AOA SUBMISSION

Consultation paper: Options for reforms and improvements to the Prostheses List

15 February 2021

AUSTRALIAN ORTHOPAEDIC ASSOCIATION

Introduction

The Australian Orthopaedic Association welcomes the opportunity to submit a response regarding the Consultation paper: Options for reforms and improvements to the Prostheses List.

The Australian Orthopaedic Association (AOA) is the peak professional body for orthopaedic surgeons in Australia. AOA provides high quality specialist education, training and continuing professional development. AOA is committed to ensuring the highest possible standard of orthopaedic care and is the leading authority in the provision of orthopaedic information to the community. AOA members have long provided a significant contribution to the Australian government health technology and regulatory processes that relate to orthopaedic prostheses and devices.

AOA's National Joint Replacement Registry (AOANJRR) provides excellent post market surveillance on joint replacement procedures carried out across Australia to ensure ongoing safety and efficacy of the orthopaedic prostheses and devices implanted.

Background

AOA has been involved in the prostheses listing processes and the Prostheses List since 2002. The Protheses List was originally developed at the request of the private health insurance industry for the purpose of capping costs of prostheses. It was thought this would be an effective tool in reducing prostheses expenditure for health insurers and thereby prevent PHI premium increases for consumers.

In 2004 the Prostheses List had few subgroups; there was no benchmark pricing and the utilization of prostheses had increased, as had the cost of the individual prosthesis on the list. The cost to the private health insurance industry had escalated to levels considered to be both unsustainable and uncontained.

At this time there were in excess of 8000 medical devices on the Prostheses List requiring classification, subgrouping and pricing. A number of AOA members played a significant role in assisting with refining and benchmarking reimbursement levels for orthopaedic devices. They assisted in establishing a more accurate descriptor system by way of utilising additional subgroups/suffixes and developing a Superior Clinical Performance (SCP) suffix for those prostheses which met stringent clinical performance criteria.

Although reimbursement levels were contained with this process the number of devices on the ARTG and ultimately on the Prostheses List burgeoned with the result that there are now almost 11,000 prostheses list within Part A. This was coupled with an increase in utilisation levels once more resulting a relatively unsustainable system.

AOA Experience with Prostheses List

AOA members have been involved with the Prostheses List over a number of years as active members of the Prostheses and Devices Committee (PDC), the Prostheses Listing Advisory Committee (PLAC), a number of Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (POCE). AOA through its AOA members and the

AOANJRR have provided significant advice, data and clinical evidence regarding the listing of orthopaedic prostheses.

It is acknowledged that orthopaedic surgeons have the appropriate training and knowledge of the patient, the condition being treated, the prosthesis, and the service providers (hospital and prosthesis sponsor) to make the choice on what prosthesis to use in a procedure, and in what setting.

Ethically, surgeons declare conflicts of interest and are required to inform the patient and hospital of these. It is illegal for the clinician to receive payment or other direct financial benefit, discount or rebate for use of a prosthesis. This is in contradistinction to the facility operator and health insurer.

It is a little disappointing therefore, that AOA was not included in the initial stakeholder consultation, despite being the least conflicted.

The incorporation of clinical input in the current system through the CAGs and the POCE has recently become flawed due to the stringent application of the Department's Conflicts of Interest (COI) policy. The CAGs and POCE require clinicians with direct relevant recent clinical experience, who are practicing surgeons who have performed large numbers of the procedures being considered within the last 5 years, and must include surgeon innovators who have an understanding of the processes involved in developing and introducing new technologies.

AOA believes conflicts of interest should be declared and appropriately managed as they were in the past and should not be an exclusion for participation in the process.

Consideration of options

Option 1

AOA has considered ***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)*** but does not support this option.

AOA is fundamentally opposed to the introduction of DRGs in any form into the private hospital system. The utilisation of DRGs into a private system, despite it being recommended for the prosthesis component only at this stage, will not always provide the best outcome for the patient and in certain circumstances will not prevent out of pocket expenses for the patient.

Unlike pharmaceuticals, a 'one size fits all' approach cannot be taken to implanted prostheses due to a considerable number of individual patient-related variables which are not present in the prescription or administration of pharmaceuticals.

Option 1, however has been considered carefully and AOA believes it is not feasible for the following reasons:

1. It excludes clinicians in the decision-making process as to what prostheses will be available to be utilised for their patients thereby providing uncertainty around joint replacement surgery outcomes.
2. Evidence demonstrates that the orthopaedic profession has been proactive in making data on usage and the outcomes of hip, knee, shoulder, ankle and

spinal replacement prostheses more accessible and transparent. The AOANJRR has been collecting data on implant survivorship for in excess of 20 years and has provided this information to surgeons, government and hospital operators. This has resulted in modifications in the usage of implants with increased usage of the most reliable and elimination from the marketplace of the least reliable. With the implementation of Option 1 the IPHA and Private Hospitals would be the decision makers regarding what prostheses would be available for surgeons to implant.

3. In spinal surgery, as an example of limitation of the surgeon's choice, it will be impossible to reconcile the limited number of DRGs with the diversity of what surgery spine surgeons actually perform. At present screws are re-imbursed $1200 in private and about $700 in public. Whether $1200 or $700, the variation in prosthesis cost between the very complex and just ordinary complex far outweighs bed stay costs and surgeons' fees.

4. The inevitable consequence of adopting a model based of spine DRGs based on median payment will be that private hospitals will no longer see spine surgery as a viable model and either cease undertaking this surgery altogether or at the very least will either refuse to do or (at best) ration complex spine procedures (or any complex surgery). As the complexity of the surgery increases, the relative proportion related to prosthesis costs increases. The private hospitals are therefore dependant on a sophisticated method of reimbursement consistent with cost (whether $700 or $1200 per screw). Without it, complex spine surgery in the private sector will disappear.

5. The option relies on the negotiation skills and fiscal backing of the private hospital which will ultimately create differing prices for prostheses, which is one of the identified issues within the report. Larger hospitals will be able to negotiate lower prices based on higher utilisation thus disadvantaging smaller hospitals.

6. The option states: *For most medical devices used in medical procedures, once TGA approved, the device could be used by clinicians and hospitals without further assessment, with DRG defined benefits payable.* This is not and has never been an option that orthopaedic surgeons have ever considered safe for their patients. AOA has in the past provided the Department with a discussion paper which clearly outlines a way forward for an expedited process for new orthopaedic devices to be introduced into Australia. AOA believes the way forward as previously presented is in fact, the process which provides the patient with the safest access to new prostheses. This process involves controlled trials of new devices implemented with AOANJRR oversight.

7. *IHPA would monitor patterns of use (utilisation and expenditure) and could undertake post market reviews (with or without the involvement of MSAC) if there were identified concerns. TGA would retain its responsibility for managing safety concerns.* The AOANJRR, which is funded by the Australian Government, collects joint replacement prostheses utlisation and performance data which is already available to both the Department and TGA. Until recently TGA had a system and processes for reviewing joint prostheses with a higher than anticipated revision rate. AOA would recommend that clinicians in the

specific craft group must be the reviewers of patient related issues with prostheses.

8. AOA believes that the introduction of DRG based reimbursement levels for prostheses on the Prostheses List will have significant unintended consequences for all stakeholders (including consumers) apart from the PHI. Some of those unintended consequences will have repercussions within the public health system impacting on public waiting lists and service provision.
9. One area in which the DRG system becomes problematic is the multiple but variable device use within procedures. There is mixing and matching of prostheses from companies in the same procedure (i.e.: different acetabular, femoral and accessory components) and the use of only some or all potential hip or knee components in revision surgery. This prosthesis use variability means that it is necessary to individually list and price the individual devices used in Arthroplasty and potentially any procedure which involves multiple device use i.e: there cannot be bundling of these devices. The Prostheses List addresses this and in a DRG system a similar prostheses list with individual pricing will still need to be used.
10. A further issue to consider with a DRG system is that there will still be a need to have a system to assess the evidence for use of individual devices. The current Prostheses List evidence requirements have been carefully determined through years of experience with respect to device performance. Although more rigorous than TGA requirements they are supported by industry and have resulted in a major reduction in devices that have been introduced into the Australian market that are eventually identified as have a less than satisfactory outcome. A similar evidence-based requirement will need to be continued no matter what option is used otherwise there will be a significant risk of a higher number of less satisfactory devices coming onto the market. The Protheses List already has this mechanism in place and with further enhancements could be made much better.
11. As outlined in Point 3 above. Within a newly established DRG funding model care would need to be taken to ensure that complex devices are appropriately reimbursed. This is necessary to ensure that more complex procedures are not moved into the Public hospital system with the inevitable cost shift to government. The current PL addresses this issue.

Option 2

AOA has considered **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** and considers this option to be the only viable option.

The Prostheses List has served the community well in the past but in recent years due to a number of issues has seen the Prostheses List processes and support mechanisms become less effective. If current deficiencies in the Protheses List are addressed then it is likely to serve the Australian community well for many years to come.

As previously mentioned, AOA believes the Prostheses List has been successful in containing costs but some issues with the management of List have become evident to AOA such as:

- The lack of a review process and timetable for prostheses listed ie: an audit process. The Prostheses List was never envisaged to become a static list with no review process for items listed. The Department and AOA commenced such a review for orthopaedic prostheses, reviewing each prosthesis with the individual sponsors to ensure the description was correct, it was grouped correctly. Present at these meetings were clinicians, a departmental representative and a representative of the PDNG to assess the reimbursement level. This process then enabled the introduction of benchmarked group benefit levels for orthopaedic prostheses;
- The change that allowed 'non-prostheses' to be included on the Protheses List within the general miscellaneous category;
- The decision to strongly align prostheses benefits setting and clinical assessment processes with that used by PBAC for pharmaceuticals when all evidence suggests this is not a suitable comparator. Prostheses may not be generic whereas one brand of a pharmaceutical chemical compound is identical to another brand. A generic description of a femoral component of a hip replacement translates to being far from identical between manufacturers. This is particularly important when considering evidence requirements for devices;
- The exclusion of surgeons with perceived COI from the assessment processes rather than managing those conflicts in the context of the experience and knowledge they bring to the process;
- The misalignment between TGA processes and CAGs/PLAC processes. AOA has long championed the better alignment between these two bodies whist acknowledging their differences. It is a fact that TGA does not have the resources to undertake clinically based reviews of documentation presented to them for the inclusion of new prostheses on the ARTG. Greater coordination of the two processes would create a better outcome for stakeholders including consumers as it will provide TGA with ready access to clinicians with high quality specialist expertise and considerable experience in medical device evaluation;
- One of the major problems with the current Prostheses List is that there is no mechanism to take things off the List. This is something that the CAG clinicians have long complained about. Clinicians have recommended and supported simplification and streamlining of the prosthesis grouping schemes. The HPCAG and the KPCAG have previously coordinated and made recommendations on this a number of years ago that have not been acted on or implemented by PLAC.
- Clinicians have not had a role in developing relative pricing models
- It was always intended from when the Protheses List was first introduced that pricing would eventually reflect performance. The mechanisms to do this particularly with joint replacement prostheses have been available for many years, however the Department has never moved to this approach. Current

comparative reimbursement levels are based on pre-Prostheses List levels and technical aspects of a device rather than its performance. Clinicians can provide quality advice and evidence to support an outcomes-based approach to funding.

- Since the removal of negotiators (PDNG) there has been no mechanism in the Prostheses List to negotiate on pricing and the ability to impact both base and comparative price has been further hampered by the failure to formally include clinicians in this process.

Reform principles

The principles guiding reform, from the clinician's perspective, are:

- Maintaining clinician/patient choice, acknowledging that there may be more than one prosthesis that satisfactorily performs in the individual's particular condition and anatomy, but the quality of the outcome is influenced also by the surgeon's knowledge and skill, the facility and the clinical support and service from the sponsor;
- Maintaining the affordability of PHI. The majority of prostheses in Australia are implanted in the private system;
- No patient out of pocket expenses for prostheses. It is accepted that out of pocket costs are a disincentive to maintaining PHI. The government and health funds have underfunded MBS payments, not indexing the services appropriately over the last 27 years, with the net result being the development of significant gaps and out of pocket costs. If applied to prostheses, this method of funding would further compromise the viability of PHI;
- Simplification and reform of the Prostheses List is required as the large number of groups, subgroups, billing codes and the system of listing and modification has a large number of unintended consequences and is not serving the community well.
- The cost of prostheses should be similar in private and public hospital settings. This should be transparent. The public health sector has negotiated lower prices for implants independent of the private sector. This has had consequences that have not been explored. In order to maintain business and usage with clinicians in private, implant sponsors have needed to ensure the implants are available in the clinician's public hospital, even though this is not the largest proportion of their implant business. As a result of public hospital bargaining for lower prices, the supplier/sponsor is tempted to cross subsidize the lower public hospital revenue, in order to maintain volume in the private sector;
- The reformed system of prosthesis funding should still enable access for Australian patients to innovations that are proven to improve their outcomes and not be an unreasonable barrier to new technology;
- Part B: Human Tissue. These prostheses form an important part of patient care. In orthopaedic surgery, musculoskeletal tissue implant usage is common. Australia has a safe supply of locally procured and processed tissue.

The Australian Tissue Banks, with one exception, are not for profit. Eliminating Part B could result in the demise of several Australian Tissue Banks. Wider consultation with this industry is required.

Responses to specific questions

What, if any, general use products should continue to be funded though the PL and why?

AOA assumes this refers to the general use products in orthopaedics such as sutures etc. However, the inclusion of screws, plates, nails, anchors etc are also going to come under this category and as such there are currently multiple billing codes assigned to those items. This is due to the expansion of the ARTG codes into suffixes etc which then allows the use of multiple billing codes to occur. Unless the changes alter the product and its subsequent potential clinical outcome then a new application has to be made. Much of the SOCAGs activities are centred around these issues. It is unknown how to regulate efficiently regarding these prostheses. The billing of individual screws, bolts, plate etc is also driven by the ACORN Standard that anything implanted needs to be recorded on the patient's operation notes and the Operating Room count sheets. The implantation of a 6-hole locking plate with screws should be simple but if you insert 6 cortical screws or 6 locking screws or a combination of how is a single billing code going to apply?

Should there be an "exceptional circumstances" list (akin to the current Part C)? If so, what types of products should be listed and why?

In orthopaedics this may apply to tumour surgery and difficult reconstructions. If an efficient system was provided from a time frame point of view then regulation would be through an application form but this could be tedious and most likely result in increased paperwork.

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?

AOA agrees that there should not be a difference between public and private pricing of implants. If the gap is reduced (and it should be) then the benefit of this needs to be passed onto patients through a reduction in PHI premiums. AOAs concern is that where control is given to a third party the profits of the health funds will always outrank any benefit to the patient. The document does state that this in no way impacts clinical care and MBS services but that may well come over time.

Should the public/private gap be closed completely or instead allow for relativity that favours the private sector? If so why?

This gap needs to be close or non-existent for the reasons above. It's the same operation done by the same surgeon for the same reason whether its public or private system.

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?

There are differences in patient population that can both adversely and beneficially impact the outcomes of a procedures involving the use of devices. In addition, differences in access to health care can also impact these assessments. If patient groups from both sectors are matched in comparable groups, the AOANJRR has previously established that the outcome for procedures using the same device perform are similar/equivalent.

Choice is limited in a number of public hospitals by tender arrangements which involve lower prices for prostheses when the cost is negotiated on bulk usage and involve a restricted range of protheses. Therefore, to use a different 'off tender' prosthesis an application with clinical justifications must be made to the hospital administrators. However, as stated previously not all prostheses are the same and there are significant variations. Therefore, if a particular prosthesis is in used the private system it should be available for use it in public and vice versa.

How should concerns about maintaining choice be addressed?

See above

What safeguards should be adopted to prevent patients being exposed to out-of-pocket expenses for prostheses?

The issue is the lack of transparency of negotiations between the private hospitals and private health insurers and the negotiated prostheses prices. A mechanism to increase the transparency in these negotiations should prevent out of pockets for patients.

What market distortions would be continued or created by this proposal and how can they be addressed?

Option 1 is likely to lead to averaging and potentially loss leading. Price setting and transparency in process is recommended. The key stakeholders should be involved.

What advantages or disadvantages does option two have over option one?

The execution risk of moving to option 1 has not been assessed and requires deeper review. Option 2 carries lower execution risk.

With with PL there is a system that is established which is understood and problems have been identified which can be addressed and by doing so build on a long experience. The first option moves into the unknown with significant associated risks.

What groups structure should be used and why? Examples include grouping by episode of care, procedure or device?

With orthopaedics it needs to be by device because of the variable on potentially high number of devices used in a single procedure and the issue of using devices from more than one company in a procedure.

Any episode of care grouping will still need to be extensive. For example, a simple varus TKR is a different surgery to a severe valgus knee requiring a significant level of constraint versus a knee with substantial bone loss post trauma requiring wedges, stems etc. It is therefore evident that there is no way that a simple DRG classification of primary total knee replacement is going to be workable.

Would it be possible to use IHPA's DRG grouping structure as part of reforming the PL under this option?

AOA is not familiar with IHPA's DRG grouping structure and has not been able to find this following a search so is unable to comment. DRGs in general do not have the required flexibility, nor are they sufficiently nuanced to account for all levels of complexity routinely encountered in orthopaedics.

As stated previously a one size fits all approach is not consistent with good outcomes, particularly in orthopaedic surgery.

If benefits are set through commercial tenders (for existing products and categories), how frequently should those tenders occur?

Tenders can result in price undercutting with resultant poor quality cheaper products. Any tender process would have to be regulated and subject to scrutiny and once again who is going to regulate this?

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?

AOA does not believe the Australian system can rely on comparison pricing with other countries. Some countries have low levels or private health, others very high. You could use similar countries and economic models as a guide.

It is AOA's position that there should be no difference between prostheses costs in the public and private sectors.

How should compliance be supported to ensure companies accurately identify referenced prices?

This would need to be regulated by an independent body. AOA would be prepared to offer guidance and advice on an approach that might work best in the circumstances.

In conclusion

AOA has been involved in discussions with all stakeholders and there is general agreement that the prostheses benefit levels need to be better aligned with those paid in the public hospital system. It is hard to understand why when there is agreement between stakeholders, the Department would be strongly in favour of disbanding a process that has been proven to work effectively when managed, and implement a system that removes the ability of a surgeon to choose the prostheses which will produce the best outcomes for their individual patients.

AOA is perplexed about this review process as the department involved in managing the Protheses List is in effect assessing itself and making recommendations about how things should be managed in the future. The review is clearly not independent, there was no clinician involvement, although clinicians are a major stakeholder in the process, and the agenda is seen to be driven by a very small number of individuals within the department.

AOA believes that the process is flawed and this increases the likelihood of inappropriate recommendations.

AOA believes that it is not so much the system that is at fault but how it has been managed. This is supported by AOA clinicians who are involved as member of four CAGs, particularly in recent years where the management has been somewhat disjointed, and has lacked continuity in its key leadership personnel.

It appears that other stakeholders (other than the Department) are happy to keep the PL after it is modified to address identified deficiencies, so as to better meet stakeholder needs. More transparency and accountability are also required. The Department has suggested that it will be too expensive. Again, this is not an independent assessment and AOA is not sure that there is any justification for this conclusion.

AOA has had discussions with all stakeholders and there is general agreement that benefit levels need to be better aligned with those prices paid in the public hospital system. It is hard to understand why when there is agreement between stakeholders the Department would be strongly in favour of disbanding a process that has worked and will continue to work after some refinement.

Again, AOA is not in favour of disbanding the Prostheses List and is keen to provide any assistance to the Department and other stakeholders to review, modify and to enhance the current system.

Thank you.

Michael Gillespie

AOA President