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. 3: Prostheses List – A modernised fit-for-purpose listing process.

AMA submission to the Department of Health on Prostheses List Reform Consultation Paper No. 3: Prostheses List – A modernised fit-for-purpose listing process.

Prostheses Reform prosthesesreform@health.gov.au

The AMA strongly believes that the key underlying principle for all reforms to the Prostheses List (PL) should be improving the clinical and health outcomes of the patient. We have advocated consistently that the policy settings and environment supporting private health insurance in Australia, including those for the PL, are not 'set and forget'. This is a dynamic policy area, medical care and technology are changing, patient demographics have shifted, as have people's health requirements and their expectations. Accordingly, we support modernising the listing process, making it more efficient and effective now, and providing for better management and support of future medical and technology changes.

We have also argued that these reforms need to deliver not just efficiencies in price, they need to improve the evidence supporting prostheses use and therefore, clinical effectiveness into the future.

There are strengths in this paper, particularly in articulating principles for a modernised approach and the development of a tiered process that increases the flexibility to deal with risk and introduces an abbreviated pathway. However, the AMA is concerned that this paper excludes details necessary to appropriate reform of the PL.

The AMA is disappointed with the missed opportunity to focus on increasing the evidence base supporting prostheses choice and use, and we look forward to seeing this aspect of PL reform covered in a future consultation paper. The only way to ensure the PL is fit for purpose and drives better clinical outcomes is to support it with a clinically driven evidence base that feeds into both the listing and pricing processes.

The AMA has issues with the lack of detail provided in this consultation paper, which makes it difficult to assess fully how any new process will work. In particular, the AMA would like to

understand how the proposed modernised listing process will dovetail into the planned Health Technology Assessment (HTA) Policy and Methods Review, due to commence later in 2022.[1]

The AMA is also concerned about the impact on smaller volume products which are not likely to make significant profits but are still important clinically and to individual patient outcomes. The AMA has concerns that any increase in regulatory burden or higher costs applied through a changed listing process may see limitations to these products being made available to Australian patients.

Principles for a modernised listing process

The AMA is generally supportive of the six core principles outlined in the consultation paper to support a modernised listing process:

1. *One part of the Australian HTA system (consistency, but not duplicative)*

   We support this principle and want to ensure that the Government manages the whole HTA system in an integrated and coordinated fashion – the planned HTA review needs to work in with this PL review. We strongly support both the HTA and PL processes being adequately resourced and supported going forward to ensure that they remain fit for purpose as medical care and technology change.

2. *A single departmental portal for Australian Government health technology assessment processes*

   We agree with this principle, but the development of this portal needs to be supported with a high level of consultation and an appropriate timeframe.

3. *Efficient for both applicants and assessors (including the use of digital options to decrease the regulatory burden; cost recovery fees proportionate to the services provided)*

   The AMA supports this principle, and strongly supports developing an appropriate balance that provides for an adequately strong assessment, without discouraging companies from bringing forward or importing niche and novel products that can improve clinical outcomes.

4. *Globally accepted health technology assessment principles underpinning Australian Government process*

   We support this principle but believe it needs to explicitly acknowledge the role of developing quality evidence to support best practice HTA.

5. *Balancing transparency (for consumers, clinicians and payers) and confidentiality (respecting privacy and commercial information)*

[1] https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/landmark-new-medicines-agreements-to-bring-significant-benefits-for-australian-patients

We agree with this principle and would like to highlight that the reason the PL exists is to ensure patients have access to safe and clinically effective medical devices.

6. *Collaborative, not compulsory - The Australian Government cannot compel a medical technology company to seek reimbursement of a device on the PL if it does not wish to do so.*
   The AMA supports this principle.

The PL was developed to ensure privately insured patients have access to safe and clinically effective medical devices.[2] The AMA believes that this intrinsic core value is not adequately reflected in this consultation paper or in the outlined principles. We believe that the central principle for the PL needs to be that decisions about use of prostheses are always clinician led, and the processes behind the PL support evidence-based care that works to ensure a quality outcome in the best interest of the patient.

Health Technology Assessment in the PL listing process

The AMA agrees that a key outcome of the PL listing process is a decision regarding reimbursement, and we would argue therefore usage by clinicians. It is critical that both comparative clinical and cost-effectiveness are key arbiters for any assessment, and we call for these reforms to be used to increase the clinical evidence base supporting prostheses use.

The AMA also agrees that use and support of prostheses is not enduring but is a dynamic area that reflects changes in medical care, technology and patient health requirements. However, we have concerns about the lack of detail provided in the consultation paper on the proposed post-market surveillance system. The paper (page 10) refers to a system being designed to show that a device represents value for money throughout the lifecycle of the device – but does not articulate how this will be achieved.

More details must be provided as to what this system will look like, how it will be run, the level of clinical involvement and the timeframes proposed. The re-introduction of rigorous methods for assessing cost-effectiveness, the enhanced post-market monitoring of reimbursement decisions and the processes for delisting (dis-investment) need to be outlined clearly and Government needs to consult on these mechanisms well before they are introduced.

A tiered listing process

The AMA agrees that pathway leading to the listing of medical devices (like the pathways for medical procedures and pharmaceuticals) needs to be fit for purpose and we support a tiered process that better marries risk to process.

The AMA believes it is vitally important that the final impact on clinicians and patients remains front and centre in finalising the new tiered listing process. The activity and costs of the listing

[2] Private health insurance protheses list RIS https://obpr.pmc.gov.au/published-impact-analyses-and-reports/private-health-insurance-prostheses-list

process need to be proportionate – processes that are over-engineered or disproportionate in their costs versus possible profits could have negative impacts on patient health outcomes, even as much as processes that understate the risks.

The AMA supports the introduction of the proposed abbreviated pathway. We believe the creation of a more efficient pathway is a positive step, that will increase the flexibility to deal with lower risk products. This will lead to decreased red tape for eligible applications and reductions in the assessment and listing processes. Ideally, this will see effective products making their way into clinicians' hands more quickly.

The listing process needs to 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.

Conclusion

The AMA would like to take this opportunity to also call on Government to ensure that future funding levels for the PL listing and review processes are maintained at levels that ensure this key plank of the private health sector is well supported. The AMA would argue that it is a false economy to underfund the processes supporting private health, including the management of the prostheses list.

In the Government's own Regulation Impact Statement *Improving the Private Health Insurance Prostheses List*,[3] it is acknowledged that this approach delivers negative outcomes:

> *The 'set and forget' model of benefit setting would be maintained, and there would be little changes to PL benefits over time. This would place increased pressure on PHI premiums and erode the value proposition of PHI for consumers*.

Modernising and improving the processes supporting the PL today are important, but equally important is maintaining a fit for purpose process that is dynamic and can be adjusted readily to meet future needs. Only with adequate Government support will the PL process allow for quality clinical involvement in decision making and policy setting informed by a rigorous evidence base. This will deliver better clinical outcomes for patients.

The AMA would like to reiterate that the key to ensuring the PL pathways work well now and into the future is support through good evidence. We are disappointed that the opportunity was not taken here to look at what evidence is feeding into the proposed system and how this might be improved.

[3] https://obpr.pmc.gov.au/published-impact-analyses-and-reports/private-health-insurance-prostheses-list

Medical practitioners have been the leaders in generating this evidence base. It was the Australian Orthopaedic Association that established the National Joint Replacement Registry (AOANJRR), which now collects information on hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement from all hospitals in Australia undertaking joint replacement surgery. This registry has saved the health system hundreds of millions of dollars by providing information on the performance of prostheses to clinicians and therefore driving change in utilisation. This style of evidence collection, analysis and the communication of these results to inform clinical practice should underpin a wider range of procedures using prostheses.

The AMA also calls for strong clinical representation in all aspects of the development and implementation of this modernised fit-for-purpose listing process. The AMA was deeply disappointed with the consultation process in the lead up to the Government announcement of this tranche of reforms in 2021. There was not significant clinical input in that process. The AMA (nor any of the other medical professional groups) was not involved in the work of the Prostheses List Reform Governance Group (or its subcommittees), work which is referred to in this paper. The AMA welcomes the current inclusion of clinical representation in the PL reform process and calls for this to extend beyond the important development stage.

The AMA is committed to ensuring Australia has a strong and healthy private health sector. We stand ready to work with all stakeholders developing a fit for purpose listing process that works for Australian clinicians and patients now and into the future.

24 February 2022

Contact

Tracey Cross
Senior Policy Advisor
Australian Medical Association