



Australian Government

Department of Health

Prostheses List

Guide to listing and setting benefits for prostheses

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Prostheses List – guide to listing and benefits for prostheses

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About this guide

What is the Protheses List Guide?

The *Protheses List: guide to listing and setting benefits for protheses* (the Guide) has been developed to provide guidance on how to submit an application to include a surgically implanted prothesis and other products on the Protheses List. The Protheses List specifies the benefits that private health insurers are required to pay for the listed protheses to appropriately insured persons.

The information in this document is provided as a guide only. Applicants are encouraged to contact the relevant Protheses secretariat for assistance and to discuss the information that should be included with an application.

The Guide also provides information for other stakeholders and decision makers about the protheses listing arrangements.

Additional information about the Protheses List and protheses listing arrangements

The Australian Government Department of Health will publish information about the Protheses List and the protheses listing arrangements from time to time on its website. Information is published in a Private Health Insurance Circular.

The information included in these publications includes:

- critical dates in the Protheses List process (e.g. publication and commencement of the Protheses List);
- meeting dates for the Protheses List Advisory Committee and its subcommittees; and
- clarification on matters of policy or process.

What is a Protheses List application?

Sponsors or suppliers of medical devices can make applications to list protheses on the Protheses List. In this document, references to sponsors will also apply to suppliers. The Protheses List Advisory Committee considers these applications, and applications to make changes to existing listings, and makes recommendations to the Australian Government Minister for Health for products to be listed on the Protheses List.

How is the Guide structured?

The Guide is divided into four parts:

- **Part I (Prostheses listing arrangements)** describes the legal arrangements for managing the Prostheses List.
- **Part II (Supporting evidence)** describes the rationale for the evidence requirements for new applications and provides a framework to assist sponsors to select the most appropriate clinical evidence to support their applications.
- **Part III (Step-by-step guide to completing an application to list a new prosthesis)** provides instructions for completing each section of the application form (particularly for new users of the application process).
- **Part IV (Changing an existing listing)** provides details about how to make changes to a current listing.

A copy of the Guide is available on the Australian Government [Department of Health website](#).¹ Frequent users of this guide should ensure that they have the latest version.

This version of the guide supersedes *Guide to listing and setting benefits for prostheses*, dated December 2015.

Relevant legislation

Legislation relating to the Prostheses List includes the following:

- *Private Health Insurance Act 2007*
- *Private Health Insurance (Prostheses) Rules*, as made from time to time
- *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*
- *Private Health Insurance (Prostheses Application and Listing Fees) Rules*, as made from time to time
- *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*
- *Private Health Insurance (National Joint Replacement Register Levy) Rules*, as made from time to time
- *Private Health Insurance (Complying Products) Rules*, as made from time to time.

Feedback

Feedback on the Guide can be sent to:

Email: Prostheses@health.gov.au

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Canberra ACT 2601

¹ [Prostheses List - Applications and Requests](#)

Part I — Protheses listing arrangements

1 Overview

Definitions

Medical device

The Therapeutic Goods Administration (TGA) defines a medical device as an instrument, apparatus, appliance, material or other article intended to be used for human beings for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

Medical devices include a wide range of products, from those used externally (such as surgical gloves, bandages and condoms) to internal devices (such as pacemakers and dialysis equipment). Prostheses are a subset of medical devices. Safety and efficacy of medical devices are assessed by the Therapeutic Goods Administration, and products must be entered on the Australian Register of Therapeutic Goods before they can be provided in Australia.

Medical service

Medical services include therapeutic, investigative and consultative procedures. When a surgically implantable prosthesis 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 prosthesis is assessed by the Prostheses List Advisory Committee. Medical services that are subsidised by the government are listed on the Medicare Benefits Schedule.

Prosthesis

The types of prostheses covered by the Prostheses List are those that meet the criteria shown in Section 2, Table 2.1 of this guide. Essentially, this is only those devices that are surgically implanted; or are essential to, and specifically designed as an integral single-use aid for, implanting such a product; or are critically important to the ongoing function of a surgically implanted product. Human tissue items such as corneas, bones and heart valves are also covered by the Prostheses List, as are insulin infusion pumps, cardiac loop recorders and cardiac home/remote monitoring systems. External prostheses, such as external legs, external breast prostheses, wigs and other such devices are not included on the Prostheses List, and are not the subject of the arrangements covered by this guide.

1.1 Health technology assessment in Australia

Health technology assessment uses scientific evidence to evaluate the quality, safety, efficacy, effectiveness and cost-effectiveness of health services and health technology. In Australia, several advisory and regulatory bodies provide health technology assessment:

- The Therapeutic Goods Administration (TGA) assesses the safety and performance of medicines and medical devices, and enters them on the Australian Register of Therapeutic Goods (ARTG). This allows the product to be sold in Australia. The TGA also regulates safety and performance of products in use.
- The Medical Services Advisory Committee (MSAC) assesses the safety, effectiveness and cost-effectiveness of medical technologies and procedures to inform decisions about public funding.
- The Pharmaceutical Benefits Advisory Committee (PBAC) assesses the effectiveness and cost-effectiveness of medicines and vaccines to inform decisions about public funding.

- The Prostheses List Advisory Committee (PLAC) assesses the comparative clinical effectiveness of prostheses and the proposed benefits to inform decisions about reimbursement by private health insurers.

1.2 What is the Prostheses List?

The purpose of the Prostheses List is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs.

Under the *Private Health Insurance Act 2007* (the PHI Act), private health insurers are required to pay benefits for prostheses that are included on the Prostheses List:

- for which an insured person has appropriate cover
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment
- for which a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

The arrangements for including products on the Prostheses List help to ensure that benefits paid by insurers are relative to clinical effectiveness. The purpose of clinical assessment for the Prostheses List is reimbursement, not regulation.

Benefit

In the context of the Prostheses List, the term ‘benefit’ means the reimbursement to health consumers when they receive treatment.

The Medicare benefit is the amount payable by Medicare for the professional service associated with the provision of the prosthesis.

The benefit shown on the Prostheses List is the amount payable by private insurers for the prosthesis.

The Prostheses List arrangements are set out in Division 72 of the PHI Act and the *Private Health Insurance (Prostheses) Rules* (the Prostheses Rules). The Minister will make the rules under the authority of ss. 72-1, 72-10 and 333-20 of the PHI Act.

The Prostheses List is the schedule to the Prostheses Rules and is in three parts:

- Part A—prostheses that satisfy the criteria for listing agreed by PLAC and approved by the Minister.
- Part B—human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law). Human tissue products are not addressed in this guide.
- Part C—prostheses that satisfy the criteria for listing on Part C. These criteria specify that a prosthesis will be listed in Part C if it is
 - an insulin infusion pump;
 - an implantable cardiac event recorder; or
 - a cardiac home/remote monitoring system.

The Prostheses List contains more than 10,000 prostheses. It is released twice a year (February and August), and the Department accepts applications on a continuous basis. A prosthesis will be incorporated in the next released Prostheses List if the Minister has granted the application and the applicant has paid the initial listing fee.

See Section 2 for further details about the Prostheses List.

1.3 Assessment of products

PLAC is appointed by the Australian Government Minister for Health and makes recommendations to the Minister about which products should be included on the Prostheses List, and the appropriate benefits for these products. In making its recommendations, PLAC considers the comparative clinical effectiveness of the product and sometimes the comparative cost.

In deciding to list a product and the benefit payable, the Minister may have regard to the recommendations of PLAC. For the purposes of this guide, all further references to the Minister in the context of decisions to list on the Prostheses List also include the Minister's delegate.

Section 3 contains further details about PLAC and its subcommittees.

The legislation requires an application to list a prosthesis to be made on an approved form.

The *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* and the Private Health Insurance (Prostheses Application and Listing Fee) Rules set out the mandatory cost-recovery arrangements, including fees for:

- making an application to list a prosthesis
- initially listing a prosthesis where the Minister has granted an application
- maintaining an ongoing listing of a prosthesis

Section 4 contains further details about the application process.

2 The Protheses List

2.1 Criteria for listing

The legislation underpinning the prostheses arrangements does not define ‘prosthesis’. Instead, criteria for listing products on the Protheses List are applied by PLAC to each product assessed for listing. This helps to ensure that every product is considered in the same way, and that PLAC’s recommendations for listing are consistent, fair and equitable.

Criteria for listing on Part A

The PHI Act provides that benefits from hospital treatment cover will be paid in respect of a kind of prosthesis listed in the Protheses Rules.

The criteria for listing a kind of prosthesis on Part A of the Protheses List are as follows:

- 1) The product must be entered and current on the Australian Register of Therapeutic Goods
- 2) The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment
- 3) A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)
- 4) A prosthesis should:
 - (a) be surgically implanted in the patient and be purposely designed in order to
 - (i) replace an anatomical body part; or
 - (ii) combat a pathological process; or
 - (iii) modulate a physiological process;
 - or
 - (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
 - or
 - (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and
- 5) The product has been compared to alternative products on the Protheses List or alternative treatments and
 - (i) assessed as being, at least, of similar clinical effectiveness; and
 - (ii) the cost of the product is relative to its clinical effectiveness.

Table 2.1 shows the criteria for listing on Part A and the rationale for each criterion. Criteria 1–3 are based on Commonwealth legislation; criteria 4 and 5 are not mandated by legislation, but PLAC has agreed that these criteria should be satisfied to list a product on the Protheses List.

Table 2.1 Criteria for listing a product on the Protheses List—Part A

Criterion	Rationale
Legislatively based criteria	
1 The product must be entered and current on the Australian Register of Therapeutic Goods	All therapeutic products must be included on the Australian Register of Therapeutic Goods before they can be lawfully supplied in Australia
2 The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment	This is a requirement of item 4 of the table in subsection 72-1(2) of the <i>Private Health Insurance Act 2007</i>
3 A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)	<p>This is a requirement of item 4 of the table in subsection 72-1(2) of the <i>Private Health Insurance Act 2007</i>. An exception to this rule is where the provision of the prosthesis is associated with podiatric treatment by an accredited podiatrist.</p> <p>It is intended that a Medicare benefit should be payable under an item that is specific to the procedure in which the product is ‘delivered’</p>
Other criteria	
<p>4 The product should:</p> <p>(a) be surgically implanted in the patient and be purposely designed in order to</p> <p>(i) replace an anatomical body part; or</p> <p>(ii) combat a pathological process; or</p> <p>(iii) modulate a physiological process;</p>	<p>The word ‘surgically’ has been chosen to convey the intention that the product be provided through an interventional process, and ‘implanted’ has been chosen to convey that the interventional process breaches the interface (or integument) between the body and the outside world (i.e. the skin or other epithelial surfaces, such as the rectal mucosa). This is to distinguish Protheses List products from those that are externally attached to the body, such as artificial limbs (which meet the ordinary dictionary meaning of prosthesis but are not items that are considered in the context of the Protheses List).</p> <p>The term ‘surgically’ is not intended to limit the performance of the intervention to surgeons, but is meant in the broader sense of performance of an interventional procedure by a suitably qualified medical, dental or podiatrist practitioner.</p> <p>Based on the ordinary dictionary meaning of implant, ‘implanted’ includes the implantation of tissues into the body, or an organ of the body, by grafting. Examples of tissues are harvested bone, heart valves and corneas.</p> <p>A product that is implanted for the purpose of replacing an anatomical body part is considered to be a prosthesis. This includes products such as knee and hip replacements.</p> <p>If an implanted product does not replace an anatomical body part, its principal function should be to either combat a pathological process or modulate a physiological process. ‘Combating a pathological process’ may include averting, repairing or correcting a pathological process; examples include cardiac and vascular stents, and cardiac defibrillators.</p> <p>‘Modulating a physiological process’ can mean either blocking or facilitating a process. Examples are</p>

Criterion	Rationale
	pacemakers (to regulate heartbeat) and nerve stimulators for pain management (modulates a physiological process and prevents a pathological process)
<p>or</p> <p>(b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted</p>	<p>This criterion is for associated products that are essential and manufactured specifically to enable the delivery of a product that meets the criteria above.</p> <p>Associated products (as opposed to equipment) are only for use once in a patient, have a unique and direct connection to the product and are integral to implanting the product into the patient. This does not include products whose use is of a more general nature (e.g. sutures, scalpels, trocars).</p> <p>‘Only for use once’ means that, once used, the associated product is of no further use. That is, it is incapable of further use, and may only be discarded. It does not have a general-purpose use. An example is a preloaded coronary stent that is supplied fixed on a balloon catheter that is needed for positioning and implanting the stent. Without the balloon catheter, the stent is unable to be satisfactorily implanted. The catheter is specific and integral to the particular stent.</p> <p>Neither the packaging of the associated product with the subject product nor its labelling as ‘single use only’ will be sufficient to determine compliance with this criterion. That is, even if the product has a manufacturer’s stamp of ‘single use only’, if the product can be reused for a practical purpose or has a purpose that is not specific to the implanted product (e.g. a screwdriver is of a general nature and not specific, even where a screw is to be implanted), then the criterion is not met</p>
<p>or</p> <p>(c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and</p>	<p>This criterion is for associated products that can only be used by the patient for whom they are provided because of their connection to the product that has been implanted in the patient. These products are critical to the continuing function of the implanted prosthesis and remain with the patient, as part of the prosthesis, after the episode of hospital treatment or hospital-substitute treatment. On their own, these products would not otherwise meet the criteria for listing on the Prostheses List. Examples are processors that are a critical element of the functioning of the implanted product, such as cochlear speech processors and patient-controlled products for pacemakers.</p> <p>Under this criterion, the associated product must have an ongoing role in the function of the implanted product and not be a generic disposable or consumable item. Batteries, catheters, cannulas and similar accessories whose association with the implanted product is not ongoing are considered to be disposable products under this criterion.</p> <p>The product’s use is also restricted to an individual patient; the product cannot be one that may be used by more than one patient. For example, office-based equipment to read and download information from implanted ECG loop recorders, which is used in multiple</p>

Criterion	Rationale
	patients, would not meet this criterion
<p>5 The product has been compared to alternative products on the Protheses List or alternative treatments and</p> <p>(i) assessed as being, at least, of similar clinical effectiveness; and</p> <p>(ii) the cost of the product is relative to its clinical effectiveness.</p>	<p>This criterion is included with the intention that clinical effectiveness and relative cost be considered.</p> <p>The term ‘alternative treatments’ is included to allow for entirely new products or technology to be compared with current treatments for the same clinical condition, as it is anticipated that not all products to be considered will have an existing counterpart on the Protheses List. For example, when cochlear implants were first introduced, the comparator would have been a conventional hearing aid or no hearing assistance at all; when pins and plates were introduced to treat fractured femurs, the comparator would have been use of an external splint and bed rest for 10 weeks.</p> <p>The word ‘similar’ is used because it is impossible to state that one product is exactly ‘equal’ to another product when considering clinical effectiveness.</p> <p>The assessment procedure for consideration of products for inclusion on the Protheses List does not involve analysis of cost-effectiveness; therefore, the term ‘cost-effective’ is not used. However, a product’s cost should be considered relative to alternative products or treatments, and relative to its clinical effectiveness compared with those alternative products or treatments</p>

Criteria for listing on Part C

The criteria for listing on Part C are contained in the Protheses Rules. Currently, a prosthesis will be listed on Part C if it is an:

- (i) insulin infusion pump;
- (ii) implantable cardiac event recorder; or
- (iii) cardiac home/remote monitoring system.

2.2 Product categories and groupings

PLAC considers information on Protheses List product grouping as an indicator of comparative clinical effectiveness in determining the most appropriate benefit for each product recommended for listing.

Categories

The Protheses List is divided into several categories of prostheses:

- cardiac
- cardiothoracic
- hip
- knee
- ophthalmic
- specialist orthopaedic
- spinal
- urogenital
- vascular

- ear, nose and throat
- neurosurgical
- plastic and reconstructive
- general/miscellaneous products (prostheses not included in other categories)

Groupings and benefits

Within categories, products are grouped according to similar clinical effectiveness. For simplicity, product categories, subcategories, groups and subgroups are identified numerically; some also have alphabetical suffixes or descriptive text to designate additional features and reflect different benefits.

Each grouping of products on the Prostheses List has a single group benefit. Groups and subgroups of products may be differentiated at the suffix level (i.e. the addition of a suffix may result in a different benefit). Sponsors can accept the group benefit, choose to list at a lower benefit or choose not to list the product.

For products implanted into privately insured patients in public hospitals, insurers are required to pay the group benefit or the patient's liability to the hospital for the prosthesis, whichever is the lesser amount.

2.3 Billing code and catalogue number

The billing code is a reference code allocated to a listed prosthesis. The billing code facilitates hospital invoicing procedures and the payment of benefits by insurers. A billing code may be allocated to:

- a single piece product;
- a 'set' comprising two or more nonidentical components;
- a pack containing different sizes of otherwise identical items; or
- a 'kit' or 'set' consisting of implantable components and other nonimplantable components that are agreed to be integral to the delivery or ongoing functioning of the implantable components

The billing code is specific to the sponsor of the product. If a billing code has been deleted, the same billing code will not be reused in future Prostheses Lists. New billing codes are created for products on the Prostheses List that are duplicated, expanded, compressed or transferred to another sponsor.

Sponsors are asked to provide a catalogue number (a unique identifier) for each component of a billing code. This assists in identifying the products that are included under the billing code.

2.4 Release dates

The Prostheses List is released in February and August of each year, and is available on the [Department's website](#).

A Prostheses List commences approximately 10–20 working days after its release. This allows insurers to update their payment systems and hospitals to update their invoicing systems before the new Prostheses List commences. Critical dates for new Prostheses Lists, along with publication and commencement dates are advised via Private Health Insurance Circulars.

3 The Prostheses List Advisory Committee

Rule 9 of the Private Health Insurance (Prostheses) Rules provides that the Minister may have regard to recommendations from the Prostheses List Advisory Committee (PLAC) in making decisions on granting applications to list prostheses on the Prostheses List.

PLAC advises the Minister for Health on appropriate listing and benefits of prostheses on the Prostheses List. In making recommendations, PLAC considers advice provided by its subcommittees.

PLAC will consider and recommend the listing of products. PLAC may also report on any other issues it may wish to draw to the attention of the Minister.

PLAC's terms of reference can be found on the [Department's website](#).

3.1 PLAC membership

The 22 members of PLAC are identified and nominated by either the Department or by the major private health industry stakeholders. Membership consists of:

- an independent chair with health policy expertise
- seven specialist surgeons with expertise in current clinical practice
- a medical bioengineer
- an epidemiologist
- two people with expertise in health economics
- a Medical Services Advisory Committee (MSAC) representative
- a health consumer advocate
- three people with expertise in the provision of private hospital health services
- two people with expertise in the health insurance industry
- two people with expertise in the medical device industry
- a member with expertise in health technology assessment from the Australian Government Therapeutic Goods Administration
- a member with expertise in health policy from the Australian Government Department of Veterans' Affairs.

Members are appointed to PLAC for their expertise in current clinical practice or a particular area of the private health industry. Each Member is appointed in either an expert or advisory capacity on the basis of their individual skills, knowledge and expertise; and holds their appointment at the discretion of the Minister and Minister's Delegate.

3.2 Support for PLAC

PLAC is supported by the Clinical Advisory Groups (CAGs), Panel of Clinical Experts (Panel), Health Economics Sub Committee (HESC) and the Department's Prostheses Sections. PLAC may seek advice on matters of probity or process from the Department and other experts, as required. Where specialist expertise on a particular matter is required and is

not held by the membership of PLAC, CAGs, Panel or HESC, relevant external expert advice may be sought, as required.

Clinical Advisory Groups and Panel of Clinical Experts

The CAGs and Panel advise on the assessment of products against the criteria for listing and appropriate grouping on the Prostheses List. They advise PLAC on the clinical effectiveness of each product proposed for listing compared with products used for the same or similar purposes that are listed as prostheses on the Prostheses List, or current treatments for the indications that the products are designed to treat.

Clinical Advisory Groups

CAGs have been established for the following product categories:

- cardiac (defibrillators, pacemakers and stents)
- cardiothoracic
- knee (replacement)
- hip (replacement)
- ophthalmic
- spinal
- specialist orthopaedic
- urogenital
- vascular

Members of the CAGs include expert practising clinicians nominated by the relevant learned colleges and craft groups, and a consumer representative nominated by the Consumers Health Forum.

Advisers to the CAGs usually include a non-affiliated adviser from the medical technology industry, nominated by the Medical Technology Association of Australia. If specialised knowledge or experience is required that is not available within the membership, CAGs may co-opt an independent clinician or clinicians, as required.

CAG's terms of reference can be found on the [Department's website](#).

Panel of Clinical Experts

Panel assesses applications to list products that do not fit into the clinical categories of prostheses for which CAGs have been established.

Panel comprises specialist clinicians with a wide range of clinical expertise. These clinicians are nominated by the relevant specialist colleges, associations and societies that include the following specialties:

- otolaryngology
- head and neck surgery
- plastic and reconstructive surgery
- neurosurgery
- interventional radiology
- general surgery

Panel's terms of reference can be found on the [Department's website](#).

Health Economics Sub-Committee

HESC advises PLAC on the validation of proposed benefits for prostheses on the Prostheses List.

Membership includes the two health economist members of PLAC and a third member with expertise in health economics.

Australian Government Department of Health

The arrangements for the Prostheses List are administered by the Prostheses Section, in the Private Health Insurance Branch, of the Australian Government Department of Health. The functions of the Prostheses Section include:

- providing secretariat support to PLAC
- providing secretariat support to the CAGs, Panel and HESC
- contributing to the development of policy on private health insurance funding of prostheses
- providing advice about legislation, regulation and other government programs, such as the Medicare Benefits Schedule (MBS) that affect the use and funding of prostheses
- maintaining and publishing the Prostheses List
- managing sponsors' applications to list products and amend existing listings, including providing advice to sponsors about applications and amendments
- coordinating internal reviews of PLAC's recommendations
- providing advice to sponsors and other stakeholders about the prostheses arrangements
- facilitating communication and discussion between individuals and external stakeholders

3.3 PLAC processes

Meetings

PLAC meets regularly to consider Prostheses List applications, and to discuss other matters relating to the prostheses listing arrangements. PLAC takes a consensus approach to making recommendations about listing products on the Prostheses List. Where a recommendation or decision cannot be reached by consensus, it is determined by vote of a majority of members.

PLAC may discuss and resolve matters out of session on occasion.

PLAC deliberations and recommendations are recorded in the record of meeting. The PLAC record of meeting is not published, but is subject to the provisions of the *Freedom of Information Act 1982*.

A PLAC Communique will be published on the [Department's website](#) after each meeting.

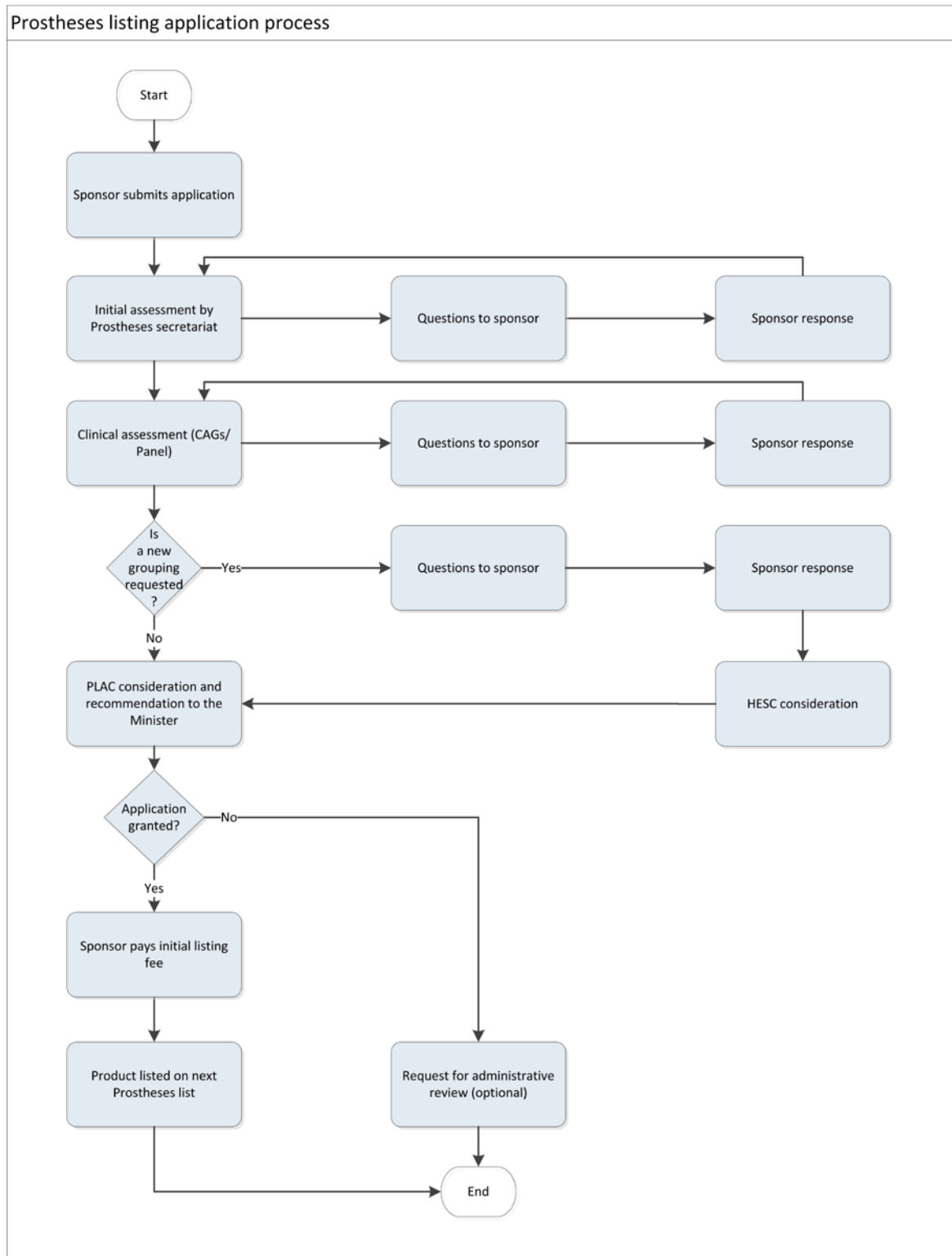
Confidentiality and conflict of interest

Much of the information considered by PLAC and its subcommittees is commercial-in-confidence. All members sign a deed of confidentiality and disclose any conflict of interest.

PLAC and its subcommittees have adopted the *Department of Health advisory committee guidelines for members and nominees: declarations of interests, managing conflicts of interests and confidentiality obligations*. As at January 2017—the guideline is being formally reviewed.

4 Application process

This section provides an overview of the application process (Figure 4.1).



CAGs = Clinical Advisory Groups; Panel = Panel of Clinical Experts; HESC = Health Economics Sub-Committee; PLAC = Prostheses List Advisory Committee

Figure 4.1 Overview of the process for submitting a new application

The Department is the primary contact for any queries that sponsors may have about the application process, and liaises with sponsors as required. Contact details are on the [Department's website](#).

All communication must be via the Department—sponsors or stakeholders must not directly contact CAG, Panel or PLAC members, particularly to query their recommendations. Members of the committees will not engage with stakeholders who are seeking information on committee recommendations.

4.1 Types of applications

Applicants can apply to:

- list a new prosthesis
- expand a current billing code
- compress current billing codes
- change details of a current listing
- transfer or duplicate a current listing
- delete a current billing code

The Department accepts all types of applications on a continuous basis.

New application

New applications are submitted for prostheses that are not already on the Prostheses List. A range of supporting evidence is required to demonstrate comparative clinical effectiveness, depending on the similarity of the product to other products on the Prostheses List. All new applications are subject to clinical assessment and are considered by PLAC. If successful, new products will be listed on the next Prostheses List.

Application to expand or compress billing codes, or change listing details

If a single billing code covers a number of products (e.g. for a range of sizes or different models of a product), it can be expanded into a number of new billing codes. This should be done if some products covered by the current billing code should be listed in other groupings.

Sponsors may apply to compress multiple current billing codes into a single billing code. This may be appropriate where related products, previously listed separately, can be grouped together (share the same grouping and benefit). This may occur for a range of sizes of the same product, or a product with multiple components that is only available as a system.

Sponsors may apply to make the following amendments to their existing listing:

- change the
 - name of a prosthesis (e.g. where there has been a change to branding)
 - catalogue numbers
 - description
 - size
 - grouping of the product
 - ARTG details
- reduce the benefit

If an application could result in changes to grouping or benefit (such as changes to the product name, size or description), the application will be subject to clinical assessment. If an application could result in listing in a new grouping that is not included on the Prostheses List, the application will also be subject to assessment of the proposed benefit by HESC.

PLAC considers all applications to expand or compress existing billing codes, or to change the current listing details of a billing code.

Successful applications to expand or compress billing codes will result in the removal of the original billing code(s) and creation of new billing codes.

Please note that changes to existing listings resulting from a successful application to change details or to expand a billing code or to compress billing codes will be reflected in the Prostheses List the next time the Minister makes the Prostheses List Rules, and the changed listings will take effect from the commencement of the Prostheses List Rules.

An application to expand a billing code or compress billing codes, or change the listing details of a current billing code cannot be used to list a new prosthesis that has not previously been listed.

Application to transfer, duplicate or delete a current listing

Sponsors can transfer billing codes if their product is transferred from another sponsor. The receiving sponsor is responsible for submitting the application to transfer a billing code. As part of the application to transfer, the receiving sponsor must supply a letter of authority from the original sponsor providing approval for the transfer.

A sponsor can apply to duplicate an existing listing held by another sponsor if they are also marketing the product (as happens with parallel importing). The product will not need to be assessed against the criteria for listing. The original billing code will remain on the Prostheses List, and a new billing code will be created for the new sponsor.

Sponsors can request that a billing code be deleted if they are no longer selling the prosthesis, and sponsorship of the prosthesis is not being taken over by another sponsor. The billing code will be deleted the next time the Prostheses List is made.

4.2 Applications

An application to list a new prosthesis should be made online via the [Prostheses List Management System](#) (PLMS). Applications forms are available on the [Department's website](#) for instances when the PLMS is not available.

4.3 Application fees



Application fee

The application fee payable is specified in the *Private Health Insurance (Prostheses Application and Listing Fee) Rules*.

The current fee for a new application is \$600.

There is no application fee associated with amendments, deletions of listings, or duplications, expansions, compressions or transfers of existing billing codes.

An application fee is payable for each new prosthesis or component of a prosthesis that a sponsor is applying to have listed on the Prostheses List. For example, for a hip system, an application fee will apply to each component—cemented femoral stem, uncemented femoral stem, femoral head, etc.

Details for payment of application fees are displayed upon successful submission of an application via the PLMS.

4.4 Application number

Each application is assigned an identifying number. This application number will be used to refer to the application throughout the process. If the application is granted, the new product will be allocated a billing code.

4.5 Clinical assessment

The CAGs and Panel assess the comparative clinical effectiveness of products, based on the evidence submitted by sponsors. The CAGs and Panel advise PLAC on whether a product satisfies the criteria for listing and the grouping in which the product should be listed.

If the CAG or Panel finds that the product does not satisfy the criteria for listing or disagrees with the grouping proposed by the sponsor, it will explain the reasons for the finding.

Clinicians are asked to advise of any potential conflicts of interest that may arise in their assessment of the applications allocated to them. Should a clinician have a conflict of interest, they are asked to return the application to the Department, and it is then forwarded to another clinician for assessment.

Each application is assessed by at least two clinicians from the CAGs or Panel.

Assessment by CAG clinicians

Products that fit into the clinical categories for CAGs are initially assessed by two clinician members of the relevant advisory group. The clinicians' assessments for each application are considered by a meeting of members of the relevant CAG. The CAG will then provide their advice to PLAC on whether or not the product is suitable to be listed and, if so, in which grouping.

If the sponsor is seeking to list the product in a new grouping, or the CAG considers that the product should be listed in a new grouping, the CAG will comment on the clinical performance of the product against the comparator(s).

The CAG may identify a different Prostheses List product grouping if it decides that the comparator(s) and/or product grouping proposed by the sponsor are inappropriate. If the CAG has identified a different product grouping, or disagrees with a sponsor's claim that a product is clinically superior to other products in the grouping, the Department will notify the sponsor of the grouping proposed by the CAG and the associated group benefit. The sponsor is given an opportunity to respond to the CAG's recommended grouping.

Assessment by Panel clinicians

Applications to list products that are not assessed by members of CAGs are assessed by two members of Panel with relevant clinical expertise. The two clinicians' assessments are considered by PLAC.

If the advice and assessments for an application differ between the two clinicians, the clinicians are asked to confer about their assessments. If they are unable to agree on an assessment, the application may be assessed by a third clinician with relevant expertise. PLAC then considers the application and formulates a recommendation to list based on the three clinicians' assessments and the reasons for their advice.

Panel may identify a different Prostheses List product grouping if it decides that the comparator(s) and/or product grouping proposed by the sponsor are inappropriate. If the Panel clinicians advise a different product grouping, or disagree with a sponsor's claim that a product is clinically superior to other products in the grouping, the Department will notify the sponsor of the grouping proposed by the Panel clinicians and the associated group benefit. The sponsor is given an opportunity to respond to Panel's grouping assessment.

CAG and Panel advice to PLAC

If a CAG or Panel conclude that their advice to PLAC is that a product should be listed, then the Department will advise the sponsor of the outcome and provide the advice to PLAC.

If a CAG or Panel conclude that their advice to PLAC is that a product should not be listed, then the Department will advise the sponsor of the CAG or Panel assessment and the reasons for it in writing. Sponsors have 10 working days in which to respond in writing.

If there is no response, the CAG or Panel advice will be provided to PLAC.

Responses may include additional information (including clinical data) to support the application and will be referred back to the CAG or Panel for reconsideration.

Please note, if additional clinical information is supplied, an application may require further consideration at the next meeting of the relevant CAG.

If there is a response, the CAG or Panel may:

- revise their advice based upon additional information provided; or
- affirm their original advice.

After reassessment, the sponsor will be informed of the outcome and the advice of the CAG or Panel will be provided to PLAC.

4.6 Health Economics Sub-Committee consideration

HESC assesses the sponsor's proposed benefit for a new product to be listed in a new grouping, subgroup or suffix on the Prostheses List. HESC provides advice to PLAC on the validity of the proposed benefit.

HESC seeks to ensure that a recommended benefit is reasonable—that is that the proposed benefit reflects the demonstrated differences in clinical outcomes between the new prosthesis and other prostheses listed on the Prostheses List, or other treatments or therapies.

The baseline for benefit validation is that all currently listed prostheses benefits are considered reasonable.

If the prosthesis under application can be compared with a prosthesis that is already listed on the Prostheses List, the group benefit for the listed prosthesis will be the basis for validating the proposed benefit for the new prosthesis.

HESC may use the benefits of other similar prostheses on the Prostheses List (that act in a similar way, have a similar shape or design, or are made of similar materials, but not necessarily used for the same indications) to establish a benefit range to assist in validating the proposed benefit.

HESC may also refer to information about the cost of the new prosthesis in other markets (either overseas or in the Australian public health system) to assist in validating the proposed benefit.

If HESC considers that the evidence and information provided by the sponsor do not support the proposed benefit, the sponsor may be asked to provide further evidence or information, or HESC may propose a different benefit. The sponsor will be given the opportunity to respond to HESC's proposed benefit.

4.7 PLAC consideration and recommendations

In making recommendations on listing and benefits for prostheses, PLAC will consider advice from the CAGs and Panel on the assessment of the product against the criteria for listing and the appropriate grouping, and advice from HESC on the appropriate group benefit for a new grouping.

Recommendation to list

PLAC may recommend products for listing that satisfy the criteria for listing.

If the product is not yet included or registered on the ARTG, PLAC may make a provisional recommendation of suitable for listing, pending ARTG. In these circumstances, an application recommended suitable, but "pending ARTG", will be held for up to 18 months from the date of application submission. The PLAC will recommend the product after the sponsor has advised that the product has been included on the ARTG and a valid ARTG certificate has been supplied.

PLAC may recommend a product for listing pending receipt of advice that there is an appropriate MBS item for the professional service during which the product is intended to be implanted or applied. The sponsor will be asked to ensure that an application is made for the

professional service to be assessed by the Medical Services Advisory Committee for public funding (if such an application has not already been made).

When advice is received that there is an appropriate MBS item, the application assessment recommendation will be referred to the Minister for consideration. If the Minister grants the application, the product will be listed on the next Prostheses List.

Recommendation not to list

PLAC may recommend that a product not be listed if one or more of the listing criteria have not been met.

If PLAC recommends that a product not be listed, the Department advises the sponsor of the recommendation and the reasons for it in writing.

Decline of components of a system

If clinical assessment of components of a system recommends that one or more of the crucial components of the system be declined for listing, PLAC will usually recommend that all components of the system not be listed. This is because the clinical data for all components of a system are common—if one crucial component of the system is called into question, then all components of the system will not be recommended for listing.

Group benefit

Where PLAC recommends listing a product on the Prostheses List, it will also recommend the appropriate grouping for the product.

The sponsor may list the product at the group benefit or at a benefit that is lower than the group benefit. If the sponsor does not accept the group benefit, they can choose not to list the product.

Parallel Processing - ARTG number

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Prostheses List if they are able to provide an ARTG application number issued by the Australian Government Therapeutic Goods Administration.

If an ARTG application number is provided, sponsors can apply to list a product on the Prostheses List without providing an ARTG certificate of inclusion number. The application will be processed; however, the product will not be listed on the Prostheses List (if recommended) until a valid ARTG certificate of inclusion has been provided.

PLACs consideration of application assessments without an ARTG certificate of inclusion number will be deferred for a maximum of 18 months from date of original application submission. After which time the application will be deemed to be non-compliant and the sponsor will need to submit a new application to list a product on the Prostheses List.

4.8 Ministerial decision on applications

When PLAC has considered applications to list products and the benefits for the products it recommends for listing, its recommendations are forwarded to the Minister. The Minister decides whether to grant, or not to grant, each application.

Decision not to grant an application to list

If the decision is not to grant an application to list a product, the Department will inform the sponsor of the reasons for the decision in writing. The letter will include information on how to seek an internal review of the process followed by PLAC that led to its recommendation to the Minister (see Section 4.10).

Decision to grant an application to list

Where the Minister decides to grant an application to list a product, the Department will inform the sponsor of the Minister's decision in writing, and advise that an initial listing fee is payable for each product to be listed. The sponsor will be advised of:

- the initial listing fee payable
- the prosthesis for which the initial listing fee is payable
- the date by which the initial listing fee must be paid
- how the initial listing fee can be paid

Initial listing fee



The initial listing fee is specified in the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*. The current initial listing fees are:

- nil for human tissue prostheses
- nil for products that were listed as a result of duplicating, expanding, transferring or compressing existing billing codes
- \$200 for all other prostheses

4.9 Minister makes the Prostheses List

Products are listed on the Prostheses List by their inclusion in the Prostheses Rules. Twice a year the Minister endorses new Prostheses Rules. The Prostheses 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.

4.10 Request for Administrative Review of the process

On occasions, applications to list a product on the Prostheses List are not recommended for listing. The sponsor may seek an internal review of the processes that led to PLAC making its recommendation if the sponsor considers that:

- there was a significant deviation from the processes set out in the Guide and/or the operating procedures of PLAC that had an adverse impact on the outcome the sponsor sought in their application
- other significant issues of process had an adverse impact on the outcome the sponsor sought in their application

As the Minister's decision is based on expert advice the decision of the Minister is not subject to merit-based appeal. However, the process followed by PLAC to reach the recommendation is subject to internal review. Sponsors are strongly advised not to submit an application for an

internal review until they have been informed of the Minister's decision to grant or not to grant an application.

The internal review process

To seek an internal review, sponsors should write to:

First Assistant Secretary
Medical Benefits Division
Department of Health
GPO Box 9848
Canberra ACT 2601

The request for an internal review must identify the product(s) to be included in the review, ground(s) of review relied upon and why the sponsor considers that the ground(s) arise. The request must be received within 10 working days of the sponsor receiving the letter from the Department advising them of the outcome of their application.

Applications for review are acknowledged in writing by the Department. Sponsors must specify each application for which they are seeking an internal review. Sponsors are asked to pay a fee of \$1,000 per internal review request to assist in defraying the cost of processing the internal review.

The internal review is conducted by the First Assistant Secretary, Medical Benefits Division. The timeframe for the review is 28 working days from the date of receipt of the internal review fee. The 'clock' may be stopped with reason (for example, to allow time for consultation with the sponsor). The reviewer may consult the sponsor and PLAC as part of the process.

On completion of the review, the reviewer makes recommendation(s) in writing to PLAC, which explain the findings and outline the recommended actions (if any) to address the findings of the review. A copy of the review recommendations is provided to the sponsor.

It is not the role of the reviewer to make recommendations as to whether or not the product should be listed or what benefits might be appropriate.

The reviewer may recommend that PLAC take specific action to reprocess the application from the point at which a significant process error arose. Reprocessing of an application as recommended by the reviewer to address a significant process error could still result in PLAC making a recommendation not to list the product.

The time taken to undertake and complete the actions recommended by the reviewer depends on the nature of the recommendations made. The Department keeps the sponsor informed of the progress of the actions recommended by the reviewer.

4.11 Removal of a prosthesis from the Prostheses List

From time to time, PLAC will consider if a prosthesis should be removed from the Prostheses List, usually because the product does not satisfy the criteria for listing.

If PLAC is considering this action, the Prostheses secretariat 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 will be referred to a CAG or Panel to provide advice to PLAC.

If the sponsor agrees that the product should be removed, or PLAC affirms the recommendation to remove the product, the matter will be referred to the Minister. If the Minister agrees with PLAC's recommendation, the Minister may remove the product from the Protheses List the next time it is made or amended.

Australian Register of Therapeutic Goods

In instances where the TGA removes an item from the Australian Register of Therapeutic Goods, and that item is listed on the Protheses List, the deregistered item will also be removed from the Protheses List at the earliest opportunity.


4.12 Ongoing fees

Ongoing listing fee

Ongoing listing fees are payable for each billing code on the Protheses List on a given imposition day (unless the billing code is new to the Protheses List because an application to list a new prosthesis has just been granted by the Minister). There are two ongoing listing fee imposition days set out in the *Private Health Insurance (Protheses Application and Listing Fee) Rules*:

- 15 March
- 15 September

The ongoing listing fee is payable in respect of prostheses listed on the Protheses List on these days, regardless of whether the sponsor of the prosthesis on the Protheses List is still selling the prosthesis.

	<p>Ongoing listing fee</p> <p>The ongoing listing fee is specified in the <i>Private Health Insurance (Protheses Application and Listing Fee) Rules</i>. The current ongoing listing fees are:</p> <ul style="list-style-type: none">• nil for human tissue prostheses• nil for new products that were added to the most recent Protheses List as a result of an application to list a new prosthesis• \$200 per billing code for all other prostheses
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When ongoing listing fees are imposed, the Department will write to sponsors to advise them of:

- the amount of their ongoing listing fees
- the prostheses for which the fees are being charged
- the due date for payment
- how to make a payment

An invoice for the ongoing listing fees will be included. Sponsors will also be advised that the Minister may remove the sponsor's product from the Protheses List if they fail to pay the ongoing listing fee.

Sponsors should be aware of the products they have on the Prostheses List and apply to delete any unused items from the list if they do not wish to pay ongoing listing fees. Deletion of an item from the Prostheses List will take effect from the date that the next Prostheses List commences.

National Joint Replacement Registry Levy

The National Joint Replacement Registry (NJRR) levy will also apply to joint replacement prostheses that are tracked on the NJRR. The NJRR levy provides sustainable funding for the NJRR to continue its work in collecting information on the performance and safety of joint replacement devices and providing this information to a range of interested stakeholders, including suppliers of joint replacement devices, surgeons, public and private hospitals, the TGA, private health insurers and PLAC.

The *Private Health Insurance (National Joint Replacement Register Levy) Rules* set out the formula for calculating the levy rate, and sets the levy day (the day on which the levy is imposed) and census day. The census occurs on 31 September each year and the respective levy is imposed on 31 October.

4.13 Key events and timeframes

The following key events and timeframes are provided as a guide (Table 4.1). They may vary depending on the circumstances at the time.

Table 4.1 Key events and timeframes

Event	Timing
Applications to list new prostheses, expand current listings, compress current listings and change listing details	Applications are accepted on an ongoing basis. The Department publishes PHI Circulars * that outline cut-off dates for applications to list new devices and requests to changes existing listing for consideration at particular CAG meetings or for consideration by the Panel. Dates for PLAC meetings are also published on the Department's website via PHI Circulars *.
Submission of ARTG certificates of inclusion	Usually 4–5 weeks before the Prostheses List is published – cut-off dates are published on the Department's website via PHI Circulars *.
Applications to transfer, duplicate or delete existing listing	Usually 4–5 weeks before the Prostheses List is published – cut-off dates are published on the Department's website via PHI Circulars *.
Publication of Prostheses List	Usually February and August
Commencement of Prostheses List	Usually February/March and August/September
Ongoing listing fee imposition days	15 March 15 September
National Joint Replacement Registry census day	31 September
National Joint Replacement Registry levy day	31 October

CAG = Clinical Advisory Group; Panel = Panel of Clinical Experts; PLAC = Prostheses List Advisory Committee;

*To subscribe to PHI Circulars, please visit the [2017 PHI Circulars webpage](#).

5 Submitting an application

Part II of this guide provides advice on what evidence sponsors should include with an application.

Part III outlines key information required to apply for a new listing.

Part IV provides information on how to complete other application types (those based on an existing listing).

The Department has introduced an online portal, the [Prostheses List Management System](#) (PLMS), enabling sponsors to complete and submit applications electronically. The system also provides sponsors with the ability to track the progress (status) of an application.

Access to the PLMS is provided on the Department's website.

5.1 General Comments

It is requested that sponsors note the following comments:

- Always refer to the relevant section of the Guide when completing every section of the application form. Ensure that you have the latest version of the Guide and grouping scheme from the [Department's website](#).
- Understand the structure of the Prostheses List and how prostheses are listed within categories and product groups.
- Clearly identify your product's comparator(s) and the features that enable your product to provide comparable or better outcomes.
- Understand why and how products are clinically assessed, and what information and evidence should be included in the application to demonstrate the comparative clinical effectiveness of your product.

Sponsors should critically assess all the evidence they identify for possible inclusion in an application to determine whether it should be included. Quality is more important than quantity.

5.2 Sponsor's details

The Department will use the sponsor's details to liaise with the sponsor about the application. The sponsor name should be as shown on the TGA Certificate of Inclusion of a medical device on the ARTG for the product. The sponsor contacts should be people who can discuss the application and provide further information, if necessary.

The application number is the number assigned to an application by the Department; applications are recorded in the Department's applications database when they are received. The application number is used as the reference for an application throughout the application process.

Please ensure you have your application number on hand when contacting the Department about the status of your application.

5.3 Submitting the application

The Department has introduced the Protheses List Management System online portal an electronic system for online completion and submission of Protheses List applications.

Applications to list prostheses on the Protheses List and requests to change current listings should be submitted via the [Protheses List Management System online portal](#).

If PLMS is not accessible, medical device sponsors and suppliers can submit applications and requests via an approved form. The forms are available on the [Department's website](#) and can be completed electronically.

Access to PLMS includes a mandatory requirement for the applicant to have an active AusKey. Please visit the [Australian Taxation Office \(ATO\) website](#) to apply for or manage an existing AusKey. The ATO has its own service level standards and timeframes for managing AusKey enquiries. Sponsors should consider this when preparing to submit their application. Please note, not having an AusKey cannot be interpreted as the PLMS is unavailable.

Part II — Supporting evidence

6 Rationale for supporting evidence

The process to assess applications to list prostheses on the Prostheses List must be consistent. Clinical evidence is required to provide consistent and clear support for expert clinical judgment.

Comparative clinical effectiveness

Comparative clinical effectiveness is a product's clinical effectiveness against a comparator—that is, the product, treatment or therapy that is most likely to be replaced by the introduction of the product for which listing is sought. In most instances, the comparator is a prosthesis that is already listed on the Prostheses List.

All new applications should include evidence of comparative clinical effectiveness. Some applications to amend listing details, or expand or compress billing codes also require evidence of comparative clinical effectiveness if the proposed change would change the listed product's grouping or benefit.

Cost relative to clinical effectiveness

The criteria for listing a product on the Prostheses List also state that the cost of the product should be relative to its clinical effectiveness. This is to ensure that products of similar clinical effectiveness have similar benefits.

If sponsors are claiming a different grouping from the comparator, with a higher benefit, evidence of measurable improvement in patient outcomes should be submitted. Some economic data, including utilisation, should also be provided.

The assessment of prostheses is different from other health technology assessment processes (such as for pharmaceuticals) for several practical reasons:

- The performance of a prosthesis may vary depending on the skill of the operator
- Blinded clinical trials are often not practicable for prostheses
- Some new prostheses may have a short life cycle and develop through incremental improvements to established devices. This affects the time over which it is useful and reasonable to expect clinical evidence to be gathered
- Prostheses are often used in low volumes; this affects the quantity of evidence available

These factors are taken into consideration by the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (Panel) during the clinical assessment.

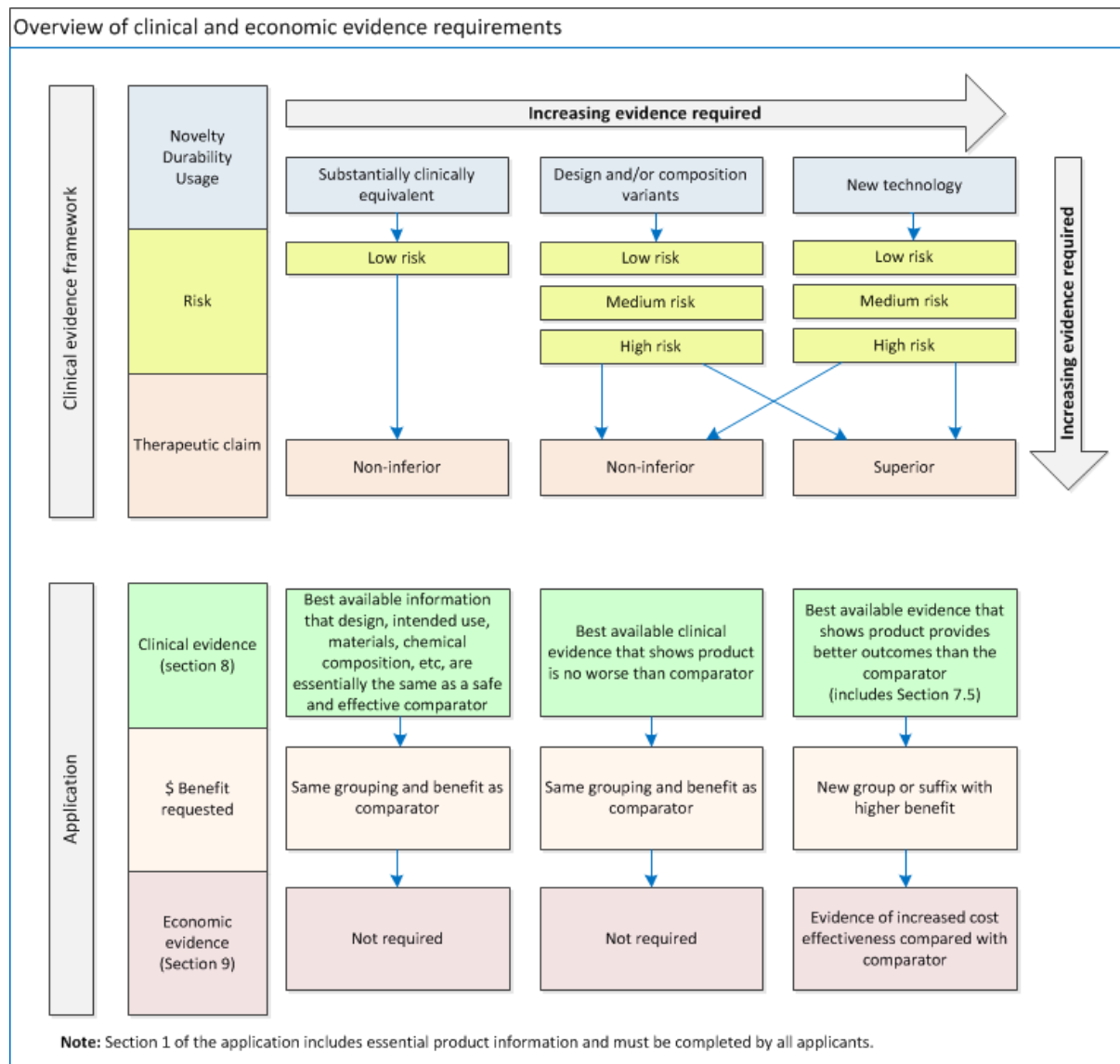
The CAGs and Panel advise their assessment outcomes to the Prostheses List Advisory Committee (PLAC) based on their assessment of information (including clinical evidence) provided by sponsors and their experience and expertise. In assessing a product, clinicians consider how effectively it achieves, or is likely to achieve, the treatment outcome(s) for the clinical indication it is designed to treat.

The clinical and economic evidence required varies according to the type of application (e.g. whether the product is a new technology or a variant of an existing product, the level of risk of the product, therapeutic claims made by the sponsor, and the grouping and benefit requested). In general, the more novel the technology, the higher the risk of the product; and the higher the benefit requested compared with the currently used comparator, the more supporting evidence required.

Sections 7 and 8 of this guide provide a detailed framework for assessing what clinical evidence sponsors need to include in their applications. A step-by-step guide to completing the clinical assessment section of the application form is in Part III, Section 10 of this guide.

A step-by-step guide to filling in the section of the application form to support the proposed benefit and grouping is in Part III, Section 10 of this guide.

An overview is shown in Figure 6.1.



Note: Section A of the application includes essential product information and must be completed by all applicants.

Figure 6.1 Overview of clinical and economic evidence requirements

7 Framework for supporting evidence and clinical assessment

In this section:

- “clinical evidence” generally means peer-reviewed clinical evidence in a published journal (unless stated otherwise)
- “appropriate length of follow-up” means follow-up that reflects factors such as the duration required for the prosthesis to have the intended therapeutic effect
- “representative cohort” generally means a number of patients that reflects the intended uses and likely patient populations for the prosthesis

The best evidence that sponsors can provide to support an application for listing is evidence that relates directly to the prosthesis in the application.

Importantly, there is no “one size fits all” requirement; sponsors should submit the best evidence that fits the design and purpose of their product.

This section describes a framework that helps to refine and clarify the minimum evidence that should be provided to support applications to list a product on the Prostheses List. The amount and type of evidence that sponsors should submit vary according to a range of factors relating to the product. The primary considerations when deciding on the clinical evidence to provide in an application are risk, novelty, durability, usage and the type of claim the sponsor makes.

7.1 Risk

The level of evidence that is appropriate to enable assessment of a prosthesis depends on the risk to the patient if the prosthesis does not perform as intended. The consequences of decisions (the potential benefit or harm from the product) are higher for some devices than others—therefore, the level of evidence required to assess these potential benefits and harms is higher.

PLAC takes a risk-based approach to assessing prostheses, similar to the approach taken by the Therapeutic Goods Administration to assess medical devices for inclusion on the Australian Register of Therapeutic Goods. Table 7.1 shows examples of prostheses in three risk categories: high, medium and low.

Table 7.1 Risk categories for clinical assessment

Level of risk	Examples
High	<ul style="list-style-type: none">• Load-bearing prostheses• Finger joints• Electronic prostheses• Prostheses in direct contact with the heart, or central circulatory or nervous system• Prostheses with a biological effect• Prostheses that are wholly or mainly absorbed into the body• Prostheses that undergo chemical changes in the body (but not teeth)• Prostheses that administer a medicine• Active implantable medical devices
Medium	Prostheses that do not meet the definitions of high or low risk, including (but not limited to): <ul style="list-style-type: none">• Intraocular lenses• Ureteric stents• Gastric bands
Low	<ul style="list-style-type: none">• Clips, staples and screws• Plates• Grommets• Tissue closure prostheses• Haemostatic prostheses

7.2 Novelty

If a product is new or uses novel technology, design or composition, sponsors should include in their application clinical evidence with an appropriate length of follow-up in a representative cohort of patients for the indications the product is designed to treat.

Novel technology is technology that is different from anything seen or known before.

Similarly, if a product is a variant of an existing design or composition, sponsors should include clinical evidence with an appropriate length of follow-up in a representative cohort of patients for the indications the product is designed to treat.

The level and strength of evidence required depend on how novel the proposed product is, or how different it is from the comparator. In all cases, sponsors are encouraged to submit the best evidence available that shows that the new or variant product is comparatively clinically effective.

7.3 Durability/life span

Durability or life span refers to the period of time for which the product remains active or functional in the patient. Clinical effectiveness should be demonstrated over a period of time that is relative to the life span of the product. For example, a product that is designed to remain functional in a patient for 20 years should demonstrate clinical effectiveness over a longer time (i.e. longer follow-up) than a device that is designed to be used for 2 years. However, this does not necessarily mean that evidence should be gathered over the entire life span of the product (although this would be ideal).

Sponsors are encouraged to use data from registries such as Australia’s National Joint Replacement Registry (and similar registries in other countries) to support their applications, where appropriate.

7.4 Usage

The level of use of a product can also influence the amount and level of evidence required to support the application. A product that is used less often (e.g. a product designed specifically for revision or oncology surgery) is likely to have a smaller body of evidence that can be used to support an application than a product that is in high use (e.g. a product designed for primary surgery).

7.5 Sponsor’s claims

Finally and most importantly, the type of evidence required also depends on the claim that the sponsor makes in relation to the product’s effectiveness for the proposed indications.

Sponsors can claim that their product is better than the comparator, which is referred to in this guide as ‘superior’. Alternatively, sponsors can claim that their product is equivalent to (i.e. no worse than) the comparator, which is referred to in this guide as ‘noninferior’.

Claims of noninferiority

Sponsors can apply to have their product listed in an existing grouping on the Prostheses List based on a claim that, although the product may have some characteristics that are different from comparators in the group, it produces a result that is equivalent to (i.e. not worse than) the appropriate comparator for the indicated uses.

The extent to which a product differs from the comparator may influence the level of evidence required to demonstrate noninferiority, depending on the potential risk of harm from use of the product. A product that is significantly different in design or composition from the comparator may require a higher level of evidence than a product that differs only in aspects that do not affect the product’s comparative safety or effectiveness.

Claims that do not need clinical evidence (low-risk products only)

In some cases, a new prosthesis may be so similar in design and function to comparators on the Prostheses List that similar performance and complication rates to the comparator might be assumed in the absence of further clinical information.

Noninferiority claims include claims that the proposed product is substantially clinically equivalent to the comparator. To be substantially clinically equivalent, the product does not need to be identical to the comparator but must be substantially equivalent with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards and other characteristics, as applicable. A product may be substantially clinically equivalent if it:

- does not raise new questions of safety or effectiveness
- is not new or novel in design
- has the same intended use as the comparator
- has the same or very similar technological characteristics as the comparator

- has a comparator that has been demonstrated in clinical studies to be safe and effective over a period of time commensurate with its intended use, risk and likelihood of failure

Substantial clinical equivalence does not apply to novel products or high-risk prostheses (e.g. load-bearing or articulating prostheses, a mobile implant or a cardiac stent). Please note that, while a sponsor may claim that a prosthesis listed in the high-risk category in Table 7.1 is substantially clinically equivalent to a listed prosthesis, supporting clinical evidence for high-risk devices should be provided to support an application.

Claims of superiority

Clinical superiority

If a sponsor claims that their product is superior to an appropriate comparator, they will need to submit evidence demonstrating that the product is clinically effective, and also evidence that demonstrates how the new product is clinically superior to the comparator.

If the product represents an incremental change (i.e. improved functionality compared with an existing item that is already on the Prostheses List), sponsors should provide supporting clinical evidence that the product delivers measurably or quantifiably better clinical outcomes relative to the nature of the change, the durability requirements of the product and the potential risk to the patient if the new functionality fails.

In most cases, a successful claim of clinical superiority will result in the product being listed in a new grouping.

Superior clinical performance

Products in the Hip and Knee categories may be eligible for a suffix and benefit premium recognising demonstrated ‘superior clinical performance’. To be eligible for this special type of superior claim, an application must provide:

- a minimum of 10 years follow-up with an appropriate cohort and with an unchanged prosthesis
- appropriate peer-reviewed publications (not from the prosthesis designer) showing greater than 95% survivorship at a minimum of 10 years
- Australian Orthopaedic Association National Joint Replacement Registry data on the performance of the prosthesis

The Hip CAG and Knee CAG will assess claims of superior clinical performance and advise PLAC.

8 Choice of clinical evidence to include in an application

An application should include the best available clinical evidence to demonstrate that the product is comparatively clinically effective. At the very least, evidence must demonstrate that the product is similar in clinical effectiveness to an appropriate comparator.

Assessment of the clinical effectiveness of a product should ideally be based on studies that have been published in peer-reviewed journals. A literature search of peer-reviewed studies is therefore the best way to identify the supporting evidence to include in the application. Unpublished studies may be considered if there are no published studies, depending on the product.

However, sponsors should not necessarily include in the application every study conducted on their product. This section outlines issues that sponsors should consider when choosing the evidence that best supports their application.

8.1 Quality, not quantity

The quality of information provided in the application is more important than the quantity. A single well-designed study with a large cohort published in an international peer-reviewed journal demonstrates a higher level of evidence than several case studies. If a product has been the subject of a large, well-designed, published trial, this may be all the evidence needed to support the application.

The National Health and Medical Research Council has developed a framework to categorise the levels of evidence that are represented by different types of published clinical trials and studies (Table 8.1). Levels of evidence are based on the level of bias that is inherent in different types of studies—the lower the chance of bias in the study, the higher the level of evidence, and the better the basis for clinical assessment.

Table 8.1 Levels of evidence

Level of evidence	Type of study or trial
I(highest)	A systematic review of Level II studies
II	A randomised controlled trial
III –1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Nonrandomised experimental trial • Cohort study • Case–control study • Interrupted time series with a control group
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single-arm studies • Interrupted time series without a parallel control group
IV(lowest)	Case series with either post-test or pre-test/post-test outcomes

Source: modified from National Health and Medical Research Council, 2009²

However, the level of evidence only refers to individual trials or studies, and is therefore only one component of evidence assessment. The final assessment is based on a judgment about all the trials or studies included as evidence for a particular issue. This is called the ‘body of evidence’. Assessment of a body of evidence includes consideration of:^{3,4}

- the level of evidence of the trials and studies included (see Table 8.1)
- the number and quality of trials and studies (where quality reflects how well the researchers were able to minimise any bias in study design)
- the size of the effect shown, and whether it demonstrates statistically significant and clinically important outcomes
- the relevance of the trials and studies to the clinical practice situation proposed for the product

Sponsors should consider the body of evidence for their product when choosing the evidence to support their application and include the best evidence available. However, the level and strength of evidence required also depend on the level of perceived risk of major complications associated with use of the product and its potential failure points. The higher the risk, the higher the strength of evidence required to demonstrate safety and clinical effectiveness.

² NHMRC (2009). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. [National Health and Medical Research Council - additional levels of evidence & grades for recommendations for developers of guidelines](#)

³ Hillier S, Grimmer-Somers K, Merlin T, Middleton P, Salisbury J, Toohar R and Weston A (2011). FORM: an Australian method for formulating and grading recommendations in evidence-based clinical guidelines. *BMC Medical Research Methodology* 11:23.

⁴ GRADE Working Group (2013). GRADE guidelines: best practices using the GRADE framework.

Although product information should be included in the application, this does not constitute clinical evidence. Published studies should be included, and these will be assessed to determine comparative clinical effectiveness.

Where a sponsor is claiming substantial clinical equivalence, supporting clinical evidence should be included, if available. If it is not provided, the assessing clinicians or PLAC may not accept that the new product is substantially equivalent to the nominated comparator, and the application may not be successful.

8.2 Relevance and focus of the information

To maximise the chances of success, sponsors should only include information that is relevant to the product under application. A frequent error in applications is to supply irrelevant data, in the mistaken belief that more paperwork and evidence pertaining to the use of similar products is helpful, when high-quality and relevant data specific to the product would be much more beneficial.

For example, sponsors should include relevant studies that demonstrate the success of the product in a human clinical setting. If the product is associated with a service that improves patient outcomes, this information should be included in the application. It should not be assumed that evidence relating to a similar product or an earlier model of a product will equally apply to a new product.

Data from animal studies may provide an indication of the potential clinical effectiveness of a product, but clinicians generally do not accept it as clinical evidence to support comparative clinical effectiveness. Where only animal studies are provided, the sponsor should explain why no appropriate human studies are available.

Wherever possible, sponsors should provide evidence from studies comparing the use of their product with the use of a comparator product or technology.

If the product uses well-established technology or procedures, it is not necessary to include extensive information about this. For example, cardiac pacemakers have been used for many years for management of arrhythmias and are a well-established treatment, so there is no need to include clinical data about the technology itself. However, it is necessary to demonstrate that the product under application is comparatively clinically effective.

Some Clinical Advisory Groups require certain information about subsets, for example:

- for any soft tissue anchor the SOCAG requests clinical information on the device's pull-out strength and the source of the clinical evidence.
- for cardiac aortic valves there are additional evidentiary requirements.

8.3 Actual or perceived conflict of interest

Sponsors should consider any conflicts of interest in the information they provide. This includes actual or perceived conflicts of interest that may be apparent in statements from clinicians, studies that were conducted by the sponsor or product designer, or follow-up studies in which the clinicians were financially linked to the product.

Statements by the sponsor or testimonials from clinicians do not demonstrate the clinical effectiveness of a product. These types of information may be included in the application if

they are relevant, but they will not be considered as evidence and should be accompanied by published studies.

8.4 Length of follow-up

The length of clinical follow-up should be relative to the life span of the product; that is, products with a longer life span generally require a longer period of follow-up. Follow-up should also be conducted on a suitable number of patients, and should have sufficient statistical power to identify problems with clinical safety or effectiveness.

For products with a relatively short life span (less than 12 months), the length of clinical follow-up should be at least equivalent to the intended product life.

Examples of indicative lengths of clinical follow-up are shown in Table 8.2.

Table 8.2 Indicative lengths of clinical follow-up

Product	Indicative length of follow-up
Major joint replacement prosthesis claiming superior clinical performance	10 years
Major joint replacement prosthesis claiming noninferiority	2 years
Implantable cardiac device	2 years
Bioresorbable screw	1 year
Polypin resorbable bone pin	1 year
Mesh	1 year

8.5 What if there are no studies?

In some instances, evidence that demonstrates clinical effectiveness and outcomes may not be available. For example, products such as internal fixation screws may not themselves have been subject to clinical trial, although the technology of using plates and screws to treat fractures has been. Clinicians will take this into account when assessing these products.

If there is no evidence of a product's comparative safety or effectiveness, it cannot be assumed that there is no potential benefit or harm associated with the product ('absence of evidence is not evidence of absence').

9 Evidence to support a new group benefit

A sponsor who is applying to list a product in a new grouping needs to provide sufficient evidence to support the proposed new group benefit.

There is no specific type of evidence required to support a proposed benefit; however, the more information that is provided, the better the chance that the proposed benefit will be validated.

9.1 Clinical evidence

Where a sponsor is seeking a new grouping on the basis that a new product delivers superior clinical outcomes, the application should provide clinical evidence of the comparison of outcomes. The evidence should quantify the improvements where possible.

The clinical evidence will be assessed by the CAG or Panel to provide advice to the Health Economics Sub-Committee (HESC) on the difference in clinical outcomes between the new prosthesis and its comparators.

Economic and cost analysis studies may be useful in supporting a proposed benefit. These should be provided if they are available.

9.2 Economic and financial information

Economic information is useful to validate a proposed benefit and to demonstrate that it is within a reasonable price range.

Such information can include:

- costs associated with the use of the new prosthesis, compared with the costs associated with the use of the comparator(s)
- prices of the new prosthesis in other markets (both overseas and within Australia)

9.3 Further development of benefit consideration

The arrangements for considering proposed benefits for new groupings and reviews of current benefits are undergoing further development. The information requests of HESC may change in the future.

Stakeholders will be involved in the development of the arrangements, and any new information requests will be communicated to sponsors.

Part III — Completing an Application to list a new prosthesis

10 Application to List a New Prosthesis – Single Product

10.1 New Prosthesis Device

Product details

Product name

The product name is the name under which the product is sold in Australia and should be as shown on the product information. If the product is a system or a kit, provide the name of the system or kit and the component as the product name (e.g. ACME Hip System—Femoral Head).

If the application is successful, this information will be transcribed onto the Prostheses List.

Description

Include a description of the product that will be recorded on the Prostheses List. The description should be sufficient to enable the reader to identify what the product is and any additional features that are unique to the product.

Because there is limited space on the Prostheses List to record a description, it should be no more than one or two sentences (256 characters or less). Include details that are specific to the product, such as:

- model number
- descriptor for the product or the components of a product (e.g. a spinal system that consists of screws, threaded rod, hex nuts, washer and endplate)
- composition
- any special features

Further details about the product can be appended to the application as an attachment(s).

Size(s)

The product size may be expressed as length, diameter, width, height, number of holes/degrees/dioptres, volume, or other specification of the product or its components, as detailed in the product information or technical documentation. The size information should be concise and accurate.

Failure to provide adequate size information may result in inappropriate grouping of the product.

Catalogue number(s)

List the catalogue number(s) under which the product is sold. A catalogue number must be provided for every component or prosthesis within an application that will become one billing code.

This information will be used to cross-reference with data sources such as the National Joint Replacement Registry (NJRR), and will assist in providing data to the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (Panel) for clinical assessment purposes.

Proposed benefit

If your product has a comparator that is already listed on the Prostheses List and you are applying to list your product in the same grouping, the benefit should be the group benefit for the group in which your product is to be listed. You may choose to list the product with a benefit lower than the group benefit.

If your product does not fit into an existing grouping on the Prostheses List, propose a benefit for the new grouping. The evidence you provide with the application should demonstrate why your product should be considered to be clinically superior to or different from the other products on the Prostheses List. See Sections 7 and 8 in this guide for more information about clinical evidence.

ARTG ID number/TGA application number

Only products that are entered on the ARTG can be listed on the Prostheses List—see Criterion 1 of the criteria for listing:

The product must be entered and current on the Australian Register of Therapeutic Goods.

Provide the product's ARTG number, which can be found on the Therapeutic Goods Administration (TGA) Certificate of Inclusion of a medical device.

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Prostheses List if they are able to provide an ARTG application number issued by the Australian Government Therapeutic Goods Administration. If the sponsor has applied to include the product on the ARTG, tick the box.

If an ARTG application number is provided, sponsors can apply to list a product on the Prostheses List without providing an ARTG registration number or an MBS item number for the professional service associated with the prosthesis. The application will be processed; however, the product will not be listed on the Prostheses List (if recommended) until valid ARTG and/or MBS item numbers have been provided.

Information about the ARTG can be found on the [TGA website](#).

Grouping

Information about grouping schemes for products can be found on the [Department's website](#).

Category

Provide the category in which the product will be listed on the Prostheses List (see Section 2.2 of this guide for a list of categories). Some products may fit into more than one category; sponsors should list the category that will represent the greatest use of the product, as only one billing code can be allocated to the product.

Subcategory

This is sometimes known as the assessment body.

Group

Indicate in which group the product should be listed.

If you believe there is no suitable group for your product on the Prostheses List, please propose a group name here. You will need to provide information with your application to support the proposed group. Your product may or may not be listed in this proposed group.

Subgroup

Indicate the subgroup and suffix that should apply to the product, if necessary.

If you believe there is no appropriate subgroup for your product on the Prostheses List, please propose a subgroup name here. You will need to provide information with your application to support the proposed subgroup. Your product may or may not be listed in this proposed group.

Suffix (es)

Suffixes are used to indicate that products within a group or subgroup have a feature or features that make the product slightly different to others in the group or subgroup. Indicate the appropriate suffix or suffixes for your product here.

If you believe that your product is slightly different to others in the same group or subgroup, and this difference is clinically significant, you can propose a new suffix here. You will need to provide information with your application to support the proposed suffix. Your product may or may not be listed with the proposed suffix.

10.2 Comparators

To demonstrate comparative clinical effectiveness for the product, you must identify at least one comparator. This may be a product or the current treatment or therapy that is most likely to be replaced by the product under application. If there is currently no treatment or therapy for the indication, the comparator will be “nil”.

First, refer to the Prostheses List to identify a listed prosthesis (or more than one) that may be proposed as a comparator(s) for your product. The list can be accessed at the [Department's website](#).

If no listed prostheses that are similar to your product in form and function can be identified as a comparator, identify a current treatment or therapy (e.g. a drug treatment or medical service) as the most appropriate comparator for your product.

When assessing the relative clinical effectiveness of your product, clinicians may consider another product to be a more appropriate comparator for your product than the one you propose. To ensure that your application progresses smoothly through the process without the need to respond to clinicians' questions, ensure that you choose an appropriate comparator for your product. If the comparator is already listed on the Prostheses List, this will generally be in the same grouping as the proposed grouping for your product.

Main comparator

If more than one comparator is identified for the product, all of them should be listed in this section, and you should identify which of these is the main comparator(s) for the product—that is, the product that would be most often replaced with the proposed product.

10.3 Medicare Benefits Schedule (MBS) item number and descriptor

Products will be listed on the Protheses List if there is a Medicare benefit payable for the professional service associated with the implantation or application of the product - see Criterion 3 of the criteria for listing:

A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist).

Provide the MBS item number and descriptor to verify that the product is used in association with a professional service for which a Medicare benefit is payable.

For a product that can be used for a number of professional services, list up to 10 MBS item numbers for professional services by which the product may be surgically implanted or applied.

MBS item numbers can be found on the [Department's website](#). Choose the downloadable PDF version and use the search facility to find the appropriate MBS items for the product. MBS item descriptors include references to body parts, procedures, and/or diseases or injuries, so searches on these terms may assist.

Please also explain why the MBS items have been selected.

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Protheses List if they have applied for an MBS item number. If there is no MBS item for the professional service associated with the product, tick the box if an application has been made for the service/s to be assessed by the Medical Services Advisory Committee.

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

10.4 Product Setting and Product Purpose

Product setting

Criterion 2 of the criteria for listing requires that:

The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment.

Indicate whether the product is implanted as part of hospital treatment, as part of hospital-substitute treatment or as part of treatment outside a hospital.

If a product is used for treatment outside of hospital (ie it is not part of hospital treatment or hospital substitute treatment) it may not satisfy this criterion. If the box (c) is ticked, please provide a description of the setting in which the product is provided.

Product purpose

Criterion 4 of the criteria for listing on the Prostheses List defines the permitted product purposes:

The product should:

- (a) be surgically implanted in the patient and be purposely designed in order to
 - (i) replace an anatomical body part; or
 - (ii) combat a pathological process; or
 - (iii) modulate a physiological process;
- or
- (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
- or
- (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted

Please tick the appropriate box that describes the purpose of the product. If box (b) or (c) is ticked, please also advise the specific surgically implanted prosthesis that the product is used with.

Provide a brief explanation of the function of the product, to support assessment against this criterion.

10.5 Overseas Status and Comparative Clinical Assessment

Overseas status

Please indicate whether authority has been given for the product to be sold in any other country. If the product has authority to be sold in other countries, please advise what authorities have been given (eg FDA, CE Mark) if this information is available. This information is used by the clinicians to determine what other health technology assessments (if any) the product has undergone.

Indicate any names that the product is being sold under overseas if these are different from the product name/s to be listed on the Prostheses List.

Comparative Clinical Effectiveness

This section provides the opportunity for the sponsor to state how the clinical effectiveness and cost effectiveness of the new product compares with the comparator.

This is where the sponsor can explain why the new product is clinically equivalent to the comparator, or clinically superior to the comparator, or clinically different. In the explanation the sponsor should refer to the clinical evidence that demonstrates their claims. The clinicians will be looking at the clinical evidence and other information provided with the application to support the sponsor's claims.

10.6 Benefit and Economic Information for the New Grouping

A sponsor only needs to complete this part of the application if they are applying to list the product in a group or with a suffix that is not currently on the Prostheses List.

Clinical Outcomes

In this section, provide information about the quantifiable or measurable clinical difference in clinical outcomes between the new product and the comparator/s. Refer to measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications and life expectancy.

Any information provided and any claims in this section should be supported by clinical evidence or data.

Cost Savings

In this section, provide information about cost savings that can be realised by using this product rather than the comparator.

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

Benefit Rationale

In this section, please explain how the information in the two sections above were used to arrive at the proposed benefit.

Product Utilisation

Please provide information about the actual and projected utilisation of the new product and the cost in local currency. The HESC will apply long term currency exchange data to estimate a cost in Australian dollars.

If the new product has been used in the public health sector in Australia, please provide utilisation data and costs in this table.

Information provided on the projected utilisation over the first two years of listing on the Prostheses List and whether the new product will replace another product is useful to compare with other prostheses on the Prostheses List.

Other Information

This section allows sponsors to provide any other information not already provided to support the proposed benefit for the new product.

10.7 Attachments

This part of the form prompts the sponsor to attach information and evidence to the application to assist with assessment.

An image of the product

A clear image of the product is required for all applications.

If the product is a component of a system, an image of the system should also be provided, with each component clearly labelled.

If the sponsor is applying to list a product in a new group or with a suffix, an image of the product should be provided that clearly identifies and labels the feature that makes the product clinically superior or clinically different to comparators.

Supporting literature

Sponsors must attach clinical papers (if available) with the appropriate follow-up data to support the application.

Sponsors should be judicious in their choice of supporting evidence. One or two papers that satisfy the clinicians' quality requirements and relate directly to the device should be sufficient to support an application. Sponsors should also attach the papers in the order of strength of evidence and relevance to the new product.

Applicants should note that the following types of documents do not constitute clinical evidence:

- product promotional material (brochures and presentations)
- non-peer reviewed papers
- conference poster presentations
- abstracts

While surgical technique documents are not clinical evidence, they can provide useful information for clinicians and these should be provided where available.

Optional attachments

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

Documentation of overseas approvals is useful if it is available.

Product documentation describing the product and how it is used can be useful. The surgical technique can be particularly useful for clinicians to show how the product is implanted and functions correctly.

Reports of economic and cost analysis studies should be provided if they are available to support the proposed benefit for a new grouping. If a sponsor is applying to list a product in an existing grouping, this documentation is not required.

10.8 Submission Declaration

The person completing the application or approving the submission of the application within the sponsor organisation should make this declaration.

11 Application to List a New Prosthesis – Product System

This process is essentially the same as the application to List a New Prosthesis – Single Product. A sponsor can apply to list all components or individual products in the system in this one form.

11.1 Product system name

This is the name of the whole system. For example, if the system is a joint replacement system, the product system name will be the name of the whole system. If the system is a type of screw to be listed in a range of sizes, the product system name will be the name of the screw.

The sponsor will need to complete the following sections for each component or individual product, as this information will be unique. The section in the Guide providing information is in brackets:

- New Prosthesis Device ([10.1](#))
- Comparator(s) ([10.2](#))
- Benefit and economic information for the new grouping (*if applicable*) ([10.6](#))

The following sections can be completed for the system as a whole, as the information will be common to all components and individual products. The section in the Guide providing information is in brackets:

- Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s) ([10.3](#))
- Product Setting and Product Purpose ([10.4](#))
- Overseas Status and Comparative Clinical Effectiveness ([10.5](#))
- Attachments ([10.7](#))
- Submission Declaration ([10.8](#))

12 Application to List a New Prosthesis – Human Tissue

12.1 New Human Tissue

Product Details

Product Name

The product name will be the name of the human tissue item. Most human tissues will be the type of human tissue and how it is presented eg bone, chips.

Sponsors should note that in the next 24 months this naming convention will adopt the ICCBBA ISBT 128 global standards.

Description

The description will provide more information to describe the human tissue item, as appropriate. If the human tissue item is adequately described by the product name, just repeat the product name here.

Size/s

The size is the size of the human tissue item as it is presented. This is relevant to human tissue items such as bone chips and cubes that are supplied in different quantities. If the human tissue item is supplied as one size only or the size or quantity is not relevant to the benefit, just enter “one size” here.

Proposed benefit

This is the benefit that the human tissue supplier proposes to list on the Prostheses List.

Please explain how you calculated this benefit

The benefit for a human tissue item is set at an amount that recovers the costs involved in supplying the human tissue to the patient. This includes, but is not limited to: costs of retrieval, processing, storage and transport.

Documentation must be provided to support the proposed benefit.

ARTG ID Number

Please provide the ARTG number for the human tissue item.

If the sponsor has applied to the TGA to include the human tissue item on the ARTG, but the item has not yet been included, tick the box.

Category

Human tissue items are currently listed on the Prostheses List in four categories:

- Orthopaedic
- Ophthalmic
- Cardiac

- Dermatologic

Enter the appropriate category for the human tissue item here.

12.2 Comparator(s)

In most cases, this will be another human tissue item on the Prostheses List. Enter the billing code, product name and grouping (or category) in the table.

If the comparator is another treatment or therapy currently available for the indication that the human tissue item will be used for, provide details in the table at (ii).

Please choose a main comparator for the human tissue item.

12.3 Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s)

The information provided at [10.3](#) – Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s) is also relevant to human tissue items.

12.4 Attachments

An application to list a new human tissue item must be accompanied by information to support the proposed benefit:

- an annual financial statement of the human tissue facility, certified by an accountant; and
- an audited service cost calculation showing the costs attributed to supplying the human tissue to the patient, certified by an accountant. Where possible, this should include actual costs, not estimates.
- an image of the item or type of item.

Information on the actual or projected utilisation of the human tissue item should also be provided, if it is available.

12.5 Submission Declaration

A person submitting the application or approving the application for submission in the organisation should make the two declarations:

- that all the information in the application is true and correct; and
- that the proposed benefit for the human tissue item is calculated on a cost recovery basis only. This ensures compliance with relevant State and Territory legislation regarding the sale of human tissue.

Part IV — Changing an existing listing

13 Application to expand a billing code

This application is for expanding billing codes on Part A or Part C of the Prostheses List. Billing codes for human tissue items on Part B are generally not expanded or compressed.

Please note that this application should not be used if the sponsor is requesting to change size range of a current listing, or adding new sizes. This can be done by applying to Amend a Listing for a Prosthesis Device.

13.1 Details of proposed expansion

Please detail the listing to expand

This section requests details of the prosthesis as it currently appears on the Prostheses List:

Reason for Expansion

There are two options in the application to choose to explain the reason for expanding the billing code. If the reason is neither of these, please explain in the space available.

The rest of the application form asks for information that is essentially the same as for the application to list a new prosthesis.

For each resultant (new) prosthesis stemming from the expansion, please complete the following information. The relevant sections in the Guide that provide information are in brackets:

- Resultant (new) Prostheses Listings ([10.1](#))
- Comparator(s) and Comparative Clinical Effectiveness ([10.2](#) and [10.5](#))
Please note that this section needs to be completed only if the sponsor is applying to list the resultant new billing code in a grouping different to the current billing code, or in a grouping that is not currently listed on the Prostheses List.
- Benefit and Economic Information for the New Grouping ([10.6](#))
Please note that this section needs to be completed only if the sponsor is applying to list the resultant new billing code in a grouping that is not currently listed on the Prostheses List.

13.2 Attachments

This section of the form provides information about the documents that the sponsor should attach to the application.

An image of the product is useful to show that the product is the same as that already listed on the Prostheses List. If the sponsor is applying to expand a current listing into billing codes to cover each component, the image should be labelled to show each component.

Supporting literature such as clinical studies is required when the sponsor is applying to list one or more of the resultant (new) listing in a group different to the current billing code. It is particularly important to provide this information to support grouping a resultant (new) listing in a grouping that is not currently listed on the Prostheses List. Supporting literature should be relevant to the product.

Economic and cost analysis studies/reports are useful to support a proposed benefit if a sponsor is applying to list a resultant (new) listing in a grouping that is not currently listed on the Protheses List. This should be provided if it is available.

Product information and documentation describing the technical specifications and surgical technique can be very useful in assessing requests for listing in a different grouping or with a suffix.

13.3 Submission Declaration

This declaration should be made by the person submitting the application or approving the submission of the application in the organisation.

14 Application to compress billing codes

14.1 Details of proposed compression

Please list the product you wish to compress in the table below:

List all the billing codes you wish to compress, their product names, their associated catalogue numbers, and the current benefit for each product.

Reason for Compression

Please advise why the billing codes are being compressed. There are three options to select from in the form. If the reason is other than one of these, please explain in the space provided.

Proposed Product Details, ARTG ID Number and Grouping

The instructions for these sections of the form are the same as for an application to list a new prosthesis ([10.1](#)).

If the proposed compressed billing code will be listed in the same grouping as the original billing codes, at the group benefit or lower, no further information is required.

14.2 Comparator(s) and Comparative Clinical Effectiveness

This section needs to be completed only if the sponsor is proposing to list the compressed billing code in a grouping other than the grouping of any of the current billing codes.

The guidance on completing this section is the same as that for an application to list a new prosthesis – [10.2](#) – Comparators and [10.5](#) – Comparative Clinical Effectiveness.

14.3 Benefit and Economic Information for the New Grouping

This section needs to be completed only if the sponsor is proposing to list the new compressed billing code in a grouping that is not currently listed on the Prostheses List.

The guidance on how to complete this section is the same as for an application to list a new prosthesis ([10.6](#)).

14.4 Attachments

An image of the product to be listed in the billing code should be attached to the application.

Supporting literature should be attached if it is proposed to list the compressed billing code in a different grouping to any of the current billing codes.

Economic and cost analysis reports should be submitted (if they are available) with the application to support a proposed benefit for a new grouping that is not currently listed on the Prostheses List.

14.5 Submission Declaration

This declaration should be made by the person submitting the application or approving submission of the application for the organisation.

15 Application to Amend a Listing – Prosthesis Device

15.1 Amend Prosthesis Device

In this section, the sponsor provides details of the product as it is proposed to be listed after the amendment.

Please provide the billing code of the product to be amended.

The guidance on the other information requested in this section on *Proposed Product Details*, *ARTG number* and *Grouping* is the same as for an application to list a new prosthesis ([10.1](#))

Reason for Amendment

Please indicate the reason why the billing code details are being amended. There are a number of options provided to select from:

- changing the product name
- changing the description
- changing the size range available in the billing code
- changing the grouping of the product

If the reason for amending the billing code details is anything other than these, please explain in the space provided.

15.2 Comparator(s) and Comparative Clinical Effectiveness

This section needs to be completed only if the sponsor is proposing to list the amended billing code in a grouping other than the current grouping of billing code.

The guidance on completing this section is the same as that for an application to list a new prosthesis – [10.2](#) – Comparators and [10.5](#) – Comparative Clinical Effectiveness.

15.3 Benefit and Economic Information for the New Grouping

This section needs to be completed only if the sponsor is proposing to list the billing code in a grouping that is not currently listed on the Prostheses List.

The guidance on how to complete this section is the same as for an application to list a new prosthesis ([10.6](#)).

15.4 Attachments

An image of the product is always helpful.

Supporting literature should be attached if it is proposed to list the amended billing code in a different grouping to the current listing.

Economic and cost analysis reports should be submitted (if they are available) with the application to support a proposed benefit if the amended billing code is proposed to be listed in a grouping that is not currently listed on the Protheses List.

15.5 Submission Declaration

This declaration should be made by the person submitting the application or approving submission of the application for the organisation.

16 Application to Amend a Listing – Human Tissue

16.1 Amend Human Tissue

Current Product Details

Please provide the billing code, product name and description of the human tissue item to be amended.

If there is more than one human tissue item to be amended, please provide the information in a table.

Please also indicate the main reason for the amendment. There are three options to choose from:

- Change in benefit
- Change to the description
- Change in size(s)

Proposed product details, ARTG ID and Category

The guidance for completing this section of the form is the same as for an Application to List a New Prosthesis – Human Tissue ([12.1](#))

16.2 Attachments

An image of the human tissue item should be attached.

If the amendment is a change in the benefit, documentation providing financial and cost information must be provided to support the proposed benefit. An annual financial statement of the facility or company supplying the human tissue must be attached. An audit of the service cost calculation, certified by an accountant, must also be supplied. The audit statement should provide details of the actual costs involved in supplying the human tissue to the patient where possible, rather than projections.

16.3 Submission Declaration

A person submitting the application or approving the application for submission in the organisation should make the two declarations:

- that all the information in the application is true and correct; and
- that the proposed benefit for the human tissue item is calculated on a cost recovery basis only. This ensures compliance with relevant State and Territory legislation regarding the sale of human tissue.

17 Application to transfer or duplicate a current listing

This form can be used to transfer a current listing from one sponsor to another, or for a sponsor to list a prosthesis that is already listed by another sponsor.

The information required in the form is self-explanatory.

A sponsor can request to transfer or duplicate a listing before the ARTG inclusion has been transferred or the sponsor has an ARTG inclusion for a duplicated product. The transfer or duplication of the billing code will not be finalised until the sponsor has an ARTG number.

In addition to the form, the transfer process requires authority from the original sponsor. Specifically, the transfer process requires that the receiving sponsor must supply a letter of authority from the original sponsor providing approval for the transfer of the billing code.

When applying to duplicate a listing, the manufacturer, GMDN and intended use stated on the ARTG certificate must match original listing.

Please note, sponsors may have to wait until the next publication of the Prostheses List for the transfer to take effect if a valid ARTG number is not supplied by the ARTG cut-off (as published in the PHI Circular).

18 Application to Delete a Listing

The 'Application to delete a current listing' form is used to have a product deleted from the Prostheses List. All details of the product are removed from the Prostheses List by this amendment, including product name, description, size, billing code and benefit.

Sponsors should list the billing codes, product names and catalogue numbers of the products they wish to delete from the Prostheses List.

19 Abbreviations and key terms

A detailed glossary of health technology assessment terminology used by the Australian Government Department of Health is available on the [Department's website](#).

Term	Definition
ARTG	Australian Register of Therapeutic Goods: a computer database of therapeutic goods within which medicines and medical devices must be entered as 'registered' or 'listed' goods before they may be supplied in, or exported from, Australia
Benefit	The amount that a private health insurer is required to pay for a prosthesis on the Prostheses List that is provided to a privately insured patient with appropriate cover as part of hospital treatment or hospital-substitute treatment.
Billing code	A reference code allocated to a listed prosthesis
CAG	Clinical Advisory Group
Comparator	The prosthesis on the Prostheses List, or treatment or therapy, that use of a new prosthesis would potentially replace. If there is no current treatment or therapy, the comparator is nothing
Description	Detail specific to the product, which could include: <ul style="list-style-type: none"> • model number • descriptors for the product or product components—for example, a spinal system that consists of screws, threaded rod, hex nuts, washer and endplate • composition • any special features
Duplication	The creation of a new billing code (for a different sponsor) for a prosthesis that already exists on the Prostheses List. The result is two different billing codes (for different sponsors) for the one prosthesis. This may occur when two or more companies are sponsors for a given product in Australia (also known as parallel importing)
Federal Register of Legislative Instruments	An authoritative database established under s. 20 of the <i>Legislative Instruments Act 2003</i> containing legislative instruments, explanatory statements for legislative instruments made on or after 1 January 2005 and compilations of legislative instruments in electronic form. It is accessible via the internet
Group	The level of classification of a prosthesis on the Prostheses List below 'category'. Within categories, products are grouped according to similar clinical effectiveness. For simplicity, product groups and subgroups are identified numerically
Group benefit	The benefit paid for all prostheses that are classified in the same category, group, subgroup and suffix
Grouping	The full classification of a prosthesis on the Prostheses List, including category, group, subgroup and suffix
HESC	Health Economics Sub-Committee
Hospital-substitute treatment	Treatment that substitutes for hospital treatment; it is any combination of nursing, medical, surgical, podiatric surgical, diagnostic, therapeutic, prosthetic, pharmacological, pathology or other services intended to manage a disease, injury or condition
Medical devices	The legislation does not include the term 'medical devices'. In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably

Term	Definition
Medicare Benefits Schedule (MBS)	The MBS lists and describes the professional services for which a Medicare benefit is payable, the amount of that benefit, and any conditions applying to the use of that service. The MBS changes from time to time to reflect, for example, the availability of new medical technologies, changing medical practice and the government's current policy parameters for determining which professional services are eligible or ineligible for Medicare benefits
NJRR	National Joint Replacement Registry
Panel	Panel of Clinical Experts
PLAC	Prostheses List Advisory Committee
Product	In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably
Product name	The name under which the product is sold in Australia
Prostheses List category	The clinical-use category that primarily reflects the purpose for which a product is listed on the Prostheses List
Prosthesis	The legislation does not define 'prosthesis'. In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably
Size	May be expressed as length, diameter, width, height, holes, degrees, dioptres, volume or other specification of the product or its components, as detailed in product information or technical documentation
Small business	Businesses employing fewer than 20 employees
Sponsor	<p>Manufacturer, supplier or importer responsible for:</p> <ul style="list-style-type: none"> • the supply of a product/prosthesis/medical device in Australia • submitting the manufacturer's evidence of conformity to the TGA • applying for entry of the product on the ARTG. <p>In this document, the sponsor is also the person or company who makes an application to list a prosthesis on the Prostheses List</p>
System	A product comprising two or more components
TGA	Therapeutic Goods Administration
Utilisation	The number of products (prostheses) used in a given period of time