Prescribed List Application

Training

Purpose of the training

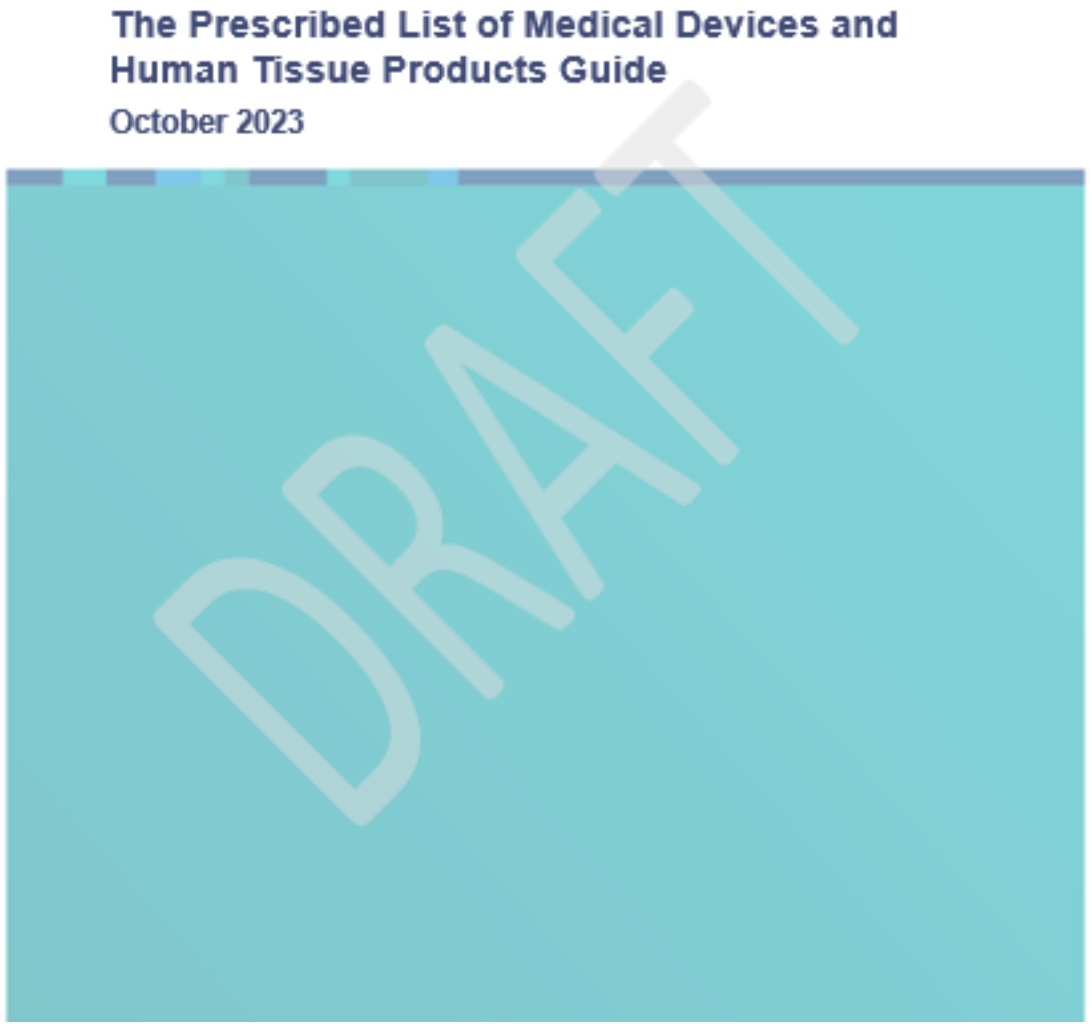
Australian Government
Department of Health and Aged Care

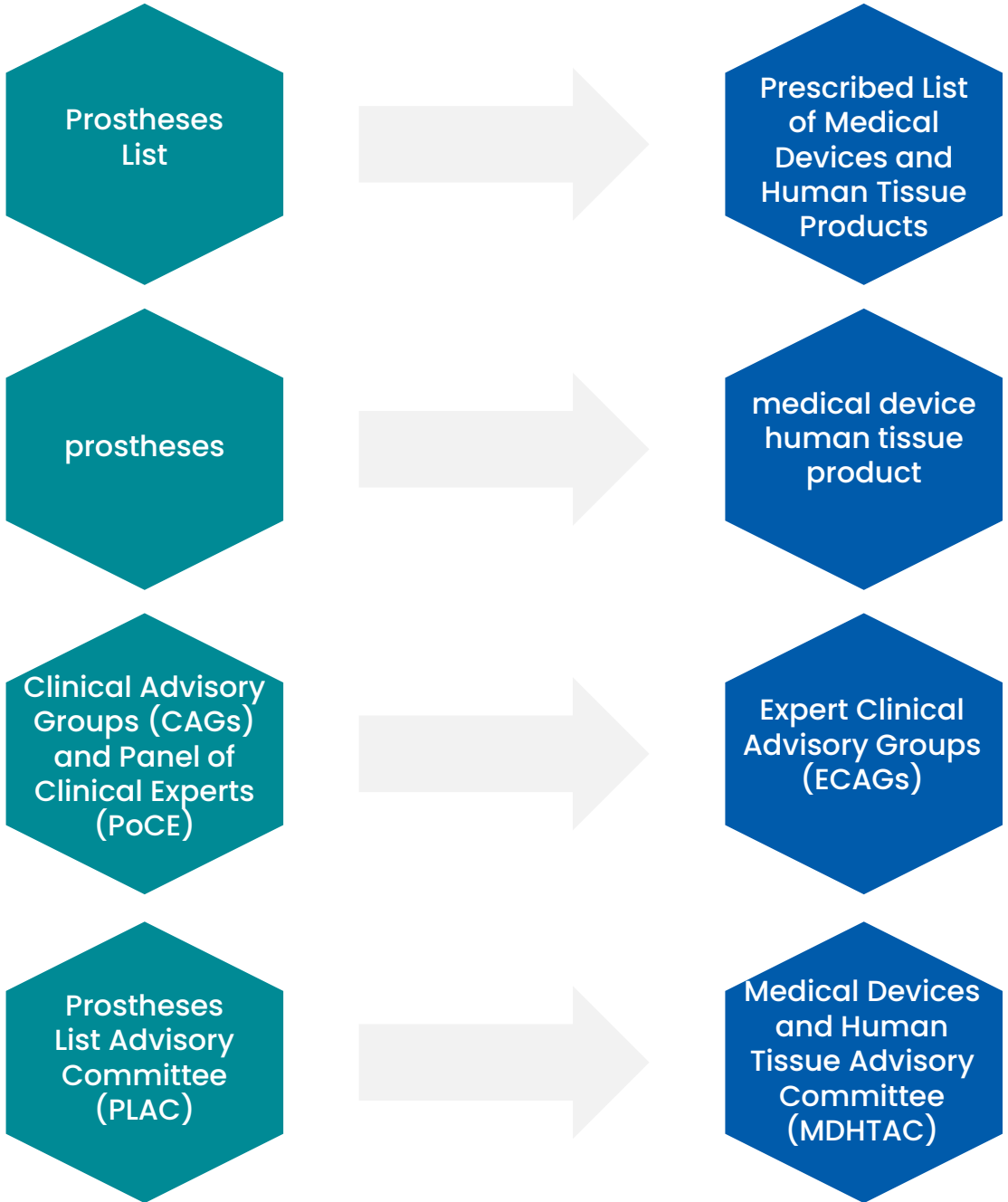
In scope

- Go through requirements and assessment process for the Prescribed List applications
- Answer participant's questions on the above

Out of scope

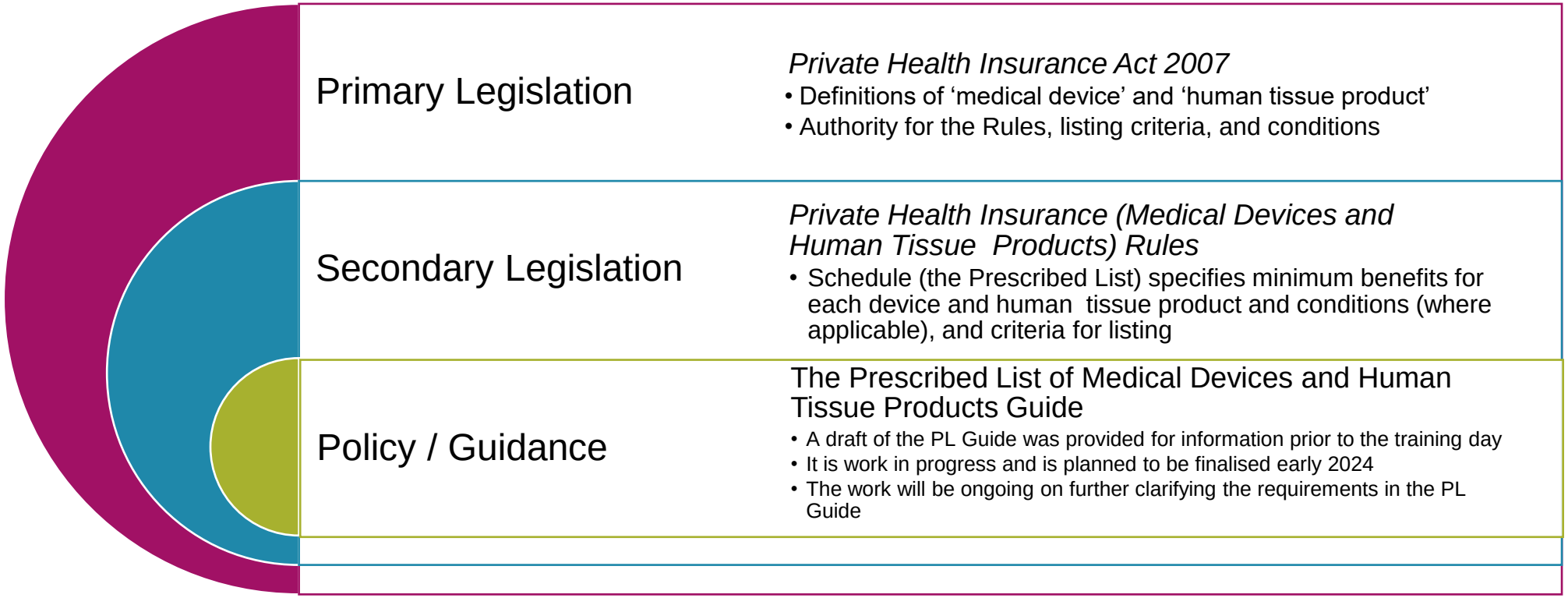
- No discussion on Prostheses List reforms and no questions on any specific applications
- No guidance on Health Products Portal





Changes effective from 1 July 2023

Legislation and guidance relevant to the Prescribed List



Purpose of the Prescribed List

Purpose

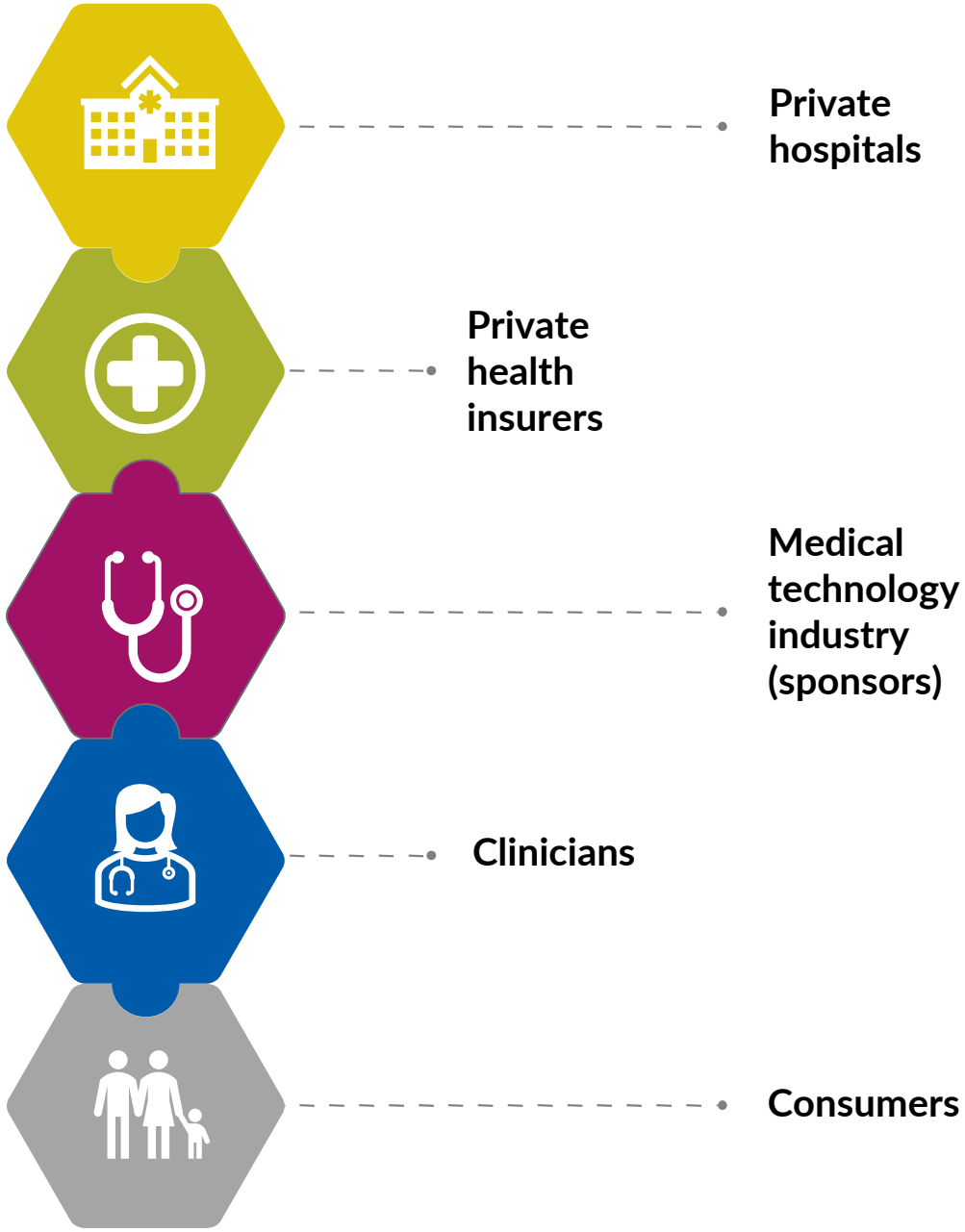
To ensure privately insured Australians who have appropriate health insurance policy to cover the treatment have access to clinically-effective products that meet their health care needs

How

By providing and administering a list of medical devices and human tissue products for which private health insurers are required to pay minimum benefits, when these are provided to or used for a person with appropriate insurance cover

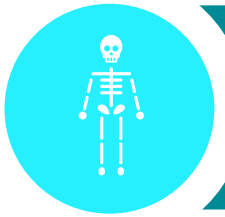
Prescribed List Stakeholders

Topics in this presentation are targeted to the medical technology industry (sponsors) and bodies responsible for assessing and administering the Prescribed List



Expert Clinical Advisory Groups (ECAG)

The ECAG assess clinical functions and comparative clinical effectiveness of medical devices in listing new applications or variation applications submitted through Tier 2 and Tier 3 pathways (or in different circumstances as required)



Specialist Orthopaedic ECAG (SOECAG)
(Including shoulder, ankle, foot, upper limb and skeletal reconstruction)

Spinal and Neurosurgical ECAG (SNECAG)

Hip and Knee ECAG (HKECAG)

Cardiovascular (CVECAG)
(Including cardiac, cardiothoracic and vascular)

Ophthalmic ECAG (OECAG)

General Surgery (GSECAG)
(Including ear, nose and throat, plastic and reconstructive surgery, urogenital and all other general surgery devices)

Australian Government
Department of Health and Aged Care

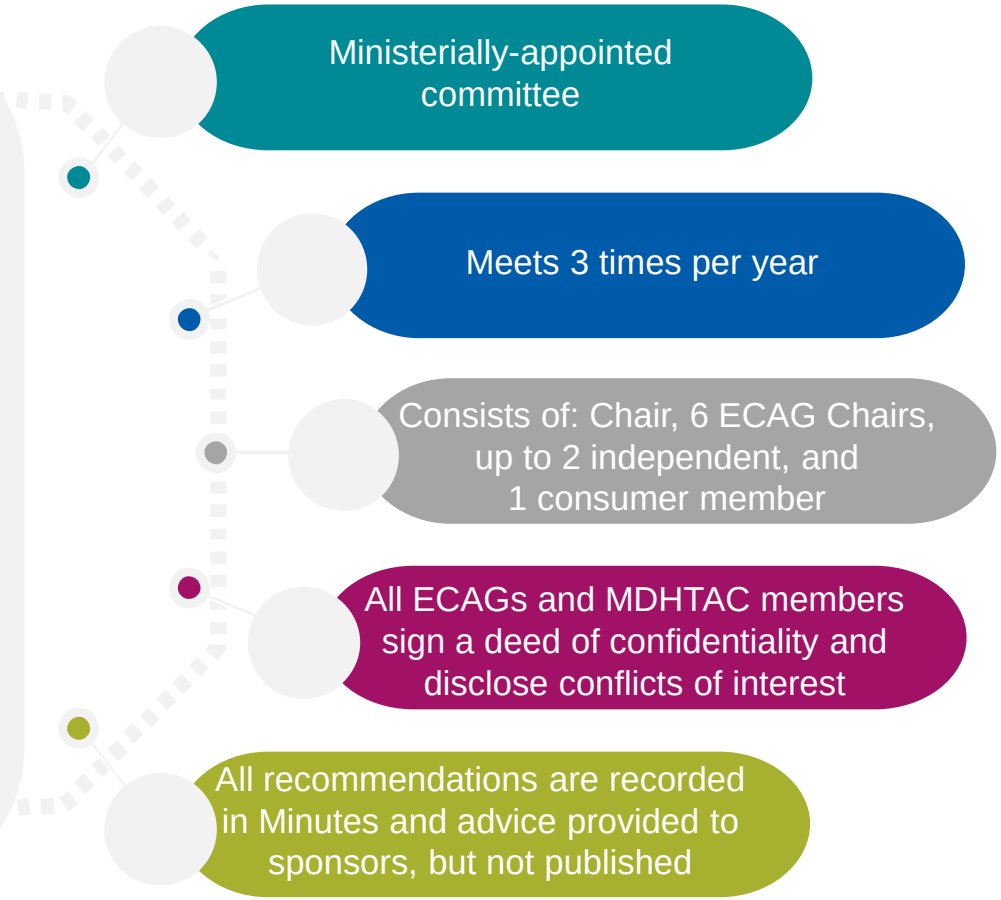
Medical Devices and Human Tissue Advisory Committee (MDHTAC)

The MDHTAC provides recommendations on:

- suitability of devices for listing and associated benefits
- amending of existing billing codes
- other matters

MDHTAC considers:

- eligibility
- correctness of the grouping
- criteria for listing [including comparative clinical effectiveness, comparative cost-effectiveness as applicable
- predicted use
- financial implications for the PL
- and other related matters



Role of the department in the Prescribed List

The department administers the Prescribed List by:

- undertaking departmental assessments
- working with ECAGs and commissioning HTA for Tier 2b and working with MSAC on Tier 3 applications
- providing support to the MDHTAC
- providing advice to sponsors and other stakeholders and recommendations and making decisions
- making the legislative instruments (the Rules)
- maintaining the HPP
- administering PL cost-recovery arrangements
- developing and implementing policy and updating guidance material
- undertaking post-listing reviews and compliance activities
- undertaking other *adhoc* activities

The department treats all sponsor-specific information lodged via the HPP or provided during meetings/discussions as *Commercial-in-Confidence* and manages it accordingly

The department manages all communications

- If sponsors have any questions (after considering the Guide), including the rationale for the recommendations, they may contact the department at prostheses@health.gov.au
- Sponsors or stakeholders should not directly contact ECAG or MDHTAC members

Structure of the Prescribed List

Medical devices
- not used for diagnosis, prediction or prognosis
- must be for a specific treatment and indication
- either surgically implantable or
- essential and specifically designed as an integral single-use aid for implanting a device or
- critical to continuing function of surgically implanted device

Human tissue products that are
- substantially derived from human tissue, where the tissue has been subject to processing or treatments,
- whose supply is governed by state or territory law

Medical devices
- specified groups stated in the Rules
- do not meet the listing criteria for Part A, but the Minister for Health and Aged Care decided to add these devices on the PL
- Currently include: insulin infusion pumps, ILR, remote monitors, cardiac ablation devices, vascular and cardiac eluting balloon catheters

General Use Items

**These items are scheduled to be removed from the PL on 1 July 2024*

This training focuses on Part A and Part C of the Prescribed List

Eligibility requirements for listing on the Prescribed List

The device or human tissue product must also meet the listing criteria for Part A, Part B or Part C on the MDHTP Rules

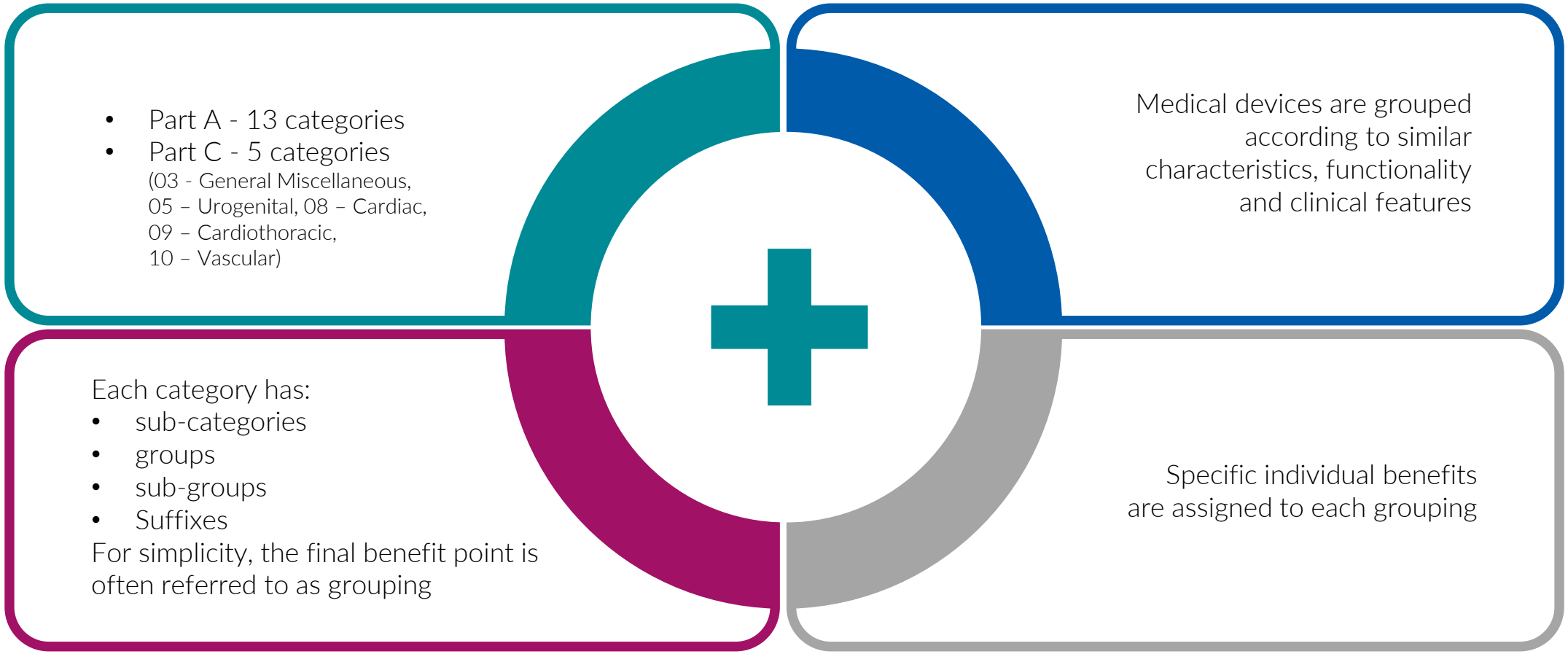
A medical device or human tissue product

Have a Medicare benefit payable in respect to the professional service associated with the use of the medical device or human tissue product in hospital

Used for or implanted in a patient as part of hospital or hospital substitute treatment

Satisfy the criteria for listing in the Rules

Part A and Part C Grouping Scheme



The current grouping structures for Part A and Part B are under review
The existing grouping scheme continue to apply until the reviews are finalised

Billing codes and catalogue numbers

A billing code is a unique code allocated to a listed device for the purposes of facilitating hospital claims and invoicing, and payment of benefits by insurers

Each billing code is listed in a particular grouping and belong to one sponsor

A billing code may only be listed in one place on the Prescribed List and may cover:

- a single device with no variations in characteristics, identified by one catalogue/product number (e.g. one model of pacemaker)
- devices with variations in characteristics, identified by multiple catalogue/product numbers (if these devices have sufficiently similar designs, characteristics, functionality, intended purpose, manufactured by the same manufacturer, and are marketed under the same product name or same product family) (e.g. orthopaedic plates of different lengths and widths)
- a kit, pack, or system, etc. identified by one catalogue number, consisting of two or more medical devices, or a medical device and other products that are designed to be used and listed together (e.g. Implantable Bone Conduction Hearing System); or
- kits, packs, or systems, etc., consisting of two or more medical devices, or a medical device and other products designed to be used together, and one or more components have variations in some of their characteristics and are identified by different catalogue numbers, although all components have sufficiently similar designs, characteristics and are marketed under the same product name or belong to the same product family (e.g. spinal cages, plates and screws of different sizes listed together)

Billing codes and catalogue numbers

- For devices to be listed under the same PL billing code, evidence is required that the devices are sufficiently similar in design and characteristics, belong to the same product range/product family, and are manufactured by the same manufacturer
- A billing code cannot belong to more than one sponsor
- The sponsor stated for the billing code in the Prescribed List must be the same as the sponsor stated on the Australian Register of Therapeutic Goods (ARTG) entry or entries (if required) relevant to the product and linked to the billing code
- New billing codes are created following successful new applications, expansion, compression, or sponsors' transfer applications

Application requirements

All Part A and Part C applications must provide sufficient information to demonstrate that:

1. The device meets the definition of medical device as outlined in the PHI Act
2. There is at least one existing MBS item appropriately describing the Medicare service relevant to the use of the device for treatment provided in hospital or hospital substitute
3. The device is always used in hospital or hospital substitute treatment, or could be used in both hospital treatment and outside the hospital
4. The grouping stated in the new application or for the billing code variation application is correct for all devices identified by catalogue numbers in the application or listed under the billing code

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

! Application cut-off dates are midnights of the 2nd Sundays in January, May or September for the July, November and March (following calendar year) Prescribed List

New applications

- Sponsors use new applications to apply for listing a medical device on the PL
- Usually it is for first time listing of a device on the PL, but also may be used for re-instating a device on PL or obtaining a separate billing code for a different sponsor
- For applications containing more than one catalogue number, sponsors are required to demonstrate that all catalogue numbers in the application are for sufficiently similar devices with minor changes in design characteristics and grouping is correct for all devices in the application
- Once an application is granted, the new billing code is listed on the Prescribed List for the sponsor next time then the MDHTP Rules are made

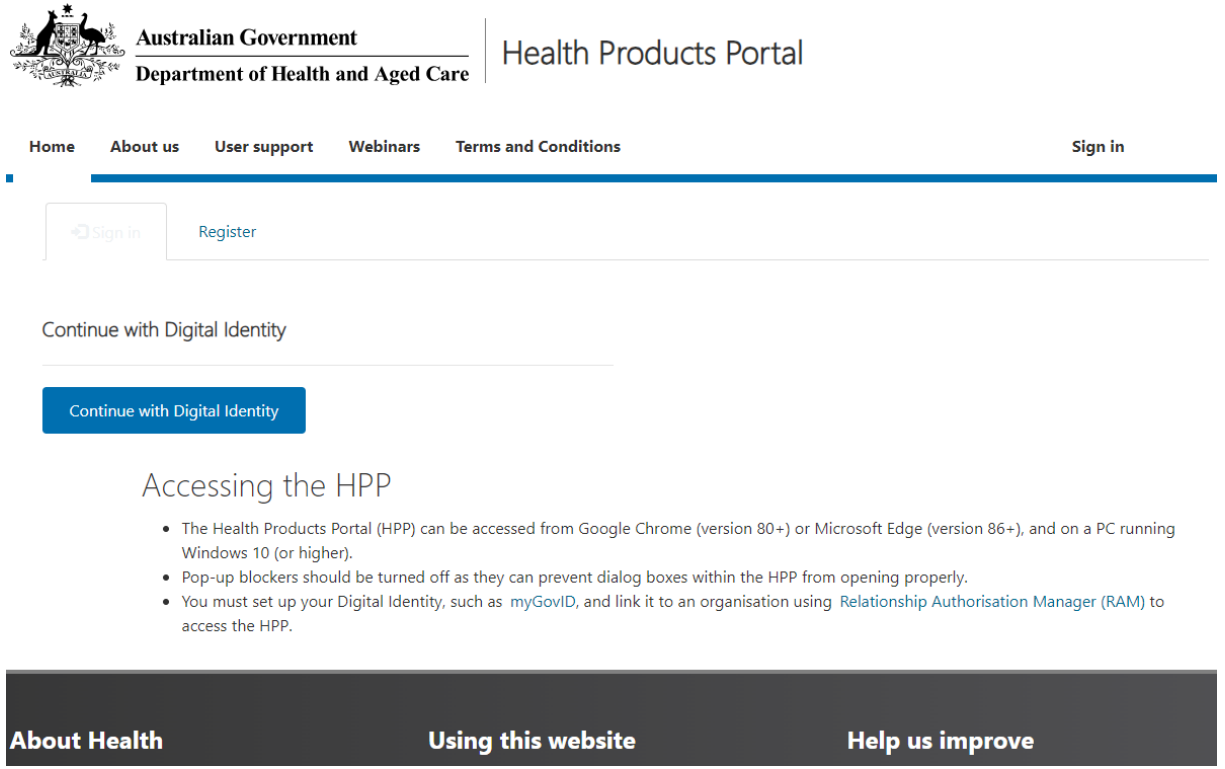
Submitting an application

All PL applications are submitted via the Health Products Portal (HPP)

Sponsors are required to have a myGovID linked to an organisation via Relationship Authorisation Manager (RAM).

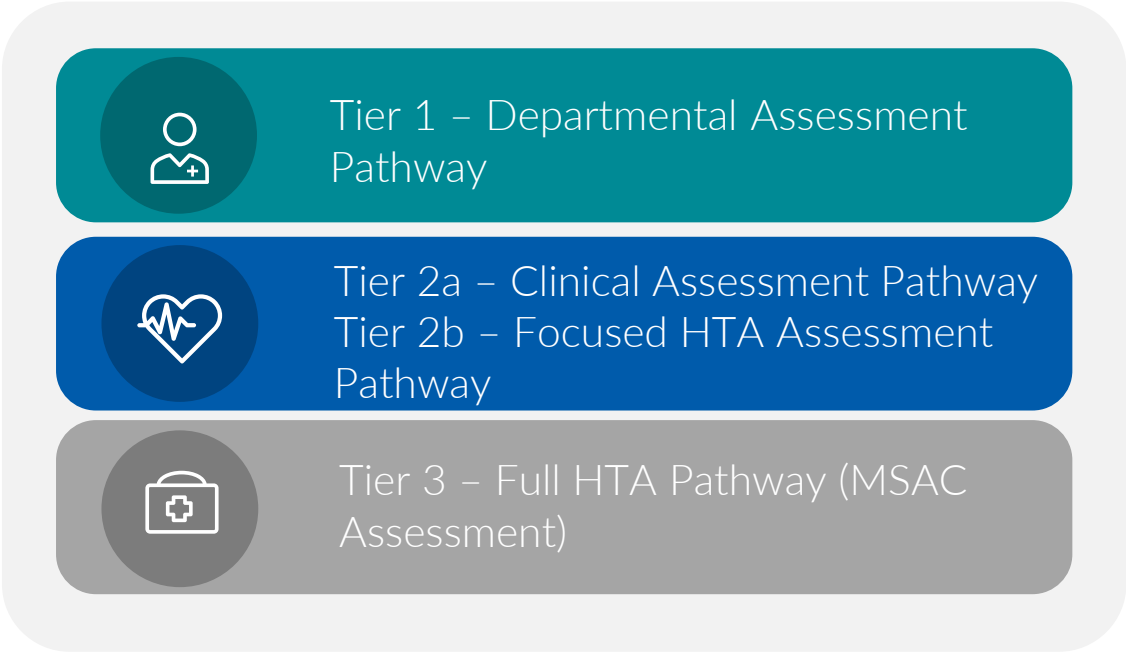
Guidance available to sponsors

- Knowledge-based articles on each page of the HPP application
- Prescribed List Guide (HPP links to this Guide where relevant)
- HPP is running user-onboarding webinars Please pass any HPP feedback on to MTAA and we will take it on notice



Sponsors are responsible for keeping their contact details current in HPP, to ensure they receive all PL-related correspondence

Tiered assessment pathway



- Evidence requirements are tailored to each pathway
- Sponsors are required to choose the appropriate pathway when submitting an application, and to provide clear, complete and relevant information to enable an assessment
- Sponsors may choose any pathway for Part A applications, but for Part C applications, Tiers 2 and Tier 3 are recommended
- We aim to provide clear direction for each pathway in the Guide
- Where, after consideration of the Guide, the appropriate pathway is still unclear, sponsors may contact the department seeking further advice

Tier 1 – Departmental Assessment Pathway

Tier 1 applications are assessed by the department only (not presented to EGAC or MDHTAC)

The following devices may be assessed under Tier 1:

- medical devices that are classified by the TGA as Class IIb or lower
- well-established technology (well-understood and stable designs and limited variations)
- interchangeable with comparators listed in the same PL grouping (i.e. have similar characteristics and are intended to be used in the established patient population with the same indications, and unlikely will cause any increase in the PL expenditure within the grouping)
- Sponsors may only apply for listing the device in one of the existing PL groupings
- Any claims, including of interchangeability with the comparator must be justified

Tier 1 Pathway is not applicable for

- PL applications for Class III device or Part C applications, or for the devices, comparators for which are currently listed on the PL with a condition, or for groupings with suffixes

Tier 1 – Departmental Assessment Pathway

Examples of devices recommended for Tier 1 Assessment Pathway

- Spinal No Integral Fixation Non-expandable Cages or Cervical plates, with the comparators listed on the PL, with very similar designs, characteristics, etc.
  [sub-group 13.05.02.01 – Plate - No Integral Fixation – Cervical, no suffix or with suffix >55mm]
- Neurosurgical Patient Programmers, rechargers, etc., designed to be used together with deep brain stimulation (DBS) or neurostimulation implantable pulse generators and leads already listed on the PL
  [groups 04.04.02 - DEEP BRAIN STIMULATION (DBS) - External Components 04.04.05 – Accessories,
  04.05.02 - NEUROSTIMULATION THERAPIES FOR PAIN MANAGEMENT - External Components, 04.05.05 – Accessories]
- Hip and Knee Accessories and Ancillary devices designed to be used together with the hip and knee main joint replacement devices already listed on the PL
  [sub-categories 11.04 – Accessories and 12.11 - Knee Accessories]

If sponsors decide to submit a Tier 1 application for any devices not considered as acceptable for Tier 1 pathway, sponsors need to be aware that application is likely will be rejected, unless the department agrees there are exceptional or compelling circumstances that warrant Tier 1 assessment.

Listing Criteria

Listing criteria are now in the Rules

G

The general listing criterion that applies for any medical device or human tissue product is for it to be included in the ARTG

Part A

Criteria require the device is surgically implantable, or a single-use device integral to implanting a surgically implantable device, or essential to the continuing function of a surgically implanted device
The device is required not to be one that is used for diagnosis, prediction or prognosis but must be for a specific treatment and indication

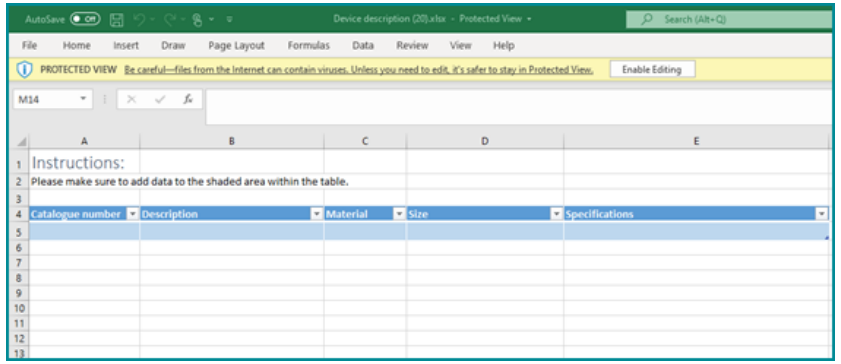
Part A and Part C

Criteria require that the medical device must have been compared with other devices listed on the Prescribed List and the comparison must demonstrate that the medical device is no less clinically effective than the other devices listed on the Prescribed List or alternative treatments, and the benefit amount is proportionate to the clinical-effectiveness of the device

Information we look at during assessment

Catalogue numbers

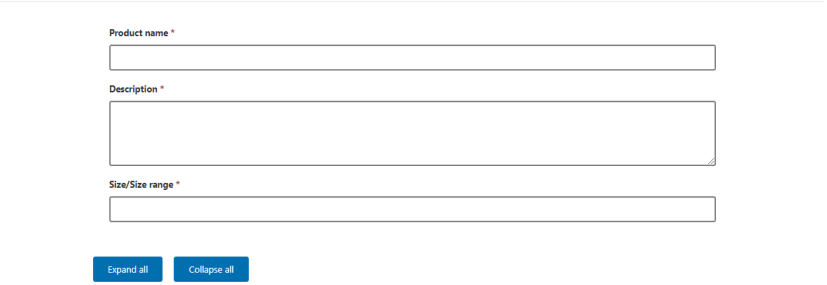
- Catalogue numbers identifying all medical devices in the application must be provided
  - Sponsors can upload a spreadsheet in the HPP with the list of catalogue numbers including details of individual devices
- For intraocular lens (IOLs) or patient specific devices, sponsors may provide a list of Stock Keeping Units (SKU), or other unique device identification numbers set up for billing purposes
- Product brochures, surgical techniques, IFU, leaflets, etc. must show catalogue numbers, devices details, and representative images for all devices (images without labels clearly stating the details of the device are not acceptable)



Information we look at during assessment

Product name, description and size

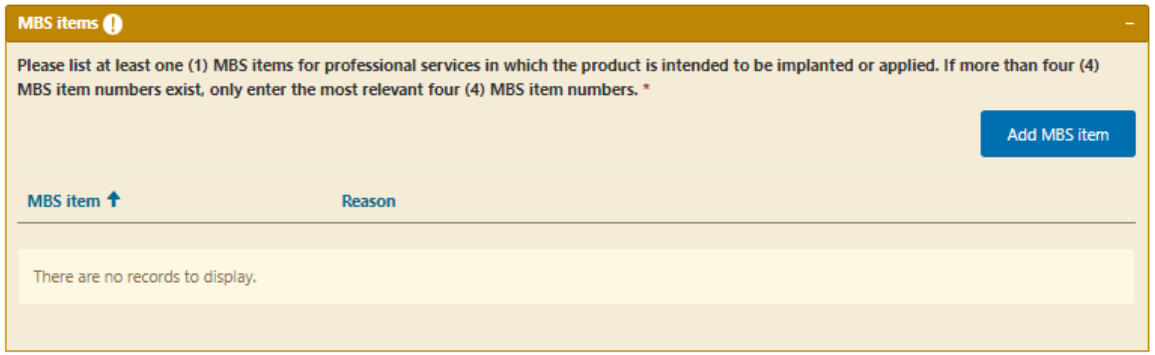
- Product name, description and size are used to identify the device (or devices where there are more than 1 catalogue number) in the application
- If the application is for a kit, system, etc. the product name and description need to explain it in detail (e.g. endobutton with tape, or artificial heart valve with a delivery catheter and a steerable sleeve, etc.)
- Generic or unclear name and description are unacceptable (e.g. Knee System without the system's name or identifying the component, or sponsor's name instead of device name, etc.)
- Product size needs to be correct for all devices in the application and consistent with the grouping (if the grouping depends on size)
- Information needs to be concise but informative, do not use it for promotional or marketing purpose



Information we look at during assessment

Medicare Benefits Schedule (MBS) items

- There must be at least one Medicare benefit payable for service with use of the device for treatment in hospital (i.e. at least one valid and correct MBS item)
  - HPP allows up to 5 MBS items to be included in the application
    - Sponsors must use Tier 3 Assessment Pathway when there are no valid MBS items
- Sponsors need to ensure MBS items stated in the application are correct for the device used in hospital treatment
    - HPP includes an MBS items search function. Alternatively, MBS items can be found online or in consultation with clinicians



Information we look at during assessment

Groupings

- For Tier 1, sponsors must not state any new groupings
- Applications where sponsors apply to list their devices with suffixes are not recommended for Tier 1
- Sponsors are required to state the grouping that correctly reflects/describes ALL devices in the application
  - If the comparator is in a different grouping, explain the rationale for selecting this comparator (e.g. groupings depend on the size and the difference between the subject device and the comparator is only in size, other characteristics are the same)
- For groupings that depend on size, ensure ALL devices in the application include the correct size (diameter, thickness, number of screw holes, etc.)
  - For example, for the specialist orthopaedic and plastic and reconstruction plates, ensure counting all screw holes in the plate and include plates with the correct thickness

Information we look at during assessment

Comparators

- For applications under Tier 1 Assessment Pathway, the comparators must always be devices already listed on the PL
  - Tier 2b or Tier 3 Assessment Pathways are required to be used when there are no valid comparators listed on the PL
- The new device and the comparators should be similar in respect to designs, characteristics, material, etc.

Information we look at during assessment

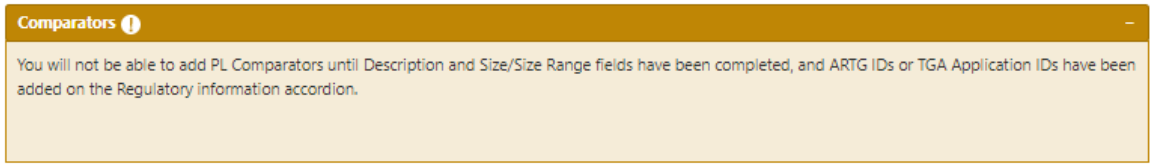
ARTG entry or TGA application ID

- Any medical devices must have a valid ARTG entry to be legally supplied in Australia, and accordingly any new application must provide either
  - a valid ARTG entry or entries (if required), or, under the parallel assessment process, a TGA application ID (ARTG inclusion or conformity assessment applications only) with details of the application and evidence that application is valid and effective
- ARTG entry or TGA application ID must state the same sponsor as stated in the PL application and cover all devices in the application
- Applications will not be finalised until ARTG entry or entries (if required) are provided

Information we look at during assessment

Other general requirements

- Any documents provided must not be password protected or corrupted
  - Any documents with the restricted access will be taken by the department as not received and will not be assessed
- Any document must be provided in English
  - When Instructions for Use are provided, please provide only the part in English



Tier 2 Clinical/Focused HTA Assessment Pathway

- Is for devices not suitable for assessment under Tier 1 Pathway
- Has two routes depending on the level of assessment required
  - Tier 2a – clinical assessment only
  - Tier 2b – clinical plus economic assessment to establish cost effectiveness

The following devices can be assessed under Tier 2

- devices classified by the TGA as Class III, or any Part C applications
- Part A applications for the devices that are not well-established technology
- devices that have high variability in the designs and characteristics
- devices for which sponsors claim any novel features, characteristics or functionality
- applications where sponsors apply for listing the devices in new groupings or ask to change the groupings (in the amendment applications)

Tier 2 = Tier 1 + clinical (and economic where required) assessment

One of the listing criteria for Part A and Part C is that:

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

- To determine if a device meets this criteria, Tier 2 applications require clinical data/evidence for the medical device.
- We aim to provide clear direction on the clinical evidence requirements in the Guide (for the 13 categories in Part A and 5 categories in Part C)
- Where, after consideration of the Guide, sponsors are uncertain of the requirements, sponsors may contact the department seeking further advice

Tier 2 Clinical/Focused HTA Assessment Pathway

Clinical data

- The information presented here and in the Guide is only a guidance. There is no ‘one size fits all’ requirement for clinical data. This depends on the device’s history, novelty, variability and other factors. Each application is assessed individually based on the information provided.
- Clinical data is considered in context of the level, quality, independency, and source of collection of the data provided
- The clinical data must be directly relevant to the device in the application, and not for the comparator (with some exceptions)
- Assessment of PL applications often relies on observational studies, and there is no specific study design mandated for different PL applications
- If a new grouping with a higher benefit is requested, provide clinical evidence comparing the difference in clinical outcomes between the device and the comparators
- Sponsors need to consider any conflicts of interest in the information they provide
- The conclusion regarding acceptance of any provided clinical data will always be made in context of the specific device
- Sponsors must apply own judgement when providing clinical data/evidence

Sponsors are required to provide an executive summary (no more than 2 pages) with the rationale how the information and clinical data is relevant to their application

Tier 2 Clinical/Focused HTA Assessment Pathway

Examples of clinical data requirements for hip and knee joint replacement devices

Used in primary procedures or in primary AND revision procedures

Clinical data is expected on minimum 250 procedures with at least 2-year adequate follow-up

Used in revision procedures OR special circumstances OR unusual situation

Clinical data is expected on minimum 50 hip or knee joint replacement devices implanted with at least 2 years follow-up

Tumour devices

Minimum 20 devices implanted with at least 2 years follow-up

Note that the data requirements for these devices may vary depending on circumstances

Tier 2 Clinical/Focused HTA Assessment Pathway

Other requirements

Testing data

Testing data may be required for some devices (e.g. soft tissue fixation suture anchors require pull-out strength data inclusive of methods used in the cyclic testing, ultimate load testing, insertion testing, statistical rationale for sample size, acceptance criteria and results

New grouping

If sponsors are applying for a new grouping, they must provide rationale and justification for the new grouping.
Clinical evidence is required to support these applications.

Device prices

Applications require:

- Public hospital price in Australia if available (provide all prices if they vary between hospitals)
- Overseas prices if public hospital prices not available

Estimated utilisation

Applications must provide information on potential impact on private health insurance expenditure

Applications for new groups in Part C

1

Application received

2

ECAG assessment

The relevant ECAG assesses the device to establish its clinical effectiveness and the clinical need. ECAGs assesses clinical data and published evidence directly related to the device (data for a different devices and testimonials from clinicians are not sufficient clinical evidence)

3

MDHTAC assessment

MDHTAC considers ECAG's advice, clinical effectiveness, clinical need, benefits of the device, and provides their view [support or not support] on whether to seek the Minister's decision regarding amending Part C criteria for listing

4

Minister decision

If MDHTAC supports change to Part C listing criteria, the department will prepare and seek the Minister's advice. The Minister may consider the MDHTAC advice and other matters, including whether the requested change to Part C criteria is consistent with the PL intent and the PL reforms, impact on the expenditure, out-pocket costs, etc.

5

Notification to stakeholders

If the Minister approves change to the Part C criteria for listing, the department will notify the sponsor and will publish a PHI Circular advising stakeholders about this decision

6

Benefit setting

The benefit will need to be estimated and set up for the new group (under Tier 2b or Tier 3 assessments)

Variation and other types of applications

Amendment

For changing the details of the existing billing code, including:

- deletion/addition of catalogue numbers
- amending product name, description or size stated for billing code
- addition or replacement of ARTG entries
- changing the grouping the billing code is listed in

Amendment applications do not delete or create any existing billing codes

Criteria for Tier 1 and Tier 2applications discussed previously apply in the same way to the amendment applications

Any changes to groupings require Tier 2 or Tier 3 pathways

Expansion/Compression

- For expanding the billing code covering multiple devices into two or more new billing codes
- For compressing multiple existing billing codes into a single billing code

Expansion/compression applications result in deletion of the existing billing codes and creation of new billing codes

Expansion/compression applications do not usually change the groupings for billing codes (but there may be exceptions)

[For example, if some devices (cat. numbers) in the billing code are incorrect for the subgroup/ suffix, the billing code is listed in, and sponsor apply to split the devices in order to list them in the correct groupings under different billing codes]

Others

Sponsors' transfer

For transferring of a current billing code to a different sponsor

(e.g. when business is sold, merged, company name changed, etc).

- The receiving sponsor is responsible for submitting the sponsors' transfer application AND providing evidence of transferred ARTG entry
- The transferring sponsor is required to provide evidence of the business transaction and agreement/authority to transfer the billing codes

Deletion

For deleting the existing billing codes from the PL.

Submitting variation or other applications

The requirements are essentially the same as for submitting a new application

- Use the HPP application form
- Select the Tier
  (does not apply to sponsors' transfer or deletion)
- Provide all required information
  - Ensure all information is correct (cat. numbers, grouping stated for the billing code, etc.)
  - Refer to prompts on each page of the HPP application
  - Refer to the PL Guide

Sponsors are responsible for including correct contact details to ensure they receive the application related correspondence

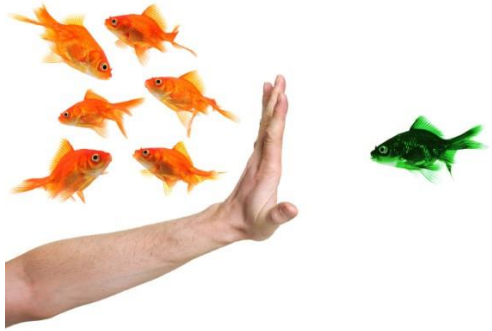
Amendment applications – what we assess

- Mostly we assess the same information as in new applications
  (i.e. catalogue numbers, grouping, product name, description and size, ARTG entry, documents attached with the application)
- Applications for billing codes with no catalogue numbers recorded (‘historical approvals’) or where sponsors apply to add devices to the billing code, sufficient information is required to establish prior approval and/or similarity of existing and additional devices (incl. brochures with images for all devices, etc.) (refer slide on the billing code and cat. numbers)
- Changes of ARTG entries (e.g. reclassification, changes in legal manufacturers, etc.) need to be clearly explained
  (e.g. changes in legal manufacturers must not result in any changes to the device design, characteristics, etc, ARTG entries that belong to different sponsors or for devices manufactured by different manufacturers are not acceptable under the same billing code)
- Applications to change the grouping need to be submitted via Tier 2 or Tier 3 pathways and clinical evidence provided is to be assessed by ECAGs and considered by MDHTAC
  (refer slide 29)

For devices to be listed under the same PL billing code, evidence is required that the devices are sufficiently similar in design, characteristics, material, etc., belong to the same product range/product family, and are manufactured by the same manufacturer

Amendment applications – common issues

- **Mix of correctly and incorrectly listed devices under the billing code**
  - Specialist Orthopaedic locking and non-locking plates (suffix LK)
  - Cannulated and non-cannulated screws (suffix CN)
  - Not all screws have dual thread (suffix DT)
  - Periarticular and standard plates (grouping for Periarticular)
  - Complex and non-complex plates (suffix COM)
  - Plastic and Reconstructive Fracture or Reconstruction Plates of different thicknesses
- **Incorrect grouping**
  - Sub-group Interbody, Integral Fixation for the spinal cages and plates
  - Knee suffix Revision



Other notes on applications

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

- When doing this sponsors are required to:
  - consider the concerns raised during the assessment of the previous application, and provide the information required to address those concerns
  - pay the fees for such application
- HPP functionality will allow for information from the original application to be pre-filled in the resubmission application, but information/evidence required may vary depending on the Tier and the issues raised during the previous assessment

Tier 2b Focused HTA Assessment Pathway

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

- This may occur when sponsors apply or when it is recommended that the device is listed in a new grouping.

Clinical evidence

- Sponsors must provide a comparative analysis of the similarities and differences between the subject device and the comparators
- Recommended sources of clinical evidence to support the comparative analysis include:
  - Clinical trials of the product (Clinical Study Reports or peer-reviewed publications)
  - Observational studies of the product (clinical registry data, cohort studies, or case series)
  - Sponsors may also use data from clinical registries to support their applications, if the quality, reliability etc of the registry may be verified
- The type of evidence required to demonstrate substantial similarity depends on the extent to which a device differs from the comparator and the potential risk of harm from use of the device.

Economic evidence

- A full economic evaluation is not required for this pathway. However, economic information is required to validate the proposed benefit and to demonstrate that it represents value for money assessed via the Tier 2b pathway
- The assessment will typically take the form of a focused commentary (appraisal) of the clinical and/or economic claims made in the application by the sponsor. Sponsors will be able to provide feedback on assessment reports
- Assessment reports will be provided to the MDHTAC together with other assessments for the devices, for their consideration

Tier 3 Full HTA Assessment Pathway

- Tier 3 Assessment Pathway is for devices requiring assessment by the Medical Services Advisory Committee (MSAC), to establish the comparative clinical effectiveness and cost-effectiveness
- In some cases, assessment of the device is conducted as part of the assessment of the related Medicare service
- MSAC oversees the HTA process and provides advice to the MDHTAC and the department, which informs assessment of the PL application
- Sponsors must submit a separate application to MSAC - refer to the MSAC Guidelines for guidance
- The PL application may be submitted prior to, concurrently with, or after the MSAC application
- Applications and related correspondence must identify and explain the link with the MSAC application (whether underway or planned)

View MSAC Guidelines

Application and assessment fees

- New cost recovery arrangements and fees started on 1 July 2023
- The fees align with the Tiered assessment pathway
- The fees are defined in legislation and reflect the activities and work involved in the assessment

		Tier 1	Tier 2a	Tier 2b	Tier 3
Standard Application Fee	$1,370	✓	✓	✓	✓
Clinical Assessment Fee	$4,090		✓	✓	✓
Simple Economic Assessment Fee	$8,940			✓	
Complex Economic Assessment Fee	$17,080			✓	
Other Economic Assessment Fee	$27,940			✓	
Full HTA Assessment Fee*	$3,300				✓

**Further fees apply for MSAC assessment*

Getting in touch with us

Prescribed List

Applications
prostheses@health.gov.au

Reforms (including Cost Recovery)
prosthesesreform@health.gov.au

Post-listing reviews
PLReviews@health.gov.au

Compliance
prosthesescompliance@health.gov.au

HPP technical support
hpp.support@health.gov.au

Australian Government
Department of Health and Aged Care