



# **Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products**

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DRAFT FOR CONSULTATION

## 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

Document Location	Document Name

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# Abbreviations and Acronyms

<b>ARTG</b>	Australian Register of Therapeutic Goods
<b>Billing Code</b>	A unique identification code allocated to a listed medical device or human tissue product
<b>Department</b>	The Department responsible for administering the <i>Private Health Insurance Act 2007</i> , currently the Department of Health and Aged Care
<b>ECAG</b>	Expert Clinical Advisory Group
<b>FAQs</b>	Frequently Asked Questions
<b>FDA</b>	Food and Drug Administration (United States)
<b>HPP</b>	Health Products Portal
<b>HTA</b>	Health Technology Assessment
<b>MBS</b>	Medicare Benefits Schedule
<b>MDHTAC</b>	Medical Devices and Human Tissue Advisory Committee
<b>MEDSAFE</b>	New Zealand Medicines and Medical Devices Safety Authority
<b>Minister/Responsible Minister</b>	The Minister responsible for administering the <i>Private Health Insurance Act 2007</i> , currently the Minister for Health and Aged Care  <i>Reference to the Minister also includes the Minister's delegate</i>
<b>MSAC</b>	Medical Services Advisory Committee
<b>PBAC</b>	Pharmaceutical Benefits Advisory Committee
<b>PBS</b>	Pharmaceutical Benefits Schedule
<b>PL</b>	Prescribed List of Benefits for Medical Devices and Human Tissue Products
<b>PHI</b>	Private Health Insurance
<b>Product/s</b>	Medical Device and Human Tissue Product
<b>RCT</b>	Randomised Controlled Trial
<b>The Rules</b>	Private Health Insurance (Medical Devices and Human Tissue Products) Rules
<b>TGA</b>	Therapeutic Goods Administration

# **PART 1: OPERATIONAL INSTRUCTIONS**

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# Chapter 1: About this Guide

## What is the Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the Guide)?

The *Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products* (the Guide) will assist applicants to prepare an application to list an eligible medical device or human tissue product on the Prescribed List of Benefits for 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:

- the PL application forms and other information on the assessment process provided in the HPP
- deadlines for submitting PL applications
- application and listing fees
- annual levies
- information sources and contacts
- frequently asked questions
- compliance approach
- post listing reviews
- legislation relevant to medical devices and human tissue products
- [Medical Services Advisory Committee](#).

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 Benefits for 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](mailto: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 Benefits for 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) 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 \(No. 1\) 2023](#) (the Rules). The Schedule to the renamed the Rules is known as the Prescribed List of Benefits for Medical Devices and Human Tissue Products, the 'PL' for short.

### Purpose of the Prescribed List

The PL is a list of medical devices and human tissue products (products) where it has been determined (in line with the listing criteria) that private health insurers are required to pay minimum benefits for the products when provided to a person with appropriate private health insurance cover. This would apply as part of an episode of hospital (or hospital substitute) treatment, for which a Medicare benefit is payable for the professional service associated with the provision of the products.

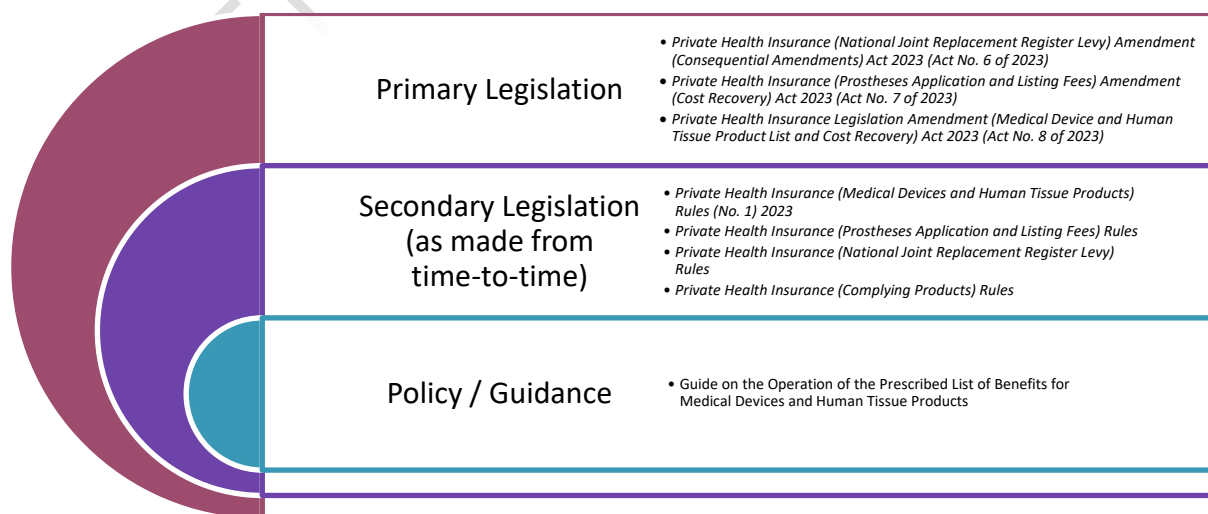
The purpose of the PL is to ensure that privately insured Australians, who have appropriate health insurance to cover the treatment, have access to clinically effective products that meet their health care needs.

The arrangements for including products on the PL help to ensure that benefits paid by insurers are relative to clinical effectiveness.

### 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, 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 set 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 makes the new or amended 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.

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 device and human tissue products categories and groupings**

There are currently 13 categories of medical devices on Part A; four (4) categories of human tissue products in Part B; three (3) categories of medical devices in Part C; and three (3) categories of general use items in Part D.

Within categories, products are grouped according to similarity in characteristics, functionality and clinical effectiveness. For simplicity, product categories, subcategories, groups and subgroups are identified numerically with the respective description of each grouping and some also have alphabetical suffixes.

**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. Billing codes are listed at the group, subgroup and suffix level. Each grouping has a single group benefit (with exception of small number groupings that historically have been having alternative benefits).

Private health insurers are required to pay the minimum benefits as specified for each billing code listed in a particular grouping.

The billing code may only be listed in one PL grouping 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)
- 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, with the same design/shape and purpose, but supplied in different lengths and widths)
- a kit, pack, tray, etc consisting of two or more medical devices, or a device and other products, that are supplied and intended to be used together:
  - identified by a single catalogue/product number; or
  - each component of the kit 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
- a kit, pack, tray, etc consisting of two or more medical devices, or a device and other products, that are supplied 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 (e.g. spinal

cages of different sizes together with the plates of different sizes and screws of different sizes).

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 or compression applications.

## Health technology assessment in Australia

Efficient and effective health technology assessment (HTA) processes are crucial to supporting sustainable management of publicly 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 for the Australian community.

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 inter-dependent relationships. Each entity has discrete functions and responds to different policy needs. HTA processes and methods are well-established to support advice provided by the PBAC and MSAC.

The Australian Government HTA framework is supported by the TGA, MSAC, PBAC and/or MDHTAC to ensure:

1. assessment of the safety and performance of medical devices and biologicals to ensure therapeutic goods are safe, perform as intended, and are produced using appropriate quality controls before marketing approval is granted in Australia through the ARTG and post market surveillance of these products
2. assessment of the comparative clinical and cost effectiveness which informs decisions about:
  - a. public funding of medical services (with or without a device); procedures and diagnostic technologies; pharmaceuticals; and vaccines through the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP) respectively
  - b. private health insurance reimbursement of medical devices through the PL
3. post-listing reviews to inform ongoing decisions about continuing reimbursement of health technologies.

## Application process

All PL applications must provide sufficient information to demonstrate that:

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. the products also need to meet the [listing criteria](#) which are set up in the Rules (including that the product is designed to be used for specified therapy [i.e., not general use]), is included in ARTG, and other criteria applicable to each PL Part].
3. the product is used in hospital or hospital substitute treatment and
4. there is at least 1 existing MBS item appropriately describing the Medicare service relevant to the device.

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 C applications. Processes for Part B applications are still being finalised. Applications for products that no longer fit the definition of an eligible device will no longer be considered (for example comparator products to those currently on Part D which will be removed on 1 July 2024).

See [Part 2](#) for further information on the application process and evidence requirements.

### *Role of the sponsor*

Sponsors are responsible for applying for listing of their product on the PL or amending the existing billing code 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 application form.

Sponsors have a responsibility to provide all information as requested in the application form in the HPP, and 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 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 composed of an independent Chair, the six Chairs of the Expert Clinical Advisory Groups (ECAGs), a consumer representative, a health economist, and up to two clinical/HTA experts who are not members of ECAGs. The ECAG Chairs provide a connection between the MDHTAC and the respective ECAG, with each Chair presenting the relevant applications to the committee for discussion.

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.

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 almost all 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)
- Hip and Knee ECAG
- Ophthalmic ECAG
- Spinal and Neurosurgical ECAG
- Cardiovascular ECAG (including cardiac, cardiothoracic and vascular)
- General Surgery ECAG (including ear, nose and throat, plastic and reconstructive surgery, urogenital and all other general surgery devices).

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 ECAG also considers the comparator (either listed on the PL or alternative treatment), appropriateness of the proposed grouping, and other matters as applicable.

ECAGs may also propose if a cost-effectiveness assessment is required including consideration by MSAC.

The ECAGs' deliberations and recommendations including statements of reasons are recorded in the minutes that inform the advice to the MDHTAC. These minutes are not published as almost all 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
- working with and providing support to the MDHTAC
- 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
- reviewing the MDHTAC's recommendations aiming for business improvements
- 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.

The department is the primary contact for any queries that sponsors may have about the application process and liaises with sponsors as required. You may contact the department at [prostheses@health.gov.au](mailto:prostheses@health.gov.au).



All communication should be via the department. 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 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 ECAGs 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. For human tissue items, the recommendations are usually 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 rejected.

If the product is not yet included in the ARTG, MDHTAC may make a provisional recommendation subject to the inclusion of the product in the ARTG. For further information see [Parallel Process](#).

MDHTAC may also recommend placing a condition on the billing code restricting the insurers' obligation to pay the minimum benefit to certain circumstances (e.g., if the product is used for 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 a product (or groups of products) will be undertaken where specific concerns have been raised. Reviews can be initiated any time to address post-listing issues as required. These will occur in accordance with the [Post-listing Review Framework](#).

The need for a review may be identified:

- through stakeholder correspondence
- during the consideration of applications or other matters by ECAGs or the MDHTAC
- by a request from the Minister
- through referral from MSAC or MBS review committees
- from outcomes of compliance activities or other departmental processes.

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

Post-listing reviews may incorporate a range of processes including targeted reviews (focussed HTAs) of specific issues, analysis of utilisation data, or complex post market reviews incorporating full HTA. Larger reviews may incorporate reports from independent/external consultants. Reviews may involve a single product, a class or category of products, or multiple classes of products.

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 placing the conditions on the billing code.

## Removal of a product from the Prescribed List

### *Instigated by the MDHTAC or the department*

From time-to-time, the MDHTAC will consider if a product should be removed from the PL, for example, if the device no longer satisfies the criteria for listing, or where there is cancellation or suspension of the ARTG entry by the TGA; or if the product does not meet the definitions of 'medical device' or 'human tissue product' in the PHI Act. Eligibility will require the product to meet the definitions (in the PHI Act) and as well as the updated listing criteria (in the Rules).

If the MDHTAC is considering this action, the department will write to the sponsor 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 sponsor agrees or the MDHTAC affirms the recommendation to remove the billing code, the matter will be referred to the Minister when the next time the Rules are made or amended.

## Removed from ARTG

In instances where a product on the PL is no longer included in the ARTG, whether at the request of the sponsor or due to compliance action (suspension or cancellation by the TGA), the Minister may decide to remove the billing code for the product from the PL, because it is no longer approved by the TGA.

Where there is regulatory action from the TGA which may include manufacturer recalls, reported safety issues, counterfeit medical devices and reported adverse clinical events, the Minister may also make a decision to remove the PL billing code for this product.

Sponsors must inform the department immediately if their product is cancelled or suspended from the ARTG by submitting a deletion application.

## 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 behaviour 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 against the established listing requirements outlined in the Rules.

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) and 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 [prosthesecompliance@health.gov.au](mailto:prosthesecompliance@health.gov.au).

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

## Parallel process

For products to be legally supplied in Australia, they must have a valid ARTG entry (information about inclusion on the ARTG can be found on the [TGA website](#)).

Consistently with the above, one of the criteria for the product to be eligible for listing on the PL is availability of the current and valid ARTG entry for the product.

Under the parallel assessment process, sponsors can submit a new PL application for listing the product on the PL, before they receive an ARTG entry, but sponsors 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 under parallel process are:

- medical device or product ARTG inclusion application
- medical device conformity assessment application.

The TGA 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, but no decision will be made regarding listing the device or 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 without a valid ARTG entry will be deferred for a maximum of 18 months since the date the application was submitted. After 18 months, the application will be deemed non-compliant and will be automatically rejected. The sponsor will need to submit a new application to list a medical device or product on the PL and pay related fees.

# Chapter 3: Criteria for listing products on the Prescribed List

The Rules set out the listing criteria that products must satisfy to be considered for listing on the PL (refer [Part 3 - Listing criteria](#)).

## General listing criteria

A product must not be listed in Parts A, B or C of the Prescribed List unless it is included in the ARTG. This ensures that the department can independently verify that the product may be legally supplied in Australia.

## Listing criteria for medical devices to be listed in Part A

A medical device must not be listed in Part A of the PL unless the following criteria are satisfied:

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.

To meet these criteria the device must be specifically designed as an integral single-use aid and be essential for implanting a device referred to in (a) or be critical to the continuing function of an implanted device referred to in (a) and only suitable for use post-implantation by the patient in whom the device referred to in (a) is implanted.

Single-use means that, 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 a device in (a) with which the device in (b) or (c) is designed to be used with, that is a listed item or will be a listed item following successful listing application or variation application.

Non-implantable devices do not meet the 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 in the Prescribed List or the alternative treatments and the benefit amount for the medical device must be proportionate to the clinical effectiveness of the device.

The term 'alternative treatments' is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the Prescribed List. The alternative treatment is general expected to be the current standard of care for the condition or indication.

The working 'no less clinically effective' is used because products are rarely identical, and a range of factors may need to be balanced against each other when comparing clinical effectiveness.

A product's cost should be compared to alternative treatments and considered in relation to its clinical benefits.

## **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*).

## **Listing criteria for medical devices to be listed in Part C**

A medical device must not be listed in Part C of the PL unless the following criteria are satisfied:

The medical device must be one of the following:

- (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.

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.

Both of the following must be satisfied:

- (a) the medical device must have been compared to:
  - (i) alternative devices listed in Schedule 1 or
  - (ii) alternative treatments
- (b) the comparison must demonstrate that:
  - (i) the medical device is no less clinically effective than the alternative devices or the alternative treatments and
  - (ii) the benefit amount for the medical device is proportionate to the clinical-effectiveness of the medical device.

For a medical device to be listed in Part C of the PL it must be specified in the list of existing groups in the PHI Rules.

Unless a medical device is one of the specified items, it is not eligible to be listed.

The specified groups of medical devices can be varied from time to time to add or remove devices from the Rules.

A medical device must be assessed to be no less clinically effective than the alternative devices listed in 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 term 'alternative treatments' is included to allow for new products or technology to be compared with current treatments for the same clinical condition, as not all products to be considered have an existing comparator on the PL. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

The wording 'no less clinically effective' is used because products are rarely identical, and a range of factors may need to be balanced against each other when comparing clinical effectiveness.

A product's cost should be compared to alternative treatments and considered in relation to its clinical benefits.

# 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 [Tier](#) of application will be available on the department's website.

All cost recovery fees are aligned with the Australian Government Charging Framework and the Cost Recovery Guidelines. All details relating to the services that are included in cost recovery fees and the financial performance of the cost recovery arrangements are available through the [Cost Recovery Implementation Statement](#) (CRIS). The CRIS is updated and published on the PL 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:

- list a medical device on the PL – listing application
- expand a current billing code – variation application
- compress current billing codes – variation application
- amend details of a current billing code – variation application.

There will be no fee payable for the following applications:

- sponsors transfer of a current billing code – sponsors' transfer application
- delete (remove or revoke) a current billing code – deletion application.

## 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 Tier. These fees include the following:

- standard Application Fee (applies to all applications regardless of Tier)
- clinical Assessment Fee (applies to all applications classified as Tier 2a and Tier 2b)
- standard Economic Assessment Fee (applies to Tier 2b applications)
- complex Economic Assessment Fee (applies to Tier 2b applications)
- other Economic Assessment Fee (applies to Tier 2b applications)



- full HTA Assessment Fee (applies to all Tier 3 applications)<sup>1</sup>

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 must be paid when the application is submitted through the HPP. This fee is non-refundable.

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

## 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.

If an application is withdrawn, or if an application has not been granted, the application may be remade. The application may be made to the same or a different Tier.

## Fee waivers and fee exemptions

There is one waiver and one exemption pathway available to sponsors.

A waiver of certain fees may be applicable for applications in which a single or abridged clinical assessment or economic assessment may be leveraged to assess applications that form a part of a series of related applications for related medical devices.

Medical devices are related if the main equipment and the accessory and ancillary medical devices are designed to be utilised together for an expected clinical outcome. Related medical devices are covered under the same product material (product brochure, surgical technique, instructions for use, etc) and the clinical data for the related device is provided under the same report from the same source (clinical trial, registry, etc) and this information allows the assessment of all the related devices together. In this instance, the medical device would also require the submission of more than one application (an application for each component) resulting in the incurrence of multiple cost-recovery fees.

Sponsors need to request a waiver when submitting an application into 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 Delegate.

An exemption will be granted for applications under [Tier 3: Full HTA \(MSAC\) Pathway](#) where an application might have undergone a clinical assessment and/or and economic evaluation

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<sup>1</sup> 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

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 applicant should not be required to pay duplicate fees for a single service. 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 that fee exemptions granted for the PL fees would not apply to MSAC services.

## Reviewable decisions

A few decisions made in relation to cost recovery are reviewable. This means that if a sponsor believes that a decision made in relation to the need for clinical, economic or full HTA, to the issuing of refund, or to the granting of fees 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 the decision.

## 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: TECHNICAL GUIDANCE**

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# Chapter 5: Making an application

## Health Products Portal

All PL applications are required to be submitted via the [HPP](#).

To access the HPP, sponsors must 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 where you can view user guidance on using the HPP, upcoming webinars and complete your applications.

## Application cut-off dates

The cut-off dates for submitting PL applications can be found on the [department's website](#).

## Application types

Applications can be made relating to Part A, B or C of the PL.

Applications will not be considered for Part D in line with the removal of these items from 1 July 2024. Further information on the general use items is available on the [department's website](#).

Within the HPP there are three (3) applications for medical devices and human tissue products:

- PL application
- Delete/Transfer application
- Resubmission application.

## PL application - Part A and Part C

For Part A and Part C, there are four (4) application types covered within the PL application in the HPP:

- New applications
- Amendment applications
- Expansion applications
- Compression applications

*New applications* are used by sponsors for applying for listing products on the PL. If the new application is successful, the sponsor will receive a new billing code covering the product.

*Amendment applications* are used for applying to change the details of the existing billing code. This may include deletion or addition of catalogue numbers recorded for the billing code, changing the product name, description or size, addition or replacement of ARTG

entries. Sponsors also may use this type of application for applying to change the grouping the billing code is listed in.

*Expansion and compression applications* are used for expanding the billing code covering multiple products into a few 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 the products that are not expected to be listed together (expansion application), or very similar products are not expected to be split (compression applications).

Based on the selection of application type, the required information and evidence will change (see [Chapter 6](#)).

## PL application - Part B

For Part B, there are three (3) application types covered within the PL application in the HPP:

- New applications
- Amendment applications
- Benefit update applications

*New applications* are used by sponsors for applying for listing products on the PL. If the new application is successful, the sponsor will receive a new billing code covering the product.

*Amendment applications* are used for applying to change the details of the existing billing code. This may include changing the product name or description.

*Benefit update applications* are used by sponsors to update the benefits across multiple Part B items, without having to lodge multiple applications.

## Delete/Transfer applications

The Delete/Transfer application can be used to delete billing codes, or transfer ownership of existing billing codes. This application is available for Part A, B and C products.

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

## Resubmission applications

Sponsors may choose to re-apply if there is a negative decision regarding their application.

Sponsors need to address the concerns raised during the assessment and recommendation when they resubmit their application and provide all required information.

Resubmission functionality in the HPP will allow the new application to be pre-filled from the previous application.

## Assessment of Part B applications

Part B applications for products are assessed by the department.

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 for Part A and Part C PL applications, covering new, amendment, compression and expansion of billing codes, with the evidence requirements tailored for each pathway.

Sponsor transfer and delete applications are administrative applications - the three tier assessment pathways do not apply to these types of applications.

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

1. Tier 1: Departmental Assessment Pathway – when the medical device is interchangeable (see [interchangeability](#)) with another listed device on the PL (the comparator), hence no clinical assessment is required. This pathway is largely administrative.
2. Tier 2: Clinical/Focused HTA Assessment Pathway – when there are features of the device that increase risk or complexity and/or the comparator is sufficiently different that interchangeability cannot be accepted BUT the threshold for requiring an MSAC assessment has not been reached.
3. Tier 3: Full HTA Pathway – when an MSAC assessment is required (i.e., new MBS item number or MBS amendments required or first-in class device with no PL comparator).

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 which pathway is most appropriate for their application, sponsors are encouraged to review the information requirements for each pathway. Where the appropriate pathway is unclear, sponsors are encouraged to contact the department for further advice prior to lodgment.

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. The chosen pathway to list a medical device or product 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.**

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## Tier 1: Departmental Assessment Pathway

Applications submitted under the Tier 1 Pathway are assessed only by the department.

Tier 1 applications are for medical devices classified by the TGA as Class IIb or lower, with product design and characteristics based on well-established technology (with well-understood and stable designs and limited variations), with proven records of satisfactory safety and performance.

**Tier 1 is not suitable for Part C applications. Part C applications are restricted to Tier 2 or 3.**

Sponsors may only apply for listing the device in one of the existing PL groupings. It is expected that a medical device assessed under this pathway will be interchangeable with devices in the same PL benefit group (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 there will be no increase in utilisation in the nominated PL benefit group because of listing the device on the PL. Claims of interchangeability and appropriate comparator must be justified (see [interchangeability](#)).

Examples of devices suitable for Tier 1 Pathway may include:

- ancillary knee, hip, shoulder joint replacement medical devices (e.g., screws, wedges, axles, bushings, extensions, spacers, etc.) but not main prostheses (femoral stem, tibial baseplate, inserts, acetabular cups, glenoid components, etc.)
- hand, foot, ankle, elbow joint replacements
- craniomaxillofacial fracture and reconstruction plates
- bone cements or bone void fillers (but not containing medicine or microbial origin substance).

The Tier 1 Pathway is not intended for any applications for:

- devices with the TGA high-risk Class III classification
- where the sponsors claim any novel features, characteristics or functionality
- the new/fast developing or novel technologies, as these applications require a more comprehensive clinical assessment
- devices with sufficient variability in design and characteristics to make interchangeability with the comparator not demonstrable
- applications for which sponsors are unable to provide information in the form required by the department.

\* these restrictions will be reviewed after 24 months of operation.

Sponsors must not ask for any new groupings or ask to change the groupings (in the amendment application) when they submit the application under the Tier 1 Pathway.

All applications that enter the Tier 1 Pathway will undergo an assessment process where the department will verify eligibility of the device for listing, appropriateness of all devices identified by the catalogue numbers to be listed together under the same billing code, that the design, material and other characteristics are standard for this type of device (do not vary from other devices listed on PL) and that the device is interchangeable with the PL-listed comparator, correctness of the grouping and the comparator, and appropriateness and completeness of the information provided by the sponsor.



Sponsors applying via this pathway will only be allowed one opportunity to provide clarification or additional information within the timeframe specified by the department that usually will not exceed 5 working days. Incomplete or inappropriate applications will be rejected.

Under this pathway, the department will provide the recommendation to the Minister, without seeking advice from an ECAG or the MDHTAC.

### ***Demonstrating interchangeability with proposed comparator***

Sponsors need to demonstrate interchangeability with another PL listed device in the same benefit group. Though the device may have some product characteristics (small design differences) that are different from comparators in the group, it must have very similar safety and performance characteristics to the appropriate comparator for the indicated uses. In general, claims of interchangeability require a medical device to be similar physically and identical in clinical use (same patient population and the same indications for use).

For devices to be considered interchangeable they must:

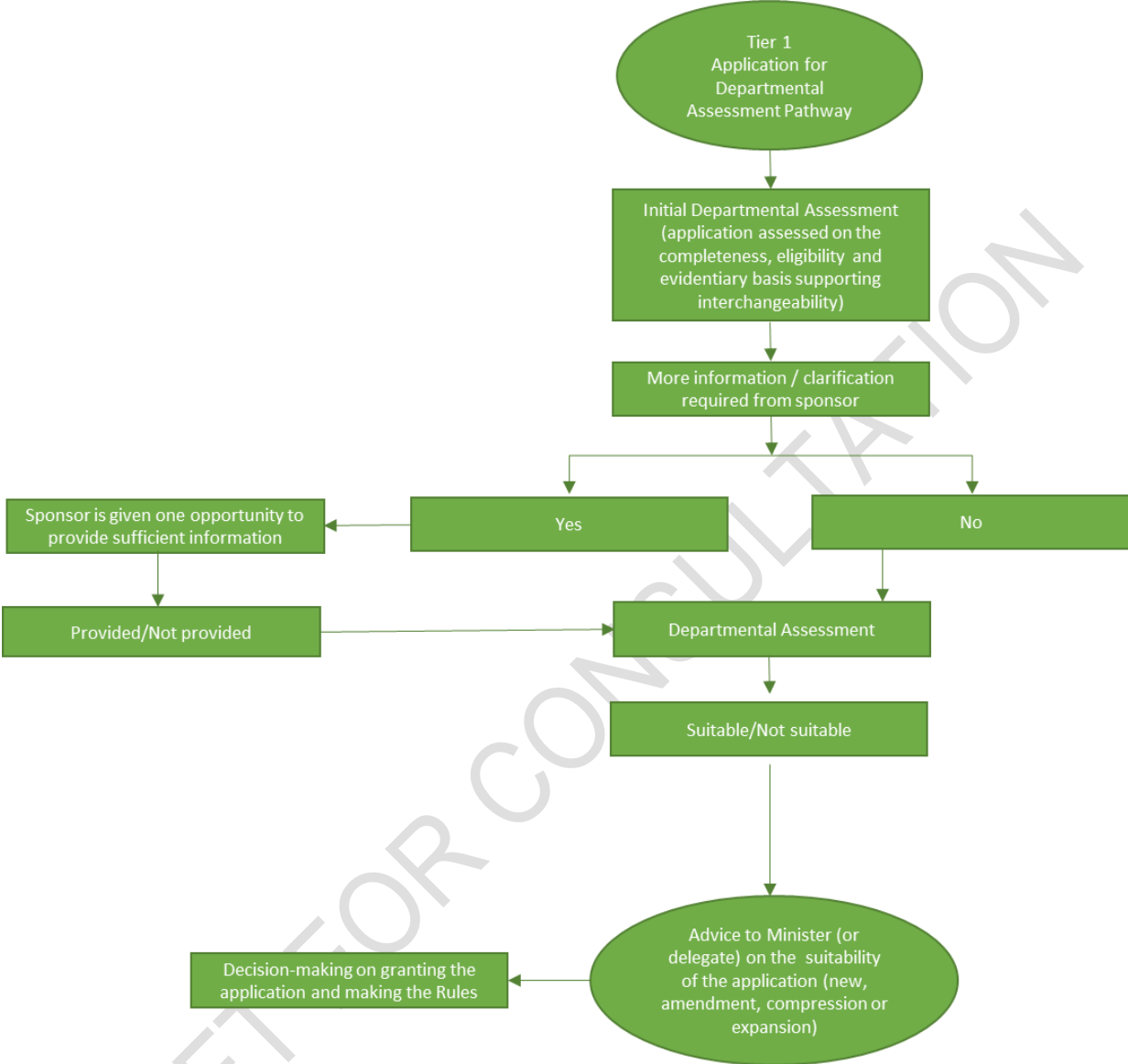
- be physically comparable (using the images with the respective catalogue numbers and identifying all devices in the application compared with the comparator)
- have the same clinical characteristics – including patient population and indications for use
- have similar technical and biological characteristics – same mechanism of action, similar materials and similar design
- have technical evidence (e.g., bench data) to establish that small differences do not affect the clinical safety or effectiveness of the device (where applicable)
- where required, have clinical evidence to establish that any differences would not adversely affect the clinical safety, effectiveness or cost effectiveness of the device.

If listed on the PL, the subject device will share the market with the comparators and is not expected to result in a marked change in aggregate utilisation.

Sponsors are required to complete a detailed comparison against each [comparator](#) within the HPP to demonstrate interchangeability, identifying the similarities and differences between the sponsors device/s and the comparator device/s, supported by relevant technical documents and/or clinical evidence. Differences require clear explanations and supportive documentation to establish that the differences will not negatively affect the comparative clinical safety and effectiveness, or cost effectiveness of the device to be listed relative to the comparator, or the aggregate utilisation of the product group. Appropriate documentation must be referred to in the comparison, and provided in the application, to allow assessment of the interchangeability claim.

Applications containing claims of interchangeability will be appropriate for consideration via the Tier 1 Pathway provided the interchangeability claim can be assessed and is accepted by the department. Exceptions to this include circumstances where there is high risk of harm from device failure, or the appropriateness of the comparator requires more extensive assessment or expert input. In such instances, the application will be required to undergo a Tier 2 Clinical/Focused assessment or a Tier 3 Full HTA assessment to evaluate the claims made by the sponsor.

**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 (Figure 3), is for devices that are not suitable for assessment via the Tier 1 Pathway and do not require a comprehensive full HTA via MSAC assessment. The assessment is conducted by the department and by the respective ECAG, and include:

- device types that are not well-established technology, and/or have broad variability in designs and characteristics, and/or have Class III classification from TGA
- devices for which sponsors claim any novel features, characteristics or functionality
- applications where sponsors apply for listing the device in new groupings or ask to change the groupings (in the amendment application)
- 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:

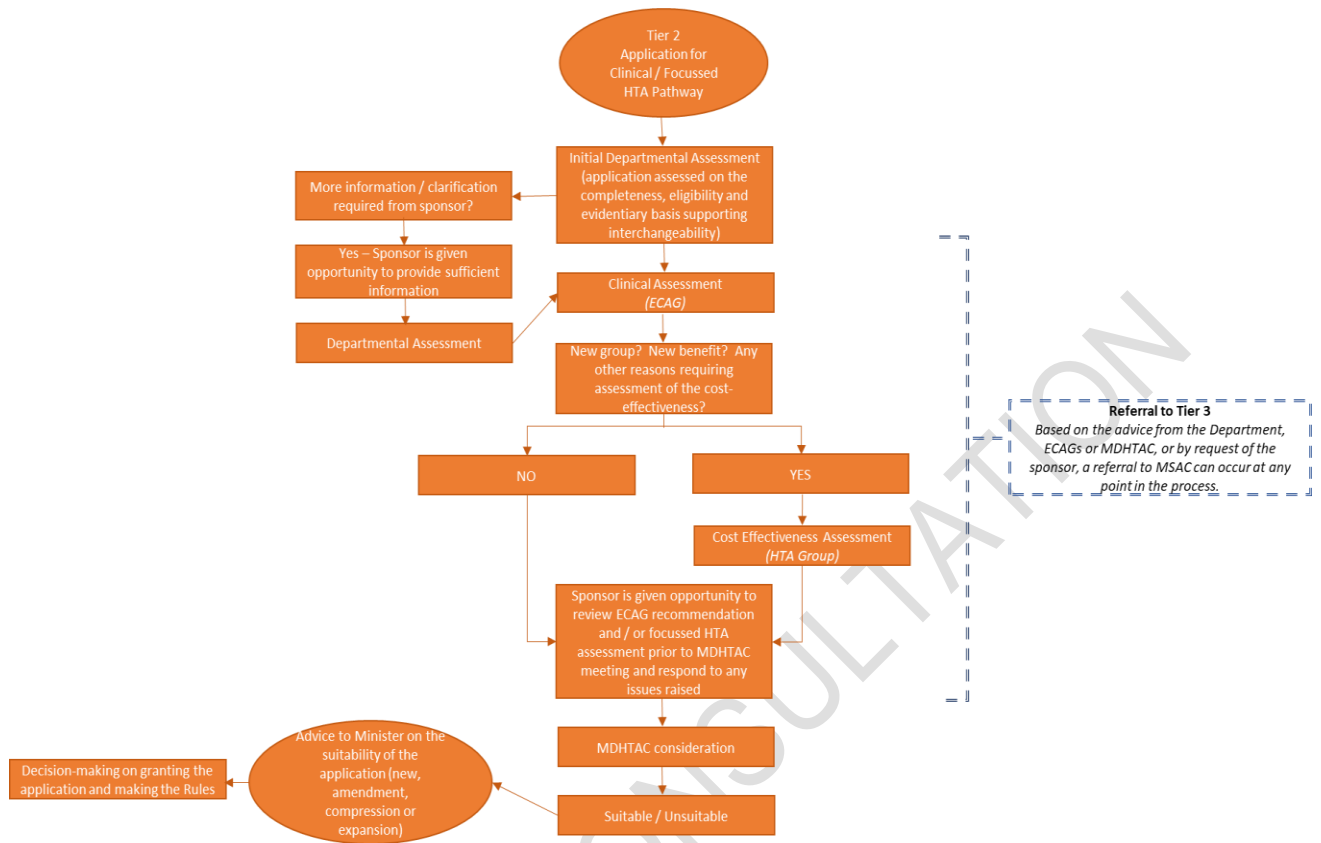
Tier 2a – clinical assessment only

Tier 2b – clinical assessment plus economic assessment to establish cost effectiveness.

An HTA may be undertaken by a HTA Group engaged by the department as required. 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. The assessment reports will be provided to the 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/Focused HTA Pathways**



## Tier 3: Full HTA Pathway MSAC and MDHTAC

The Tier 3 Pathway, the Full HTA Pathway, is for devices that require a comprehensive HTA to establish the comparative clinical effectiveness and cost-effectiveness and, in some cases, total cost of the medical device and the related medical service. Examples of applications that require Tier 3 Pathway include:

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

Tier 3 applications may be initiated by sponsors who identify this as the most appropriate pathway, or they may be referred by the department, ECAG or MDHTAC from the Tier 2 Pathway. Sponsors will be required to submit an application to MSAC, and the applications and all correspondence must identify and explain the link between the PL application (whether underway or planned in the future) and the MSAC application. The PL application may occur concurrently or subsequent to the MSAC application.

When applications are referred, the department/ECAG/MDHTAC will liaise with MSAC regarding the reason for referral and monitor the application progress. Alternatively, 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. In these cases, advice will be provided to the sponsor that assessment via the Tier 3 Pathway is more appropriate (Figure 4). The sponsor may then decide to continue proceeding down the Tier 2 Pathway, noting there is a risk the application may not be considered suitable; 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.

The MSAC and PL applications will undergo separate assessments, but information may be shared throughout the assessment process. The MSAC will appraise the evidence presented to MSAC and:

- consistent with usual practice, provide advice to the Minister on whether or not it supports a new, or change to an existing medical service associated with the device and if so, in what circumstances and
- provide advice to the MDHTAC to inform their recommendation regarding the listing of the device on the PL, including in respect of any associated medical service associated with the device and if so, in what circumstances.

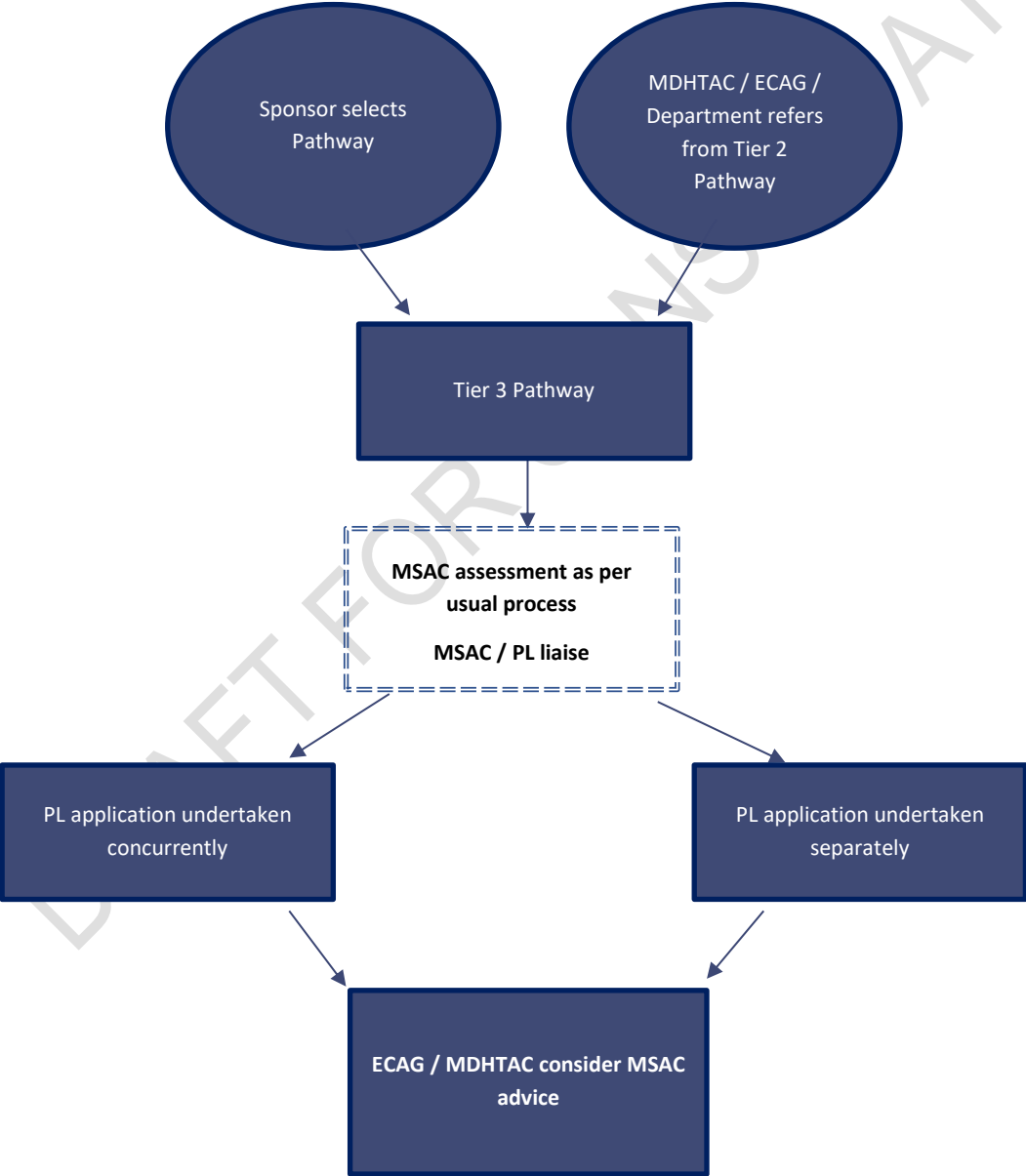
Where an application to the MSAC is seeking a new or amended MBS item, the completed application form must be accompanied by a brief 'Statement of Clinical Relevance' from the professional body/college representing the group(s) of health professionals who provide the service. The application will not progress to suitability assessment until this Statement of Clinical Relevance is received.

When the MSAC Secretariat receives a completed MSAC application form and Statement of Clinical Relevance, it conducts an assessment to determine if the application is suitable to proceed through the MSAC process and, if so, the most appropriate assessment pathway. The suitability assessment takes account of the nature of the service and/or technology, its novelty and complexity, availability of supporting evidence and the technologies involved. Once suitability has been confirmed and the appropriate MSAC assessment pathway determined, the department will email the applicant to advise next steps.

If the MSAC application is found suitable, it will be subject to the same processes, timeframes and requirements as other MSAC applications.

Information about MSAC 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**



# Chapter 6: Information and evidence requirements

## Information per application type

Information and evidence are provided within the application in the HPP. The assessment pathways differ in the types of information and evidence required to be submitted by the sponsor.

This section will provide detail on the types of information sponsors will need to have available to enter into their application in the HPP.

For amendment applications, the sponsor will select an existing billing code and detail which information is being amended. The product level information will be pre-filled from the existing billing code (where available), and only the amended elements will need to be updated.

A summary of the type(s) of information required for each pathway is shown in Table 1.

## Application and contact details

Sponsors must select the relevant Part of the PL, the relevant assessment pathway (Tier), and the type of application. Sponsors must also list at least one primary contact and can add multiple contacts for the application.

## Product details

An application may contain one or more products. A product is a proposed billing code, or a billing code to be amended. Products added to the same application must be related, either as products from the same range, or as products within a product system. If all products are related and may be assessed together, sponsors may be eligible for a waiver of the assessment fee (see [Cost Recovery](#)).

For each proposed or amended billing code, sponsors will need to provide/update the product name, description and size or size range, and the regulatory information, product information per catalogue number, grouping, comparators and MBS items. This information is at the product level and needs to be defined per product.

## Regulatory information

For a product to be listed on the PL it must be approved by the TGA and be listed on the ARTG. PL applications can be made in parallel with ARTG inclusion applications. To lodge a PL application, either an ARTG ID or Application Identifier must be provided.

**Table 1: Types of information required for applications assessed via each of the pathways, and Part B applications.**

Information requirements	Tier 1: Departmental pathway	Tier 2: Clinical / Focused HTA pathway	Tier 3: Full HTA pathway*	Part B application
Application and contact details	Yes	Yes	Yes	Yes
Product details	Yes	Yes	Yes	Yes
Regulatory details	Yes	Yes	Yes	Yes
Product information per catalogue number	Yes	Yes	Yes	No
Grouping	Yes	Yes	Yes	Yes
Clinical claim and outcomes (proposed new group only)	No	Yes	Yes	No
Comparator details	Yes (PL only)	Yes	Yes	Yes
MBS Items	Yes	Yes	Yes	Yes
Estimated utilisation	No	Yes	Yes	Yes
Product supporting documents	Yes	Yes	Yes	Yes
Clinical evidence	No (unless required to establish interchangeability)	Yes	Yes	No
Economic evidence	No (unless required to establish interchangeability)	Yes (but limited)	Yes (comprehensive)	No

\* Please refer to the MSAC Guidelines for evidence information requirements in 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

## Product information per catalogue number

For Part A and C applications, catalogue numbers must be provided along with information about each catalogue number.

The HPP allows sponsors to upload a spreadsheet of catalogue numbers.

## Grouping

For Part B applications, an existing grouping must be selected for the new/amended product. The proposed benefit must be entered along with a rationale for the benefit and supporting cost analysis.

Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products



For Part A and C Tier 1 applications, an existing grouping must be selected for the new/amended product. The benefit will be pre-filled from the selected grouping in HPP.

For Part A and C Tier 2 or 3 applications, an existing grouping can be selected, or a new group or sub-group can be proposed.

## Clinical claim and outcomes (proposed new group only)

If a new grouping has been proposed for a Tier 2 or 3 application, sponsors will need to provide a rationale for the new grouping. Sponsors will need to answer whether the product provides greater clinical effectiveness, cost effectiveness or time efficiencies, and detail the resulting outcomes (see [clinical and economic evidence requirements](#)).

### *Use of the medical device in practice*

If the medical device has been used in the public health sector in Australia, sponsors should advise where it is being used and who covers its cost (e.g., the patient, special access scheme, public hospitals) including providing actual utilisation data. If the medical device has been used in other countries, actual utilisation data for each country should be provided. If projections are available for other countries, this information should also be included.

## Comparator details

At least one comparator must be added for each product on a PL application.

### Part B applications

For Part B applications, comparators can be selected from the PL, from the MBS and added where the comparator is not on the PL or MBS. Information will need to be entered on why the selected product/health technology/service is a comparator. There is no requirement to provide a detailed comparison.

### Part A and C applications

To demonstrate comparative clinical effectiveness and determine an appropriate benefit for a medical device, sponsors must identify at least one comparator. Typically, this will be another medical device, ideally a PL listed medical device. If there are no medical devices that can be identified as a comparator, current standard of care (e.g., a drug treatment or medical service) should be used. If the comparator/s are treatments or therapies not on the PL, a brief description of the treatment and current reimbursement mechanism/s must be provided (e.g., if the comparator is medical management, then the payment mechanism for the pharmaceuticals may be the PBS).

If more than one comparator is identified for the medical device, the intervention that would be most often replaced with the proposed device should be identified.

When assessing the application, the department, ECAG / MDHTAC and / or HTA Group may consider a different listed PL device to be a more appropriate comparator to the one(s) proposed by the sponsor. If the comparator is already listed on the PL, this will generally be in the same grouping as the proposed grouping for the proposed device.

For Tier 1 applications, the description of a PL comparator has a specific purpose – to demonstrate interchangeability (see [Interchangeability](#)) and hence eligibility for Tier 1 pathway. Similarities identified must be supported by technical documentation. The differences identified between the applicant and comparator devices must not adversely affect the clinical safety, effectiveness or cost effectiveness of the device. Explanations supported by relevant evidence must be provided to satisfy this requirement. An application with incomplete comparators demonstrating interchangeability and identifying similarities and differences between the proposed medical device and the proposed comparator, will most likely be rejected.

For similarities identified, technical documentation must be provided as part of the application, and differences require a reference(s) to indicate that the differences will not adversely affect the clinical effectiveness of the proposed medical device relative to its comparator.

For Tier 2 and Tier 3 applications, if a sponsor proposes a different grouping for the medical device to that of the main comparator, an explanation for why the grouping should be different should be provided.

For Tier 1 applications, comparators must be selected from the PL. For Tier 2 or 3 applications, comparators can be selected from the PL, or from outside of the PL.

### ***PL Comparators***

For Tier 1 applications, comparators must be selected from the PL. For Tier 2 or 3 applications, comparators can be selected from the PL, or from outside of the PL.

Where a comparator is selected from the PL, a detailed comparison will be required against each attribute of the proposed/amended product vs. the comparator product. The sponsor will be required to provide detail against each of the following attributes and assess whether the attribute is equivalent to the comparator, and detail of the equivalence or differences.

References must be provided for any information included in the comparator comparison for validation and verification purposes. Supporting documentation should be attached against the comparator.

- Description
- Design
- Material
- Specification
- Size
- Risk classification
- GMDN
- Intended use
- Intended indications
- Intended population

- Contraindications
- Adverse events

For all applications, sponsors must undertake a search of adverse events databases in Australia and overseas for records of adverse events / complaints / warnings for the new medical device and the proposed predicate or appropriate comparator(s) on the PL. At a minimum, the search should include the websites of the TGA, the United States Food and Drug Administration (FDA), and the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). Details of the databases searched for each device and the nature of any adverse event(s), complaints or warnings identified must be provided. In addition, advise whether the event relates to medical devices supplied in Australia and the action taken to address the problem. If no records of adverse events/complaints/warning were identified in the searches, this should be recorded.

This information is required because there may also be 'new' or 'potential' safety issues/concerns that have arisen in the time since the original TGA assessment and marketing approval. If no records of adverse events are identified in the searches, this should be noted against the comparator.

### ***Comparators outside of the PL***

For Tier 2 and 3 applications, comparators can be selected from outside of the PL.

The HPP allows sponsors to select an MBS item as a comparator, or for a non-MBS comparator to be added. For comparators outside of the PL, sponsors will be required to provide a description of why the health technology or service is a comparator and the pattern of substitution (None, displaced, partial, or full).

### **MBS items**

Medical devices will not be listed on the PL unless there is a Medicare benefit payable for the professional service associated with the implantation or application of the device.

All applications must have between 1 and 5 MBS items added against each product in the HPP.

If there is no MBS item for the professional service associated with the medical device, an application must be submitted for the professional service(s) to be assessed by the MSAC. To support parallel processing with relevant Australian HTA bodies, sponsors can apply to list a medical device on the PL if they have applied for an MBS item number even if the number has not been provided at the time of PL application.

If the MDHTAC recommends listing a medical device but there is no appropriate MBS item for the professional service, the application will not proceed to listing until an appropriate MBS item number has been created for the professional service.

## Estimated utilisation

For Part A and C Tier 2 and 3 applications, sponsors must describe the impact the introduction of their product will have on the market and the estimated utilisation of the product will inform the impact level.

For Part A and C Tier 2 and 3 applications, sponsors must also provide an estimate of the expected utilisation of the medical device (number of devices and number of patients receiving the device) over the first four (4) years of listing on the PL.

Any barriers and enablers (e.g., specialised surgical training, use restricted to accredited centres) for the uptake of the device in Australia should be described in the application.

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. For example, the ARTG certificate describes the intended population, and the MBS item number restricts use to a particular subgroup.

## Product supporting documents

Sponsors can either provide product supporting documents at the product level, or at the application level within the HPP. If the supporting document relates to more than one product (such as a product brochure) then it can be uploaded at the application level and referred to from each product, rather than being uploaded multiple times.

### *Specifications for supporting documentation*

All relevant data in supporting documentation should be flagged/highlighted. All literature must be accurately cited.

All supporting documentation must be provided in English. If source documents are written in a language other than English, a certified translation must 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.

When providing supporting documentation, sponsors are asked to provide references, including pages and section numbers, for clarity and ease of finding relevant information.

### **Attachments**

In addition to the information requirements in the HPP application, sponsors are required to attach:

- 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 (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)

- comparator's product brochure or surgical technique (the sponsor is required to enter the details of the comparator in the HPP application form demonstrating similarities and differences between the subject device and the comparator, but the comparator manufacturer's product material is also required to support the information provided and demonstrate the correctness of the comparator)
- any additional information that may assist in establishing the subject device is used in hospital treatments, that the MBS items stated in the application are correct and the grouping and the comparator are appropriate (the sponsor may need to summarise this information in 1-2 pages document if required).

Tier 2 and 3 applications may also require:

- testing reports from manufacturers for some specified types of devices (e.g., pull-out strength data for soft-tissue fixation devices)
- direct clinical data to demonstrate the device is no less clinically effective than the comparator listed on the PL or an alternative treatment if there are no comparators listed on PL
- data for assessment of the cost-effectiveness specific for the device and sufficient to support the clinical claims and the proposed PL benefit ([Tier 2b](#))
- any documentary evidence to support the information provided in the application concerning public hospital prices for the device or alternatively international prices if there are no public hospital prices (Tier 2b)
- any complementary documents to support the information provided in the application concerning estimate of utilisation of the device once included on the PL.

Tier 3 sponsors will also be required to provide the data required to inform an MSAC assessment. Information about MSAC processes is available on the [MSAC website](#).

When providing supporting documentation, including when referencing this in discussions and explanations, sponsors are required to provide references, including pages and section numbers, to aid the assessment process.

### ***Optional attachments***

Sponsors can also provide other information that will assist in assessing the application.

### ***Service delivery and setting***

Criterion 2 of the criteria for listing requires that a medical device must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment.

If a device is used for treatment outside of hospital (i.e., it is not part of hospital treatment or hospital substitute treatment) it may not satisfy this criterion and the description of the setting in which the device must be provided.

Health professional services to implant and/or apply the device need to be provided, including if specialised training or qualifications are required, and if so, the nature of the training and who provides it will need to be described. If the provision of the new medical device has a learning

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curve, the number of patients/procedures before the health professional is considered proficient is to be advised.

## Clinical and economic evidence requirements

Sponsors are responsible for providing all clinical and economic evidence required to support their application as part of Supporting Documentation in the HPP application. The purpose of the evidence is to demonstrate that the sponsors claims regarding comparative clinical effectiveness and/or cost effectiveness are accurate.

When considering the type of evidence to be included in an assessment, it is important to consider the quality and applicability of the studies. 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.

Product information, promotional material, company position papers, statements and testimonials by clinicians do not constitute clinical or economic evidence.

## Justification for the proposed benefit and/or grouping

If the sponsor is requesting a new benefit, supported by a claim of superiority, the application should provide evidence comparing the difference in clinical outcomes between the new medical device and the appropriate comparator(s) for the intended use. The evidence should quantify the improvements.

Where a sponsor is seeking a new grouping, a benefit should be proposed for the new grouping. The evidence provided with the application should demonstrate why the medical device should be considered either clinically superior to or significantly different from the other devices on the PL.

The proposed benefit amount should be stated, together with a clear rationale for how this amount was determined. Where the proposed benefit is higher than the Australian public pricing or there is no or limited Australian data available, the application must contain comparative international pricing data (what public hospitals are paying for the medical device or are predicting to pay for the device). An economic analysis, including description and justification for the approach taken is required to support requests for a higher benefit amount. Reports of economic and cost analyses studies should be provided. Any files relating to economic or financial analysis undertaken by the sponsor (e.g., Excel workbook; TreeAge files) should be attached to the application, including calculations of the proposed benefit.

## Clinical evidence

Clinical evidence is required to support the claims of comparative clinical safety and comparative clinical effectiveness. Clinical evidence will be assessed to determine its quality, relevance to the device or comparator, and its clinical significance considering the target population and indication. This will assist in determining the contribution of each piece of evidence to the profile of the comparative clinical effectiveness of the subject device.

Assessment of evidence quality considers: study type, size and design (based on the [NHMRC](#)

[framework](#)); the data generation/collection methods and potential sources of confounding or bias; and comparability (to standard of care or alternative treatments).

An overview of comparative clinical safety information to support safety claims should provide the following:

- a summary of the databases searched to identify safety information, including the date of search
- the information/evidence used to support each safety claim, including the type and level of evidence and the risk of bias
- the characteristics of the information/evidence in terms of the number of patients, patient characteristics, treatment regimen, duration of treatment/follow up
- the definitions and methods used to measure safety outcomes/impacts
- critical analysis of the results for each of the claimed safety impacts.

An overview of comparative clinical effectiveness information to support clinical effectiveness claims should provide the following:

- a summary of the databases searched to identify relevant information, including the date of search
- the information/evidence used to support each clinical effectiveness claim, including the type and level of evidence and the risk of bias
- the characteristics of the information/evidence in terms of the number of patients, patient characteristics, treatment regimen, duration of treatment/follow up
- the definitions and methods/instruments used to measure treatment effects/outcomes/impacts
- critical analysis of the results for each of the claimed clinical effectiveness impacts.

The following should be noted regarding evidence quality and strength:

- where possible, studies should be statistically powered to demonstrate the claims (i.e. non-inferiority or superiority against the comparator). Lower rates of expected use should not be seen as a justification to collect no evidence, but assessments will take expected rates of use into consideration when appraising the level and quality of available evidence
- comparisons of datasets obtained through different methodologies (for example, a case series using the subject device with standard of care outcomes established from a literature search) are generally considered poor quality evidence
- comparative clinical safety and effectiveness should generally be expressed in terms of person-centred outcomes, such as mortality, morbidity, adverse events; and patient reported outcome measures (PROMs). Where study findings are expressed in terms of markers or intermediate measures of safety and performance, a clinically reasoned argument should be provided linking the study findings with patient centred outcomes
- preferred sources of clinical evidence include articles published in peer-reviewed journals, on the independent clinical trials (without conflicts of interest) or the data from the quality registries for the device

- when sponsors use the data from the registries to support their applications, the data from Australian registries is preferred, although data from registries in other countries may also be considered in some cases
- the complete evidence base should be reflected in applications. Neutral and negative findings should also be considered when determining the overall clinical and economic claim for the device and be included in the application. For example, a medical device may reduce rates of stroke (a 'positive' impact) but also prolong theatre time (which may be perceived as a 'negative' impact) and have no impact on training requirements for the physician ('neutral' impact)
- evidentiary requirements will be higher for higher risk applications.

Note: ECAGs and MDHTAC may bring their specific expertise to tailor evidence requirements to specific circumstances by medical device category (see [Appendix A](#)).

Where applicable, the application should separate the claimed impacts into the following:

- those that relate to patients (e.g., mortality, quality of life, complications)
- those that relate to health care practitioners (e.g., ease of use, training requirements)
- those that relate to health care systems (e.g., readmission rate, theatre time).

Information for all impacts that apply to the medical device should include the actual claim outcome (e.g. reduced risk of stroke at five years; reduced length of hospital stay) and a high level description of the extent of the impact in terms of the difference in effect between the device and the comparator (e.g. relative risk of stroke at five years is 0.70 [95% CI 0.56, 0.98] compared with the comparator; average length of hospital stay is 3.5 days shorter for the new device compared to the comparator)

### **Overall clinical claim**

The overall clinical claim in terms of consequences for patient health outcomes relative to the comparator(s) should be indicated in the application. The overall clinical claim should take health benefits (effectiveness) and harms (safety) into consideration.

### **Economic evidence**

Economic evidence is required to support claims regarding cost effectiveness.

When sponsors apply to list the device in a new grouping, an economic assessment will likely be required. This may include when the subject device has some claimed superior characteristics or different characteristics.

A minimum amount of economic information is required for all applications assessed via the Tier 2b and 3 assessment pathways to validate the proposed benefit and to demonstrate that it represents value for money for the subject device in the proposed setting of use.

Such information includes:

- the cost of the subject device
- any relevant associated/downstream costs associated with the use of the device
- the cost of the comparator(s)



- any relevant associated/downstream costs associated with the use of the comparator(s)
- expected rates of use of the subject device compared with the comparator(s). Prices of the subject device in the public and private hospitals in Australia and in other markets
- an economic evaluation.

High quality assessment of cost-effectiveness must be founded on sound evidence regarding clinical effectiveness. Any economic claims made in the application should 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 demonstrating that these are real reductions and not potential or theoretical.

### **Overall economic claim**

The overall impact in terms of cost effectiveness of care relative to the comparator(s) 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 comparator(s) should be provided in the application. Refer to the [MSAC Guidelines](#) for guidance on this.

### **Service delivery and setting**

Criterion 2 of the criteria for listing requires that a medical device must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment.

If a device is used for treatment outside of hospital (i.e., it is not part of hospital treatment or hospital substitute treatment) it may not satisfy this criterion and the description of the setting in which the device must be provided.

Health professional services to implant and/or apply the device must need to be provided, including if specialised training or qualifications are required, and if so, the nature of the training and who provides it will need to be described. If the provision of the new medical device has a learning curve, the number of patients/procedures before the health professional is considered proficient is to be advised.

### **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.

## **PART 3: APPENDICES AND GLOSSARY**

DRAFT FOR CONSULTATION

# Appendices

DRAFT FOR CONSULTATION

## Appendix A

The ECAGs request clinical data depending on the category and types of medical devices. Table 2 outlines these ECAGs requirements.

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**Table 2: Clinical evidence requirements by medical device category**

Medical Device Category	Medical Device type	Type of information required	Relevant outcomes	Minimum duration of follow-up	Minimum no. patients/implants [minimum required patient sample]
Ophthalmic ECAG	IOL	Clinical evidence direct for the device, relevant to the intended use	Relevant outcomes including failure, complications, revisions	12 months	100 implanted devices
Ear, Nose & Throat (General Surgery ECAG)	NS	NS	NS	NS	NS
General Miscellaneous (General Surgery ECAG)	NS	NS	NS	NS	NS
Urogenital (General Surgery ECAG)	NS	Clinical evidence, preferably comparative	Relevant outcomes including failure, complications, revisions/re-operation	12 months [NS]	NS
Plastic and Reconstructive (General Surgery ECAG)	NS	NS	NS	NS	NS
Neurosurgical (Spinal and Neurosurgical ECAG)	NS	NS	NS	NS	NS
Spinal (Spinal and Neurosurgical ECAG)	Expandable spinal fusion cages	Biomechanical information and direct clinical evidence, preferably comparative	Relevant outcomes including failure, complications, revisions/re-operation	12 months [Full postoperative recovery typically takes 1 year]	40 patients

Medical Device Category	Medical Device type	Type of information required	Relevant outcomes	Minimum duration of follow-up	Minimum no. patients/implants [minimum required patient sample]
	Disk replacements				
Specialist Orthopaedic ECAG	Soft tissue anchor with sutures	Clinical information on the pull-out strength of the medical device	NS	NS	NS
	Shoulder joint replacement devices				
	Wrist and ankle joint replacement devices				
	Orthopaedic surgical meshes				
	Rib fixation devices				
Cardiac (Cardiovascular ECAG)	NS	Direct clinical evidence, preferably comparative	NS	24 months for CIEDs [NS]	NS
Cardiothoracic (Cardiovascular ECAG)	NS	Biomechanical information and clinical evidence, preferably comparative	Relevant outcomes	'Adequate' [NS]	NS
Vascular (Cardiovascular ECAG)	NS	Clinical evidence, preferably comparative, relevant to the intended use	Relevant outcomes including failure, complications, revisions/re-operation	12 months [NS]	NS
Hip (Hip and Knee ECAG)	Primary hip joint replacement devices	Published articles on the independent clinical study or data from the quality and reliable registry well-known in Australia	Relevant outcomes including failure, complications, revisions/re-operation	24 months [Complications typically occur beyond 2 years]	250 patients

Medical Device Category	Medical Device type	Type of information required	Relevant outcomes	Minimum duration of follow-up	Minimum no. patients/implants [minimum required patient sample]
	Revision hip joint replacement devices				
Knee ( <i>Hip and Knee ECAG</i> )	Primary knee joint replacement devices	Published articles on the independent clinical study or data from the quality and reliable registry well-known in Australia, stratified by stability/fixation or bearing materials corresponding to application	Relevant outcomes including failure, complications, revisions/re-operation	24 months [NS]	40 medical devices in each stratified group. Greater numbers are required for designs known to have higher revision risk. [NS]
	Revision knee joint replacement devices	Published articles on the independent clinical study or data from the quality and reliable registry well-known in Australia	NS	NS	NS

Abbreviations: CIED - cardiac implantable electronic device; NS - not specified

## Appendix B

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. 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
- small design differences which do not affect the clinical safety or effectiveness of the device (where applicable)
- if listed, the subject device would share the market with the comparators and is not expected to result in a marked change in aggregate utilisation.



## Glossary

<b>Advisory Committee on Medical Devices (ACMD)</b>	A statutory committee that provides independent medical and scientific advice to the Minister and the TGA on the safety, performance and manufacturing of medical devices supplied in Australia including issues relating to pre-market conformity assessment and post-market monitoring.
<b>Analysis, economic</b>	An umbrella term covering any type of economic evaluation (cost analysis, cost-benefit analysis, cost consequence analysis, cost-effectiveness analysis, cost-utility analysis) but excluding financial analysis (budgetary analysis, budget impact analysis).
<b>Analysis, financial</b>	A procedure for comparing the financial costs and cost offsets of competing health technologies for one or more payers, rather than comparing their clinical and economic cost and impact. Also called a 'budgetary analysis' or 'budget impact analysis'.
<b>Analysis, utility</b>	A method of measuring outcomes in terms of the preferences or utilities that individuals express for specific health statuses or health outcomes; it provides a common unit that can be used to compare different types of outcomes under conditions of uncertainty.
<b>Application</b>	The information provided by an 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.
<b>Australian Register of Therapeutic Goods (ARTG)</b>	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.
<b>Assessment, clinical</b>	An assessment by ECAG of evidence provided in an application.
<b>Assessment, health technology</b>	See 'Health technology assessment'
<b>Benefit, Prescribed List</b>	The minimum amount that a private health insurer is required to pay for a device or human tissue on the PL that is provided to a privately insured patient with appropriate cover as part of hospital treatment or hospital-substitute treatment.
<b>Benefit, Medicare</b>	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.
<b>Billing code</b>	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

<b>Biological characteristics</b>	Relates to use of materials or substances in contact with the same human tissues or body fluids. Biological safety is considered by the TGA in the demonstration of equivalence.
<b>Budget impact analysis</b>	See 'Analysis, financial'
<b>Case series</b>	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.
<b>Case series with historical controls</b>	A quasi-experimental study in which the outcomes measured in a group of participants (with a specified indication) who are managed with a proposed health technology are compared with outcomes measured in a similar group of participants (usually seen previously in the same setting) who are managed with an existing health technology.
<b>Circumstances of use</b>	A description of the circumstances surrounding the use of a health technology in a population, which are expected to affect its overall effectiveness.
<b>Clinical assessment</b>	See 'Assessment, clinical'
<b>Clinical data</b>	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 of evidence depending on the category and type of device], and can be sourced from: <ul style="list-style-type: none"> <li>• reports/articles published in reputable journals on the independent clinical trials for the subject device</li> <li>• data from the quality and reliable registries, preferably in Australia or from overseas but well-known in Australia</li> </ul>
<b>Clinical investigation</b>	Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a health technology.  Note: 'clinical trial' or 'clinical study' are synonymous with 'clinical investigation'.
<b>Clinical management algorithm</b>	A description of the health care resources provided over time (including how frequent and when) for one or more clinical pathways for a population of individuals, accounting for the proportion of individuals managed through each clinical pathway.
<b>Clinical pathway</b>	A description of the health care resources provided over time (including how frequent and when) to an individual under the circumstances defined for the health technology.
<b>Commentary, focused</b>	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.
<b>Comparator</b>	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.
<b>Cost, comparative</b>	How much one health technology costs compared to an alternative health technology.
<b>Cost, direct</b>	The value of all health care resources that are provided with a health technology or in dealing with adverse outcomes, or other current and future consequences linked to the health technology.
<b>Cost, health care resource</b>	The monetary value of a resource provided to deliver health care services as part of the clinical management of a medical condition, disease or disorder.
<b>Cost, incremental</b>	The absolute difference between the costs of alternative health technologies for the same medical condition, disease or disorder.
<b>Cost, opportunity</b>	The value of the best alternative use of a resource that is foregone as a result of its current use.
<b>Cost analysis</b>	An economic evaluation that compares the cost of two health technologies without consideration of health outcomes
<b>Cost-benefit analysis (CBA)</b>	An economic evaluation that compares health technologies in which both costs and benefits (i.e. health outcomes) are measured in monetary terms to calculate a net monetary gain/loss or health gain/loss.
<b>Cost-consequence analysis (CCA)</b>	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.
<b>Cost-effective</b>	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.
<b>Cost-effectiveness analysis (CEA)</b>	An economic evaluation that compares health technologies that have a common health outcome in which costs are measured in monetary terms and the outcome is measured in natural units.
<b>Cost-minimisation analysis (CMA)</b>	An economic evaluation that identifies the least costly health technology after the proposed health technology has been demonstrated to be no worse than its main comparator(s) in terms of effectiveness and safety.
<b>Cost-utility analysis (CUA)</b>	An economic evaluation that compares health technologies in which costs are measured in monetary terms, and outcomes are measured in terms of extension of life and the utility value of that extension (such as quality-adjusted life-years (QALYs) or healthy-year equivalents).
<b>Critical appraisal</b>	The process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a

	decision. Critical appraisal is one step in the process of evidence-based decision making.
<b>Direct cost</b>	See 'Cost, direct'
<b>Economic analysis</b>	See 'Analysis, economic'
<b>Economic evaluation</b>	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.
<b>Economic evaluation, study-based</b>	A cost-consequence analysis that is based directly on outcomes and resource use observed during the course of a clinical study.
<b>Economic evaluation, trial-based</b>	An economic evaluation based only on inputs and outcomes reported in one or more direct randomised trials.
<b>Effectiveness, clinical</b>	The extent to which a health technology produces its intended outcome(s) in a defined population in uncontrolled or routine circumstances.
<b>Efficacy, clinical</b>	The extent to which a health technology produces its intended outcome(s) in a defined population in controlled or clinical trial circumstances.
<b>Evidence</b>	Information gathered from scientific research or direct measurement. Current best evidence is up-to-date information from relevant, valid research.  See 'Clinical data'
<b>Evidence, quality of</b>	The degree to which bias has been prevented through the design and conduct of research from which data-based evidence is derived.
<b>Evidence, strength of</b>	The magnitude, precision and reproducibility of the effect of the health technology. In the case of non-randomised studies, additional factors such as biological plausibility, biological gradient and temporality of associations may be considered.
<b>Expert Clinical Advisory Group (ECAG)</b>	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.
<b>Fee, Schedule</b>	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.
<b>Financial analysis</b>	See 'Analysis, financial'
<b>Fit-for-purpose</b>	Structuring the size and type of a review or evaluation to fit the type, complexity and cost of the item(s) involved.
<b>Focused commentary</b>	See 'Commentary, focused'
<b>Focused health technology assessment</b>	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.
<b>Follow-up</b>	The observation, during a specified time period, of trial or study participants to measure changes in outcomes of interest.
<b>Group</b>	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.
<b>Group benefit</b>	The benefit paid for all medical devices that are classified in the same category, sub-category, group, subgroup and suffix.
<b>Grouping</b>	The full classification of a medical device on the PL, including category, sub-category, group, subgroup and suffix.
<b>Health care resource</b>	A resource provided as part of the clinical management of a medical condition, disease or disorder — for example, a medicine, medical service, hospital service, diagnostic service, investigational service or community-based service.
<b>Health-related quality of life (HRQoL)</b>	The physical, social and mental aspects that are relevant and important to the health aspects of an individual's overall wellbeing.
<b>Health technology</b>	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.
<b>Health technology assessment (HTA)</b>	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.

<b>Health technology assessment (HTA) advisory committee</b>	Expert HTA advisory committees, appointed by the health minister, that provide advice to the Australian Government about which proposed health technologies should be considered for funding, including listing on the PBS, MBS and the PL, and what the recommended benefit or subsidy should be. Current HTA advisory committees include PBAC, MSAC and MDHTAC.
<b>Health technology assessment (HTA) report, full</b>	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.
<b>Health technology management</b>	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.
<b>Health technology re-assessment</b>	A structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology or service currently used in the healthcare system, to inform optimal use of that technology or service in comparison to its alternatives.
<b>Health technology assessment group</b>	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.
<b>Hierarchy of evidence</b>	See 'Level of evidence'
<b>Hierarchy of information</b>	A ranking of information typically considered by the TGA and/or MDHTAC that encompasses National Health and Medical Research Council (NHMRC) levels of evidence and a range of other information sources typically considered by the TGA and/or MDHTAC
<b>High-value care</b>	An intervention in which evidence suggests it confers benefit on patients, or probability of benefit exceeds probable harm, or, more broadly, the added costs of the intervention provide proportional added benefits relative to alternatives.
<b>Hospital-substitute treatment</b>	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
<b>Human Tissue Product</b>	has the meaning given by section 72-12 of the Private Health Insurance Act 2007.

<b>Impact</b>	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.
<b>Incremental cost-effectiveness ratio (ICER)</b>	A comparison of two alternative health technologies calculated by dividing the incremental costs from substituting the proposed health technology for its main comparator by the incremental health outcomes from this substitution.
<b>Indication</b>	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.
<b>Indication, main</b>	The indication likely to account for the largest proportion of patients that will receive the new medical device.
<b>Intended purpose</b>	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.
<b>Interchangeability</b>	Has the meaning explained in Appendix B.
<b>Knowledge</b>	An umbrella term covering evidence, data, opinion and lived experience.
<b>Leakage</b>	Using a health technology beyond its approved funding conditions.
<b>Level of evidence</b>	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.
<b>Lived experience</b>	The independent reporting of the impact of a medical condition and/or use of a health technology for that condition by consumers or their representatives.
<b>Low-value care</b>	An intervention in which evidence suggests it confers no or very little benefit for patients, or risk of harm exceeds probable benefit, or, more broadly, the added costs of the intervention do not provide proportional added benefits.
<b>Medical device</b>	has the meaning given by section 72-11 of the Private Health Insurance Act 2007
<b>Medical device classifications</b>	has the meaning given by section 41DB of the <i>Therapeutic Goods Act 1989</i> and Division 3.1 of the Therapeutic Goods (Medical Devices) Regulations 2002
<b>Medical Device and Human Tissue Committee (MDHTAC)</b>	An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the responsible Minister on appropriateness of listing of , medical

	<p>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.</p>
<b>Medical service</b>	<p>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.</p>
<b>Medical Services Advisory Committee (MSAC)</b>	<p>An independent non-statutory expert committee established by the Australian Government Minister for Health in 1998. MSAC provides 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).</p>
<b>Medicare benefit</b>	<p>See 'Benefit, Medicare'</p>
<b>Medicare Benefits Schedule (MBS)</b>	<p>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.</p>
<b>Mini health technology assessment (mini HTA)</b>	<p>A report that includes a comprehensive systematic literature review, or a systematic review of high-level evidence, evaluating the safety and effectiveness of a technology, but that does not include 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; and provides information on costs and financial impact. A mini-HTA may be as rigorous as a full HTA report but typically has a restricted scope and so is quicker to produce.</p>
<b>Minister</b>	<p>The Minister responsible for administering the <i>Private Health Insurance Act 2007</i>, currently the Minister for Health and Aged Care.</p>
<b>Novel device</b>	<p>A new type of device. <i>'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'</i></p>



	<i>to enable straightforward appraisal of its future real-world safety and performance’ (European Union Medical Device Regulation).</i>
<b>Obsolete</b>	Superseded by other technologies or demonstrated to be ineffective or harmful.
<b>Opinion</b>	The view of one or more individuals that does not present direct measurement.
<b>Outcome</b>	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.
<b>Outcome, patient-relevant</b>	An umbrella term covering any health outcome that is perceptible to the patient (the more meaningful to the patient, the greater the patient relevance); any resource provided as part of ongoing clinical management of the patient’s medical condition, disease or disorder; any working time changes; or any intangible outcome. Common examples of patient-relevant outcomes include primary outcomes, quality-of-life or utility measures, and economic outcomes.
<b>Outcome, surrogate</b>	A variable that is suspected, but not necessarily demonstrated, to occur on the causal pathway from a clinical management or factor to the clinically relevant final outcome (such as intraocular pressure as a surrogate for glaucoma).
<b>Over-use</b>	Provision of a service that is unlikely to increase the quality or quantity of life, that poses more harm than benefit, or that patients who were fully informed of its potential benefits and harms would not have wanted.
<b>Patient-relevant outcome</b>	See ‘Outcome, patient-relevant’
<b>Pharmaceutical Benefits Advisory Committee (PBAC)</b>	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.
<b>Pharmaceutical Benefits Scheme (PBS)</b>	Under the authority of the National Health Act 1953, a listing and description of the medicines that are subsidised by the Australian Government, the amount of that subsidy and any conditions applying to the use of that medicine.
<b>Post-market review</b>	A systematic post-market approach to monitoring medical services or devices in use to inform decision-making at all levels throughout the cycle (from the registration right through to its use by consumers).
<b>Post-market surveillance</b>	Once a device has been included in the ARTG, the sponsor has ongoing responsibilities to monitor and report to the TGA adverse events, vigilance reports, complaints, performance issues and regulatory actions in other jurisdictions.

<b>Predicate</b>	A previous iteration of the device, within the same lineage of devices, with the same intended purpose and from the same manufacturer. The predicate may differ in characteristics such as design, composition, indication, packaging, or size/range.
<b>Price advantage</b>	The larger requested or listed price of a health technology compared to its main comparator(s).
<b>Product information</b>	Information approved by the TGA relating to the safe and effective use of a therapeutic good, including information regarding the usefulness and limitations of that good.
<b>Prescribed List</b>	Under the authority of the Private Health Insurance Act 2007, a listing of the medical device that private health insurers must fund and the benefits payable for them.
<b>Public pricing</b>	The price public hospitals pay for the medical device/or are predicted to pay for the medical device.
<b>Quality-adjusted life year (QALY)</b>	An outcome measure calculated by weighting the number of life-years by utility values of the quality of life experienced during those life-years.
<b>Quality of life (QoL)</b>	The extent to which an individual perceives themselves to be able to function physically, mentally and socially.
<b>Rapid review</b>	A report that usually includes a review of the highest level of evidence or of recent evidence and that may restrict the literature to one or two electronic indexed literature databases. The report briefly describes the characteristics and current use of the technology, and evaluates safety and effectiveness issues. The report does not always critically appraise the quality of the evidence base nor provide information on costs or financial impact. A rapid review is typically not as rigorous as a mini-HTA or a full HTA report.
<b>Randomised controlled trial (RCT)</b>	See 'Trial, randomised controlled'
<b>Real-world data (RWD)</b>	Observational or administrative data that provides information on the routine delivery of health care and the health status of the target population.
<b>Real-world evidence (RWE)</b>	Evidence derived from the analysis of real-world data.
<b>Registry</b>	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.
<b>Resource</b>	A factor of production, an input or a produced good.
<b>Responsible Minister</b>	See 'Minister'

<b>Robustness</b>	The extent to which the conclusion of an economic analysis is likely to remain unchanged, even if estimates of key variables, assumptions or a model's structure are changed in the analysis to reflect remaining uncertainties.
<b>Safety, comparative</b>	The safety of one health technology compared to an alternative health technology.
<b>Safety, incremental</b>	The absolute difference between the safety profiles of alternate health technologies for the same medical condition, disease or disorder.
<b>Search strategy</b>	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.
<b>Size</b>	May be expressed as length, diameter, width, height, holes, degrees, dioptres, volume or other specification of the medical device or its components as detailed in the product information or technical documentation.
<b>Sponsor</b>	For the purposes of the PL, it has the same meaning as defined under section 3 of the <i>Therapeutic Goods Act 1989</i> , and it must be the same legal entity as stated on the ARTG entry as the sponsor for the relevant medical device or human tissue product.
<b>Standard, gold</b>	The gold standard is a method, procedure or measurement that is widely accepted to be the best available.
<b>Study</b>	An investigation of the health and/or economic consequences of one or more health technologies in people, which may or may not involve a randomisation step. If a randomisation step is involved, the preferred term is trial.
<b>Study, before-and-after</b>	A quasi-experimental study in which participants are observed before and after a health technology is started.
<b>Study, case-control</b>	An observational study in which the past history of exposure to a suspected risk factor (such as clinical management involving the proposed health technology) is compared between cases (who have the outcome or disease) and controls (who come from the same population as the cases but do not have the outcome or disease).
<b>Study, cohort</b>	An observational study where a cohort of people (for example, people born in a certain year; people admitted to hospital for a certain condition) are followed over time to compare the incidence of the outcome(s) in people who are exposed and not exposed at the start of the study. Cohort studies can be prospective (where cohorts are identified at a current point in time and followed forward in time to collect health records) or retrospective (where cohorts are defined at a point of time in the past and information is collected on subsequent outcomes).

<b>Study, cross-sectional</b>	A study in which resource provision and/or health status is measured across a defined population at the same time.
<b>Study, diagnostic accuracy</b>	A study that compares the accuracy of a proposed investigative health technology with a gold standard test.
<b>Study, observational</b>	<p>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.</p> <p>According to the TGA, observational studies are a valid alternative to RCTs provided appropriate matching of treatment groups is performed, e.g., through the application of propensity scores.</p>
<b>Study, quasi-experimental</b>	A nonrandomised study in which the investigator lacks full control over the allocation and/or the timing of the clinical management, but otherwise conducts the study as a randomised trial. An umbrella term for before-and-after study, case series with historical controls and a comparison of the results of single-arm studies.
<b>Study, single-arm</b>	A group of participants with a specified indication and managed with a specified clinical management (such as involving the proposed health technology) are systematically observed to measure outcomes of interest. A quasi-experimental study can be generated by comparing the results of one or more single-arm studies of clinical management involving the proposed health technology with the results of one or more similar studies (usually by different investigators in different settings) of clinical management involving its main comparator(s).
<b>Subject device</b>	The device which is the subject of an application (new, or amendment, or compression, or expansion as applicable).
<b>Subject product</b>	The device or human tissue product which is the subject of an application (new, or amendment, or compression, or expansion as applicable).
<b>Substantial similarity</b>	<p>Devices are considered substantially similar if, they:</p> <ul style="list-style-type: none"> <li>• have similar designs and characteristics</li> <li>• are made of the same material</li> <li>• have similar intended uses and indications</li> </ul>
<b>Suffix</b>	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.
<b>Surrogate outcome</b>	See 'Outcome, surrogate'
<b>Systematic review</b>	Research that summarises the evidence on a clearly formulated question according to a predefined protocol. Systematic and explicit methods are used to identify, select and critically appraise relevant studies, and to extract, collate and report their findings. Statistical meta-analysis may or may not be used.

<b>Technical characteristics</b>	From the perspective of the TGA, these relate to the design, specifications, physicochemical properties including energy intensity, deployment methods, critical performance requirements, principles of operation and conditions of use.
<b>Therapeutic good</b>	Health technologies regulated by the TGA, including medicines, medical devices, human cells and tissues, and blood.
<b>Therapeutic Goods Administration (TGA)</b>	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.
<b>Therapy</b>	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.
<b>Translation of outcomes</b>	Extrapolation of timeframe or transformation to utility weights.
<b>Treatment, first-line</b>	The preferred initial treatment of a patient at a particular stage of their medical condition.
<b>Treatment, second-line</b>	The next preferred treatment of a patient at a particular stage of their medical condition after the first-line treatment cannot be used.
<b>Trial</b>	An investigation of the health and/or economic effect of one or more therapies in humans that involves a randomisation step.
<b>Trial, randomised controlled</b>	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.
<b>Trial, direct randomised</b>	A trial in which participants are randomly allocated to groups that receive either the proposed health technology or its main comparator. When practical, this should be the preferred study design.
<b>Triangulation</b>	The use of multiple sources of data or multiple approaches to determine the consistency or otherwise of the conclusions from those sources or approaches.
<b>Uncertainty</b>	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.

<b>Under-use</b>	Failure to deliver a service that is highly likely to improve the quality or quantity of life, that represents good value for money, and that patients who were fully informed of its potential benefits and harms would have wanted.
<b>Utilisation</b>	The number of uses of a health technology in a specified time period.
<b>Utility</b>	The numerical value assigned by an individual to a preference for, or a desirability of, a specific level of health status or a specific health outcome. The process of eliciting a utility involves a trade-off between quality and quantity of life. By convention, utility is measured on a cardinal scale, with 0 = death and 1 = full health.
<b>Utility analysis</b>	See 'Analysis, utility'
<b>Validity, external</b>	A trial or study has external validity if it is free of confounding and can produce unbiased inferences regarding a specified target population beyond the participants in the trial or study.
<b>Validity, internal</b>	A trial or study has internal validity if, apart from possible sampling error, the measured difference in outcomes can be attributed only to the different interventions assigned.
<b>Validity, trial or study</b>	The extent to which an inference drawn from a trial or study is justifiable when the following are taken into account: <ul style="list-style-type: none"> <li>• the methods of the trial or study</li> <li>• the representativeness of the sample investigated</li> <li>• the nature of the population from which the sample is drawn.</li> </ul>
<b>Value</b>	In economics, a quantitative measure of the desirability of an outcome. This may be measured in monetary terms — for example, the maximum amount that an individual is willing to pay for a good or a service, a defined benefit, or to avoid a defined harm. In science, the magnitude of a measurement.
<b>Value for money</b>	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.
<b>Well-established technology</b>	A device group proven to have sound safety and performance characteristics. <p>“The common features of the devices which are well-established technologies are that they all have:</p> <ul style="list-style-type: none"> <li>• well-understood and stable designs (with any changes being incremental, well-explained and demonstrated to be low risk)</li> <li>• well-known safety profiles with no significant safety issues in the past</li> </ul>

- 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 technology
- a long history on the matter” (Medical Device Coordination Group Document, MDCG 2020-6)

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All information in this publication is correct as at June 2023

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