Australian Government
Department of Health and Aged Care

The Prescribed List of Medical Devices and Human Tissue Products Guide - DRAFT

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Version Control

This table is to record the document's history as changes are made. As each version is drafted and submitted for acceptance, update the version number and in the table record the changes made to the prior version.

Major changes should increment the version number by 1.0 and minor changes should increment the version number by 0.1.

Document Location

Version	Date	Author	Distribution	Change Description

Related Documents

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Abbreviations and Acronyms

ARTG	Australian Register of Therapeutic Goods
ECAG	Expert Clinical Advisory Group
HPP	Health Products Portal
HTA	Health Technology Assessment
MBS	Medicare Benefits Schedule
MDHTAC	Medical Devices and Human Tissue Advisory Committee
MSAC	Medical Services Advisory Committee
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Schedule
PL	Prescribed List of Medical Devices and Human Tissue Products
PHI	Private Health Insurance
The Rules	Private Health Insurance (Medical Devices and Human Tissue Products) Rules
TGA	Therapeutic Goods Administration

PART 1:
OPERATIONAL INSTRUCTIONS

Chapter 1: About this Guide

What is the Prescribed List of Medical Devices and Human Tissue Products Guide (the Guide)?

The *Prescribed List of Medical Devices and Human Tissue Products Guide* (the Guide) will assist applicants to prepare an application to list an eligible medical device or human tissue product on the Prescribed List of Medical Devices and Human Tissue Products (the PL), or to amend an existing PL billing code.

The information in this document is provided as a guide only.

Who is the intended user of the Guide?

Sponsors of eligible medical devices or human tissue products can make applications to list the product on the PL or amend the existing PL billing code. Sponsors may engage public health and health economic experts to assist their organisation to prepare an application.

This Guide will assist these people in their task. The Guide is also intended as a reference point for both industry and government, by outlining the required information and presentation of the information that meets government requirements.

Additional information and resources that support this Guide

This Guide is available as an online resource on the Department of Health and Aged Care (the department) website. The Guide is expected to be read together with the information provided in the Health Products Portal (HPP) and other information sources available on the department's website, including:

- Overview of the Prescribed List
- Cost recovery fees and charges for the Prescribed List
- Expert Clinical Advisory Groups (ECAGs) membership and Terms of Reference
- Medical Devices and Human Tissue Advisory Committee (MDHTAC) membership and Terms of Reference
- PL application forms and information on the assessment process provided in the HPP
- Prescribed List Grouping Schemes (under review)
- Deadlines for submitting PL applications
- Prescribed List reforms
- Prescribed list compliance framework and post-listing reviews
- Legislation relevant to medical devices and human tissue products

- Medical Services Advisory Committee, MBS Online, and Australian Register of Therapeutic Goods (ARTG)

Instructions on how to use the Health Products Portal are available via the HPP website.

How is this Guide structured

The Guide is divided into three parts:

- Part 1 provides operational instructions about the PL and listing arrangements
- Part 2 provides technical guidance about PL assessment pathways and applications
- Part 3 provides the appendices and glossary of terms relevant to the PL application process.

Updates to the Guide

The Guide is available as an online resource at the Prescribed List of Medical Devices and Human Tissue Products page of the department's website. Users of the Guide should ensure that they are referring to the latest version. Information on updates to the Guide will be published in Private Health Insurance (PHI) Circulars.

The department will update the Guide as required, to ensure its currency. A summary of each change will be recorded at the front of the electronic version published on the website. Stakeholders will continue to be advised about any changes via PHI Circulars.

How to provide feedback on the Guide

Feedback on this Guide is welcome and should be forwarded to the department via prosthesesreform@health.gov.au. Feedback will be collated and considered for future revisions to the Guide.

Chapter 2: Overview

What is the Prescribed List?

The Prescribed List of Medical Devices and Human Tissue Products (the PL) was formerly known as the Prostheses List.

The amendments to the *Private Health Insurance Act 2007* (PHI Act), effective 1 July 2023, provided authority for the Private Health Insurance (Prostheses) Rules to be re-named to the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* (the Rules). The Schedule to the renamed Rules is known as the Prescribed List of Medical Devices and Human Tissue Products, the 'PL' for short.

Please note that the Rules are amended from time to time. For the existing version, please search the Federal Register of Legislation. The Department also publishes the Prescribed List on its website.

Prescribed List eligible products

For a product to be eligible for listing on the PL, it must be either medical device or human tissue product, must be provided or used for a patient as part of hospital or hospital substitute treatment, and there must be a Medicare benefit payable [i.e. there must be a valid Medicare Benefits Schedule (MBS) item] in respect of the professional service associated with the use of the medical device or human tissue product. The device or human tissue product also must satisfy the criteria for listing on one of the four Parts of the PL: Part A, Part B, Part C or Part D.

Purpose of the Prescribed List

The purpose of the PL is to ensure that privately insured Australians, who have appropriate health insurance to cover the treatment, have access to clinically effective products that meet their health care needs.

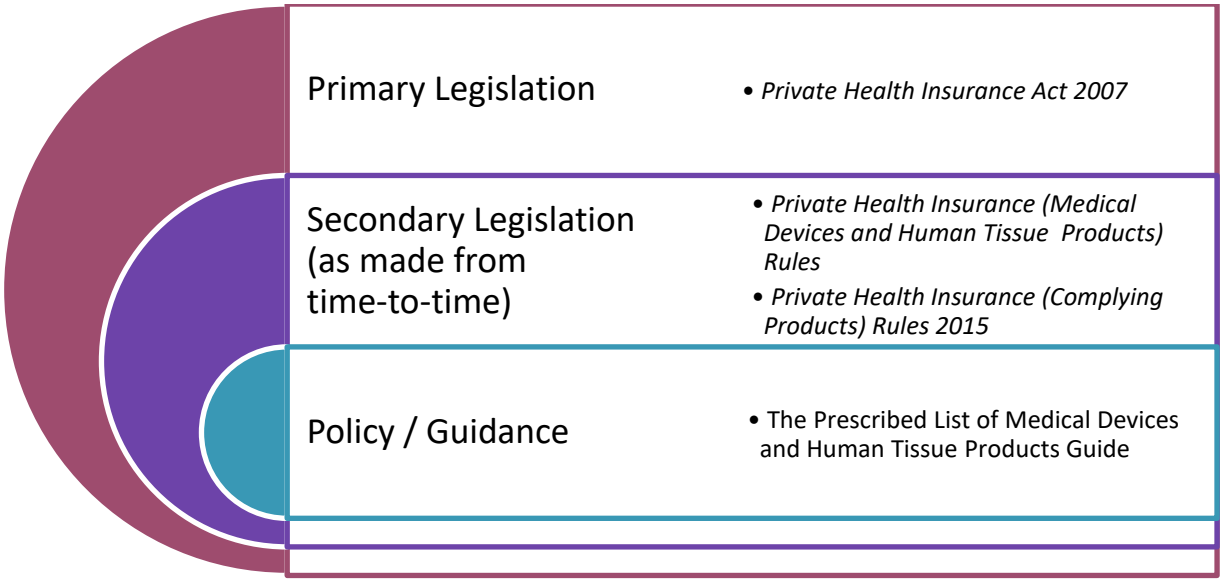
It is achieved by providing a list of medical devices and human tissue products for which private health insurers are required to pay minimum benefits when these medical devices and human tissue products are provided to or used for a person with appropriate private health insurance cover.

The arrangements for including products on the PL help to ensure that benefits paid by insurers are relative to clinical effectiveness and comparable to prices paid in other sectors.

What is the relevant legislation?

The legislative framework for the PL encompasses a range of primary legislation, secondary legislation and policy and guidance material, as outlined in the diagram below.

Figure 1: Legislative framework for the PL



There may also be other legislation relevant to products listed on the PL, including state and territory legislation (e.g., Human tissue products are governed by state or territory law), consumer law, therapeutic goods legislation, etc.

Users of this Guide are responsible for familiarising themselves with the relevant legislation.

The Private Health Insurance Act (2007)

The PHI Act provides for the Rules to specify minimum benefits that must be paid for products listed in the Rules. These benefits are specified for each product in a schedule to the Rules (the PL).

The PHI Act also provides for the Rules to include listing criteria that must be satisfied by the product for an application to be granted.

The PHI Act includes definitions for 'medical device' and 'human tissue product'.

The definitions in the PHI Act and the listing criteria in the Rules operate together to define the kinds of products that are eligible for inclusion in the PL, and for which minimum benefits must be paid.

Where the Minister for Health and Aged Care (the Minister) decides to grant an application, the Minister must make the Rules as soon as practicable to add the product to the Rules (see, Ministerial decisions on applications).

The Minister re-makes the Rules at least 3 times a year. The Rules are then registered on the Federal Register of Legislation and are tabled in both Houses of Parliament. Following tabling, either House of Parliament may disallow the instrument within 15 sitting days.

Structure of the Prescribed List

The PL has four parts:

- Part A – consists of medical devices used for specific therapy (not general use) that must be either surgically implantable devices, or be essential and specifically designed as an integral single-use aid for implanting a device, or be critical to the continuing function of the surgically implanted device
- Part B – consists of human tissue products (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 – covers the specified groups of medical devices stated in the Rules that do not meet the listing criteria for Part A, but which the Minister considers suitable for benefit payments by private health insurers
- Part D – covers the general use items. These items are planned for removal on 1 July 2024.

Some information in this Guide is applicable for all Parts, while other information is specific to one or some Parts. The Guide will specify which information relates to which Part.

Medical devices and human tissue products grouping scheme

There are currently 13 categories of medical devices listed on Part A, 4 categories of human tissue products on Part B, 4 categories of medical devices in Part C, and 3 in Part D.

The categories have sub-categories, groups, and sub-groups, that are identified numerically, and alphabetical suffixes, where applicable. This scheme determines the benefits payable for

the devices or human tissue products. For simplicity, the final benefit point (e.g. sub-group, if there is no suffix, or sub-group and suffix, if there is a suffix) often referred to as grouping.

Medical devices and human tissue products are grouped according to similar characteristics, functionality and clinical features.

The current grouping structures for Part A and Part B products are under review.

Billing codes and catalogue numbers

The billing code is a unique identification code allocated to a listed product for the purposes of facilitating hospital claims and invoicing, and payment of benefits by insurers. Each billing code is listed in a particular grouping (group, sub-group and suffix, as applicable) with a specific individual benefit amount assigned to the grouping, that is the minimum benefit, private health insurers are required to pay.

The billing code may only be listed in one place on the PL and may cover:

- a single product with no variations in any characteristics identified by one catalogue/product number (e.g., one model of the pacemaker; or one specified product listed on Part B), or
- a product with variations in some characteristics identified by multiple catalogue/product numbers if these products:
  - are marketed under the same product name or belong to the same product family
  - have sufficiently similar design, characteristics, functionality and/or intended purpose (e.g., orthopaedic plates used in the same body part, manufactured by the same manufacturer[1], with the same design/shape and purpose, but supplied in different lengths and widths), or
- a kit, pack, tray, system, etc consisting of two or more medical devices, or a medical device and other products, that are designed and intended to be used together:
  - identified by a single catalogue/product number; or
  - each component of the kit, pack, system, etc is identified by one catalogue number and there are no variations in any characteristics of any of the individual components or composition of the kit, pack, or system (for example, an artificial heart valve with a delivery catheter and a steerable sleeve), or
- a kit, pack, tray, etc consisting of two or more medical devices, or a medical device and other products, that are designed and intended to be used together, and one or more components have variations in some of the characteristics but all components are marketed under the same product name or belong to the same product family and have sufficiently similar designs and characteristics (e.g. spinal cages of different sizes

[1] Manufacturer is defined in the Glossary

together with the plates of different sizes and screws of different sizes, where a cage and a plate and a number of screws are designed to be used and claimed together as a unit).

For products to be eligible for listing under the same PL billing code, evidence that the products are sufficiently similar and belong to the same product range/product family and manufactured by the same manufacturer is required.

A billing code cannot belong to more than one sponsor and the sponsor stated for the billing code must be the same as the sponsor stated on the Australian Register of Therapeutic Goods (ARTG) entry relevant to the product.

If a billing code has been deleted, the same billing code will not be reused in the future.

New billing codes are created following successful new applications, expansion, compression, or sponsors' transfer applications.

Health technology assessment in Australia

Efficient and effective health technology assessment (HTA) processes are crucial to supporting sustainable management of funded health technologies. Consistent application of evidence across Australian Government HTA processes is an important element in ensuring not only stakeholder confidence by creating certainty in how decisions regarding the funding of health technologies are made and reviewed over time, but also ensuring decisions represent value-for-money.

There are several bodies in Australia that contribute to the regulation and reimbursement of health technologies in Australia, including: the Therapeutic Goods Administration (TGA); the Medical Services Advisory Committee (MSAC); the Pharmaceutical Benefits Advisory Committee (PBAC); and the Medical Devices and Human Tissue Advisory Committee (MDHTAC) which have some level of inter-dependent relationships. Each entity has discrete functions and responds to different policy needs.

For further information on the HTA assessment see Role of health technology assessment groups.

Application requirements and assessment pathways

All PL applications must provide sufficient information to demonstrate that the below is correct:

1. the product meets the definition of 'medical devices' or 'human tissue products' as outlined in the PHI Act (from 1 July 2023, refer 72-11 – Meaning of medical device and 72-12 – Meaning of human tissue product).
2. there is at least 1 existing MBS item appropriately describing the Medicare service relevant to use of the device or human tissue product for treatment provided in hospital or hospital substitute [MBS items and use of device for hospital treatment]
3. the device or human tissue product is always used in hospital or hospital substitute treatment, or can be used in both hospital treatment and outside the hospital
4. the grouping stated in the new application or for the billing code [in amendment, compression, expansion application] is correct for all devices identified by catalogue numbers in the application or listed for the billing code

5. the comparator stated in the application is correct, has similar functionalities, characteristics, and is used for the same or sufficiently similar indications and purposes
6. the product name, description and size are clear and consistent with the devices or human tissue products in the application/billing code and with the grouping
7. the device or human tissue product meets all required listing criteria which are set up in the Rules.

There are three listing pathways (Tiers 1-3) for the assessment of new, amendment, expansion and compression PL applications, with the evidence requirements tailored for each pathway. These arrangements currently apply to Part A and Part C applications. Processes for Part B applications are still being finalised.

See Part 2 for further information on the application assessment and evidence requirements.

Role of the sponsor

Sponsors are responsible for applying for listing of their medical devices and human tissue products on the PL or amending the existing billing codes using the HPP and providing all information required to inform the assessment and decision-making process. This includes selecting the appropriate assessment pathway (see, Part 2) and completing the appropriate HPP application form.

Sponsors also have a responsibility to ensure the information provided is complete and correct. Failure to do so will result in the application being rejected or a delay in the assessment process.

Sponsors should endeavour to submit a complete application that allows and informs proper assessment at the time of lodgement and should not assume that they will always have additional opportunities to provide the required information.

Role of the responsible Minister

The Minister is responsible for administration of the PHI Act. The Minister makes decisions on whether to list a medical device or human tissue product on the PL or amend the existing billing code and whether the conditions are to be placed on the billing code. The Minister is also responsible for giving effect to these decisions by making or updating the Rules or other legislative instruments.

Under section 333-1 of the PHI Act, the Minister may delegate responsibility to people occupying certain positions within the department (the Minister's Delegates).

Role of the Medical Devices and Human Tissue Advisory Committee (MDHTAC)

The MDHTAC is a Ministerially appointed committee with the Chair, and membership consisting of six Chairs of the Expert Clinical Advisory Groups (ECAGs), up to two independent members with expertise in the medical technology and/or HTA who are not members of any of the ECAGs, and a consumer member. The ECAG Chairs provide a connection between the MDHTAC and the respective ECAG, with each Chair leading the discussion on the matters related to their ECAG.

The MDHTAC's membership and Terms of Reference can be found on the department's website.

The primary role of the MDHTAC is to make recommendations to the Minister and advise the department about the suitability of products for listing on the PL, and their associated benefits, or on amending the details of the existing billing codes (for the products already listed on the PL), or on any other post-listing activities as required. The MDHTAC's recommendations and advice are based on an assessment of comparative clinical effectiveness and cost-effectiveness of products using the best available evidence compared with other similar products already listed on the PL or alternative treatments. Although it is the TGA's role to oversee safety, safety will be considered as part of the effectiveness of the product. The MDHTAC may request further information regarding certain applications or issues and may refer certain matters to MSAC based on the need for HTA advice.

When making recommendations, MDHTAC consider eligibility of medical device or product for listing on the PL, criteria for listing, the correctness of the grouping for all medical devices or human tissue products in the application, comparative clinical effectiveness, comparative cost-effectiveness (where sponsors apply to list the device in a new grouping or due to other factors), predicted use and financial implications for the PL, and other related matters.

The MDHTAC meets three (3) times per year to consider PL applications, and to discuss other matters relating to listing arrangements. The MDHTAC takes a consensus approach to making recommendations about listing medical devices on the PL. Where a recommendation or decision cannot be reached by consensus, it is determined by a majority vote of members. In the event of a tied vote, the Chair will cast the deciding vote. The MDHTAC may also discuss and resolve matters out-of-session.

The MDHTAC deliberations and recommendations are recorded in Minutes, however they are not published as the information considered by the MDHTAC and its subcommittees is commercial-in-confidence. All members are required to sign a deed of confidentiality and to disclose any conflicts of interest.

Role of the Expert Clinical Advisory Groups (ECAGs)

The ECAGs are sub-committees of the MDHTAC, with membership that is reflective of a broad cross-section of contemporary clinical practice in Australia.

There are currently six (6) ECAGs:

- Specialist Orthopaedic ECAG (including shoulder, ankle, foot, upper limb and skeletal reconstruction) (SOECAG)
- Hip and Knee ECAG (HKECAG)
- Ophthalmic ECAG (OECAG)
- Spinal and Neurosurgical ECAG (SNECAG)
- Cardiovascular ECAG (including cardiac, cardiothoracic and vascular) (CVECAG)
- General Surgery ECAG (including ear, nose and throat, plastic and reconstructive surgery, urogenital and all other general surgery devices) (GSECAG)

The membership and Terms of Reference for the ECAGs can be found on the department's website.

The primary role of the ECAGs is to assess the clinical functions and comparative clinical effectiveness of medical devices (and in some cases human tissue products) being considered for listing or listed on the PL in the applications submitted through Tier 2 and Tier 3 Pathways.

The ECAGs also consider the comparators (either listed on the PL or alternative treatment), and appropriateness of the proposed groupings, and advise on the correct grouping (where required) and other matters as applicable.

The ECAGs' deliberations and recommendations including statements of reasons are recorded in the ECAGs meetings Minutes that inform the advice to the MDHTAC. These Minutes are not published as the information considered by the ECAGs is commercial-in-confidence.

ECAG members are required to advise the department of any potential conflicts of interest that may arise and if conflicts of interest are declared, the respective members are excluded from assessment and discussion of the respective applications.

Role of the department

The arrangements for the PL are administered by the department. The relevant functions of the department include:

- undertaking departmental assessments and providing advice to sponsors (all Tiers)
- working with ECAGs on the clinical assessments for Tier 2 and Tier 3
- commissioning HTA for Tier 2 when required and working with MSAC on Tier 3 applications
- working with and providing support to the MDHTAC in making recommendations
- providing recommendations and making decisions on listing the products, or amending the existing billing codes, and setting up benefits as required
- making the legislative instruments (the Rules) and maintaining the PL
- maintaining the HPP (enabling access for sponsors, external assessors and departmental staff)
- administering PL cost-recovery arrangements
- developing and implementing policy on private health insurance funding of medical devices and products
- updating guidance material and relevant legislation as required
- providing advice to and facilitating discussions with sponsors and other stakeholders about the PL arrangements
- commissioning, coordinating and/or undertaking post-listing reviews when required
- maintaining and providing advice on the compliance, assurance and enforcement principles and provisions to support the effective administration of the PL compliance capability.

If sponsors have any questions (after they considered the Guide) regarding the application process, they may contact the department at prostheses@health.gov.au. When sponsors submitted their applications, they may contact the department via HPP. The department is

also the primary contact for any queries regarding any other matters concerning Prescribed List.

All sponsor-specific information lodged via the HPP or provided during any meetings or discussions is treated as Commercial-in-Confidence and managed accordingly. Sponsors or stakeholders should not directly contact ECAG or MDHTAC members. Members of the committees will not engage with stakeholders who are seeking information on the rationale for the committee recommendations.

Role of health technology assessment groups (HTA groups)

A HTA group may be engaged when clinical effectiveness and/or cost-effectiveness assessment of the products is required.

This may occur when sponsors apply for new groupings and benefits for their products claiming improved/different characteristics compared with the existing products listed on the PL. The assessment reports will be provided to the MDHTAC together with other assessments for the products.

Role of the Medical Services Advisory Committee (MSAC)

MSAC provides advice to government on whether a medical service or health technology or program should be publicly funded under the MBS or other programs. Where a full HTA is required (for applications assessed under the Tier 3 Pathway), an application must also be made to MSAC. MSAC oversees the HTA process and provides advice to the MDHTAC and department that informs assessment of the PL application.

Recommendations by the Medical Devices and Human Tissue Advisory Committee

The MDHTAC considers the applications and make recommendations.

Recommendations for the new application may include that the device is suitable for listing on PL, suitable but not in the sponsor proposed grouping and/or subject to some changes in the application, or not suitable for listing.

MDHTAC usually does not consider applications for human tissue items [although recommendations by the department are either suitable or not suitable for listing on the PL].

For the amendment, compression and expansion applications, the recommendations may be that the application is accepted, accepted subject to some changes to the billing code and/or application, or application is not accepted.

If the medical device or human tissue product is not yet included in the ARTG, a provisional recommendation may be made that it is suitable for listing, subject to inclusion of the device or human tissue product in the ARTG. For further information see, Parallel Process.

MDHTAC may also recommend placing a condition on the billing code restricting the circumstances when the insurers have an obligation to pay the benefit for the billing code (e.g., limiting payment to the use of the medical device in the procedures described by specified MBS items).

Ministerial decisions on applications

MDHTAC recommendations will be provided to the Minister who may decide whether to grant or not to grant the application or amend the billing code.

Where the Minister decides to grant or accept an application, the Minister will make the Rules as soon as practicable to add the product in the Rules or amend the details of the billing code.

Post-listing reviews

Post-listing review of listed medical devices or human tissue products will be undertaken where specific concerns have been identified. These will occur in accordance with the Post-listing Review Framework.

The department is responsible for commencing, conducting and implementing the findings of post-listing reviews. The sponsors also play a crucial role in providing the required information and data to enable the review.

Post-listing reviews may be targeted (for example, using focussed HTA) addressing specific issues, or analysing utilisation data, or complex post-listing reviews (including incorporating full HTA). Larger reviews may incorporate reports from independent external consultants. Reviews may involve a single billing code for the device or human tissue product, or a group billing codes, or multiple groups or sub-groups of billing codes.

A range of actions arising from a review can include, but are not limited to, deleting the billing code from PL, correcting the listing details of the billing code, changing the benefit for the billing code, and/or placing the condition on the billing code.

Once a review is commenced, affected sponsors will be notified by the department. During the review process, sponsors will be contacted and requested to provide information and evidence as required to inform the review. If a consultant report is commissioned, sponsors will be asked to review and provide feedback on the draft report. A post-listing review process may take 3 to 12 months, or longer, depending on complexity.

Removal of a product from the Prescribed List

The department may consider if a device or human tissue product should be removed from the PL, and MDHTAC may provide advice in relation to this. The reasons for such decisions may vary but may include, for example, if the device does not satisfy the criteria for listing, or where there is cancellation or suspension of the ARTG entry by the TGA for the device, or the billing code is listed in an incorrect group.

If such action is being considered, the department will write to sponsors informing them of the consideration and offering them the opportunity for comment. If the sponsor provides further information or evidence to support continued listing, the matter may be referred to an ECAG and/or MDHTAC for further advice.

If the department recommends removing the billing code, the matter will be referred for the decision the next time the Rules are made.

Removed from ARTG

Sponsors are required to inform the department as soon as practicable if their device or human tissue product is cancelled or suspended from the ARTG and submit a deletion application for removal of the respective billing code from the PL. If no deletion application is received, the recommendation will be provided to the Minister to delete billing code from the PL.

Compliance and assurance

The compliance and assurance function was established to maintain the integrity of the PL. Under this function, the department will continue to monitor the actions of PL stakeholders (hospitals and day clinics, clinicians, sponsors of medical devices and human tissue products, and private health insurers) and the operations of the PL for compliance with the requirements of the PL, as outlined in legislation and policy documents.

Where the department identifies inappropriate behaviour related to a PL listing, it may make a referral to the relevant regulator, such as the Australian Prudential Regulation Authority (APRA), the Australian Competition and Consumer Commission (ACCC) or the TGA.

The department is committed to preventing the occurrence of fraud and other inappropriate practices that pose risks to the administration of the PL. Any concerns relating to the PL related issues can be sent to prosthesescompliance@health.gov.au.

Information on compliance and assurance activities, including the PL Compliance Strategy, can be found on the department's website.

Parallel assessment for PL and TGA applications

For medical devices and human tissue products to be legally supplied in Australia, they must have a valid ARTG entry (information about inclusion in the ARTG can be found on the TGA website). Consequently, one of the criteria for medical devices and human tissue products to be eligible for listing on the PL is current inclusion in the ARTG.

Under the parallel assessment process, sponsors may submit a new application for listing a device or human tissue product on the PL, before they receive an ARTG entry for the same medical device or human tissue product, but they must provide appropriate evidence of a valid effective application 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. The application submitted to the TGA must state the same sponsor as stated in the PL application.

The TGA applications acceptable for the parallel process are:

- application for inclusion of a kind of medical device or human tissue product in the ARTG, or
- medical device conformity assessment application.

The application must be submitted, paid and accepted for the assessment by the TGA before it can be used in the PL application submitted under the parallel assessment process.

The following applications are not acceptable: manufacturer's evidence applications, device change request applications, or variation applications.

PL applications submitted under the parallel assessment process will be assessed (as required according to the Tier stated in the application), but no decision will be made regarding listing the device or human tissue product on the PL until a valid ARTG entry is issued by the TGA.

If at any time during the assessment, it becomes apparent that the application with the TGA is no longer valid (withdrawn, rejected or lapsed), the PL application will also be considered invalid.

PL applications received with a valid TGA application [but without a valid ARTG entry] will be deferred for a maximum of 18 months from the date the application was submitted. After 18 months, the application will be considered as non-compliant and may be recommended as not acceptable.

If the application is rejected, the sponsor will need to submit a new application and pay related fees.

Chapter 3: Criteria for listing products on the Prescribed List

The Rules set out the criteria for listing that products must satisfy to be considered for listing on the PL and remain to be listed on the PL.

General listing criteria

Medical devices and human tissue products will not be listed on the PL unless they are included in the ARTG. This ensures that the department can independently verify that the device or human tissue product may be legally supplied in Australia.

Listing criteria for medical devices to be listed in Part A

The Rules specify that a medical device must not be listed in Part A of the PL unless the prescribed criteria for listing are satisfied.

The below is an extract from the Rules.

The medical device:

(a) must be an implantable medical device, or an active implantable medical device, that is designed to:

(i) replace an anatomical body part or

(ii) combat a pathological process or

(iii) modulate a physiological process or

(b) must:

(i) be specifically designed as an integral single use aid and be essential for implanting a device mentioned in paragraph (a) and

(ii) be designed for use for the patient in whom the device mentioned in paragraph (a) is intended to be implanted or

(c) must be:

(i) critical to the continued functioning of an implanted device mentioned in paragraph (a) and

(ii) only suitable for use by the patient in whom the device mentioned in paragraph (a) is implanted.

The meaning of 'implantable medical device' and 'active implantable medical device' is the same as provided in the Therapeutic Goods (Medical Devices) Regulations 2002.

Single-use device means a device that is intended to be used on one individual during a single procedure and once used, the device cannot be used again and may only be discarded, and the expression 'integral' has its common meaning.

These criteria effectively mean that there is an implantable device in (a) [listed or to be listed on the PL] with which the devices in (b) or (c) are designed to be used with. Non-implantable devices do not meet the Part A criteria for listing if such connection in the design does not exist.

A medical device for listing in Part A must not be designed to be solely used for diagnosis, prediction or prognosis.

A medical device must be for a specific treatment and indication.

This means that the medical device is specifically designed to deliver the main treatment or be part of the main treatment rather than be designed to be supplementary to the main treatments or provide general support during a variety of different procedures.

A medical device must be assessed to be no less clinically effective than the alternative devices listed on the PL or the alternative treatments [***the comparators***] and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.

For the devices that are sufficiently similar to other comparator devices already listed on the PL, sponsors are required to demonstrate similarity in respect to the designs, materials, characteristics, etc of their device with the existing devices and provide sufficient evidence to demonstrate that their device is no less clinically effective than the comparators. If application is successful, the billing code will be listed in one of the existing grouping with the benefit set up for that grouping.

However, for the devices for which there are no similar devices listed on the PL, sponsors are required to provide comparison with the available treatments that are considered to be the current standard of care for the same condition or indication. The assessments of comparative clinical effectiveness and cost-effectiveness are required to establish eligibility of the device for listing on the PL and set up an appropriate benefit.

Listing criteria for human tissue products to be listed in Part B

Only human tissue products may be listed in Part B of the PL (as defined in section 72-12 of the *Private Health Insurance Act 2007*) as per s14 of the Rules.

Listing criteria for medical devices to be listed in Part C

Part C lists medical devices from specified groups explicitly stated in section 15 of the MDHTP Rules. These groups are stated below.

(a) an insulin infusion pump
(b) an electronic device and software designed to control an insulin infusion pump
(c) an implantable cardiac event recorder
(d) a cardiac home/remote monitoring system
(e) an irrigated cardiac ablation catheter
(f) a mapping catheter for catheter cardiac ablation
(g) a patch for cardiac ablation
(h) a monopolar device for surgical cardiac ablation
(i) a bipolar device for surgical cardiac ablation
(j) a system for surgical cardiac ablation
(k) a probe for surgical cardiac ablation
(l) a Non irrigated cardiac ablation catheter
(m) an intracardiac electrophysiology catheter
(n) a vascular drug eluting balloon catheter
(o) a coronary drug eluting balloon catheter
.(p) a radiofrequency delivery device for transurethral water vapour ablation (TUWA).

Note: The *Private Health Insurance (Medical Devices and Human Tissue Products) Rules* may be varied from time to time to add additional devices to or remove devices from the list above. Always refer to the MDHTAC Rules for the current Part C criteria.

Part C is considered for the devices that do not meet the criteria for listing in Part A, i.e., these devices are not implantable devices or devices intended to be used in associated with an implantable device.

A medical device must be assessed to be no less clinically effective than the alternative devices listed on the PL or the alternative treatments and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.

The process for addition of a new group to the Part C criteria for listing is usually triggered when the department receives a PL application. The respective Expert Clinical Advisory Group (ECAG) will be tasked to assess the device to establish its clinical effectiveness but also consider the clinical need and reasons for addition of this type of device on Part C. ECAGs assess the appropriate clinical data and published evidence directly related to the devices, data for a different device and testimonials from clinicians are not taken as sufficient evidence of clinical effectiveness (for the clinical evidence requirements for different device categories see, ECAG clinical requirements).

Following assessment by the ECAG, MDHTAC will consider ECAG's advice, the clinical effectiveness, clinical need for the device, benefits the device may provide (e.g. it is less invasive than an alternative device or treatment, or delivers better care to patients, or it has a significantly lower cost than the alternative device, or improves access or acceptability of treatment for a patient group), other factors, and will provide their view [support or not support] on whether to seek the Minister's decision regarding amending Part C criteria for listing.

Overall, it is expected that MDHTAC will look at the proposed devices on an exceptional

basis when considering addition of any new specified group on the criteria for listing.

If MDHTAC provided its support for seeking the Minister's decision regarding changing Part C criteria, the department will follow-up the established protocol for approaching the Minister and providing the required information to inform the Minister's decision.

The Minister may have regard to the MDHTAC advice, although the Minister may also consider other matters, including whether the requested change to Part C is consistent with the PL intent and the PL reforms aiming at clarifying the scope of the PL and improving the sustainability of the private health insurance.

If the Minister approves change to the Part C criteria for listing by including an additional type/group of devices, the department will advise the sponsor and will publish the PHI Circular advising stakeholders about this decision.

The next step will be proceeding with setting the benefit for the new group. For this process see sections on Tier 2b and Tier 3 assessments.

Chapter 4: Cost recovery

Cost recovery associated with applications relating to medical devices

Sponsors who are seeking to list a medical device on the PL will be required to pay cost recovery fees when they request services from the department, including when they submit an application in the HPP. Cost recovery fees are not applicable to listing applications or variation applications relating to products in Part B of the PL. Information on key dates and fees payable for each Tiers of application will be available on the department's website.

All cost recovery fees are aligned with the Australian Government Charging Framework and e Cost Recovery Guidelines. All details relating to the services that are included in cost recovery fees and the financial and non-financial performance of the cost recovery arrangements are available through the Cost Recovery Implementation Statement (CRIS). The CRIS is updated and published on the department's website at a minimum of once annually. The CRIS is updated when there are changes to the cost recovery arrangements, including new fee amounts.

For the purposes of cost recovery, fees are payable for all listing applications and all variation applications relating to medical devices on the PL. This categorisation includes the following application types:

- new listing application – for listing a medical device on the PL
- variation applications:
  - amendment application for changing details of billing code
  - expansion application for expanding billing code
  - compression application for compressing two or more billing codes

There will be no fee payable for the following applications:

- application for sponsors' transfer of a current billing code
- deletion application for deleting billing code.

Fee categories

The new fee categories for the PL have been constructed to align directly with the new application Tiers. The fee categories are defined in legislation and are reflective of the specific work associated with each application Tier. For the existing Rules with the fees, please search the Federal Register of Legislation.

These fees include the following:

- standard Application Fee (applicable to all applications regardless of Tier)
- clinical Assessment Fee (applicable to all applications classified as Tier 2a, Tier 2b, Tier 3)
- standard Economic Assessment Fee (applicable to Tier 2b applications)
- complex Economic Assessment Fee (applicable to Tier 2b applications)
- other Economic Assessment Fee (applicable to Tier 2b applications)
- full HTA Assessment Fee (applicable to all Tier 3 applications)[2]

A complex Economic Assessment Fee is applicable if the application requires economic assessment from an external HTA Group to establish cost-effectiveness for a single device to which multiple clinical purposes are attributed. The application may also incur a complex Economic Assessment Fee if the application involves related devices.

The other Economic Assessment Fee is applicable if the application requires the preparation of 'fit-for-purpose' cost-effectiveness advice from an external HTA Group that extends beyond a critique of the information supplied by the applicant.

The costs attributed to the other Economic Assessment Fee include the development of a commentary (or appraisal) of the economic claims, performed by the external HTA group, and, for the evaluation performed by ECAG and MDHTAC. All fees also include the costs associated with any administrative work completed by departmental staff. The difference in the economic fees is a direct reflection of the level of work effort involved in undertaking the various assessments and preparing all necessary documentation.

Further information on the specific tasks and activities that contribute to each of the above listed fees is available in the CRIS.

Payment of fees

The standard application fee is due and payable at the time an application is submitted through the HPP. This fee is non-refundable.

For all other fees, the fee must be paid within 28 days of an invoice being issued by the department. It is important to note that assessment of an application may not occur, and decisions associated with an assessment may not be provided until all outstanding fees are paid.

[2] Please note this fee only includes the Prescribed List component of work and does not include any future fees that may be payable for MSAC assessment

Withdrawal of applications and refunds

Sponsors are permitted to withdraw their application at any stage of the application process. However, it should be noted that all cost-recovery fees are non-refundable except in the instances that an applicant has overpaid or, in the instances that exceptional circumstances apply that render a refund required. Exceptional circumstances include instances of overpayment as a result of fee waiver deemed eligible post payment of cost recovery fees or overpayment as a result of a request to review certain decisions related to cost recovery fees. See Reviewable decisions section for more information.

If an application is withdrawn, or if an application has been rejected (not granted or not approved), the sponsor may decide to re-submit an application. The sponsor will be required to pay the application and assessment fees for such re-submission application.

Fee waivers

A fee waiver may be granted for applications seeking listing of 'related medical devices' in instances where an abridged clinical assessment or economic assessment can be conducted.

Medical devices in the applications are related if they are designed to be used together (e.g. the main device and accessories) for an expected clinical outcome and the information to be assessed (including product material and clinical data) is common for all devices. Sponsors may request a waiver when submitting an application in the HPP and provide reasons for the request together with supporting documents.

The number of waivers granted is a decision at the discretion of the Minister's Delegate.

Fee exemptions

An exemption may be granted for applications under Tier 3: Full HTA (MSAC) Pathway where an application have undergone a clinical assessment and/or and economic evaluation prior to being identified as requiring a Full HTA (MSAC) Pathway assessment. In this circumstance, for cost recovery purposes, the Full HTA (MSAC) Pathway assessment fee may be exempted on the basis that the assessment can be reduced. Note this provision only relates to the services provided for the assessment of the medical device. Any services provided by the department in relation to the MSAC application are not included in the calculation of these fee amounts, and fee exemptions granted for PL fees would not apply to MSAC services.

Reviewable decisions

If a sponsor believes that a decision made in relation to the need for clinical assessment, economic assessment or Full HTA, to the issuing of refund, or to the granting of fee waivers is incorrect, they are able to request a review of that decision. Review requests must be made in writing to the department within 10 days of issue of reviewable decisions.

Cost recovery levy

A cost recovery levy is payable once annually for each billing code the sponsor has listed on the PL. The levy will commence from 1 July 2024. Details relating to the cost recovery levy will be available on the department's website and through the CRIS.

PART 2:
INFORMATION TO BE PROVIDED IN THE APPLICATION

Chapter 5: Making an application

Health Products Portal

All PL applications are required to be submitted via the HPP.

To access the HPP, sponsors are required to have a myGovID (an Australian Government recognised identity) linked to an organisation via Relationship Authorisation Manager (RAM).

Knowledge base articles are provided in the HPP alongside the application to assist sponsors to complete each page of the application. HPP guidance will link back to this Guide where relevant.

For further information on the HPP, please visit the website [Health Products Portal].

Application cut-off dates

The Rules are made 3 times per year updating the PL on 1 March, 1 July and 1 November. The deadlines for submitting applications are provided below:

Submission closes	**PL update**
Midnight[3] of the 2nd Sunday in January	July
Midnight of the 2nd Sunday in May	November
Midnight of the 2nd Sunday in September	March (the following calendar year)

The information on the due dates for the sponsors' transfers and deletion applications, and providing ARTG entries in the deferred applications will be included at a later date.

Application types

Applications may be made for listing medical devices on Part A or Part C, and human tissue products on Part B of the PL.

Presently no applications are considered for listing devices on Part D due to the scheduled removal of general use items from the PL in July 2024. Further information on the general use items is available on the department's website.

[3] For the avoidance of doubt, this is to be read as the midnight between the Sunday and Monday.

Sponsor my submit the following types of PL application in the HPP:

- new listing application – for listing a medical device on the PL
- variation applications:
  - amendment application for changing details of billing code
  - expansion application for expanding billing code
  - compression application for compressing two or more billing codes
- application for sponsors' transfer of a current billing code
- deletion application for deleting billing code.

New applications

Sponsors may apply for listing medical devices or human tissue products on the PL using new applications. Usually new applications are used for first time listing of a device or human tissue product on the PL, but this application also may be used if a sponsor needs to apply for re-instating a device or product on PL or obtain a new separate billing code for a different sponsor.

For any new applications containing more than one catalogue number, sponsors are required to ensure that all catalogue numbers stated in the application are for sufficiently similar devices with minor changes in design characteristics to be eligible for listing under the same billing code and grouping is correct for all devices in the application [Billing codes and catalogue numbers].

When new applications are successful and granted, new billing codes are listed on the Prescribed List for the sponsor, covering the respective medical devices or human tissue products, next time then the MDHTP Rules are made.

Variation applications

Sponsors may use ***amendment application*** to apply for changing the details of the existing billing code. This may include deletion or addition of catalogue numbers recorded for the billing code, amending product name, description or size, addition or replacement of ARTG entries, changing the grouping the billing code is listed in.

Where sponsors apply to amend the product name, description or size in order to clarify or correct information currently recorded for the billing code, the application may fit the parameters for Tier 1 assessment pathway.

But when sponsors apply to change the grouping, the billing code is listed in, the application is required to be submitted under Tier 2 or Tier 3 pathway.

When sponsors apply to add catalogue numbers to the billing codes, sponsors are required to provide evidence that the devices in the application and devices already listed for the billing code are sufficiently similar in design and other characteristics to be eligible for listing together [Billing codes and catalogue numbers].

Amendment applications do not delete or create any existing billing codes.

Expansion and compression applications are used for expanding the billing code covering multiple devices into two or more new billing codes or compressing multiple existing billing codes into a single billing code respectively. This may occur when the single billing code covers different ranges of devices that are not expected to be listed together (expansion application), or very similar devices that are not expected to be split (compression applications).

It is not usually expected that sponsors use expansion or compression applications for changing the groupings for billing codes. However, there may be exceptions. For example, when it has been discovered that subgroup or suffix are incorrect for the devices with some catalogue numbers recorded for the billing code, in such instances, sponsors may apply to split the devices in order to list them in correct groupings under different billing codes.

Successful expansion and compression applications result in deletion of the existing billing codes and creation of new billing codes.

For Part B applications, sponsors do not usually apply for expanding or compressing billing codes. Sponsor however are able to use variation application for changing ***benefits for multiple Part B billing codes***, instead of lodging multiple applications.

Sponsors of any applications may choose to ***re-apply*** if there is a negative decision regarding their application. In such instances, sponsors will need to address the concerns raised during the assessment and recommendation when they resubmit their application and provide all required information. HPP functionality will allow information from the previous application to be pre-filled in the resubmission application. Sponsors will be required to pay the fees for such applications [Withdrawal of applications and refunds].

The information and evidence required may vary depending on the PL Part and type of application. For assessment of applications see, Assessment of Part B and Assessment of Part A and Part C.

Deletion applications

Sponsor may submit deletion application to delete the existing billing code from the PL.

Sponsors' transfer applications

Sponsors may also apply to transfer the billing codes to different sponsors by submitting sponsors' transfer applications.

Sponsors' transfer applications are used when the ownership of the medical devices or human tissue products listed under one or more billing codes is transferred to another company (e.g., business was sold, acquired, merged, etc.), or company name has changed. The receiving company is responsible for submitting this type of application, but the transferring sponsor is required to provide documentary evidence of the business transaction and agreement/authority to transfer the billing codes (e.g., letter or agreement of sale, etc).

The receiving sponsor also must provide evidence that ARTG entry has been amended with the name and details of the new sponsor. If the receiving sponsor does not have a valid ARTG entry in their name, the PL sponsors' transfer application will not be accepted.

Assessment of Part B applications

Part B lists human tissue items, including donated human tissue such as bone, corneas and heart valves and products that are derived substantially from donated human tissue. There are 4 categories in this Part: Ophthalmic; Orthopaedic; Cardio-thoracic; Dermatological.

Part B applications are assessed by the department and are not presented to the MDHTAC. The assessment of applications is focusing on verifying correctness of the information provided in the application, including product name, description, size, ARTG entry, MBS items, comparator, and category. No application can be finalised until the human tissue product is included in the ARTG.

The assessment also verify that the information provided supports the benefit requested in the application.

State and Territories legislation prohibits trade of human tissue products for profit, so the benefits for Part B are intended to reflect the costs of manufacturing and supplying human tissue products to patients, including retrieval, testing, storage and transport costs.

Sponsors therefore must provide documentation to support the proposed benefits. This information includes annual financial statement of the human tissue facility and an audited service cost calculation showing the costs attributed to manufacturing and supplying the human tissue product to the patient, independently certified by an accountant. This needs to include actual costs, not only estimates. Information on the actual or projected utilisation of the human tissue product is also required to be provided.

Ongoing discussions are occurring on the possibility of the three tier pathway arrangements for Part A and Part C, being extended for Part B applications in future.

Assessment of Part A and Part C applications

There are three (3) assessment pathways, covering new, amendment, compression and expansion applications, with the evidence requirements tailored for each pathway.

Sponsors' transfer and deletion applications are administrative applications and the Tiered assessment pathways do not apply to these types of applications.

Sponsor may choose any of the three pathways for Part A applications, but for Part C applications, Tier 2 and 3 are recommended.

The three-tiered assessment pathways aim to tailor the assessments to different types of devices and the information provided.

1. Tier 1: Departmental Assessment Pathway
2. Tier 2: Clinical/Focused HTA Assessment Pathway
3. Tier 3: Full HTA Pathway –MSAC assessment

! It is the responsibility of sponsors to select the appropriate pathway at the time of submitting an application in the HPP, and to provide clear, complete and relevant information to enable an assessment.
In determining pathway appropriate for the device and application, sponsors are encouraged to review the information requirements for each pathway provided in the Guide. Where, after consideration of the Guide, the appropriate pathway is still unclear, sponsors may contact the department seeking further advice.

Figures 2 to 4 provide an overview of each assessment pathway from lodgement of the application through to the sponsor being informed of the Minister's decision regarding application. The chosen Tier 1 pathway to list a medical device on the PL is not expected to impact on the time required for completion of the application.

The most important factor for an application being assessed in a timely manner is for the application to be complete, with all required information provided and the correct pathway selected upon submission.

Tier 1: Departmental Assessment Pathway

Applications submitted under the Tier 1 Pathway are assessed only by the department and are not expected to be presented to MDHTAC for consideration.

The baseline requirements for Tier 1 pathway are that the medical devices in the application are classified by the TGA as **Class IIb or lower**, and they are **well-established technology** (with relatively simple, well-understood and stable designs and limited variations, and with proven records of satisfactory safety and performance (see Glossary).

Sponsors may only apply for listing the device in one of the existing PL groupings and do not ask to change the groupings for the billing codes in the amendment applications.

It is expected that a medical device assessed under this pathway will be interchangeable with the comparator devices listed in the same PL grouping (i.e. the devices will have very similar characteristics and are intended to be used in the established patient population with the same indications, and it is unlikely the device will cause any increase in the PL expenditure within the grouping, see Glossary). Claims of interchangeability with the comparator stated in the application must be justified.

Tier 1 **is not applicable for PL applications for Class III** or **Part C** applications. Tier 1 is also not applicable for any applications for the devices, comparators for which are currently listed on the PL with a condition.

**Note. If sponsors decide to submit an application for any of such devices under Tier 1 pathway, sponsors need to be aware it will likely be rejected, unless, the department agrees, the application may be assessed under Tier 1 pathway due to exceptional or compelling circumstances. Sponsors are required to provide sufficient justification to the department for this to be considered.*

The below are examples of the devices from the PL categories [according to the existing PL grouping structure] that are considered as eligible for Tier 1 assessment pathways (subject to the above limitations).

Spinal and Neurosurgical devices

- Spinal Standard Bone screws, for which there are the comparators with very similar design characteristics and specifications, including material (titanium or stainless steel), already listed on the PL, and where sponsors did not ask to list the devices with any suffixes (such as Dual Thread, Complex, etc) [Standard Bone screws are currently listed in group 13.01.03 – Standard]
- Spinal Screw accessories, such as set screws, caps, screw caps, cover plates, for which there are comparators with very similar design characteristics and specifications already listed on the PL [sub-groups 13.02.01 … 13.02.08 of group 13.02 - Accessories for bone screws and connector components]
- Spinal No Integral Fixation Cervical plates, for which there are comparators with very similar design characteristics and specifications already listed on the PL [sub-group 13.05.02.01 – Plate - No Integral Fixation – Cervical, without suffix or with suffix >55mm]
- Spinal Standard Rods, for which there are comparators with very similar design characteristics and specifications, including material (titanium or stainless steel), already listed on the PL, and where the sponsors did not ask to list the devices with any suffixes (such as Dual Diameter, etc) [group 13.06.01 – Rod – Standard]
- Spinal No Integral Fixation and non-expandable Fusion Cages, for which there are the comparators with very similar design characteristics and specifications already listed on the PL, and where the sponsors did not ask to list the devices with any suffixes [group 13.10.02 - Fusion Cage - Interbody, No Integral Fixation]
- Neurosurgical Patient Programmers, rechargers, connectors and cables, that are designed to

be used together with deep brain stimulation (DBS) implantable pulse generators or neurostimulation implantable pulse generators, and leads already listed on the PL [groups 04.04.02 - DEEP BRAIN STIMULATION (DBS) - External Components, 04.04.05 – Accessories, 04.05.02 - NEUROSTIMULATION THERAPIES FOR PAIN MANAGEMENT - External Components, and 04.05.05 – Accessories]

Cardiac, Cardiothoracic and Vascular devices

- Cardiac pacing lead adaptors, extenders and accessories that are designed to be used together with cardiac implantable electronic devices (CIEDs) [pacemakers and implantable cardioverter defibrillators] and with leads already listed on the PL [groups 08.11.01 - Pacemaker/Lead Accessories, 08.10.01 - Pacemaker/ICD Adaptors, 08.10.01 - Pacemaker/ICD Adaptors]
- Cardiac radiofrequency ablation reference patches [sub-group 08.18.01.02 - Radio frequency (RF) Ablation – Patch]
- Vascular peritoneal dialysis catheters [group 10.10.01 - Peritoneal Dialysis, Long Term Implantable Catheters]

  [*The above devices are classified as Class IIb. Majority of other devices listed in cardiac, cardiothoracic or vascular categories are Class III (or AIMD transitioning to Class III), or are Class IIb devices with limited utilisation (e.g., Pectus Bar) that require clinical assessment*].

Knee and hip devices

- Hip and Knee Accessories and Ancillary devices that are designed to be used together with the hip and knee main joint replacement devices already listed on the PL [sub-categories 11.04 – Accessories and 12.11 - Knee Accessories].
  Examples of the ancillary devices are: augments, axles and connectors for hinged knee joint replacements, bolts, end caps, offset couplers/adaptors, screws, offset stems, cement restrictors, centralisers, dome plugs, nuts, plugs, rings, etc. Sponsors are required to specify the devices which the accessories are designed to be used with.
  [*The accessories and ancillary hip and knee devices are classified as Class IIb or lower. The main joint replacement devices such as those designed to replace the articulating surface of the joint, or provide primary fixation, or are an intrinsic element of the joint replacement (e.g. femoral stem, tibial baseplate, inserts, acetabular cups, etc.) are classified as Class III and are not eligible for Tier 1 pathway*].

Specialist Orthopaedic devices

- Standard plates, for which there are the comparators with very similar design characteristics and specifications already listed on the PL, and where the sponsors did not ask to list the devices with any suffixes (such as COM, VAL, LK) [sub-groups 06.03.03.01 … 06.03.03.09, sub-groups are classified based on sizes (standard, small, mini), diameters of the screw holes, and the numbers of screw holes].
- Standard screws for which there are the comparators with very similar design characteristics and specifications already listed on the PL, where the sponsors did not ask to list the devices with any suffixes (such as Breakoff, DT, CN, LK, etc), and where the device is not intended to be used as an accessory to a joint replacement device (e.g. it is not a screw that is one of the components of the Modular Glenoid System), where other components have not yet been listed on the PL [sub-groups 06.03.04.01 … 06.03.04.04, sub-groups are classified based on sizes (standard, small, mini, micro), and diameters of the screws].
- Screw Washers, screw post or pegs, screw accessories, for which there are the comparators with very similar design characteristics and specifications already listed on the PL [sub-groups 06.03.04.06 … 06.03.04.10]
- Orthopaedic staples for which there are the comparators with very similar design

characteristics and specifications already listed on the PL, where the sponsors did not ask to list the devices with any suffixes (such as COMP, MI, MM, etc) [sub-group 06.03.06.01].

- Soft Tissue Fixation Devices such as buttons for which there are the comparators with very similar design characteristics and specifications already listed on the PL [sub-group 06.03.07.06] [but not the devices with tapes or sutures, for example listed in 06.03.07.05 - Button/thread/tape or Button/thread/button]
- The accessories for elbow or shoulder devices such as cement restrictor, fixation screws that are designed to be used together with the main elbow or shoulder joint replacement devices already listed on the PL and are not designed to replace an articulating surface [sub-groups 06.02.03.07, 06.02.03.08, 06.02.03.10, or 06.02.06.06].

  [*the ankle, wrist, elbow or shoulder main joint replacement devices are not proposed to be eligible for Tier 1 pathway*].

Ear, Nose, Throat, General Miscellaneous, Plastic and Reconstructive and Urogenital devices

- Craniomaxillofacial reconstruction and fixation plates, for which there are comparators with very similar design characteristics and specifications already listed on the PL, and where the sponsors did not ask to list the devices with any suffixes (such as Complex, Compression, Locking, etc.) [sub-groups 07.01.05.01 … 07.01.05.20 for Fracture or Reconstruction Plates, classified based on the thickness and numbers of screw holes].
- Craniomaxillofacial reconstruction and fixation screws for which there are comparators with very similar design characteristics and specifications already listed on the PL, where the sponsors did not ask to list the devices with any suffixes (such as Compression, Locking, etc) [sub-groups 07.01.06.01 and 07.01.06.02 for the Craniomaxillofacial reconstruction & fixation – Screws, classified based on the diameter].
- Pins, washers, clamps, wedges, etc., for which there are comparators with very similar design characteristics and specifications already listed on the PL [group 07.01.07 - Ancillary Components, with sub-groups 07.01.07.01 … 07.01.07.09].
- Dental implants, abutments - temporary or permanent, or cover screw/cap for which there are comparators with very similar design characteristics and specifications already listed on the PL [groups 07.03.01 - Dental implants – Abutment]
- External accessories for sacral neuromodulation devices for which there are comparators with very similar design characteristics and specifications, and the neuromodulation generator already listed on the PL [groups 05.07.02 – External components and 05.07.04 – Accessories, including 05.07.02.01 - patient programmer, 05.07.02.03 - recharger, 05.07.04.01 - implant/ revision kits, 05.07.04.02 - foramen needles, and 05.07.04.03 - connectors and cables].

Ophthalmic devices

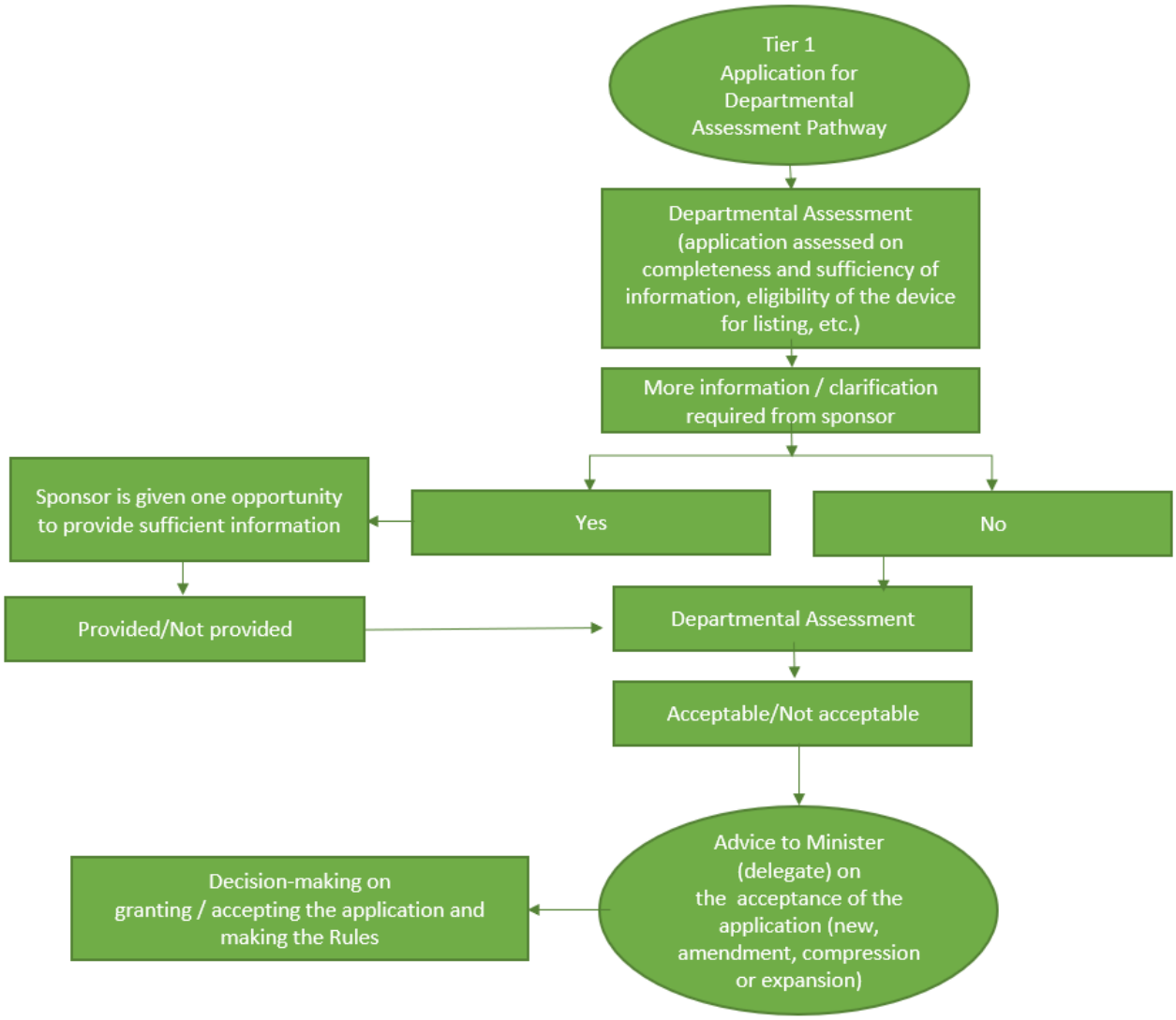
- There are no devices proposed to be assessed under Tier 1.

  * Selecting of the above groups of devices for Tier 1 pathway has been made based on the department's in-house capabilities, expertise, experience, knowledge and internal quantified staffing resources. The list will continue to be reviewed after the implementation of the Tiered assessment pathways and may be varied in the future.

Sponsors applying via this pathway are usually given only **one** opportunity to provide clarification or additional information within the timeframe specified by the department that usually does not exceed 5 working days. It is at the discretion of the department on whether to give the sponsor another opportunity to provide missing information or extend the time for the

response. Incomplete or inappropriate applications will be rejected. Should an application be rejected from Tier 1 for any reason, the application will need to be resubmitted under Tier 2 or Tier 3 (whatever is applicable) pathway, and it will be subject to further application and assessment fees.

Figure 2: Overview of the Process for Tier 1: Departmental Assessment Pathway



Tier 2: Clinical/Focused HTA Assessment Pathway

The Tier 2 Clinical/Focused HTA Assessment Pathway is for devices that are not suitable for assessment via the Tier 1 Pathway and require clinical assessment by the respective ECAG, and in some cases HTA consultant.

Specifically, the devices for which Tier 2 applications will be required include the devices classified by the TGA as Class III, or any Part C applications. Additionally, any Part A applications for the devices of any risk-classification, that are not well-established technology [e.g. devices of this type are reasonably new/do not have a long history, or have known issues with performance/safety problems, etc.], and/or have high variability in the designs and characteristics, and/or the devices for which sponsors claim any novel features, characteristics or functionality, or applications where sponsors apply for listing the devices in new groupings or

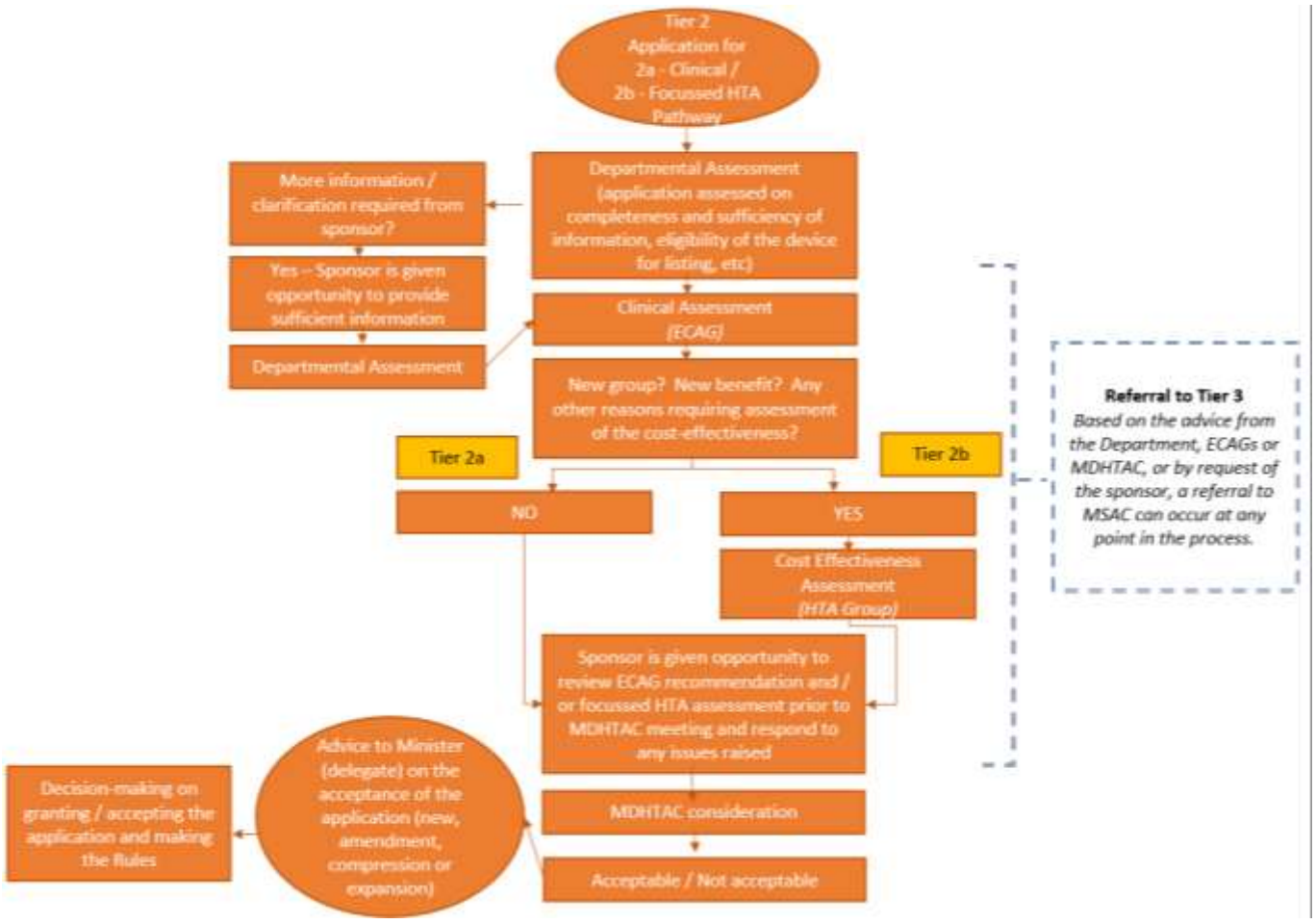
ask to change the groupings (in the amendment applications), or applications previously rejected under the Tier 1 pathway, including where the sponsors were unable to provide the required information in the form required by the department.

This pathway has two routes depending on the level of assessment required: Tier 2a – clinical assessment only and Tier 2b – clinical assessment plus economic assessment to establish cost effectiveness.

For Tier 2b, an HTA may be undertaken by a HTA Group engaged by the department. This will typically take the form of a focused commentary (appraisal) of the clinical and/or economic claims made in the application by the sponsor. Sponsors will be able to provide feedback on assessment reports before they are provided to MDHTAC.

All applications assessed via the Tier 2 Pathway will be considered by the MDHTAC.

Figure 3: Overview of the Process for Tier 2: Clinical/Focussed HTA Pathways



Clinical evidence requirements for devices assessed under Tier 2a or Tier 2b Pathways

The expectations in respect to the clinical data depend on the device in the application, its history or the history of the comparative devices, the request in the application (e.g. the sponsor applied to list the device in a new grouping), the novelty, variability and other factors. Each application is assessed individually based on the information provided. The below information is only a guidance, and the sponsors are required to apply judgement and common sense when they submit their application and provide the relevant information.

The data such as the number of implanted devices and follow-up time is considered in context of the quality, independency, and source of collection of the data provided (including comprehensiveness of the registry where the data has come from, information in the peer-reviewed publications published in the reputable journals with the independent data and with authors declaring conflicts of interest.
The clinical data needs to be directly relevant to the subject device in the application. The data on comparator devices does not replace direct clinical evidence for the subject device, except where there is evidence (e.g., the manufacturer's design documentation) demonstrating the subject device and the comparator have identical design characteristics, material, and other specifications.

The National Health and Medical Research Council (NHMRC) developed a framework to categorise **the levels of evidence** represented by different types of clinical studies according to the type of clinical question. This is referred to as a hierarchy of evidence. For the Prescribed List applications, the relevant NHMRC hierarchy of evidence is for 'intervention' studies, as a criterion for listing on the Prescribed List is that products are to be used for therapy.

Levels of evidence are based on the extent to which the design of a clinical study is suited to answering a particular clinical question. Clinical studies can be broadly divided into two main types of studies: controlled clinical trials and observational studies. Controlled clinical trials represent higher levels of evidence because their design seeks to minimise the potential for different types of bias (such as patient selection, placebo effects, non-blinded outcomes assessment, and the number of patients lost to follow-up).

Although specific study designs are not mandated for different PL applications, in general, evidence requirements for devices with novel/new material, designs, and other new characteristics, is higher than for devices that are similar to the existing devices with less significant changes in characteristics.

Where a sponsor is seeking a new grouping with a higher benefit on the basis that a new device delivers superior clinical outcomes, the application is expected to provide clinical evidence comparing the difference in clinical outcomes between the subject device and the comparators. The evidence should quantify the improvements.

When considering the type of evidence to be provided it is also important to consider the **quality and applicability of the studies**. This is referred to as 'critical appraisal'. There are many validated methods for undertaking critical appraisal and sponsors should refer to the relevant chapters of the MSAC Guidelines for guidance on appropriate critical appraisal methods.

The expected rate of use of a device can also influence the volume of evidence able to be collected. Lower rates of expected use should not be seen as a justification to collect no evidence, but assessments may take expected rates of use into consideration when appraising the level and quality of available evidence.

Sponsors should consider **any conflicts of interest** in the information they provide. It is not uncommon that studies related to medical devices are funded by manufacturers, however an indication for acceptance of any data is that the study is conducted by an independent clinical

research organisation [**where the researchers do not receive any royalties or have any financial interests in either the device or the manufacturer, and state clearly any conflicts of interest**], the study design is appropriate for the type of device with the acceptable minimum follow-up, the data is recent and current, and the study is completed and the outcomes are analysed and published in a peer-reviewed article in the reputable journal [the manufacturers' summaries or clinical evaluation reports, and unpublished data are usually not acceptable].

The final conclusion regarding acceptance of any provided clinical data will always be made in context of the specific device.

Sponsors are required to provide an **executive summary** (no more than 2 pages) with the rationale how the information and clinical data is relevant. All documents provided must be in English.

Specific requirements

Examples on the specific requirements for the clinical evidence for the devices from different categories are provided below, subject that the quantitative data requirements meet the qualitative requirements as explained above.

Spinal and Neurosurgical devices (SNECAG)

- For expandable spinal fusion cages, the clinical data required to be provided is for minimum 40 devices implanted with at least 12 months follow-up. This requirement is due to the dynamic nature of the implant.
- For any spinal fusion devices made of material different from other devices listed on PL or with significant variation in the design, the clinical data required to be provided is for minimum 40 devices implanted with at least 2 years follow-up.
- For non-fusion devices, such as disc arthroplasty, vertebral tethering, non-rigid fixation implants etc., the data on minimum 40 subject devices implanted with at least 2 years follow-up is required.
- For the spinal devices designed to be used in pediatric patients, the minimum follow-up time is expected to be longer than 2 years (5 years for any new technology), and this depends on the device and the intended patient cohort.
- For any neurosurgical implantable pulse generators (IPG) and leads that are next generation of the existing technology, the outcome data required to be provided is from appropriately controlled clinical trials (comparing with other existing treatment methods) for minimum 20 subject devices implanted with at least 2 years follow-up.

  The data is required to be published in a peer-reviewed articles in reputable journals and inclusive of prospectively collated, objective clinical outcomes, intra and post-operative complications, hospital readmission rates and re-operations. The manufacturer's summaries are not acceptable in lieu of the actual publications. The data on the predicate devices may be provided to support the application [showing the satisfactory performance and comparison with the subject device] but it does not replace the need for the direct data for the subject device in the application.

Cardiac, Cardiothoracic and Vascular devices (CECAG)

- There is currently TAVI Guidelines, published on the department's website. This was developed by the former TAVICAG in 2017, aiming to use it for assessing transcatheter aortic valve implants (TAVI).
  For noting: The guidelines are currently under the review as part of the guidance work, and will be consolidated into this Guide as soon as practicable.
- Requirements for the quantity, quality and level of evidence for the clinical data depend on

the significance of the changes between the subject device and the comparator.

- For CIEDs, if the subject device in the application is an enhancement/variation of the existing comparator device [when the comparator is manufactured by the same manufacturer], the information is required to outline the similarities and differences in the designs, characteristics, specifications, technology between the subject device and the comparator device, and the direct clinical data is required for the subject device demonstrating comparative clinical effectiveness for the new/enhanced characteristics of the subject device.
- The requirements in respect to different cardiac, cardiothoracic and vascular devices may vary in respect to the quantity (the minimum number of the devices implanted and the least follow-up), quality and level of evidence depending on the significance of the changes in the material, design, other characteristics of the subject device.
  Examples of the evidence requirements include (it is not applicable to novel/bespoke devices):
  - For cardiac stents, the clinical data is required on minimum 200 devices with at least 12 months follow-up, and for vascular stents - minimum 100 devices with at least 12 months follow-up [with measures discussed on the stent fracture rates/restenosis rates]
  - For vascular grafts the clinical data is expected on minimum 100 devices with at least 12 months follow-up [with measures on graft porosity rates) and for stent grafts - minimum 150 devices with at least 18 months follow-up [with measures discussed on early and late proximal, distal leakage rates/distal migration rates]
  - For left atrial appendage occlusion devices, the clinical data is expected on minimum 200 devices with at least 12 months follow-up
    [Procedural Death <0.2%; Procedural Stroke <0.2%; Pericardial Tamponade/effusion <1.5%; Device Embolisation (<0.2%)] [Post Procedural Pericardial Effusion (<1%); Device Leak at ~ 45 days (> 5mm < 3%); Device Leak at ~ 45 days(>3mm <25%); Device related thrombosis at ~ 45 days (<5 %); Stroke rate Less than 1.5 per 100 years follow up]
  - For mitral valve repair devices, the clinical data is expected on minimum 200 devices with at least 12 months follow-up
  - For embolic protection devices, the clinical data is expected on minimum 100 devices with at least 12 months follow-up [with measures on the device removal failure rate/embolism rate at time of insertion or removal]
  - For ventricular assist devices, the clinical data is expected on minimum 200 devices with at least 12 months follow-up
  - For cardiac defect occludes, the clinical data is expected on minimum 200 devices with at least 12 months follow-up
  - For long term vascular access devices (implantable ports and haemodialysis catheters),the clinical data is expected on minimum 100 devices with at least 3 months follow-up
  - For Cardiothoracic Tissue Valves, the data on minimum 200 devices with at least 2 year follow up whenever there has been a change in the structure of any of the valve components or the preservation treatment of any tissue used

Joint replacement devices (knee, hip, shoulder, elbow wrist, ankle)

The below are the baseline requirements, and if there are significant changes in the design / coating / material or the device is novel in some characteristics or is associated with a higher perceived risk, or in other relevant circumstances, the sponsor may be required to provide additional data or data with a longer duration of follow-up. The data from the registry/full registry reports are required, and manufacturers or sponsor's summaries or analysis are not acceptable.

The number of implanted joint replacement devices intended for the primary or both primary and revision procedures is expected to be higher compared with the prostheses mostly used in revision or difficult/complicated/unusual surgery.

For noting, not all registry data is acceptable. The criteria for the quality of the registry include, but is not limited to, that the registry is a comprehensive national arthroplasty registry [versus regional or institutional registry] with no less than 90% coverage [number of hospitals contributing arthroplasty data compared to number of hospitals performing arthroplasty]; proven completeness [number of procedures recorded compared to number of procedures performed] and accuracy of the data [verified correctness of entered data]; with survivorship analysis, independency of data assessment, etc. Further, any acceptable reliable quality registry has its reports published no less than annually.

Finally, the data must not be combined/aggregated from multiple sources as it makes the results statistically not viable and provides an inaccurate representation of device survivorship.

Knee and Hip devices (HKECAG)

- For hip and knee joint replacement devices used in primary or in both primary and revision procedures, the clinical data is required on minimum 250 procedures with at least 2 year adequate follow-up
- For hip and knee joint replacement devices, used in revision or special circumstances or unusual situation devices (e.g. constrained acetabular cup designed for use in high risk of dislocation patients) procedures, the clinical data is expected on minimum 50 hip or knee joint replacement devices implanted with at least 2 years follow-up
- For the tumour devices, minimum 20 devices implanted with at least 2 years follow-up may be accepted, although these devices may have variability in the data requirements depending on circumstances.

Specialist Orthopaedic devices (SOECAG)

- For shoulder joint replacement devices, the clinical data is required on minimum 100 devices implanted with at least 2 years adequate follow-up. A year 2 cumulative percentage revision with confidence intervals is required to be included with any registry data submission. The shoulder joint replacement devices used in both anatomic and reverse shoulder replacements must have separate data for both procedures.
- For ankle, elbow, wrist joint replacement devices, the clinical data is required on minimum 25 devices implanted with at least 2 years adequate follow-up. A year 2 cumulative percentage revision with confidence intervals is required to be included with any Registry data submission.
- For suture anchor devices the device’s pull-out strength data inclusive of the methods used in the cyclic testing, ultimate load testing, insertion testing; statistical rationale for sample size; acceptance criteria and results is required.

Ear, Nose, Throat, General Miscellaneous, Plastic and Reconstructive and Urogenital devices (GSECAG)

- For implantable hearing systems (cochlear implants, bone conduction and middle ear) and sacral neuromodulation systems, if the subject device in the application is an enhancement/variation of the existing predicate device, the information is required to outline the similarities and differences in the designs, characteristics, specifications, technology between the subject device and the predicate device, and the direct clinical data is required for the subject device demonstrating comparative clinical effectiveness for the

new/enhanced characteristics of the subject device.

- For any Urogenital Sacral Neuromodulation implantable pulse generators (IPG) and leads that are next generation of the existing technology, the clinical outcome data required to be provided is for minimum 20 subject devices implanted with at least 2 years follow-up.

  The data is required to be published in a peer-reviewed articles in reputable journals and inclusive of prospectively collated, objective clinical outcomes, intra and post-operative complications, hospital readmission rates and re-operations. The manufacturer's summaries are not acceptable in lieu of the actual publications. The data on the predicate devices may be provided to support the application [showing the satisfactory performance and comparison with the subject device] but it does not replace the need for the direct data for the subject device in the application.

- The requirements for brachytherapy, drug delivery devices (pharmaceutical beads and infusion ports), surgical mesh (hernia and other abdominal repair, incontinence), insulin infusion pump systems, tubal obstruction devices, artificial skin, tissue expanders, breast implants, may vary in respect to the quantity (the minimum number of the devices implanted and the least follow-up), quality and level of evidence depending on the significance of the changes in the material, design, other characteristics of the subject device.

Ophthalmic devices (OECAG)

- For Intraocular lenses (IOLs) [subcategory 01.02 - Posterior Chamber Intraocular Lenses], the clinical data required to be provided is for minimum 100 implanted devices with at least 12 months follow-up, to enable assessment of comparative clinical effectiveness, this direct clinical data is required for any new IOL.
- For IOLs that are variations of the IOLs already listed on the PL, the requirement for the direct clinical data may be reduced (e.g. standard IOL is listed on the PL, and the sponsor applied for listing the same brand IOL but with violet-blue light filter, or Toric IOL).
- For devices used in oculoplastic and orbital surgery, focused on the structures surrounding the eye [sub-categories 01.06 - Eyelid prostheses, and 01.08 - Orbital prostheses] (the rare conditions) and retinal detachment devices [subcategory 01.09 - Retinal detachment prostheses] data on minimum 30 – 40 implanted devices with at least 12 months follow-up is required for novel devices. Modifications of existing devices may be acceptable with lesser implantation numbers.
- For liquids and oils [groups 01.09.04 - Intraocular Gases, 01.09.05 – Intraocular Heavy Liquids, and 01.09.06 - Intraocular Silicone Oils], where the device is made of the same material/has the same ingredients and characteristics, the data on the comparator devices may be acceptable.
- For the devices listed in sub-categories 01.05 - Glaucoma drainage or 01.03 - Intraocular fluids, the data with 6 months follow-up will be required.

  For noting: When strong peer reviewed data is available, less follow-up time could be accepted, but as a general rule at least 6 months or 12 months follow-ups [as stated above] is required.

Further information for Tier 2b applications

For Tier 2b applications, sponsors are required to provide a ***comparative analysis of the similarities and differences*** between the subject device and the comparators either listed on the Prescribed List or alternative treatment.

Appropriate sources of clinical evidence to support the comparison include:

- Clinical trials of the product (Clinical Study Reports or peer-reviewed publications)
- Observational studies of the product (clinical registry data, cohort studies, or case series).

Claims of superiority need to be supported by direct evidence demonstrating that the device is clinically effective and is clinically superior to the nominated comparator.

The type of evidence required to demonstrate substantial similarity depends on the extent to which a device differs from the comparator and the potential risk of harm from use of the device. A device that is significantly different in design or composition from the comparator will require more extensive information (which may include a higher level of clinical evidence) than a device that differs only in aspects that are not expected to affect the comparative safety or effectiveness of the device. Likewise, if there is high potential risk to the patient if the new device fails or does not perform as intended, clinical evidence will be required to demonstrate that the new device is no worse than the comparator. In this case, higher level clinical evidence may be an appropriate source of clinical effectiveness data but the most reliable source of comparative safety data may be a large observational study with adequate follow-up.

Sponsors may also use data from clinical registries to support their applications, if the quality, reliability etc of the registry may be verified [Joint Replacement Devices].

A minimum amount of ***economic information*** is required for all applications assessed via the Tier 2b pathway. While a full economic evaluation is not required for this pathway, economic information is required to validate the proposed benefit and to demonstrate that it represents value for money for the new product in the proposed setting of use.

Such information include:

- the cost of the subject device
- any relevant downstream costs associated with the use of the subject device
- the cost of the comparators
- any relevant downstream costs associated with the use of the comparators
- expected rates of use of the new product compared with the comparators.

Such information could also include prices of the subject device in other markets (both overseas and within Australia), and an economic evaluation.

Any economic claims made in the application are required to be supported by appropriate clinical evidence or data. For example, where a claim is made about reductions in theatre time, hospital stay, post-surgical care costs, fewer complications, or reduced revision surgery, evidence should be provided that these are real reductions and not potential or theoretical.

In order for an application to be assessed via the Tier 2b pathway, any included economic evaluation must be wholly based on one or more clinical studies with no economic modelling. In other words, economic evaluations will have a time horizon that is no longer than the longest duration of the available clinical study and will rely on outcomes collected in clinical studies. In technical terms, this means there can be no extrapolation of outcomes (i.e. extending the duration of the economic evaluation beyond the duration of the clinical studies), and no transformation of outcomes (i.e. no mapping of particular outcomes to changes in quality of life; or linking of surrogate outcomes from a clinical study of the product to predicted final outcomes from other sources). The exception to this will be situations where a clinical study has directly collected patient reported outcome measures in the form of health-related utility weights (e.g. via validated ‘multi-attribute instruments’ such as the EQ-5D, HUI-3 or AQoL).

The ***overall impact*** in terms of cost effectiveness of care relative to the comparators should be indicated in the application. An indication that the new medical device is expected to reduce, increase or not change the total cost of care per patient (i.e., the net cost) within the health system relative to the comparators should be provided in the application. Refer to the MSAC Guidelines for guidance on this.

Tier 3: Full HTA Pathway MSAC and MDHTAC

The Tier 3 (Full HTA) Pathway, is for devices requiring assessment by the MSAC in order to establish the comparative clinical effectiveness and cost-effectiveness and, in some cases, assessment of the device is conducted as part of the assessment of the related Medicare service. The PL application may be submitted prior to, or concurrently with, or subsequent to the MSAC application. Applications and the respective correspondence must identify and explain the link between the PL application (whether underway or planned in the future) and the MSAC application. Examples of applications that require Tier 3 Pathway include:

- applications for listing medical devices on the PL where there is no relevant MBS item associated with the use of the device (a new MBS item is required, or an MBS item descriptor is required to be amended)
- the device is a novel or first in class technology and/or there are no appropriate comparators on the PL
- applications where listing of the device on the PL will likely cause significant financial impact on the overall PL expenditure, and therefore a detailed financial assessment is warranted.

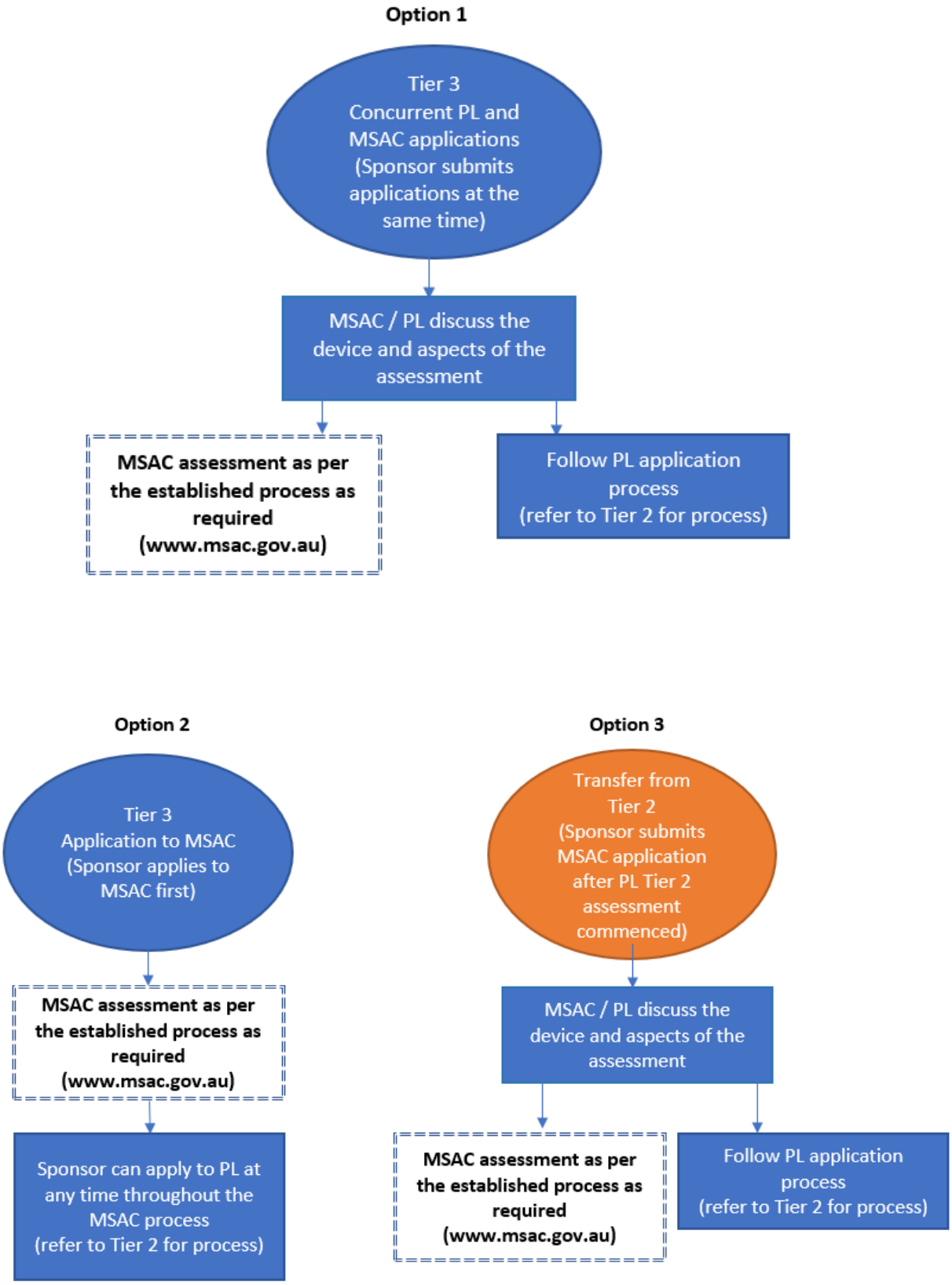
It is often a decision of the sponsor who submits a Tier 3 application, or the department, ECAG or MDHTAC may recommend the device is required to be assessed by the MSAC. This may occur at any time during assessment of an application submitted under Tier 2 Pathway.

The sponsor will be advised that assessment via the Tier 3 Pathway is required (Figure 4). The sponsor may then decide to continue down the Tier 2 Pathway, noting there is a risk the application may be rejected; or the sponsor may agree to proceed down the Tier 3 Pathway. Where a sponsor agrees to proceed to the Tier 3 Pathway, they will be required to submit a completed MSAC application form via the HPP. The PL application may or may not require further consideration by ECAGs and/or the MDHTAC. This will be dependent on what stage the application was at in the PL process.

MSAC may seek advice from the relevant ECAG or MDHTAC. The information provided to MSAC as part of these processes will be shared with the sponsor. The MSAC and PL applications will undergo separate assessments, but information may be shared throughout the assessment process.

Information about MSAC requirements and processes, cut-off dates for lodgement, timelines and the technical guidelines for preparing assessment reports are available on the MSAC website.

Figure 4: Overview of the Assessment Process for the Full HTA Pathway


Option 1
Tier 3
Concurrent PL and MSAC applications (Sponsor submits applications at the same time)
MSAC / PL discuss the device and aspects of the assessment
MSAC assessment as per the established process as required (www.msac.gov.au)
Follow PL application process (refer to Tier 2 for process)
Option 2
Tier 3
Application to MSAC (Sponsor applies to MSAC first)
MSAC assessment as per the established process as required (www.msac.gov.au)
Sponsor can apply to PL at any time throughout the MSAC process (refer to Tier 2 for process)
Option 3
Transfer from Tier 2 (Sponsor submits MSAC application after PL Tier 2 assessment commenced)
MSAC / PL discuss the device and aspects of the assessment
MSAC assessment as per the established process as required (www.msac.gov.au)
Follow PL application process (refer to Tier 2 for process)

Chapter 6: Information and evidence to be provided in the applications

The sponsors are required to fill in the HPP application form and attach the documentation required to inform the assessment. The information required to be provided depends on the assessment pathway the sponsor selected, the device category, group etc, clinical claims, novelty etc.

Information required in the application

This section provides details on the information sponsors are required to provide when filling in their HPP applications.

In the HPP, certain information will be pre-filled in the application. This will include the sponsor's details, descriptors for the MBS items, information from the previous similar applications, and other information. For amendment, compression and expansion applications, after selecting an existing billing code in the application, the details of the billing code will also be pre-filled, and the sponsor will only need to enter the information they apply to amend.

Table 1: Information required to be provided by the sponsor in the HPP application
(the below table does not include the information sponsors are required to attach with the application).

Information required	Part A and Part C			Part B
	Tier 1	Tier 2	Tier 3	
Application form				
Sponsor's contact details	✓	✓	✓	✓
Product name, description, size	✓	✓	✓	✓
ARTG entry or TGA application ID	✓	✓	✓	✓
MBS items	✓	✓	✓	✓
List of catalogue numbers with details of devices (product name, description, size)	✓	✓	✓	✗
Category - Sub-category – Group - Sub-group - Suffix (as applicable)	✓	✓	✓	✓
Comparator details	✓	✓	✓	✓
Rationale for new groupings (if applicable)	✗	✓	✓	✓
Public hospital or overseas prices	✗	✓ (for 2b)	✓	✗
Estimated utilisation	✗	✓	✓	✓
Documents to be attached				

Information required	Part A and Part C			Part B
	Tier 1	Tier 2	Tier 3	
Product brochure, surgical technique, instructions for use, etc	✓	✓	✓	✓
Technical information (e.g. pull-out strength tests data for the device)	✗	✓ (if applicable)	✓ (if applicable)	✗
Clinical data	✗	✓	✓	✗
Economic evidence	✗	✓ (for 2b)	✓	✗

** Please refer to the MSAC Guidelines for evidence information requirements for the Tier 3 Full HTA Pathway. For the Tier 3 pathway, sponsors are required to submit two applications – one for MSAC and one for PL*

Application

Sponsors are required to select the relevant Part of the PL, the relevant assessment pathway (Tier), and the type of application (new, amendment, expansion, compression, etc).

Sponsor's contact details

Sponsors are required to list details of the primary contact person in the application, and other contacts may be also added. The application contacts will be notified when the department sends correspondence relating to the application.

Product details

Any applications require sponsors to include the product name, descript and size. This information is required to clearly identify and be consistent with the device (or all devices) or human tissue product applied to be listed or listed under the PL billing code.

Where the billing code covers or will be covering a construct, kit, pack, tray, etc consisting of two or more medical devices, or a medical device and other products, that are intended to be used together and therefore reimbursed together, the product name, description and size are required to clearly identify all components covered under the billing code (e.g. for integral fixation spinal cages, description is required to include reference to cage and fixation plates and screws; for implantable heart valve, the product name and description are required to specify the valve and the relevant delivery catheter, etc.).

Further, the product name, description and size are required to be consistent with the group, subgroup and suffix stated in the application or for the billing code [for variation application] (e.g. the product name and description need to refer to the button and thread components of the subject device if it is applied to be listed or listed in subgroup Button/thread/tape or Button/thread/button; or for the Craniomaxillofacial Fracture or Reconstruction Plates, for which the subgroups refer to the size and number of screw holes, the size stated in the application or for billing code is required to be consistent with this grouping information). [Billing Code]

Regulatory information

For a device or human tissue product to be listed on the PL it must be included in the ARTG.

Accordingly, sponsors are required to provide valid and correct ARTG entries in the PL applications. For new applications, where the devices or human tissue products are not yet included in the ARTG, under the Parallel Assessment Process, sponsors may use some TGA applications in lieu of the ARTG entry. In such instances, sponsors are required to state the TGA Application Identifier.

For more information, see Parallel Assessment Process.

MBS items and use of device for hospital treatment

Medical devices or human tissue products are not eligible for listing on the PL unless there is at least one existing MBS item for Medicare service associated with the implantation or use of the device or human tissue product for hospital or hospital substitute treatment [existing MBS items can be found at MBS Online].

The HPP application forms are designed to allow sponsors to provide up to 5 MBS items for each application. This is because sponsors are not required to provide all possible MBS items that possibly can be associated with the use of device or human tissue product, but rather sponsors are required to state (based on functions, description, and clinical information available for the device or product) the most appropriate and correct MBS items associated with the use of the device for hospital treatments.

Unless billing codes are listed on the Prescribed List with the condition restricting reimbursement to specific MBS items, or procedures, or patient indications, or in connection with implantation of specific devices, the claims for PL listed devices may be associated with any MBS items interpreted as correct to the use of the device.

If there is no MBS item for the Medicare service associated with the use of medical device or human tissue product, an application is required to be submitted to the MSAC seeking a new MBS item or amending the descriptor of an existing MBS item.

Sponsors can submit a new PL application while proceeding with the MSAC assessment for a new MBS item, but no decision on PL application will be made until MSAC assessment is finalised.

Catalogue numbers

For Part A and Part C devices, catalogue numbers must be included in the application for all devices to be covered under the billing code. Sponsors are also required to include devices' names, descriptions, sizes, and other details for each catalogue number.

The HPP allows sponsors to upload a spreadsheet with the list of all required catalogue numbers.

Grouping

For any Part A Tier 1 applications, sponsors may only apply for listing the subject device in one of the existing PL groupings and do not ask to change the groupings for the billing codes in the amendment applications. The benefit will be automatically pre-filled in the HPP when the grouping is selected in the application [Tier 1].

For Part A and Part C Tier 2 or Tier 3 applications, sponsors can select an existing grouping, or propose a new group, sub-group or suffix in the application [Tier 2].

The group, sub-group and suffix, sponsors stated in the application, must be correct for the devices identified by all catalogue numbers stated in the application or recorded for the existing billing code (as applicable).

For example, if the sponsor applied to list plates on the PL with suffix LK (Locking) but catalogue numbers in the application are for a mix of locking and non-locking plates, or subgroup stated in the application is for the plates with 16 or more number of screw holes, but there are plates with 15 or less number of holes in the application, such application is not acceptable, unless the sponsor removes incorrect catalogue numbers for non-locking and smaller plates.

For Part B applications, sponsors are expected to select an existing grouping and state their proposed benefit. Sponsors are required to provide explanation and sufficient evidence and cost analysis to support the amount requested in the application [Part B].

Comparator details

At least one comparator must be stated in each PL application. The comparators, sponsors decide to state in their applications, are required to be the most relevant in respect to the functionality, design, and characteristics, and appropriate in respect to the clinical indications and intended use for the subject device or human tissue product.

For Part B applications, comparators are expected to be nominated from the existing PL listed human tissue products. Sponsors also may state MBS items for Medicare service as a comparator, but in this case, subject human tissue product may require further assessment in respect to eligibility for listing on the PL. There is no requirement to provide a detailed comparison, but sponsors are expected to provide rationale for choosing the comparator.

For Part A and Part C applications, sponsors are required to provide detailed comparison between the subject device in the application and the nominated comparator.

A medical device must be assessed to be no less clinically effective than the alternative devices listed on the PL or the alternative treatments [the comparators] and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device [listing criteria with reference to the comparator].

For the devices that are sufficiently similar to other comparator devices already listed on the PL, sponsors are required to demonstrate similarity in respect to the designs, materials, characteristics, etc of their subject device with the existing devices and provide sufficient evidence to demonstrate that the subject device is no less clinically effective than the comparators.

However for the devices for which there are no similar devices listed on the PL, sponsors are required to provide comparison with the devices that are not listed on the PL or available treatments that are considered to be the current standard of care for the same condition or indication. The assessments of comparative clinical effectiveness and cost-effectiveness are required to establish eligibility of the subject device for listing on the PL and set up an appropriate benefit.

The HPP allows sponsors to select an MBS item as an alternative comparator or state a non-MBS listed treatment. Sponsors are required to provide clear description of the treatment and rationale why this treatment is an appropriate comparator.

To inform assessment of the subject device against the comparator, sponsors are required to provide the following information for the comparator: product billing code (if applicable), product name, description, size, design features, material, ARTG entry, indications and contraindications, adverse events/issues (if known).

It is the responsibility of the sponsor to undertake a thorough assessment of both the subject device and the comparator, and identify any issues or concern, that relate to the device stated as the comparator.

This process is expected to include a search of adverse events databases in Australia and overseas, with attachment of the relevant information on adverse events, complaints, warnings if any found.

At a minimum, the search of adverse event databases is expected to include the TGA website and websites of the United States Food and Drug Administration (US FDA), and the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). If no records of adverse events, complaints, or warning were identified in the searches, this should be recorded in the application. Evidence of search findings is required to be provided with the application.

The same information is required for the subject device if applicable.

Rationale for new groupings (if applicable)

For Part A and Part C Tier 2 or Tier 3 applications, sponsors may apply for listing the device in a new grouping. The sponsor is also required to state a benefit for the new grouping. To support such request, sponsors are required to provide a clear rationale and justification. All such applications will undergo assessment by the relevant ECAG, and additionally either focussed or full HTA. [Clinical evidence requirements for devices assessed under Tier 2a or Tier 2b pathways]. Sponsors will be able to provide economic evidence either at the time when application was submitted or after ECAG and MDHTAC assessments.

The benefit may also be estimated if sufficient information is available for calculating average weighted public price for the device (based on the factual information).

Information on public hospital or overseas prices

For Part A and Part C Tier 2b or Tier 3 applications, if the medical device has been used in the public hospital sector in Australia, sponsors are required to advise the price for the subject device charged in public hospitals.

If the medical device is not used in public hospitals, sponsors will be asked to provide information on any available prices charged for the device internationally. This may include information (name of the device, approval status, utilisations per year, cost in local currency) available for supply in Canada, France, New Zealand, Singapore or the United Kingdom.

Estimated utilisation

For Part A and Part C Tier 2 and 3 applications, sponsors are required to provide utilisation data that allows the department to understand the potential trend and impact of the subject device, if

approved, on total PL benefit amounts payable over the first four (4) years of listing on the PL. It is acknowledged that these are estimates only, and a range of expected values can be provided.

Where the device targets an existing population group or indication, the size of and expected growth in the existing market should be discussed, estimates may reflect the proportion of the established market the sponsor expects to achieve. Where the device targets a new population group or indication, the number of eligible patients and the expected levels of uptake of the device should be discussed, estimates may reflect the expected growth in the new market.

The reasoning behind the estimates provided should be explained in the application. This may include uncertainties, such as any barriers and enablers (e.g., specialised surgical training, use restricted to accredited centres) for uptake of the device in Australia. If the medical device is intended to be used in a subgroup of patients, the mechanisms that are in place to prevent the device from being used in a broader population than intended should be explained.
This utilisation data requested as part of the application process is prospective, and by nature an estimate. It is different from utilisation data used in post listing reviews and other PL administrative functions, which is retrospective and derived from CaseMix data and other sources available to the department. The primary purpose of this prospective data is to enable a more complete understanding of the impact of new PL listings on total PL benefits and the broader health system. Comparison of prospective application estimates to actual utilisation levels identified from retrospective sources does not form part of the department's routine post listing review or compliance activities (though this might occur in individual cases where utilisation varied significantly from expectations, and other issues of concern were identified).

Documents required to be provided

Sponsors are also required to provide documents that inform the assessment of their applications.

Sponsors must ensure that the documents provided are not password protected and not corrupted. **Any documents with the restricted access will be taken by the department as not received and will not be assessed**.

Any documentation is required to be provided in English. If source documents are written in a language other than English, a certified translation is required to be provided with the application following National Accreditation Authority for Translators and Interpreters Ltd (NAATI) standards. Untranslated and/or uncertified documentation will not be considered.

Further, sponsors are required to flag/highlight all relevant data and include references to pages and sections in the documents provided. All literature is required to be accurately cited.

If the supporting documents are the same for more than one application, HPP provides functionality for uploading documents once and link them to multiple applications, rather than uploading multiple times.

Sponsors are required to provide attachments, including but not limited to:

- executive summary (no more than 2 pages) explaining and mapping all documentation and information provided for the application
- manufacturer's product material (brochure, surgical technique, Instructions for Use [IFU]) providing the details of the device, including product name, description, sizes, intended use,

and other relevant information, and the representative images for all devices identified by the catalogue numbers stated in the application, including images of the devices insitu (if the brochure does not clearly identify all devices, additional product images may be required, but an image/photograph without label clearly stating the details of the device is not acceptable)

- any additional information that may assist in establishing the MBS items stated in the application are correct, subject device is used in hospital treatments, and the grouping stated in the application are correct
- any additional information [including product brochure and surgical technique] assisting in verifying the applicant's claims regarding the similarities and differences with the comparator [it is acknowledged that this may be limited to publicly available information, when the comparator is listed under a different sponsor]
- Testing data if applicable
- Clinical data required for Tier 2 and Tier 3 applications [ECAG requirements].

For Tier 3 applications, sponsors will also be required to submit an MSAC application and provide the relevant data, further information is available on the MSAC website.

Lodging an application

At the time of submission, the person completing the application will declare that all information provided in the application is true and correct at the time of the application. Additionally, sponsors are required to ensure the application includes all information on the essential elements of the device or system so that the HTA assessment ensures that the benefit covers all costs incurred and to ensure no out-of-pocket expenses for consumers. Sections 137.1 and 137.2 of the Criminal Code (*Schedule to the Criminal Code Act 1995*) provide for offences for providing false or misleading information or documents. Penalties apply for false declarations.

Glossary

Application	The information provided by a sponsor in the HPP in support of a request to list medical device or human tissue on the PL or amend the existing PL billing code.
Australian Register of Therapeutic Goods (ARTG)	The register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia. All medical devices, including Class I, must be included in the ARTG before supply in Australia. There are limited exceptions to this requirement specified in the legislation.
Benefit	For the purpose of Prescribed List, the minimum amount that a private health insurer is required to pay for a device or human tissue listed on the PL that is provided to a privately insured patient with appropriate cover as part of hospital treatment or hospital-substitute treatment.
Billing code	A unique identification code allocated to a listed medical device or human tissue product for the purposes of facilitating hospital claims and invoicing, and payment of benefits by insurers
Case series	A study where the use of a health technology has been assessed in a series of cases (which may or may not be consecutive patients) and the results reported. There is no separate control group for comparison.
Clinical assessment	An assessment by ECAG of evidence provided in an application.
Clinical data	For the purposes of assessing comparative clinical effectiveness of the devices by ECAGs, the clinical data means the data directly related to the subject device in the application [the ECAG may specify the level, quality and quantity of evidence depending on the category and type of device], and can be sourced from: • reports/articles published in reputable journals on the independent clinical trials for the subject device • data from the quality and reliable registries
Clinical effectiveness	The extent to which a health technology produces its intended outcomes in a defined population in uncontrolled or routine circumstances.
Comparator	Another medical device or human tissue product or an alternative treatment if there are no comparative products listed on the PL against which comparative clinical effectiveness and cost-effectiveness of the subject product are assessed.
Cost, comparative	How much one health technology costs compared to an alternative health technology.
Cost analysis	An economic evaluation that compares the cost of two health technologies without consideration of health outcomes
Cost-consequence analysis (CCA)	An economic evaluation that compares health technologies as an array of all material costs and outcomes measured in their natural units rather than a single representative outcome as presented in a cost-effectiveness analysis.
Cost-effective	MSAC considers a proposed medical service to be cost-effective if it considers that, for a specified main indication, the incremental benefits of clinical management involving the proposed medical service over clinical management involving its main comparator(s) justify its incremental costs and harms.

Department	The Department responsible for administering the Private Health Insurance Act 2007, currently the Department of Health and Aged Care
Economic evaluation	A comparative analysis of the costs and outcomes of health technologies. An umbrella term covering cost-benefit analysis, cost-effectiveness analysis, cost-consequence analysis, cost minimisation analysis and cost-utility analysis. The analysis involves identification, measurement and valuation of the differences in costs and outcomes caused by substituting health technologies.
Evidence	Information gathered from scientific research or direct measurement. Current best evidence is up-to-date information from relevant, valid research.
Expert Clinical Advisory Group (ECAG)	An independent HTA advisory committee of the Australian Government that primarily provides advice to the Medical Devices and Human Tissues Advisory Committee on appropriateness of listing of medical devices or human tissue products (if required) on the PL. This advice is based on assessment of comparative clinical effectiveness of medical devices and human tissue products (where applicable) using the best available evidence.
Fee, Schedule	A Schedule Fee is determined by the government for each medical service listed in the MBS. It is determined on the basis of being reasonable, on average, for that service, having regard to usual and reasonable variations in the time involved in performing the service on different occasions, and to reasonable ranges of complexity and technical difficulty encountered.
Fit-for-purpose	Structuring the size and type of a review or evaluation to fit the type, complexity and cost of the item(s) involved.
Focused commentary	A brief written analysis of an application to evaluate the validity of the information provided to support the clinical and/or economic claims and the proposed benefit, and to identify the main clinical and/or economic issues.
Focused health technology assessment	A tailored assessment of a device or other health technology that is conducted with the needs of the decision-maker in mind and is appropriately targeted to a policy question or main area of clinical, economic and/or financial uncertainty. The assessment approach is rigorous but pragmatic, and designed to aid decision-making within a shorter timeframe than a full HTA.
Follow-up	The observation, during a specified time period, of trial or study participants to measure changes in outcomes of interest.
Group	The level of classification of a medical device on the PL below ‘category’. Within categories, medical devices are grouped according to similar characteristics, designs, purposes and functionalities. For simplicity, medical device groups and subgroups are identified numerically.
Group benefit	The benefit paid for all medical devices that are classified in the same category, sub-category, group, subgroup and suffix.
Grouping	The last benefit point, including category, sub-category, group, subgroup and suffix.
Health technology	A technology used in a health care system — for example, therapeutic services (such as medicines and procedures), medical devices, investigative medical services (such as diagnostic tests and imaging services), equipment and supplies, and organisational and

	managerial systems.
Health technology assessment (HTA)	A multidisciplinary field of policy analysis studying the medical, economic, social and ethical implications of development, diffusion and use of health service delivery, and associated technologies, in a systematic, transparent, unbiased and robust manner. HTA encapsulates a range of processes and mechanisms that use scientific evidence to assess the comparative quality, safety, efficacy, effectiveness and cost-effectiveness of health technologies.
Health technology assessment (HTA) report, full	A report that includes one or more comprehensive systematic literature reviews, or a systematic review of high-level evidence, evaluating the safety and effectiveness of a technology, as well as an analysis of the cost-effectiveness of the technology. The report describes the characteristics and current use of the technology; critically appraises the quality of the evidence base; provides information on costs and financial impact; and discusses organisational considerations. The report should also address any ethical, social and legal considerations arising from use of the technology. When appropriate, the cost-effectiveness of the technology may be addressed through economic modelling.
Health technology management	An umbrella term for the range of health technology assessment and re-assessment activities that can inform decisions regarding the introduction, use, refinement of use, and removal of technologies or services from the health system.
Health technology 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.
Hierarchy of evidence	Framework for ranking of evidence developed by National Health and Medical Research Council (NHMRC)
Hospital-substitute treatment	Treatment that substitutes for hospital treatment; it is any combination of nursing, medical, surgical, podiatric surgical, diagnostic, therapeutic, prosthetic, pharmacological, pathology or other services intended to manage a disease, injury or condition
Human Tissue Product	has the meaning given by section 72-12 of the Private Health Insurance Act 2007.
Impact	A collective term to describe the effects that accrue at one or more levels of the health system as a consequence of the use of a device or other health technology. Impact includes one or more of: health outcomes for patients, service delivery changes for specific healthcare professionals, or health system changes for healthcare providers.
Indication	The disease or condition the device or human tissue product will treat, prevent, cure or mitigate, including a description of the patient population for which the technology is intended.
Intended purpose	The purpose that the manufacturer intends the device to be used for, as ascertained from the product information provided with the device, including labelling, instructions for use for the device, any advertising material related to the device, or technical documentation.
Interchangeability	Interchangeability is a concept that describes how closely a subject device relates to a PL-listed comparator device in terms of clinical, technical and biological characteristics [relates to use of materials or substances in contact with the same human tissues or body fluids]. 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) • same clinical characteristics – including patient population and indications for use • similar technical and biological characteristics – same mechanism of action, similar materials and similar design • any small design differences do not adversely affect the clinical safety and/or effectiveness of the device • 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.
Knowledge	An umbrella term covering evidence, data, opinion and lived experience.
Level of evidence	A ranking of study designs based primarily on their internal validity. This method is used to determine the weight that should be given to a study. Various hierarchies of evidence are used in HTA but in this Guide it has the meaning given by the NHMRC hierarchy.
Manufacturer	Manufacturer of a medical device has the meaning given by section 41BG of the Therapeutic Goods Act 1989. Manufacturers are responsible for applying conformity assessment procedures to the devices they manufacture and ensure compliance with the essential principles (Part 4-3 and Part 4-2 of the Therapeutic Goods Act 1989)
Medical device	has the meaning given by section 72-11 of the Private Health Insurance Act 2007
Medical device classification	has the meaning given by section 41DB of the *Therapeutic Goods Act 1989* and Division 3.1 of the Therapeutic Goods (Medical Devices) Regulations 2002
Medical Device and Human Tissue Committee (MDHTAC)	An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the responsible Minister on appropriateness of listing of , medical devices and human tissue items (where applicable) on the PL and the respective benefits. The MDHTAC's recommendations and advice are to be based on assessment of comparative clinical effectiveness and cost-effectiveness of medical devices and human tissue products (where applicable) using the best available evidence. This process ensures that privately insured Australians have access to a range of medical devices that have been shown to be clinically effective and represent value for money.
Medical service	Medical services include therapeutic, investigative and consultative procedures. When a surgically implantable device is provided to a patient, it is linked to a medical service. The evidence supporting the safety, effectiveness and cost effectiveness of the medical service is assessed by the Medical Services Advisory Committee; the evidence supporting the clinical effectiveness and cost effectiveness of the device is assessed by the MDHTAC. Medical services that are subsidised by the government are listed on the MBS.
Medical Services Advisory	An independent non-statutory expert committee established by the Australian Government Minister for Health in 1998. MSAC provides

Committee (MSAC)	advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence. Amendments and reviews of existing services funded on the MBS or other programs (for example, blood products or screening programmes) are also considered by MSAC. MSAC currently has two sub-committees: the PICO Advisory Sub-committee (PASC) and the Evaluation Sub-committee (ESC).
Medicare benefit	The payment of a rebate for a professional service listed in the MBS. Medicare benefits are claimable only for clinically relevant services rendered by an appropriate health practitioner. When a service is not clinically relevant, the fee and payment arrangements are a private matter between the practitioner and the patient.
Medicare Benefits Schedule (MBS)	Under the authority of the Health Insurance Act 1973, a listing and description of the professional services for which a Medicare benefit is payable by the Australian Government, the amount of a patient's cost that is met through a government rebate, and any conditions applying to the use of that service.
Minister/Responsible Minister	The Minister responsible for administering the *Private Health Insurance Act 2007*, currently the Minister for Health and Aged Care.
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).
Outcome	An effect produced by, or as a result of, clinical management or other factor(s), which may include a subsequent change in the provision of resources following the start of clinical management.
Pharmaceutical Benefits Advisory Committee (PBAC)	An independent expert advisory committee of the Australian Government that primarily makes recommendations to the health minister on the listing of medicines on the PBS. When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments.
Prescribed List	Under the authority of the Private Health Insurance Act 2007, a list of medical devices and human tissue products, for which private health insurers must pay the benefits to the patients with the appropriate insurance policy.
Public pricing	The price public hospitals pay for the medical devices or are predicted to pay for the medical devices.
Quality of life (QoL)	The extent to which an individual perceives themselves to be able to function physically, mentally and socially.
Randomised controlled trial (RCT)	A trial in which participants are randomly allocated to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice ('standard or care'), a placebo, or no intervention at all.
Registry	Registries within Australia and other jurisdictions that collect health-related information, including the safety and performance data for specified devices, that can be used to inform assessments and of safety and performance and comparative clinical effectiveness of a

	device or procedure.
Resource	A factor of production, an input or a produced good.
Search strategy	One or more series of commands defined by a researcher that directs the identification of relevant citations in one or more citation databases using combinations of indexing terms. An effective search strategy retrieves as many relevant citations as possible without retrieving an unmanageably large number of irrelevant citations. Choosing appropriate databases to search is also a critical element.
Single-use device	Means a device that is intended to be used on one individual during a single procedure
Sponsor	For the purposes of the Prescribed List, the sponsor is the same person as described in the Therapeutic Goods Act 1989 and stated on the ARTG entry. The sponsor is responsible for including the medical device or biological (human tissue product) in the ARTG, and maintaining the validity of their ARTG entry stated on their Prescribed List billing code.
Study, observational	A nonrandomised study that observes the characteristics and outcomes over time of participants who do and do not use a particular health technology. An umbrella term covering cohort and case-control studies.
Subject device or human tissue product	The medical device or human tissue product which is the subject of an application (new, or amendment, or compression, or expansion as applicable).
Substantial similarity	Devices are considered substantially similar if, they: • have similar designs and characteristics • are made of the same material • have similar intended uses and indications
Suffix	An identifier that denotes a device is similar in design and function to other devices in the same group or subgroup but has additional features that deliver different clinical outcomes.
Therapeutic good	Health technologies regulated by the TGA, including medicines, medical devices, human cells and tissues, and blood.
Therapeutic Goods Administration (TGA)	A division of the Australian Government Department of Health and Aged Care that regulates the quality, safety and efficacy of therapeutic goods available within Australia.
Therapy	Clinical management of an individual for the purpose of improving health outcomes by combating (such as preventing, curing, ameliorating) a medical condition, disease or disorder; all resources provided in this management or care.
Uncertainty	Any reduction of confidence in a conclusion. Statistical uncertainty arises from chance (or random variation), when a variable includes a range of estimates within which the true value of the variable is likely to be found. Inferential uncertainty arises from bias (or systematic variation) when there are alternative explanations for a measured difference or arises when translations are made from an estimate. Clinical uncertainty arises when the proposed health technology has both clinical advantages and disadvantages compared with its main comparator(s). Structural uncertainty arises in a model when all the relationships between the various components are not fully demonstrated. Uncertainty also arises when assumptions need to be

	made in the absence of relevant data.
Utilisation	The number of uses of a health technology in a specified time period.
Value for money	A proposed health technology is considered to represent value for money by an HTA advisory committee if it considers that, for a specified main indication, the incremental benefits of the proposed health technology are valued higher than the opportunity costs of obtaining those benefits.
Well-established technology	A device group proven to have sound safety and performance characteristics. "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 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)

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All information in this publication is correct as at December 2023