



Australian Government

**Department of Health
and Aged Care**

Prostheses List Reform Consultation Paper 6(a)

Proposed Listing Criteria



Context for the consultation paper

Building on the previous reform activities, the Government has agreed to maintain the Prostheses List, with some improvements.

Following extensive consultation over recent years, this consultation paper will canvass views on proposed implementation of improvements to the Prostheses List as announced in the Budget. The Government considers these improvements are necessary to benefit consumers, because several reviews of the system have consistently found a high variance in the prices on the Prostheses List compared to prices paid in the public hospital system, with a limited ability for market forces to exert a downward pressure that would benefit consumers.

The Prostheses List is the primary mechanism governing the reimbursement for the medical devices and human tissue products as part of the private health system in Australia.

The Prostheses List specifies a set benefit amount for listed prostheses. The Prostheses List benefit is payable to appropriately covered privately insured patients that receive a prosthesis as part of treatment, where there is a Medicare benefit payable for the medical service associated with the provision of the prosthesis. The treatment can be delivered in a private or public hospital, or in a hospital substitute setting.

The *Private Health Insurance (Prostheses) Rules (the Prostheses Rules)* is a legislative instrument made under the *Private Health Insurance Act 2007 (PHI Act)*, that sets up requirements in relation to provision of minimum price for prostheses. The Schedule to the Prostheses Rules is known as the Prostheses List.

Purpose

The purpose of this paper is to provide additional information about the listing criteria that are proposed to apply for medical devices and human tissue products included in the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (the Rules)*. The Department is seeking feedback on the proposed listing criteria, including any related evidence or data supporting this feedback.

From 1 July 2023, the *Private Health Insurance Act 2007 (PHI Act)* provides for the Rules to specify benefits that must be paid for medical devices and human tissue products included in the Rules. These benefits will be specified for each medical device or human tissue product in a schedule to the Rules.

The PHI Act also provides for the Rules to set out listing criteria (see subsection 72-10(6) of the PHI Act). These criteria must be satisfied for an application to be granted. The Minister must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application (see subsection 72-10(7)).

From 1 July 2023, the PHI Act includes definitions for 'medical device' and 'human tissue product'. The definitions in the PHI Act and the listing criteria in the Rules operate together to define the kinds of medical devices and human tissue products that are eligible for inclusion in the Schedule to the Rules, and for which set benefits must be paid.

Primary Legislation

The Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023 (the PHI Amendment Act) introduces definitions of 'medical device' and 'human tissue product' into the PHI Act. The PHI Amendment Act commences on 1 July 2023.

The PHI Amendment Act removes current references to 'prosthesis' and 'prostheses' in the PHI Act and replaces them with 'medical device' and 'human tissue product'.

The PHI Amendment Act also renames the 'Private Health Insurance (Prostheses) Rules' to the 'Private Health Insurance (Medical Devices and Human Tissue Products) Rules'. The Schedule to these rules is to

be known as the ‘Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List)’. The following table describes these changes.

| Old Law terms | New Law terms |
|---|--|
| prostheses or prosthesis | medical device or human tissue product |
| Private Health Insurance (Prostheses) Rules (Prostheses Rules) | Private Health Insurance (Medical Devices and Human Tissue Products) Rules (the Rules) |
| Prostheses List (Schedule to the Prostheses Rules) | Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List) (Schedule to the Rules) |

In this document we use ‘Prescribed List’ to refer to the Schedule to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules and ‘Prostheses List’ to refer to the current Schedule to the Prostheses Rules.

Listing Criteria Legislative Context

The proposed listing criteria operate with all the provisions in the PHI Act, including the definitions of ‘medical device’ and ‘human tissue product’.

Definitions in the PHI Act

The definitions in the PHI Act along with the listing criteria in the Rules establish the eligibility requirements for including medical devices and human tissue products in the Prescribed List. This ensures that all devices and products that are included in the Prescribed List meet the purpose and scope of the Rules.

Importantly, while the definition of ‘medical device’ in the PHI Act is consistent with the definition of ‘medical device’ in the *Therapeutic Goods Act 1989*, there is an important distinction. Unlike the definition of ‘medical device’ in the *Therapeutic Goods Act 1989*, the definition in the PHI Act does not include medical devices used for diagnostic purposes and is limited to the medical devices that meet the criteria for listing. Similarly, the definition of ‘human tissue product’ in the PHI Act is consistent with the definition of ‘biological’ in the *Therapeutic Goods Act 1989* but only includes human tissue products.

The definitions of ‘medical device’ and ‘human tissue product’ in private health insurance legislation reflect the kinds of devices and human tissue products that are intended to be included in the Prescribed List and excludes those devices and products that are not eligible to be included in the Prescribed List.

Additional Legislative Context

Under the PHI Act, private health insurers will be required to pay benefits for medical devices and human tissue products that are included in the Prescribed List:

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

This is a requirement of item 4 of the table in subsection 72-1(2) of the PHI Act. The proposed listing criteria do not and cannot alter this requirement. There is no need for the proposed listing criteria to duplicate this requirement because it applies irrespective of any listing criteria that may be specified.

Proposed listing criteria

In developing the proposed listing criteria, the Department has sought to:

- ensure the criteria are consistent with measures in the PHI Act
- align the criteria with the current administrative practices used for listing items
- preserve the three parts of the current Prostheses List (Parts A, B and C) [Part D would be removed from the PL in July 2023]
- develop criteria that are as objective as possible, recognising that these criteria would be included in a legislative instrument (rather than guidance material)
- consider issues previously raised about the criteria.

The proposed listing criteria are described as:

- a general listing criterion, applicable to all items listed in the Prescribed List; and
- specific listing criteria that would apply for each of the three parts of the Prescribed List. Parts A and C of the Prescribed List are only relevant for medical devices and Part B of the Prescribed List is only relevant for human tissue products.

The proposed listing criteria are consistent with the current administrative approach for listing items in the Prostheses List.

Proposed General Listing Criterion

The general listing criterion is the following:

It is a listing criterion for listing in the Rules that a medical device or human tissue product must be included in the Australian Register of Therapeutic Goods (ARTG), within the meaning in section 3 of the *Therapeutic Goods Act 1989* (TG Act) (see Part 4-5 of the TG Act).

The general listing criterion applies to all medical devices and human tissue products for inclusion in the Prescribed List (the Schedule to the Rules). The criterion refers to medical devices or human tissue products included in the ARTG because verifying and long-term monitoring other kinds of approvals that may authorise supply of medical devices or human tissue products in Australia is practicably difficult and time consuming.

Proposed Part A Criteria

All these listing criteria apply to a medical device for listing in Part A of the Prescribed List.

Part A Criterion 1

In this criterion, an 'implantable medical device' has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

1. It is a listing criterion that the medical device must be:
 - a. An implantable medical device designed to:
 - i. replace an anatomical body part; or
 - ii. combat a pathological process; or
 - iii. modulate a physiological process;
 - or
 - b. essential to and specifically designed as an integral single-use aid for implanting a medical device in (a) above, which is only suitable for use with the patient in whom the medical device is implanted;

or

- c. critical to the continuing function of the surgically implantable medical device to achieve (a) (i), (ii) or (iii) above and which is only suitable for use by the patient in whom the medical device is implanted.

This criterion reflects what is currently applied administratively for including medical devices and human tissue products in the Prostheses List.

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).

'Modulating a physiological process' can include blocking or facilitating a process. Examples are pacemakers (to regulate heartbeat) and sacral nerve stimulators to improve bladder and bowel function.

This criterion is also for associated products that are essential and manufactured specifically to enable the delivery of a product that meets the criteria above.

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).

'Single-use' means that, once used, the product cannot be used again 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.

If the product can be reused or has a purpose that is not specific to the implanted product (e.g. a screwdriver is of a general nature and not specific), then the criterion is not met.

This criterion is also 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 (medical device or human tissue product) and remain with the patient, as part of the prosthesis (medical device or human tissue product), 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.

Under this criterion, the associated product must have an ongoing role in the function of the implanted product and not be a 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.

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 patients, would not meet this criterion.

Part A Criterion 2

2. It is a listing criterion that the medical device must be a medical device that is not used solely for diagnosis, prediction or prognosis.

This criterion reflects the new definition of medical device in the PHI Act but refines the scope of eligible items further to exclude devices used solely for the purposes of diagnosis, prediction or prognosis. The criterion only excludes a medical device from inclusion in the Prescribed List where the medical device is used solely for diagnosis, prediction or prognosis. Whilst such devices are important, they are funded through other mechanisms. These excluded devices are not intended to be included in the Prescribed List. The definition of 'medical device' may already exclude devices used for the purposes of diagnosis but

the criterion makes that clear. Medical devices used for prognosis or prediction are included in the definition of 'medical device', but the listing criterion would exclude the devices from inclusion in the Prescribed List if they are used solely for prediction or prognosis. This criterion reflects current administrative arrangements.

Part A Criterion 3

3. It is a listing criterion that the medical device must be for a specific treatment and indication.

The purpose of this criterion is to reflect the current administrative practice and exclude general use items from inclusion in the Prescribed List. General items will be funded by an alternative funding arrangement for a transitional period. This issue is being dealt with separately through the Private Health Insurance (Benefit Requirements) Rules. Please refer to the [Prostheses List Reforms - Consultation Paper 5 - Bundling of Benefits for General Use Items](#) to provide your feedback on this issue (by 27 March 2023).

To meet this criterion a medical device must be designed to be used for a specific treatment and indication. Devices used for multiple kinds of treatment or in multiple circumstances would be general use items and these general use items would not be eligible for inclusion in Part A.

For example, fibrin sealants can be used in multiple procedures where there is a risk of internal bleeding. These sealants are general use items as they are used for a variety of indications. Sutures are ineligible because they can be used in multiple body sites in a variety of procedures, hence are considered general use items. Coronary stents are eligible because they are designed for coronary vessels, and treat the condition coronary artery disease which causes vessel narrowing and occlusion.

However, some sealants are for a specific indication or specific treatment (for example, vascular sealants) and would not be considered general use items.

Part A Criterion 4

4. It is a listing criterion that:

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

This criterion reflects what is currently applied administratively for including items in the Prostheses List.

This criterion is included with the intention that comparative clinical effectiveness and relative cost be considered.

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 Prostheses 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. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

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

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

Proposed Part B Criterion

This listing criterion applies to a human tissue product for listing in Part B of the Prescribed List.

It is a listing criterion that a human tissue product must be human tissue. Human tissue includes but is not limited to:

- a. human tissue that is substantially derived from human tissue that has been subjected to processing or treatments; and
- b. human tissue for which the supply (however described, including trade, sell, give or gift) is regulated by state or territory law.

This criterion reflects what is administratively applied now for human tissue products.

Proposed Part C Criteria

All these listing criteria apply to a medical device for listing in Part C of the Prescribed List (Schedule to the Rules).

Part C Criterion 1

1. It is a listing criterion that the medical device must be a medical device that does not meet all the criteria for listing in Part A of the Schedule to the Rules (i.e. ineligible for listing in Part A of the Schedule to the Rules).

The purpose of this criterion is to create a clear distinction between medical devices that may be included in Part A and those that may be included in Part C. A medical device can only be included in Part C if it does not meet all the criteria for listing in Part A. This reflects current administrative arrangements.

Part C Criterion 2

2. It is a listing criterion that:
 - a. the medical device must have been compared to either of the following:
 - i. alternative devices listed in the Schedule to the Rules; or
 - ii. alternative treatments; and
 - b. the comparison specifies:
 - i. the medical device is no less clinically effective than the alternative devices or treatments; and
 - ii. the benefit amount for the medical device is proportionate to the clinical effectiveness of that device.

This criterion reflects what is currently applied administratively for including items in the Prostheses List. This criterion is included with the intention that clinical effectiveness and relative cost be considered.

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 Prostheses List. The alternative treatment is generally expected to be the current standard of care for the condition or indication.

The wording 'no less clinically effective' is used because it is impossible to state that one product is exactly 'equal' to another product when considering clinical effectiveness.

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.

Part C Criterion 3

3. It is a listing criterion that there must be exceptional circumstances for listing of the medical device. Exceptional circumstances include that the medical device is or does any of the following:

- a. is less invasive than the alternative device or treatment; or
- b. delivers better care to patients than the alternative device; or
- c. improves patient access to beneficial therapies; or
- d. is a significantly lower cost than the alternative device; or
- e. improves access or acceptability of treatment for a patient group.

The purpose of this criterion is to provide the basis for including medical devices in Part C and the kinds of exceptional circumstances that may warrant inclusion in Part C. The criterion refers to exceptional circumstances for including medical devices and the matters specified in paragraphs (a) to (e) are not exclusive but merely indicative of the kinds of circumstances where inclusion in Part C may be appropriate. The specified matters in paragraphs (a) to (e) should not be seen as the only circumstances where including a medical device for exceptional circumstances should be exercised. The criterion reflects what is currently applied administratively.

How would the listing criteria apply

The listing criteria would apply from 1 July 2023. The proposed listing criteria would apply for:

- a listing application made on or after made on or after 1 July 2023; and
- any kind of medical device or human tissue product included in the Prescribed List (ongoing listing).

Listing Application

The listing criteria would apply for deciding to grant an application made under subsection 72-10(2) of the PHI Act. These criteria must be satisfied for an application to be granted. The Minister must not grant a listing application if any applicable listing criteria are not satisfied in relation to the application (see subsection 72-10(7)).

Ongoing listing

From 1 July 2023, the listing criteria would also apply for a medical device or human tissue product that is already included in the Prescribed List. This would mean that if the listing criteria are no longer satisfied for a kind of medical device or human tissue product in the Prescribed List then this would form the basis to remove the kind of device or product from the Prescribed List. The authority for removing a kind of medical device or human tissue product from the Prescribed List is based on section 333-20 of the PHI Act (which provides for the making of the Rules), together with subsection 33(3) of the *Acts Interpretation Act 1901* (which deals with the power to vary, revoke etc. an instrument).

The PHI Act does not provide for an application to be made to the Administrative Appeals Tribunal for the review of a decision to remove a kind of medical device or human tissue product from the Prostheses Rules (section 328-5 of the PHI Act). This includes where a decision may currently be made to remove a kind of medical device or human tissue product from the Prostheses Rules because of unpaid listing fees (subsection 72-15 (3)). This is because the making of the current Prostheses Rules are legislation-like decisions of broad application and there is more than one kind of medical device or human tissue product in the Prostheses Rules that is varied, added or removed each time the Prostheses Rules are made.

The same arrangements apply for the Private Health Insurance (Medical Devices and Human Tissue Products) Rules from 1 July 2023. However, from 1 July 2023, new section 72-20 of the PHI Act continues to provide for the removal of a kind of medical device or human tissue product from the Prostheses Rule if there are unpaid fees or levies; and new section 72-25 provides that the Minister may refuse to carry out or direct a person not to carry out specified activities until unpaid fees or levies are paid. When exercising the powers in sections 72-20 and 72-25 the Minister must have regard to:

- whether the exercise of these powers would be detrimental to the interests of insured persons (patients); and
- whether the exercise of these powers would significantly limit the professional freedom of medical practitioners (clinicians) to identify and provide appropriate treatments.

Anticipated stakeholder impact

The proposed listing criteria are not expected to result in any additional impact because the proposed listing criteria reflect the current administrative practice for including items in the Prostheses List but moves the listing criteria from a guidance document into subordinate legislation. The Department is seeking specific comment on this including supporting information.

Next Steps

The Department will consider comments provided as part of this consultation.

Any proposed listing criteria would then need to be considered by the Minister for Health and Aged Care and if supported, will then be included in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (the Rules).

The Rules are a legislative instrument and the making of this instrument and any amendments to this instrument are subject to Parliamentary Scrutiny under the *Legislation Act 2003*. This includes disallowance by either House of the Commonwealth Parliament.

What we invite you to do

We ask that stakeholders provide feedback on the proposed listing criteria and any ideas they have regarding the above issues via the consultation hub. This feedback will then be used to inform any further refinement of the listing criteria.

The Department intends to publish the submissions so stakeholders should clearly identify commercial in confidence information preferably under a separate attachment, noting it may still be accessible under Freedom of Information processes.

In preparing a submission, stakeholder feedback is sought on the following matters:

1. Do you agree that there is no impact for each proposed listing criterion? Please provide the justification for any alternative view on the impacts of each proposed listing criterion.
2. Provide suggestions of additional listing criteria to be included, along with the justification for these suggestions?
3. How often should the listing criteria be reviewed?
4. Should we include notes in the legislative instrument to refer to measures that the PHI Act imposes?

This paper will close for consultation on 1 May 2023. Stakeholders are encouraged to attend an information webinar on 3 April if they have questions regarding this paper, where the Department will be available to provide more information on Consultation Papers 6(a) and 6(b). [Register here](#).