not have significant differences that may affect the comparative clinical effectiveness of the subject device (e.g. specialist orthopaedic plates and screws, craniomaxillofacial fracture and reconstruction plates, fusion non-expandable spinal cages, spinal rods, ancillary joint replacement devices, etc.).

The exclusion of Class III devices and AIMD from the Tier 1 (Departmental Assessment) Pathway

As stated previously, the Tier 1 Pathway became clearly defined by workshop #3 as suitable for only those applications where the device(s) was a well-established technology of low to medium risk that could be evaluated using existing Departmental resources and expertise. Any device requiring external clinical or HTA input would be required to apply via the Tier 2 Pathway (assuming they were not required to apply for the Tier 3 Pathway).

In preparation for workshop #3, a specific sub-pathway within the Tier 2 Pathway was developed to capture devices that could make a convincing claim of interchangeability, but for which the Department would request expert clinical input for making a determination of whether the devices were interchangeable. This part of the Tier 2 Pathway would be expected to attract a lower cost recovery amount than the other parts, where more clinical evaluation and HTA expert input would be involved.

Further discussion with the Department indicated that the sub-pathways within Tier 2 would not be required and that the "PL Guidelines" (to be developed) would inform sponsors of the evidence requirements related to their Tier 2 claim.

<u>One subject device substitutes for >1 comparator devices</u>

During workshop #1, an example was provided where a single subject device would substitute for two comparator devices. The subject device would therefore not be interchangeable with the comparator device (in this case, it was larger). However, the stakeholder raising the example argued two points:

- The larger device was functionally the same as the use of the two smaller devices; and,
- The proposed PL benefit for the subject device should account for a reduction in the use of multiple comparator devices.

This example has been used to guide the development of the Tier 2 Pathway and would most likely be evaluated using a claim of no less clinically effective, and require clinical evidence to support the claim. Any cost savings from substituting for two smaller devices would also be captured should a cost comparison be conducted.

<u>Evidence to satisfy a conclusion of noninferiority</u>

It was noted during the workshops that the term 'noninferiority' may have a specific meaning in clinical trials and HTA that does not necessarily apply to devices. While the term 'noninferiority' may be used more generally to mean 'no less effective', it is also a term used to describe a statistically established relationship between two interventions. Stakeholders explained that, in many cases, evidence to support a statistical conclusion of noninferiority was not likely to be necessary, or even possible.

While a goal may be to establish noninferiority, the evidence required to adequately satisfy this may be inferential. For example, using a comparator table to establish interchangeability, or clear evidence to support functional equivalence, may be adequate to infer that the devices would be noninferior. Whereas, in other circumstances, differences between the subject device and comparator devices would preclude simpler approaches, and comparative clinical evidence would be required to establish noninferiority. Post-market surveillance and device registries could be subsequently used to validate claims of noninferiority.

In rare cases where the subject device is particularly novel and no comparator device exists, noninferiority may need to be established using comparative clinical evidence against the current standard of care. In this case, as no PL benefit exists as a reference, a statistical definition of noninferiority may be required to ensure that there is no loss of health due to the use of the subject device, as well as to inform the PL benefit.

Availability of public pricing

While benefit setting is not within the scope of the development of the assessment pathways, the requirement to provide a public price or international prices (if available) will be required by legislation for all pathways.

For applications in which a different PL benefit is sought, stakeholders raised the concept of a public price as an indicator to inform PL benefit setting. The relevance of a public price of a device that is submitted for listing on the PL was not well explained and was not supported by all participants at the workshops.

Key concerns relating to the use of a public price were:

- A public price may not necessarily reflect a cost-effective price. The HTA processes employed in the public sector are unclear.
- It was noted by some stakeholders that some devices with a public price may not be used in sufficient quantity in the public hospital sector to provide a robust signal of value. If only a few devices are used, HTA is unlikely to be implemented and procurement may not seek to negotiate on price.
- The availability of public prices, or the ability of sponsors to provide prices that may form part of a confidential agreement, is unclear.
- The ability of PL staff to verify the public price is unclear.
- As it is difficult to compel sponsors to provide public prices that may be protected by confidential agreements, it is possible that these would only be provided if they are advantageous for price setting.

Similar suggestions regarding the provision of international pricing were raised by payers.

There are clear benefits to the sustainability of the PL if international pricing is available to ensure that Australian consumers and payers are not paying substantially more than sponsors are willing to price devices in other markets. A comparison of international pricing may be relevant for a review of reimbursement for current PL benefit groups. However similar concerns were raised regarding the transparency of international pricing, and whether pricing reflects robust HTA methods. This may limit the usefulness of international prices as reference prices for the purpose of establishing value.

It is recommended that claims for increases in PL benefits, relative to an appropriate comparator, be informed by HTA for both the clinical and economic domains.

Prostheses List Reforms – Consultation Paper No 3(b) –

Pathways for Applications to the Prostheses List

Attachment B – Cost Recovery Proposal and Indicative Fees

Introduction

The Department of Health and Aged Care (the Department) invites comments in relation to the proposal for cost recovery on applications seeking listing on the Prostheses List (PL) under the new application pathways outlined in Prostheses List Reforms – Consultation Paper No 3(b) – Pathways for Applications to the Prostheses List.

This proposal amends the current cost recovery arrangements for applications seeking listing on the PL to ensure that the cost recovery arrangements are consistent with these amended application and assessment pathways.

Under the Australian Cost Recovery Guidelines, there are various government charges which may be applied:

- A **cost recovery fee** is charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation.
- A **cost recovery levy** is imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g. an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

There will be both cost recovery fees and cost recovery levies in the proposed PL cost recovery arrangements.

The new cost recovery arrangements for PL will include new activity based 'fee for service' application fees. The Department will also amend the existing levy-based fee system to reflect the costs of ongoing management of the PL. The levies will also include the costs of new post-listing review and compliance frameworks activities. These new arrangements will be consistent with the Australian Government Charging Framework (the Charging Framework)[1]. This framework requires that non-government entities using the PL services pay the minimum efficient costs of the work effort required to administer the regulation of such services.

This attachment provides additional information on the changes to cost recovery, including draft indicative cost recovery fees and draft indicative levy. Further consultation may be undertaken on the Cost Recovery Impact Statement (CRIS).

The Department is inviting responses on the cost recovery component of this consultation from those who will be affected by this proposal, including all current sponsors of PL applications.

[1] Australian Government Charging Framework

Why make changes to Prostheses List Cost Recovery?

Consistency with the Australian Government Charging Framework and the Cost Recovery Guidelines

The Charging Framework is a policy of the Australian Government. The Charging Framework covers activities where the government charges the non-government sector for a specific government activity such as, regulation, goods, services, or access to resources or infrastructure.

The Charging Framework applies to non-corporate and corporate Commonwealth entities as defined in the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). The Department is a non-corporate Commonwealth entity.

The Australian Government's cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the cost of those activities.

The Charging Framework applies to all new and existing charging activities and relates to:

- regulatory charging activities;
- charging activities involving access to public resources, infrastructure and/or equipment; and
- commercial charging activities, including the sale of goods and services and acceptance of advertising and sponsorship payments.

Under the Charging Framework, regulatory activities such as registrations, applications, monitoring and compliance are cost recovered from the identifiable entity seeking the activity, unless the Government has decided the activity will not be cost recovered.

The changes to the PL cost recovery arrangements will support consistency with the Charging Framework by ensuring that fees reflect the services provided to individual organisations. Namely, this will mean that there will be alignment between expenses of the activity and revenue where:

- the charges are clear and easy to understand;
- closely linked to the specific activity;
- set to recover the full efficient costs of the specific activity;
- efficient to determine, collect and enforce; and
- set to avoid volatility, while still being flexible enough to allow for changes based on fluctuations in demand or costs.

Existing Levy-Based Fee Arrangement

The current cost recovery arrangements for the PL are outlined under the Cost Recovery Implementation Statement – Administration of the Prostheses List. As outlined in 3.3 Design of regulatory charges, there are three levies associated with the PL:

1. An application levy of $600 per application that covers the cost of processing and assessing an application to include an item on the List.
2. An initial listing levy of $200 per prostheses that covers the cost of granting applications and adding new prostheses on the List.
3. An ongoing listing levy of $200 that is paid every six months. The ongoing listing fee is required to be paid for as long as a prostheses remains on the List. The ongoing listing fee contributes to the cost of maintaining the List, including making amendments to listing as required from time to time.

These existing PL levy arrangements do not reflect the levels of effort, cost, and complexity of current activities such as administration and evaluation undertaken by the Department as they are based on a historical model which has not been adjusted since 2009. This means that these charges have not been aligned with expenses on a yearly basis which is inconsistent with the Cost Recovery Guidelines.

Policy and Statutory Authority to Cost Recover

Statutory authority to charge, in addition to the current levy arrangements, will be implemented to allow for the charging of new fees and an amended levy. There will be changes made to the Private Health Insurance Act 2007 (the PHI Act) and the Private health Insurance (Prostheses Application and Listing Fees) Act 2007.

More information regarding legislative changes is outlined in Consultation Paper 4(a) – Legislative amendments.

Stakeholders will be provided with the opportunity to comment on legislative changes through the legislative process.

The Cost Recovery Model Proposal

Scope, eligibility criteria and application pathways

The administration of the PL and all applications received through the PL pathways will be subject to cost recovery. The following government processes are in-scope for Cost Recovery Fees:

- List Management Services:
    - List Deletions
    - List Transfers
- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical/Focused HTA Pathway
    - 2a – a clinical assessment only
    - 2b – a clinical assessment plus health economic evaluation.
- Tier 3: Full HTA Pathway (Medical Services Advisory Committee (MSAC))

Detailed information on each pathway is outlined in Consultation Paper No 3(b) – Pathways for Applications to the Prostheses List.

A Cost Recovery Levy charge the industry for costs which cannot be assigned to a specific sponsor; the Cost Recovery Levy reflects efficient overall costs of the cost recovered activities. Under the new PL pathways, the following are in-scope for the Cost Recovery Levy:

- Prostheses List Administration
- Depreciation of relevant IT systems (e.g. Prostheses List Management System)
- Compliance Assessment
- Post Listing Reviews

Who will pay the regulatory charges?

All applicants (sponsors) are charged fees for the services provided. There are currently no fee waivers and no fee exemptions offered.

Outputs and business processes of the activity

The key output activity is the Prostheses List, which is published at a minimum of three times a year in March, July and November. This will not change under the new cost recovery model proposal.

The key business processes associated with applications to list prostheses on the List first time, or amend current codes on the List are:

- application input by sponsor into the Prostheses List Management System, which is facilitated by mandatory data fields to guide integrity of the application process;
- application fee;
- applications are assessed by the Department and relevant expert clinicians for compliance with the
- listing criteria and comparative clinical effectiveness of the device;
- if the device is new or novel, benefit validation through a health technology assessment;
- the PLAC consideration of clinical and/or cost-effectiveness recommendations;
- the PLAC advice provided to the Minister or Minister's Delegate;
- granting of application by the Minister or Minister's Delegate;
- initial listing fee;
- Prostheses Rules updated; and
- ongoing listing fee.

Costs of the regulatory charging activity

Under the new cost recovery model proposal of fees in addition to an amended levy, the cost drivers for the cost recovered activity will be:

- staffing and associated costs to manage applications, provide Departmental assessment for Tier 1 applications, coordinate health technology assessment and reviews, and provide secretariat and support services to the PLAC and Clinical Advisory Groups (pending the review of governance arrangements associated with the PL listing process);
- maintenance and improvements to the IT systems that manage and store applications and related information;
- payment to clinicians and health technology assessors for application assessment and reviews;
- Committee costs (including sitting fees for members); and
- Staffing and associated costs for compliance and post-listing review services.

Services for cost recovery and Estimated Indicative Cost Recovery Fees

This section provides an outline of the activities which will be cost recovered and the indicative fees. Note that these are indicative fees only.

In line with the Australian Government Charging Framework, the costs estimated in the following tables are calculated using an activity-based cost model. The model identifies discrete activities involved for each application category and assigns the cost of all products and services required to complete the activities. This includes:

- Direct costs – These costs include the staff salaries (including on-costs for superannuation and leave) for those directly included in the activity, committee costs (e.g. sitting fees for PLAC) and supplier costs (e.g. cost of contracts for HTA evaluators and consultants).
- Indirect costs – These costs include overheads for staff directly involved in the activities using the Department of Finance's approved costing methodology. Indirect costs include staff training and development, workers compensation premium, human resources support, organisational services, desktop ICT services and property operating expenses.

List Management Services

Sponsors with existing listings on the PL are able to request minor administrative changes to these PL listings. These are sponsor-requested services and are not covered under the levy which covers ongoing administration of the PL.

Table 1

Fee Category	Activity Description	Indicative fees
List Management Services – Deletion	The following activities are included: • Assessment of the request for List Management Services – Deletion. • Administrative processing of the request if appropriate. • Notification to the sponsor when the request is completed; or notification to the sponsor if a different Tier of application is required. This fee is non-refundable if after assessment of the request, the application is deemed to be unsuitable to be processed.	$101
List Management Services – Transfer	The following activities are included: • Assessment of the request for List Management Services – Transfer. • Administrative processing of the request if appropriate. • Notification to the sponsor when the request is completed; or notification to the sponsor if a different Tier of application is required. This fee is non-refundable if after assessment of the request, the application is deemed to be unsuitable to be processed.	$101

Application submission

In all Tiers, sponsors will be required to pay a non-refundable application fee. This will cover the processing of the application through the online submission portal and assessment by the Department of whether the application is suitable to progress in the submitted Tier. If the sponsor is advised by the Department that the application is not suitable to progress in the submitted Tier, the sponsor may resubmit to another Tier, however another application fee may be payable.

Table 2

Fee Category	Activity Description	Indicative fees
Non-refundable application fee	This is required for each application submitted to Tier 1, Tier 2 and Tier 3, and payable before the application is received by the Department. The category of submissions is nominated by the Sponsor. The following activities are included: • Administrative processing of the request following submission through the online application portal. • Department assessment of application submitted by the sponsor. • Department decision. • Department preparation of relevant PL legislation. • Department invoicing for application cost recovery.	$1,310

Assessment

If an application is found to be suitable to progress to assessment, sponsors will be required to pay an assessment fee. These fees are scaled depending on the level of effort by the Department in each of the Tier pathways.

Tier 1 applications will not be required to pay an additional fee for assessment.

All Tier 2 applications will be required to pay a clinical assessment fee. Tier 2 applications which are then identified after the clinical assessment to require health economic evaluation in addition to clinical analysis, will be required to pay an additional assessment fee.

Table 3

Fee Category	Activity Description	Indicative fees
Tier 2 Clinical Assessment	This is required for each application submitted to Tier 2. The following activities are included: • Clinical and expert advice sought to assess clinical aspects of the application. • Consideration from the following committees are expected to be included in this pathway (reflected in the assessment fee):	$2,874

Fee Category	Activity Description	Indicative fees
	○ Clinical Advisory Groups ○ Prostheses List Advisory Committee This fee is non-refundable if the application does not result in a PL listing.	
Tier 2 Focused HTA Assessment	This is required for each application submitted to Tier 2 and determined to be required to progress to an economic assessment in addition to a clinical assessment. The sponsor will be notified if the economic assessment is required. This fee is paid in addition to the Tier 2 Clinical Assessment Fee. The following activities are included: • Development of an economic assessment of application. • Liaison between sponsor and the Department to inform the development of an economic assessment of application. • HTA and expert advice (supplier costs). This fee is non-refundable if the application does not result in a PL listing.	Dependent on the complexity of the analysis: Standard $8,900 Complex $17,043 Other $27,900
Tier 3 Full HTA (MSAC) Pathway Assessment Fee	This is required for each application submitted to Tier 3 and determined to be suitable to progress to assessment in Tier 3. The following activities are included: • Administrative processing of the request. • Clinical and expert advice sought to assess clinical aspects of the application. • Liaison between internal areas of the Department throughout the MSAC application process. • Department decision. • Department preparation of relevant regulation and legislation. • Department invoicing for application cost recovery. Consideration from the following committees are expected to be included in this pathway (reflected in the assessment fee): • Medical Services Advisory Committee (not included in PL application cost recovery) • Clinical Advisory Groups • Prostheses List Advisory Committee	$2,318

Risk Sharing Agreement

Table 4

Fee Category	Activity Description	Indicative fees
Risk Sharing Agreement Fee	This fee is payable where a PL found suitable for listing is subject to a Risk Sharing Agreement with the Commonwealth. The following activities are included: • Decide if complex or simple arrangement necessary (negotiations / cost-recovery) • Liaise with sponsor • Undertake work with legal team • Follow-up meeting with sponsor • Draft Deed of Agreement (AGS) • Finalise Deed of Agreement • Administration and record keeping	$23,239

Cost Recovery Levy

The cost recovery levy is payable for each billing code on the Prostheses List on a given imposition day (unless the billing code is new to the Prostheses List because an application to list a new prosthesis has just been granted by the Minister).

The cost recovery levy is payable in respect of prostheses listed on the Prostheses List on 15 March and 15 September of each year, regardless of whether the sponsor of the prostheses on the Prostheses List is still selling the prosthesis.

Sponsors may be advised that the Minister may remove the sponsor's product from the Prostheses List if the cost recovery levy is not paid.

Table 5

Levy	Activity Description	Indicative levy amount
Prostheses List Cost Recovery Levy	A cost recovery levy charges the industry for costs which cannot be assigned to a specific sponsor; the Cost Recovery Levy reflects efficient overall costs of the cost recovered activities. Under the new PL pathways, the following are in-scope for the Cost Recovery Levy: • Prostheses List Administration • Depreciation of IT systems • Compliance • Post Listing Reviews	$73 per year

Next Steps

Next steps after the consultation:

- The Department will develop an implementation plan for cost recovery alongside the new PL assessment pathways. These will be developed in accordance with the Australian Government Cost recovery framework.
- Implementation of cost recovery fees and levies would be subject to Government consideration and agreement and would require passage of legislation. More details can be found at Consultation Paper 4(a) – Legislative amendments.
- If the proposal is agreed by Government, future consultation would occur through the Cost Recovery Implementation Statement (CRIS) to ensure stakeholder concerns and regulatory impacts are addressed prior to the commencement of charging.
- Guidelines and education material would be developed to ensure clarity around changes to cost recovery for stakeholders.
- Following the implementation of new cost recovery arrangements, the Department will instigate a review of the arrangements. It is intended that this will occur approximately 18-24 months following implementation.