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Options for Reforms and Improvements to the Prostheses List

AMA submission to the Department of Health consultation in relation to options for reforms and improvements to the Prostheses List.

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The AMA understands the need to ensure that private health insurance (PHI) is sustainable moving forward and hence the need to reform current PHI settings. We have contributed and, at times, lead the debate on possible mechanisms of reform to ensure that Australia's private health sector is sustainable and thrives into the future. The AMA recognises the need to address the full range of policy settings and levers to improve the position of PHI and this includes the need to reduce costs to insurers, especially where they do not support quality clinical outcomes.

The AMA supports the need to reform the protheses list, to deliver not just efficiencies in price, but to improve the evidence supporting prostheses use and therefore the clinical effectiveness of practice. 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 next year will have been operating nationally for 20 years collecting 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.

But we are also aware that our patients want three things from their insurance products – they want transparency, choice, and value. Recent history has shown us that leaving PHI to the marketplace, unchecked will not deliver these:

Transparency – Over reliance on the marketplace previously delivered 70,000+ different policies making insurance impossible to navigate. This variation led to the recent Government reforms to the regulation of policies and the introduction of the gold, silver, bronze and basic categories.

Choice – Consumers want to choose their doctor and their hospital. However, the system of contracting between insurers and hospitals left many hospitals without contracts and therefore provided no coverage for consumers. The Government was required to fix this problem by introducing second-tier default benefits.

Value – Consumers trust their PHI to cover them for their hospital and procedure costs. Under the current system patients are covered for the prosthesis that works for their individual clinical circumstances – regardless of the cost of that item. This gives them value from their insurance.

Key criteria that need to support the Prostheses List

Currently the Prostheses List 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 here. The current policy parameters do not deliver the efficiency outcomes that are required to increase the sustainability of PHI. The AMA is happy to work with Government and industry on this issue, provided the reform of the prosthesis list includes maintaining the above key criteria.

For these reasons, the AMA supports reforming the current structure of the prostheses list and agrees with the need to overhaul the General Miscellaneous (GM) category. The AMA supports clinician led, evidence-based care that works to deliver a quality outcome in the best interest of the patient. The AMA hopes that, as part of these reforms, the Government takes this opportunity to support increasing the evidence base for prosthesis use. But evidence must also be communicated well – investing in evidence must be supported by investment in communication and dissemination. The AMA does not support low value care, but medical practitioners must be supported by a strong and accessible evidence base if they are to adopt the most effective practices.

The AMA does not support Option 1 – the consolidation of the Prostheses List using the Diagnosis Related Groups (DRGs). The data and evidence to move to such a radical departure from the current process is not available. The AMA sees considerable threats to the benefits of the current process in this proposal, especially given the limited consultation and hasty timeline proposed for implementation.

The AMA supports Option 2 – to consolidate and redesign the Prostheses List with extensive changes to pre- and post-listing assessment and benefit setting processes. But the AMA understands that this option still requires extensive work to be done in consultation with the whole sector to achieve the best possible outcomes.

The choice of prosthesis system should not be based on what costs the least to Government in terms of administrative support – this is a false and dangerous logic. If we had used that logic we would not have quality regulation of food standards, an independent safety and quality commission supporting the safe delivery of health care in Australia and we would not have the Pharmaceutical Benefits Scheme we have today.

The AMA would like to highlight that these schemes demonstrate that that investment in a quality system delivers quality outcomes – outcomes for patients, outcomes for providers and outcomes for governments, both in terms of the health of Australians but also in ensuring expenditure is maintained at affordable levels.

General Questions

1. **What, if any, general use products should continue to be funded though the PL and why?**
2. **Should there be an "exceptional circumstances" list (akin to the current Part C)? If so, what types of products should be listed and why?**
3. **How should general use items be transitioned to other payment arrangements in a phased manner? What time period and should some items continue to be listed for longer than others? If so why?**

The AMA does not have the detailed expertise to provide a comprehensive answer to the specific clinical aspects of these questions and we defer to the relevant colleges, societies, associations and hospitals to provide this information to Government.

The AMA does believe that the general use items (currently found under the GM category) do need to be examined and that many that do not meet a reasonable definition of 'prosthesis' and should be removed from the Protheses List. The AMA supports the following principled approach to the general use product category of the prostheses list:

- Any arrangement needs to support good clinical practice. Items that are removed from the list are still essential and will likely become consumables and funded through contracts between private hospitals and PHI funds. As consumables, hospitals have the control over the contracts they develop, and medical practitioners will need to make an appropriate case for changes to these contracts;
- Appropriate changeover arrangements need to be developed to ensure a smooth transition to the new system;
- Transition arrangements need to be developed that support appropriate financial underpinning of private hospitals likely to be adversely affected by the proposed reforms of the GM category;

- Some of the items in the GM category contribute to patients having a shorter stay in hospital and therefore reduce the cost of the episode of care (for example infusion pumps). Such items should continue to be funded appropriately and included in any negotiations; and
- Clinically beneficial items (especially patient matched devices) that have not got another funding pathway should be subject to a review mechanism and retained until an alternative payment pathway is determined.

The AMA wants to ensure that any transition arrangements do not end in brinksmanship, loss of clinical outcomes or increased out of pockets for patients. The current funding arrangements could be continued until hospital contracts are due to be renegotiated anyway. This would lead to a staggered implementation timeframe. Alternatively, insurance funds could put up appropriate funding to support a more consistent implementation approach.

Reforms to the GM category will bring about savings regardless of the PL list reform model adopted.

Based on Australian Prudential Regulation Authority (APRA) data for the year ending March 2020 (before any COVID-19 impact on elective surgeries) spending on the GM category was just over $300m [1]. Moving many of these items from the GM category and turning them into consumable items is likely to reduce the cost of these items as they are subject to increased market pressure and scrutiny of utilisation. Based on this APRA data, expenditure on GM category items, even for privately insured patients, is about 12% less when the patient is admitted to a public hospital versus a private hospital. The AMA can see no reason why such savings (or even higher) could not be achieved with review of the GM category and increased market pressure in the private sector.

However, the AMA cannot see how savings from changes to the GM category could be seen to be in the order of 50% of this expenditure or more. Savings of this order are likely to accrue to payers at the expense of the providers or patients. The AMA does not believe that the providers are in a financial position to absorb costs in excess of $150m per year and the only way for them to remain viable will be if they pass on these costs to patients in the form of increased out of pocket expenses.

[1] Prostheses statistics at https://www.apra.gov.au/quarterly-private-health-insurance-statistics

OPTION 1: Consolidate the Prostheses List using the Diagnosis Related Groups (DRGs) model and set benefits with reference to the prostheses price components of relevant DRGs, with administration moved to the Independent Hospital Pricing Authority (IHPA).

1. **Should the public/private gap be closed completely or instead allow for relativity that favours the private sector? If so why?**
2. **What evidence is there that choice of prostheses in the public sector is more limited than the private hospital sector? Is there any evidence of difference in outcomes in the public and private settings?**
3. **How should concerns about maintaining choice be addressed?**
4. **What safeguards should be adopted to prevent patients being exposed to out of pocket expenses for prostheses?**
5. **What market distortions would be continued or created by this proposal and how can they be addressed?**

AMA does not understand why, in such a significant reform proposal, the Department has not undertaken this analysis and appears to be leaving it to the myriad of stakeholders (each with differing perspectives) to provide the evidence base to their choice of policy direction. Additionally, the short time frame across the holiday period leaves stakeholders with virtually no ability to contact members and develop a detailed understanding. The AMA has also not been included in the work of the Prostheses List Reform Governance Group (or its subcommittees) so has had very little time to develop a comprehensive understanding of these major proposals and their likely consequences.

The AMA has the following observations about how this model will fail to deliver on the key principles needed in a revised prostheses list approach.

Private and public systems are different

The private and public systems are different, they have a different mix of health issues, severity of health issues and comorbidities. Patient expectations also vary. Patients with private health insurance, especially those paying the highest level of premiums to have Gold level of coverage, expect choice of hospital, choice of doctor and they also expect high quality prostheses.

There are other differences between the two systems. The private sector can rarely achieve the volume levels which can be reached by the public system (where purchase arrangements can cover the public hospitals of an entire jurisdiction). Additionally, the private system has different procurement processes, different distribution systems, different geographical issues and different costs of servicing.

These differences cannot be ignored or glossed over and must be adequately accounted for and built into any reformed system. This issue is highlighted further below.

Tier pricing for orthopaedics

Private hospitals should have access to benchmark pricing for prostheses. But there needs to be recognition of the differences in scale and of service for devices provided to the private sector when compared with the public sector. Surgeons working with new orthopaedic devices require training and ongoing support in the adaption and use of new devices and device companies routinely provide staff support for the implantation of their devices which provides a substantial service to hospitals. It is reasonable for devices to then be sold at a price to cover these additional service elements that are not required to the same extent in the public system where scale provides offsetting benefits. In other countries (such as the UK) device companies provide a much smaller amount of support to hospitals.

It is therefore reasonable that devices be benchmarked against the public sector price at a reasonable premium up to a specified volume measure.

Clinical choice of prosthesis

Moving to a DRG funding model has potential significant failings, if left unchecked. DRGs are used to classify patients who have broadly similar conditions. Payment based on DRGs is calculated on the patient being 'typical' in terms of length of stay and funding is assigned in a range of relatively normal stays centred around the mean. DRGs by design require a large volume of cases to 'even out' the occasional outlier. Smaller private hospitals cannot gain the volume of patients to get the same outcome as the volume of the public system. Furthermore, people with special requirements, particularly those in the younger cohorts are more likely to seek out PHI making these 'outliers' more common.

Moving to a DRG payment based on an episode of care will put pressure on hospitals to ensure they have the lowest price prosthesis to maintain margins. This pressure will be exacerbated by contracts with private health insurers that will assume hospitals are paying these lower prices. To achieve these price efficiencies, hospitals will need to enter into contracts with device providers offering volume for reduced price.

Volume can only be delivered at the expense of choice. Without benchmark pricing to those paid in the public setting, private hospitals will not get the best value for the overall system. A benchmark price may include a premium over public hospital pricing which allows for volume differences and additional resources like training. While a small premium is not ideal, it allows for the benefits of volume pricing in the public setting while allowing for the additional service component to the private hospitals.

There are a wide range of prostheses and this has arisen to suit the significant variation in patient and clinical needs. Some of these will come at a much higher price well outside the average costs factored into the DRG amount. The current system covers most of these outliers in the interests of the individual patient. The AMA has grave concerns that under the proposed model of funding these patients could be excluded from getting the prosthesis they need or face expected or unexpected out of pocket costs.

Reduced range of prostheses

Reducing the range of available prostheses available for use by medical practitioners leads to other risks, including inferior patient outcomes, higher complication rates, hastened deterioration rates and increased levels of revision surgery. This was highlighted by the adoption of a particular hip prosthesis in the United Kingdom (see Example 1 below).

Example 1

The 3M Capital hip prosthesis was introduced in 1991 as a low-cost hip replacement. Adverse reviews had already been reported, and its failure rates of 19-21% at five years were four times what would normally be expected and suggested an intrinsic problem.

Yet, because of its cost, over six years 4669 were implanted in 95 centres throughout Britain (almost all Capital Hip prostheses that were sold, were sold in the UK). Compared to primary hip replacement, revision surgery is more complex, more expensive, and has higher failure rates. Therefore, the costs required to rectify this problem far outweighed the small amount of savings generated by the low initial purchase price, not to mention the human cost of this burden of revision surgery.

Support for Australian specialists in their use of specific prostheses

Surgeons spend significant time learning about and training in how to implant/use prostheses. Any system that requires surgeons to change the prostheses they have consistently used will reduce patient clinical outcomes in the short term during this period of adjustment. A DRG based system may lead to different hospitals or hospital groups supporting a more limited and different range of protheses than the surgeon is used to and if this occurs it will have a direct and measurable impact on patient outcomes and overall costs to the PHIs and the health system in general.

The increased cost of prostheses in Australia compared to other parts of the world needs to be recognised. There are multiple reasons for this, and it should not be characterised as simply a direct outcome of the Prostheses List mechanism. Australian medical device companies support their products at a higher level than in some other countries and this provides a direct benefit to surgeons, hospitals and patients. There are also a number of costs associated with importing products into Australia, maintaining inventory, registration and servicing our relatively small market that results in our public hospital pricing also being higher than pricing in other countries.

Additionally, some sizes and types of prostheses do not have the same volume of use. These can perish and are no longer usable; they become wastage. These costs are borne by the manufacturers and under a DRG system could be transferred to hospitals. Differences such as this explain some of the price differences with other countries.

No out of pocket costs for a prosthetic item regardless of its expense

The current system delivers the right prosthesis to the right patient, for no out of pocket cost to consumers. Leaving prostheses pricing and coverage to the marketplace without stringent Government mandated protections will introduce an unacceptable level of risk. As outlined earlier there are virtually no aspects of PHI that have not required Government intervention to ensure the system works for consumers. The Prostheses List is no different.

The marketplace is set up for a provider purchaser split – but this is not the situation in Australia for the provision of prostheses. The device companies are the provider, but the purchaser is not the patient - it is the hospital. Operating margins and costs will be a large part of the criteria used by any hospital when looking at contracts for the purchase of protheses. Hospitals are under considerable fiscal pressure, so maintaining their margins is important (companies will also be looking to ensure they provide a return to their shareholders). The assessment of the clinical merits of prostheses needs to be left to the medical specialists and this assessment needs to be paramount when considering prostheses choice.

OPTION 2: Consolidate and redesign the Prostheses List with extensive changes to pre- and post-listing assessment and benefit setting processes, with administration of benefit setting supported by the Department of Health

1. **What advantages or disadvantages does option two have over option one?**
2. **What groups structure should be used and why? Examples include grouping by episode of care, procedure or device?**
3. **Would it be possible to use IHPA's DRG grouping structure as part of reforming the PL under this option?**
4. **If benefits are set through commercial tenders (for existing products and categories), how frequently should those tenders occur?**
5. **If benefits are set through reference pricing, should this include public hospital prices and international prices? Which countries should be referenced, how and why? For public hospitals, how would reference pricing be supported outside the IHPA framework, and should this include averaging?**
6. **How should compliance be supported to ensure companies accurately identify referenced prices?**

The AMA is supportive of consolidating and redesigning the Prostheses List with extensive changes (including significant revisions of the GM category) but believes there is a significant amount of work needed to achieve a satisfactory outcome. However, at the end of this process there is potential to deliver a system that is superior to any form of DRG funding for prostheses.

The main advantage of maintaining a reformed Prostheses List over DRG funding is that it will protect the key features of the Prostheses List that benefit patients - ensuring a full range of prosthesis choice with no out-of-pocket costs. A reformed Prostheses List will also avoid the pitfalls associated with various DRG models as detailed previously. We believe that a reference pricing mechanism can be developed that will achieve better value for PHI policyholders without discarding the positive features of the Prostheses List.

Grouping prostheses can be easily achieved for some of the high volume, high-cost procedures such as hip and knee replacement. However, there is very large variation of procedures and prostheses within other DRGs and applying pricing to the Prostheses List through large groupings would be extremely complex and would be unlikely to achieve the desired outcomes. Detailed analysis and consultation would be required before the AMA could support using DRG groupings to set prosthesis prices.

Commercial tenders have been effective at a state level for reducing prosthesis prices compared with the Prostheses List, but there may be a level of cross-subsidisation with the private sector. In some cases, the prices are achieved by guaranteeing volumes, which of course reduces prosthesis choice to individual clinicians. This mechanism for price reduction will not be effective on a national level and it is difficult to see how a tender mechanism would work.

Reference pricing is more likely to be effective and the AMA is supportive of using public hospital benchmarks rather than international pricing. We believe this is most likely to reflect the real cost of providing prostheses for the Australian market, although a premium to the public hospital reference price is likely to be required.

Ensuring this system focuses on quality and is not just based on price is paramount. The Independent Hospital Pricing Authority (IHPA) already works with the Australian Commission on Safety and Quality in Health Care (ACSQHC) recognising that price alone is an inadequate determining factor for the provision of health services. This is especially the case for prostheses. A cheap prosthesis that is not appropriate for a patient's clinical needs is likely to result in poorer clinical outcomes, more expensive revision surgery down the track and higher costs to all parties in the long run.

Prostheses handling fee

The AMA supports the end of the rebate structure for protheses as it currently stands, but hospitals will require a handling fee to cover the costs to them of stocking prostheses. The AMA believes that such a fee could be set by the IHPA as it develops cost and pricing models and the associated documents and tools that outline how these are calculated each year. Additionally, the IHPA already has access to considerable data sets that should support this determination.

Concluding remarks

The options and questions in the consultation document focus on price and costs alone. Any system must focus on quality and health outcomes – regardless of the reform pathway taken. The AMA would like to see this reform process lead to an improved evidence base through the better funding of additional registries and dissemination of this information. The current joint replacement registries in operation here and overseas demonstrate that when you provide information to medical practitioners this will change their practice.

The AMA is deeply disappointed with the consultation process to date. There has not been significant clinical input in this process. The AMA (nor any of the other medical professional groups) was not at the table for the work of the Prostheses List Reform Governance Group (or its subcommittees). For such significant reforms, a hurried paper put out for consultation across the Christmas holiday period is profoundly inadequate.

The AMA is committed to ensuring Australia has a strong and healthy private health sector. We have participated with all Government reforms in a responsible and meaningful way. We stand ready to work with all stakeholders on the next body of work that must happen to bring about the quality reform of the Prostheses List.

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