



# **Prostheses List Reform – Mixed Benefit**

## Groups

March 2023

#### Contact:

Ben Harris – Director Policy and Research 0418 110 863 ben.harris@pha.org.au

## 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 14.4 million Australians.

### Introduction

Private Healthcare Australia welcomes the regrouping of the Prostheses List to ensure that items with similar function are grouped together, that the list is simplified, and the other overriding principles and objectives are met.

However, the government's approach to repricing of these groups has resulted in a poor policy outcome for consumers.

The Memorandum of Understanding between the previous Minster and the multinational device companies (the MoU) included a clause that consumers should not receive any financial benefit from regrouping, with a clause specifying that revenue to device companies should remain approximately the same from this process.

The proposed structure elevates this clause of the MoU above the clause that requires price cuts for consumers. There is no public benefit in this decision, and significant benefit for multinational device companies.

It is unacceptable that the prices of more than 4000 items will increase – particularly when most of the price increases are for low cost of production, generic items, in plentiful supply and with multiple providers in the market. This is not what consumers were promised by the reform process, and does not serve the public interest.

This is a missed opportunity for meaningful reform. Implementing a new grouping structure with a pricing structure using the principles and objectives outlined in the Hereco report would ensure consumers receive the best quality devices and reduce costs for consumers, simplify the list and remove several of the distortions of the current PL.

Under the current plan, the excellent work done by the Department of Health, Hereco and the Clinical Reference Advisory Group will be compromised, with:

- significant unjustified price increases for over 4300 items,
- items with similar clinical function having different prices,
- a failure to adhere to HTA principles, with demonstrably poor performing items being granted higher benefits,
- removal of lower priced items in several categories, which will be inflationary and impact on state and territory procurement,
- significant market distortion, which may lead to suboptimal patient outcomes, and
- previous poor decisions are baked into the current list, making the task of future governments more difficult.

The losers will be consumers, who will miss out on reduced premiums and higher quality medical devices.

PHA's submission will be in two parts. First, we will note the distortions caused by the government choosing to implement one part of the MoU which suits the commercial interests of device companies, while compromising on the part of the MoU that reduces prices to consumers.

Second, we will provide broad commentary on the groupings, with more detail on individual groups to involve discussion with the department and possible supplementary submission. Overall, the reasoning is sound, and the structure logical. However, there are clear anomalies, and with over 7000 items subject to manual adjustment, some possible errors or oversights.

## Pricing

Almost 10,000 items are be regrouped. According to the draft proposed regrouping list circulated by the department:

- 3621 items reduce in price
- 1927 items stay the same price
- 4385 items increase in price

Thus, for around 40% of the items on the Prostheses List, the previous government's promise - that PL prices will be brought down closer to in line with public reference prices – will not be honoured.

There is a fundamental contradiction between the clauses in the MoU that result in consumers achieving lower prices through movement towards the public reference price, and device companies not being penalised through regrouping. The results of this exercise appear to be consumers lose out to the interests of multinational device companies – while noting the department's policy intent that the net effect on expenditure in the short term should be around zero. The department's work assumes that changed incentives will not result in changed behaviour; theory and history suggest that changes in behaviour will occur. This introduces significant risk to payors, and if sponsors do change their product offering to take advantage of overpricing, the result will be upwards pressure on premiums.

The policy decision that one part of the MoU supersedes another, to the advantage of suppliers rather than consumers, is fundamentally flawed and PHA urges reconsideration.

Consumers and the payors that represent them were promised that the very high prices on the PL would be slowly reduced over time to the public reference price, less a 7-20% surcharge to be paid by private patients (for reasons yet to be explained by government).

However, the department is now proposing that more than 4300 items increase in price. In many cases, the price of items is increasing significantly while already much higher than the public reference price. The number of items that will be many multiples of the public reference price will grow significantly. For example, it is particularly problematic to see bare metal stents increase in price from \$458 to \$1396 when the estimated public reference price is \$211.

There is no public benefit in this decision, and we ask that government ensure that price cuts promised are delivered – with exceptions possible where there is a compelling public interest case that consumers should pay more.

PHA recommends that:

- The Australian Government honours the promises made to consumers to reduce prices of medical devices, including no prices increases
- prices in the new groups are set to the lowest price as the default position, having reference to:
  - o utilisation of the group (i.e., remove low-volume outliers)
  - the public reference price, where it is different to the PL price and thus may reflect competitive pressures
  - $\circ$  the pattern of utilisation in the public sector (where available)
  - the number of suppliers in the product category, as more suppliers means that the benefits of competition should be available to consumers
  - o quality and safety data (where available)
- The Australian Government consider the effect of removing low priced items on state and territory governments.

#### Repricing outside the scope of MoU

Increasing the price of over 4300 items breaches the provisions of clause 2.1.2 of the MoU, which mandates price decreases so that PL prices are closer to the public reference price.

Consumers were promised the gap between PL prices and public prices would decrease by 40% in the first year, and 20% in each of the next two years. This commitment is not being honoured.

As well as breaking this commitment on more than 4300 occasions, the commitment will also not be honoured in aggregate - several hundred items will have their price increased so that the gap between the initial PL price and the public reference price is greater than 40% or 60% in the relevant periods.

#### Outliers: items more than doubling in price

The government's formulation results in 157 items more than doubling in price. In some cases, pricing is increasing dramatically.

Most of these devices are generic, off-patent items that are cheap to produce, with many suppliers in the market. There is no justification for these items to increase in price, let alone double in price.

#### Five items will be priced 10-32 times higher:

Billing Code	Sponsor	Product Name	Description	1 July 2023 Adjusted Benefit amount	Single Benefit Value	Benefit change (\$)	Benefit change (%)
			M6 Screw used to bolt the LUMiC Cup and	\$336	\$4,344		
LH696	Lifehealthcare Pty Ltd	MUTARS LUMiC Screw, M6	LUMiC Stem together			\$4,008	1192.9%
	Johnson & Johnson	TeleFix Spinal	Posterior	\$144	\$2,039	+ .,	
SY304	Medical Pty Ltd	System	Locking Screw			\$1,895	1316.0%
		Howmedica Modular		\$200	\$4,387		
	Stryker Australia	Resection	Wedge -				
HW202	Pty Ltd	System Howmedica Modular	Vitallium	\$206	\$4,387	\$4,187	2093.5%
	Stryker Australia	Resection	Plug Screw Axis -				
HW200	Pty Ltd	System MUTARS	Vitallium MUTARS	\$57	\$1,908	\$4,181	2029.6%
	Lifehealthcare Pty	Cancellous	Cancellous				
LH675	Ltd	Screws	Screws			\$1,851	3247.4%

Most of the items above are simple screws. There is no public interest justification in increasing the price of these items by such a large margin – or indeed any margin. Each of these products are supplied to consumers at the current pricing.

In two instances, more than one device is used per procedure (H200 and LH675). Where the Stryker system is used, the cost to the consumer for the same procedure will now increase by over \$8000.

#### Outliers: items more than double the public reference price

PHA has estimated the public reference price from the IHACPA work, although any items which had a PL price no more than 7% higher than the public reference price were not disclosed- approximately 12% of the total number of items. Thus any estimates based on public reference price has the potential to understate the scope of the problem.

Under the Department's proposed formulae, 258 items will cost consumers in the private system more than double the price for the same items in the public system. Currently, the are only 60 such devices.

The government's stated intention to bring private pricing slowly back to par with public pricing is inconsistent with a four-fold increase in the number of items where private patients pay double the public price.

Many of the items which will be more than double the public price are simple, off-patent generic items where there are many suppliers in the market, such as screws and staples.

#### Penalising quality care

One key objective of medical device pricing should be to encourage the use of safe and effective devices. The current PL has several examples of encouraging poor quality care. Hip stems offer a clear example. The work of Hereco, informed by the NJRR and clinical advisers, showed HA coating added no value to clinical outcomes despite it traditionally having a \$400 premium (non-coated stems have better results at lower prices). With higher prices, most of the sales in hip surgery were

in the more expensive HA coated stems. The intent of Hereco was to remove the premium for HA as it delivered no value. However, by adopting the MoU provisions, the prices for uncoated stems have increased markedly. This penalises consumers, rewards poor quality care, and increases the substantial differences between public and private prices, and Australian and international prices, for the most effective devices.

Locking in higher prices based on the use of lower quality items is poor public policy and does not serve the public interest.

Where there are clear quality data, such as the NJRR, it would be simple to set the price based on a basket of the most efficient items in the group, and then reference this basket against the public reference prices, then use this price for the group.

This will ensure the sponsors of high quality products are not penalised, provide a reasonable benchmark price for consumers (until the government considers international reference pricing), and improve quality care for consumers.

#### Pricing to a weighted average rather than the lowest price

The department has sought to use a weighted average price to address the policy aims set by the previous government through the MoU. This ensures that with no change in behaviour, consumers and sponsors end up in a net zero position. However, changing the incentives in the system means that consumers are likely to be worse off.

Bad policy remains bad policy regardless of how well it is implemented. It is clear that consumers are best served by the lowest price in a commoditised market, as long that price is high enough to ensure supply is maintained. For thousands of items, prices will increase under this proposal.

Part of the stated intent for medical device reform was to reprice generic devices to ensure greater public value, rather than allowing multinational device companies to keep supernormal profits. Many countries across the world have struggled to implement medical device pricing reforms, but none have actually gone backwards by requiring consumers to pay more for generic devices.

Australia will be going backwards. For example, generic foot plates such as SY807 (which have a public reference price of \$353) will increase in price from \$619 to \$731 – more than double the public price, which are in turn higher than the international prices available to PHA.

Where items have low costs of production, many suppliers, are old technology and off patent, moving prices up instead of down simply penalises consumers. For many orthopaedic items such as washers, plates and screws, simple economic theory suggests that overall public benefit is best served by lower prices. These items are already overpriced compared to international benchmarks, and this process will exacerbate these differences.

If the government is not prepared to use the lowest price in the group, then to ensure a fair comparison with the public reference price, usage data from the public system should be used to set the PL price. Many of the most expensive devices are rarely used in the public system, who place a higher value on consumer/taxpayer cost. Ensuring that the PL prices are set with reference to public sector usage will help ensure that a reasonable basket of items is used for benchmarking, rather than current usage which is distorted by the current incentives.

#### Removing low-cost items will result in inflationary pressures

Many items which are the lowest cost in their category will have significant price rises. Examples include intraocular lenses (the cheapest moving from \$126 to \$253), washers (\$35 to \$55) and screws (\$109 to \$355). This means that all new items in these categories will automatically be granted the higher price. Over time, this will be inflationary, as consumers cannot benefit from lower-cost devices which undertake the same function being added to the PL. Recently, the Department has assessed a greater proportion of items as attracting lower benefits – these new generic items will now receive higher benefits.

Sponsors will now be able to receive mid-range benefits regardless of the quality of the item. If the argument is this doesn't matter as all the items are of suitable quality, then the logical response is that the lower prices would provide higher consumer benefit.

Medical device companies will be closely analysing these changes to see how they can move individual product codes between billing codes to maximise revenue. An example of how this might work is shown in the following groupings: 06.02.01.03 - Hand and Foot which will rebate for \$273, 06.02.01.04 - Hand and Foot (Plates) which will rebate for \$1083 and 06.02.01.05 - Hand and Foot (Plates) which will rebate for \$731. Sponsors will review their products in all three of these groups to see how they can be moved from the lower to the higher benefit. It will require skill, diligence and transparency to ensure that the new grouping will not be inflationary with sponsors seeking to regroup their items.

#### Removing low-cost items will penalise state and territory governments

State and territory governments will be disadvantaged by the repricing of the PL, as they will no longer be able to use the cheapest devices as comparators, as these devices will have significant price increases. As new items will get higher benefits through the PL, negotiations with state governments will be based on high prices on the PL rather than a range of prices.

All Australian state tenders for medical devices in recent years have followed a similar format to or relied heavily on the Prostheses List. Each state health department does their tenders differently, but all have a clause that states that no item can be priced higher than the current PL benefit for the life of the tender. With the costs of healthcare rising significantly and state governments looking for savings, the revised PL regrouping may have the opposite or neutral effect.

Many device companies will be doing a detailed analysis of every product code to see where they can maximise prices to not only keep them static, but will be looking to raise those items that will now be well below PL prices up to match the new benefits, especially on those items that have seen significant increases in their benefit as a result of the restructure and are high use items. This will see prices on tenders either remain static, resulting in no savings by the states, or, more likely, will see an overall increase in spend as companies look to drive up the cost of high usage items to the match the increases to drive up revenue.

#### Making the next reform process more difficult

Locking in higher prices for generic items will make the task of any government wanting to make serious efforts to reduce pricing for consumer more difficult. Australians have seen a unilateral deal between government and the MTAA in 2017 fail to produce savings for consumers. A second unilateral deal signed in 2022 included a range of worthwhile reforms, but still is heavily weighted against consumers on pricing. These deals, which have excluded consumers and payors, have not made significant inroads into supernormal profits for multinational companies, meaning Australian consumers are paying more than they should.

Previous Australian Governments have not chosen significant or rapid reform, such as rapid price reductions, using international benchmarks, or using modern funding techniques such as diagnostic reference groups. Removing lower cost items changes the benchmark, and will make meaningful reform more difficult in future.

One way to address this concern is greater transparency – publishing what the prices would have been in the absence of the MoU, based on health economic principles, lowest possible cost to the consumer, and other factors. These prices could then be used in the evaluation process to determine if the public value has been served, and inform governments now and into the future.

## Grouping – initial response

Overall, the groupings are sound and Hereco should be proud of its efforts. However, as over 7000 items have been manually adjusted with the creation of additional groupings, the original intent of many of Hereco's objectives have been compromised.

PHA will engage with the Department of Health to discuss concerns about individual groups. Most of these concerns arise from the compromises made to fit the poor policy decision of government to ensure that one part of the MoU, suiting device companies, supersedes the price cuts promised to consumers.

As PHA works through the groupings, some immediate issues have been uncovered:

- Sub-groups with the same name but different benefits
  - o 06.02.02.10 Ankle Arthordesis (Plates)
  - o 06.02.02.11 Ankle Arthordesis (Plates)
  - o 06.02.02.21 Hand and Foot (Plates, Periarticular anatomic)
  - o 06.02.02.22 Hand and Foot (Plates, Periarticular anatomic)
- Similar sub-groups in different categories and the same benefits
  - o 06.01.05.02 Fracture Nails (Arthrodesis ankle)
  - o 14.01.03.05 Ankle Arthrodesis Nails (Arthrodesis ankle)
- Subgroups with similar items and different benefits
  - o The same screws with different prices in different groups
- Subgroups that should be removed or have many items removed:
  - 04.04.06.02 Intraoperative accessories includes many items which are surgical tools. It's time that government acknowledged the mistake of allowing a \$152 screwdriver or wrench to be split out from the main PL item and remove these items, as per the Hereco recommendations.
  - Knee screws under 12.05.02.01 Stems. Items BB404, LO159, EX030, BV049, LH593 and DP155 should be removed as they are components of the main item. The

Hereco recommendations suggest they should be rolled up, and as most devices don't bill these screws separately, they should not attract a premium.

There are a number of points where clarification or explanation is requested:

- Knee revision components have been retained, with many items in the category used predominantly for primary procedures
  - Will these devices include conditions on listing, as recommended by PHA since 2019?
- 13.01.01.01 Pedicle Screws including connecting components to rods, cables and/or staples
  - Our data suggest that the vast majority of usage previously has been in the set screw group 13.02.01 Nut/Set Screw/Locking Screw (38,244 utilisations compared with 3,209 for the higher priced benefit that is locking caps) which currently rebates currently at \$148. Yet the majority of devices receive a \$93 lift. The result appears to be that a basic 1 level posterior fusion (4x pedicle screws, 4 x set screws, 2 x rods, 2 x PLIF cages) has gone from \$10,762 to \$11,446, despite all the other components taking reductions.
- 13.01.01.04 Plate, Fusion Cage or Spinal Device to Bone
  - The majority of the screws pulled into this group were basic non locking bone screws without any suffix - 13.01.03 – Standard – (4429 v 291) yet the largest part of the group gets a raise of \$8.
    - What is the reasoning here?
- 13.01.04.03 Anterior Cervical Discectomy and Fusion (ACDF) and Anterior lumbar interbody fusion (ALIF) (Interbody, No Integral Fixation)
  - The cervical and thoracolumbar cages have been grouped together, resulting in the cervical cages receiving a significant price increase. This is despite the procedure these cages are used in, Anterior Cervical Discectomy & Fusion (ACDF), being performed at a significantly higher rate than the procedure where thoracolumbar cages are used, Anterior Lumbar Interbody Fusion (ALIF). We recommend that these two groups be split with both seeing significant price reductions.
- 13.01.04.02 Anterior Cervical Discectomy and Fusion (ACDF) and Anterior lumbar interbody fusion (ALIF) (Interbody, Integral Fixation)
  - This sees the same issue as the above, i.e. cervical and thoracolumbar cages have been grouped together, resulting in the cervical cages receiving a significant price increase, despite having a significantly higher usage.
    - do these prices now include the screws and locking caps for each device, as per the latest additions to the PL?
    - Is the intention that the screws and locking caps are no longer claimable with the integral cages?

There will likely be more issues uncovered as this process continues.