AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | ama@ama.com.au
W | www.ama.com.au
39 Brisbane Ave Barton ACT 2600
PO Box 6090 Kingston ACT 2604

Prostheses List Reform Consultation Paper No. 2a: Prosthesis List – Modernisation of Part B of the Prostheses List.

AMA submission to AMA submission to the Department of Health on Prostheses List Reform Consultation Paper No. 2a – Modernisation of Part B of the Prostheses List

Prostheses Reform prosthesesreform@health.gov.au

The AMA has agreed that the Prostheses List currently delivers well against a range of key criteria. The current process:

- supports the clinical choice of prosthesis by the medical practitioner, to ensure that the best prosthetic product is used for any particular patient;
- provides for the medical device companies to support Australian specialists in their use of specific prostheses;
- provides access to a full range of prosthetic items to suit patients' different clinical needs; and
- ensures that patients do not have out of pocket costs for a prosthetic item regardless of its expense.

The one criterion that current arrangements do not support well is price, and the AMA agrees reform is needed on this. The current policy parameters do not deliver the efficiency outcomes that are required to increase the sustainability of private health insurance.

In seeking to address this missing criterion, it is essential that the strengths delivered in the current system are retained. The AMA is concerned that the proposals, as outlined in this consultation paper, will undermine or diminish the current arrangements.

Technology is changing rapidly in this area, and Australian medical professions are often quick to use these new products in their treatment of patients. This level of change is going to continue, and the system must be prepared for the questions and issues that will arise going forward. Use of human tissues in any context is always a sensitive issue. This requires an appropriate balance between the desired policy and health outcomes but also the ethical issues involved – this is the case with Part B of the PL list.

We need to build a robust system that has considered the full range of issues at play and build a solid ethical foundation to support future changes.

The AMA supports further work being undertaken on the ethical underpinnings of human tissue use in therapeutics. We agree that health technology assessment (HTA) of human tissue products should give greater weight to ethical, social, cultural and legal issues (particularly when there is little guidance available in Australia or globally).

The AMA believes that this paper is a good beginning to a bigger body of work – it is not sufficiently developed to allow stakeholders to fully comment or endorse any approach proposed to modernise Part B of the PL.

The AMA believes that the following work should flow from this paper and should be consulted on broadly as these issues are pivotal to underpin the modernised Part B listing process:

- The proposed National Eye and Tissue Framework currently under development (the consultation paper states this is a necessary complement to the proposed Part B reforms);
- Guidance on an ethical framework for human tissue and human tissue products used for medical treatment developed in consultation with the NHMRC and other relevant medical bodies such as Australia's Organ and Tissue Authority and the Royal College of Pathologists of Australasia;
- The additional work required to benchmark products supplied by product area, weight or volume; and
- A review of the criteria used by the Therapeutic Goods Administration (TGA) to establish osteoinductivity (the AMA agrees that this is needed in order to determine whether a supplement should be established or whether an HTA should be undertaken).

Additionally, the AMA believes that there needs to be stronger consideration and exploration of the impact of moving the listing of Part B items to a cost recovered basis – especially where there are still limitations on companies and organisations deriving profit from these items.

To be able to fully comment or support proposed revisions to modernise Part B – the AMA will need be consulted on this body of work.

Proposal: **That the PL Guide should clarify whether autologous products are eligible for listing and, if ineligible, that skull flaps and an autologous femoral head are removed from the list.**

The AMA supports the proposal to clarify whether autologous products should be included on Part B of the PL. The AMA supports this work being submitted to Clinical Implementation Reference Group (CIRG) for their clinical input. If the result of this review is that these items become ineligible for listing, the Department should ensure that the MBS items that would end up being used for these procedures adequately cover the removal of autologous skull flaps and femoral heads.

Proposal: **That further work is undertaken to develop guidance on an ethical framework for human tissue and human tissue products used for medical treatment, possibly in consultation with the NHMRC.**

The AMA supports the development of guidance on an ethical framework for human tissue and human tissue products for use in medical treatment. Further we believe that this work **MUST** be done in consultation with the NHMRC (not possibly as stated in the consultation paper) as well as other relevant medical bodies such as Australia's Organ and Tissue Authority and the Royal College of Pathologists of Australasia. The AMA agrees that there is simply not enough guidance currently provided on therapeutic (rather than research) application of human tissue and related products.

Proposal: **That the number and nature of ARTG listings for human tissue products is discussed with the TGA to explore the feasibility of greater specificity of ARTG listings for these products.**

The AMA supports appropriate harmonisation across Government systems. We believe that both the HTA and PL processes need to be managed across Government in an integrated and coordinated fashion. As this work is developed, we expect that it will be well consulted both through the CIRG and broadly with stakeholders.

Proposal: **That the application and assessment pathways for human tissue products mirror the three proposed application and assessment pathways (i.e., Abbreviated, Focused HTA, and Full HTA) for medical devices.**

The AMA does not support the contention that the application and assessment pathways for human tissue products can mirror those for Part A of the PL. The AMA has concerns that the proposed modernised listing process may not have an appropriate balance that provides for an adequately strong assessment without discouraging companies from developing or importing products. This is especially the case for

- niche and novel products with smaller profit margins, and
- products labelled high risk where there are already similar products on the PL and no new clinical evidence is really required.

Increasing the assessment processes on such products will increase the costs and may create an environment where it is not viable to introduce them into the Australian market.

Our concern here is that the products in Part B of the PL list are the niche and novel products where companies have limited or no ability to make a profit. The AMA believes that there needs to be a more thorough investigation of the likely fiscal impact of this proposal on the viability of these products. Whilst many of these items may only be used in limited occasions, they are still clinically important to the medical practitioner and patient requiring them.

Levying application or listing fees as part of the approval process

The AMA appreciates that unlike applications for listing on Part A or C, applications for listing on Part B are not currently subject to any PL application or listing fees. The proposal to move these items to the HTA listing process used for the rest of the list brings with it presumably the same costs that apply to the more typical commercial items in the PL. However, the ability to make a profit from these products remains constrained.

The AMA appreciates that it is critically important to maintain public trust and confidence in Australia's organ and tissue donation and transplantation system. Damage in that trust could lead to reduced levels of donation and as we are already unable to meet the current level of need, this would have negative outcomes. There is a balance needed in this area that allows companies to sustainably underpin their work on these items but without moving to a free for all profit taking approach which could undermine potential donors' belief in the system.

The consultation paper highlights that Australia is unable to produce enough of many of these products to meet our needs. We currently import a range of products and the companies that do this are still limited in their ability to derive significant or any profit from this service. The AMA has concerns that if extra cost hurdles are placed in this pathway without changes to the limit on profit taking some companies may not see a fiscally viable pathway for bringing their products to Australia. This would not be in the best interests of patients reliant on these items.

Proposal: **That advice is sought from the TGA regarding whether a Class 3 biological has an equivalent risk level to a Class 3 medical device.**

The AMA supports getting more advice on this issue. We agree that there should be consistency through the entire HTA and PL processes. However, changes stemming from this advice would need to be considered and evidence based. The AMA expects that there will be further consultation both through the CIRG and broadly with stakeholders.

Proposal: **That Part B products undergoing HTA assessment have an agreed list of appropriate MBS items assigned to them to enable their use to be restricted to specific clinical indications.**

The AMA has some concerns about this proposal. While there are typical pathways in medical care – there are also many exceptions.

The AMA is assuming that this proposal is aimed at:

- increasing the ability to track protheses and collect data about their performance. The AMA supports this intention. We understand that when prostheses and implants are used in the private system it is difficult for Government to obtain downstream data on them (except where they are covered by a register); and
- to discourage inappropriate use of donated tissues in some settings.

The AMA supports the use of registry mechanisms as mandatory. Inclusion on an appropriate clinical register would increase the availability of data and grow the evidence base for that item.

If the Department is to take this proposal forward, we would expect a body of work will be done (in consultation with the medical profession - through its Colleges, Associations and Societies) that maps clearly current pathways of use and demonstrates that any proposed framework will not remove clinical choice and freedom.

Proposal: **That there is a clear understanding of the nature of the assessments undertaken by the TGA for different groupings of tissue products, before the Abbreviated Pathway is used to determine Benefits for tissue products.**

The AMA has supported integrated management of the whole HTA and PL systems. We therefore support the need for clarity in the earliest – TGA assessment – part of this process.

Conclusion

As stated at the beginning of our submission the AMA believes that this consultation paper is the start of a bigger body of work. To be able to fully comment on revisions proposed to modernise Part B, the AMA will need be consulted on this body of work. This is a technical and ethically difficult area what warrants an appropriate level of consideration and consultation to ensure there are no unintended consequences.

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Contact

Tracey Cross
Senior Policy Adviser
Australian Medical Association