Private Healthcare Australia
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Prostheses List reform – Listing criteria

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 24 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for over 14 million Australians.

PHA welcomes the opportunity to contribute to the ongoing process of medical device and human tissue funding arrangements.

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.

PHA agrees there is minimal impact for the proposed changes to the listing criterion. We support moving these criteria from guidelines, as per the current situation, to legislated as this should remove any ambiguity on eligibility of any given item listed. It should, in theory, reduce the amount and length of disputes over the eligibility of an item, but will not remove disputes over items being placed in the incorrect grouping. The rules around listing into any given group need to be tightened and disputes over these listings must be dealt with in a timely manner to better reduce the financial impacts on consumers.

PHA supports the proposed listing criteria, with commentary on specific items below.

ARTG

All items on the Prescribed List (PL) must be included in the Australian Register of Therapeutic Goods (ARTG). Any item found to not have a valid and active ARTG listing should automatically not be eligible for funding, and removed from the list as soon as practicable. In practice, device sponsors must not seek reimbursement through the PL, and/or funds should refuse funding, for items not on the ARTG as soon as they become aware that the item is not on the ARTG.

Proposed Part A Criterion 1

PHA welcomes the inclusion of "essential" in relation to an integral single-use aid for implanting a medical device. PHA expects that this will result in conditions be placed against most items on the PL listed under this criterion so that they are only funded for those procedures where the sponsor has demonstrated meeting the criteria.

PHA expects that sponsors must have to prove that an item is essential to the implantation of a medical device and not just an aid to make it more convenient for the surgeon or hospital.

Part A Criterion 3

Suggested additions are listed in the next section.

Part A Criterion 4

Suggested additions are listed in the next section.

PHA agrees that any device application that proposes to replace an alternative treatment must go through a health technology assessment (HTA) review to prove efficacy and cost effectiveness.

Proposed Part B Criterion

Suggested additions are listed in the next section.

Part C Criterion 2

Suggested additions are listed in the next section.

PHA agrees that any device application that proposes to replace an alternative treatment must go through HTA review to prove efficacy and cost effectiveness.

Part C Criterion 3

Suggested additions are listed in the next section.

Ongoing Listing

PHA supports these criteria being applied to existing items on the PL, with the swift removal of devices that fail to meet the new criteria.

PHA notes that the Minister must have regards to whether the exercise of these powers would be detrimental to the interests of insured patients, to which we are in agreement. However, it further notes that the Minister must have regard to whether the exercise of these powers would significantly limit the professional freedom of medical practitioners to identify and provide appropriate treatments and would comment that given the vast amount of clinically similar items available in all groupings within the PL, PHA expects that this should occur very rarely indeed.

Provide suggestions of additional listing criteria to be included, along with the justification for these suggestions

PHA recommends that the Minister or his delegate may, if the listed criteria have been met, have regard to whether listing a device on the PL is in the public interest. This will provide the ability for the delegate to decide not to list an item where it otherwise meets the criteria, where it is not in the public interest to do so. This occurrence would be exceedingly rare, but the PL should be designed to help consumers rather than be a subsidy scheme for device manufacturers. Should the delegate or Minister make such a decision to deny listing in the public interest where other criteria are met, PHA recommends that the Rules require public disclosure and explanation.

Part A Criterion 3

PHA recommends that conditions be placed on what specific treatments a device can attract a benefit for. The example given in the consultation paper is fibrin sealant and discusses how a vascular sealant would still be eligible for listing. However, by not placing specific conditions on when that item could attract a benefit, there is no mechanism to prevent the product being used off label, as we have seen with many other items on the PL.

PHA recommends:

1. All items on the PL be listed on the condition that reimbursement will not be required where the item is used for a proscribed purpose per the ARTG listing.
2. All existing items on the PL be listed on the condition that reimbursement will only be required where the item is used for the clinical category in which it is listed.
3. All new items on the PL be listed on the condition that reimbursement will only be required where the item is used as it has been assessed. This will be:
    a. In accordance with the intended purpose described in the ARTG listing, and
    b. With the nominated MBS items or clinical category in the application approved by the Minister or the delegate.
4. A medical practitioner may certify that any item on the PL is reasonable and necessary for a procedure outside the requirements in recommendations two and three, in which case the item would then be eligible for reimbursement.

Part A Criterion 4

PHA is concerned that this criterion in this section is not strict enough to prevent the continuation of low value care where a low value item is already on the PL.

Simply using a comparator which has never been subjected to a HTA review will not demonstrate good value care. A prime example of this flaw in the current system is neuromodulation for chronic pain. There are a number of current reviews of this very expensive treatment modality, following a Cochrane review that casts significant doubt on efficacy, safety and cost-effectiveness. However, despite the being underway, a sponsor could in fact make an application for a new Neuromodulation device being listed by using the substantial equivalency criteria.

PHA recommends that new applications must show that their device is cost effective for the treatment modality rather than just be a match for a device already listed that has never had such a requirement. Where there is already an existing assessment, this is a simple matter of highlighting the HTA process. Should a sponsor be unable to demonstrate that their device is cost effective, this should trigger a review of the group that it was applying to be part of.

Proposed Part B Criterion

PHA notes the ongoing review of Part B, and we recommend that the existing Part B be split. Those items that are imported and highly processed or refined, such as demineralised bone graft, should be moved to Part A or a subsection of Part B which has equivalent listing criteria as Part A. These items should also have their cost effectiveness reviewed and benefits adjusted if required.

Those items that are not imported or subject to highly processed or refined procedures, such as a corneal graft, should remain on Part B.

Part C Criterion 2

As with Part A Criterion 4, PHA is concerned that the criterion in this section is not strict enough to prevent the continuation of low value care.

PHA agrees that any device application that proposes to replace an alternative treatment must go through an HTA review to prove cost effectiveness and is not perpetuating low value care.

Part C Criterion 3

Benefit should only be payable once the device has actually been used. An example of this would be the remote monitoring of cardiac devices. Currently, a benefit is paid whether or not the patient uses the device / service. A benefit should only be paid where it can be demonstrated that a device / service is utilised, as is the case for all items in Part A.

Many Part C devices is should include a condition that the benefit is only payable for a replacement device where the existing device no longer being able to perform at required clinical benefit must be shown before a replacement device attracts a benefit. An example of this is with Insulin pumps. Some sponsors are contacting patients who are using their device shorty before the warranty on that device expires (usually four years) to advise them that the device is eligible for an upgrade and that they should contact one of their preferred medical specialists to have a new device installed. This happens whether or not the current device is functioning adequately and to minimum clinical standards. This generates excessive costs to consumers without demonstrating any improvements in clinical value or outcomes to the patient.

How often should the listing criteria be reviewed?

To allow some level of certainty for sponsors, clinicians and payors, these criteria should be reviewed after three years and subsequently every five years. This would strike the right balance of fairness and ensuring that the latest clinical and HTA principles are maintained.

Should we include notes in the legislative instrument to refer to measures that the PHI Act imposes?

This is unnecessary and would simply lead to confusion or attempts at finding loopholes in the legislation.