



Australian Government
Department of Health

Ministerial Submission – Standard
MS22-000002
Version (1)
Date sent to MO: 14/01/22

To: Minister Hunt

Subject: Prostheses List Reforms – further implementation issues

Critical date: 21 January 2022 – to inform PL reform stakeholders of the way forward

Recommendations:

- | | |
|---|---|
| <p>1. Agree in principle to defer price reductions for prostheses where the public/ private gap is less than or equal to 5% (noting that the gap on most PL items will be reduced by 80% over three years, with the quantum of price reduction in year 4 to be by government at that time and that the proposed 5% threshold would be included in the final private adjustment factor)</p> | <p>1. Agreed/Not agreed/Please discuss</p> |
| <p>2. Agree in principle to the proposed interim arrangement for funding technical support services associated with cardiac implantable electronic devices (CIEDs) by rebalancing price reductions for all cardiac devices</p> | <p>2. Agreed/Not agreed/Please discuss</p> |
| <p>3. Note that subject to your agreement on Recommendation 2, the Department will use the strategy outlined in this submission to commence further negotiations with the relevant stakeholders through the distribution of the draft letter (<u>Attachment A</u>)</p> | <p>3. Noted</p> |
| <p>4. Note that subject to stakeholders supporting these proposals, policy approval will be sought through a further letter to the Prime Minister no later than 31 January 2022.</p> | <p>4. Noted</p> |
| <p>5. Note that the Prime Minister has granted policy authority for the alternative approach and implementation timeline for the staged removal of approximately 400 general use items from the Prostheses List (MS21-001606 and <u>Attachments B</u> and <u>C</u> refer)</p> | <p>5. Noted</p> |

Date: / /

Signature

Media Release required? YES/ NO

Comments:

Contact Officer:	Elizabeth Flynn	First Assistant Secretary (A/g), Technology Assessment and Access Division	Ph: (02) 6289 s22 Mob: s22
Clearance Officer:	Adriana Platona	Deputy Secretary (A/g), Health Resourcing Group	Ph: (02) 6289 s22 Mob: s22

Issues:

1. The Prime Minister approved the staged removal of more than 400 general use items by 1 July 2023 (**Attachments B and C** refer). The Department now seeks your in-principle approval to propose to stakeholders two further variations to implementation arrangements for the Prostheses List (PL) reforms. These are:
 - a. Defer price reductions for prostheses where the public /private gap is less than or equal to 5%; and
 - b. modifying the schedule of price reductions for cardiac devices to address the claim for ongoing funding for technical support services while achieving the overall PL price reductions anticipated for cardiac devices.

The Department will then continue discussions with stakeholders through the attached draft letter (**Attachment A**) and direct negotiations with Medical Technology Association of Australia (MTAA). Should stakeholders support these proposals, policy approval will be sought through a further letter to the Prime Minister.

2. Since the provision of industry data to the Independent Hospital Pricing Authority (IHPA) on 15 November 2021, IHPA has made good progress in identifying the gap between public hospital prices and the prices paid on the PL. This work is on track for the first reduction of the gap of a minimum 40 per cent on 1 July 2022.
3. The data disclosed show that there is considerable variation in the level of gap between classes of devices. For instance, public hospital prices for many high cost cardiac devices are less than half of the PL price (see below). In contrast, for many orthopaedic devices, the price gap is much smaller. It has been previously agreed with MTAA that the final price reduction will take account of any need for a private sector adjustment factor of up to 20% of the public/private gap. However, the MTAA has insisted that the IHPA calculations include this gap right away to protect as many products from price reductions, which is not consistent with the intent of the Government's decision.

As a compromise, the Department and IHPA could propose to MTAA that where the current gap is less than or equal to 5% of the public price, there should be no reduction. The 5% margin was chosen because it has only a very small impact on the overall quantum of price reductions. This proposal can be administered with the condition that the suppliers of these products are required to submit data each year to ensure that the gap does not exceed the 5% threshold. This Ministerial Submission seeks your in-principle approval of this additional element of the reforms, to enable the Department to negotiate with stakeholders.

4. Another key issue requiring resolution under the PL Reforms is the treatment of technical support services for Cardiac Implantable Electronic Devices (CIEDs). Medical device companies assert that the benefit on the PL represents the combined cost of the device and the ongoing technical support, which is necessary to ensure ongoing function for the life of the device. It is acknowledged that these services are necessary, but the appropriate use and reasonable cost has never been defined.
5. The MTAA engaged KPMG to develop a report that estimated the cost of CIED technical support services provided by industry (the KPMG report). Industry has refused to provide information about the actual cost to them of these services asserting that this information is commercially sensitive. Instead they seek to avoid the scheduled minimum 40% price reductions on 1 July 2022 by a sum equivalent to the KPMG calculated annual cost, which for 2022/23 is claimed to be \$103 million.
6. After reviewing the KPMG report and following ongoing consultation with the MTAA Cardiac Forum (the five CIED companies – see background), the Department has found insufficient evidence to support KPMG's costing of cardiac technical support services at \$103 million for the 2022–23 financial year. The report's estimates are inflated and although the CIED companies have acknowledged that many of the estimates of service numbers and costs have weak foundation, they are unwilling to moderate their claim. However, they have agreed to evaluation of the true need for and cost of these services by the Medical Services Advisory Committee (MSAC) with an industry application to MSAC expected in March 2022.
7. Recognising that it is important that industry continue to provide these services while MSAC considers their true value and an appropriate service delivery and financing model, the Department proposes that the schedule of price reductions for cardiac devices be modified to allow time for the MSAC evaluation and achieve a similar quantum of PL savings over 4 years had 40/20/20 reductions been applied to the CIED items. The additional advantage of this approach is that it does not rely on the KPMG estimates. The Department recommends that any proposal to industry to vary the schedule of price reductions should require industry to provide actual service use and cost data to MSAC and IHPA.
8. IHPA's analysis reveals that the public/private price gap for all cardiac devices is very large and price reductions for these devices will be key to achieving overall PL savings. For instance, for the most popular implanted defibrillator the PL benefit is around \$36,500 and the public price is around \$14,500. In addition, the largest aggregated gap observed is for another cardiac category which is also used in much higher volume - cardiac stents which are not CIEDS. For cardiac stents, the 40% reduction from 1 July will realise \$16M in PL savings in year one.
9. Most of the impact for stents will be on the same five CIED companies although there will be small impacts on a small number of other stent companies that don't have CIEDs. (see Sensitivities).
10. To overcome the impasse with the CIED sponsors, the Department proposes a negotiated outcome so that the price reductions for CIEDs are delayed while reductions for cardiac stents are brought forward. It is suggested that the three-year schedule for CIED reductions

be 20/40/20 with cardiac stents reduced by the full 80% in year one. A fallback would be 10/50/20 for CIEDs along with 80% for stents in year one (this option most closely aligns with the MTAA's proposal that the 40/20/20 be applied to the revenue gap minus \$103 million).

11. This Ministerial Submission seeks your in-principle approval of this approach so that the Department can continue negotiations with the relevant stakeholders through the distribution of the draft letter (**Attachment A**). The final details and timing of the letter will be settled with your Office.
12. In addition to the above, approximately 400 general use items have been identified for removal from the PL. As approved by you in December 2021 (MS21-006106 refers) and subsequently approved by the Prime Minister (**Attachment B**), the revised approach and implementation timeline for the staged removal of approximately 400 general use items from the Prostheses List, will now involve:
 - the group of identified general use items (**Attachment C**) as endorsed by the CIRG, being reference priced to public hospital prices with the gap fully closed on 1 March 2022 for eight topical adhesives (skin glues) and 1 July 2022 for all remaining items (this is in lieu of delisting);
 - close monitoring of these items to manage volume control over 12 months;
 - IHPA will develop advice on appropriate bundling arrangements for the identified general use items, which will be provided to insurers and private hospitals to facilitate the negotiation of new funding arrangements before the end of 2022;
 - no new similar items being added to the PL during this time; and
 - implementation of bundling arrangements and removal of these items from the PL on 1 July 2023.
13. This combination of proposals will reduce the anticipated PL savings as outlined below.

Approach	IHPA estimates of PL saving over 4 years	Savings difference from currently approved approach
1. Currently approved approach (N:521-001606) Minimum 40/20/20 reductions applied to all devices from 1 July 2022 and 100% reduction of the gap for the 400 identified general use items on 1 March and 1 July 2022 followed bundling and removal on 1 July 2023 ¹ .	\$45	
2. 1 plus foregoing price reductions for prostheses where the public/private gap is less than or equal to 5% Minimum 40/20/20 reductions applied to all devices excluding those where the public/private gap is less than or equal to 5%		
3. 1 and 2 plus CIEDs Option 1 <ul style="list-style-type: none"> - CIED reductions of 20/40/20 plus cardiac stents reduced by the full 80% in year one; 		
4. 1 and 2 plus CIEDs Option 2 (fallback) <ul style="list-style-type: none"> - CIED reductions of 10/50/20 plus cardiac stents reduced by the full 80% in year one 		

1. This base case includes savings of \$166.4 million over four years estimated for the 100% reduction of the gap for the 400 identified general use items on 1 July 2022 followed by bundling and removal on 1 July 2023.

Background:

CIEDs are pacemakers, internal defibrillators and closed loop recorders. In Australia they are supplied by five overseas-based medical device companies being Medtronic, Abbott, Biotronik, Microport and Boston Scientific.

In 2018/19, PL benefits paid by private health insurers for insertion of 16,683 pacemakers and defibrillators were \$218 million. In addition, these devices were supplied with 14,411 remote monitors for \$22 million. The total PL expenditure was \$240 million. A similar number of CIEDS are provided in the public sector.

Attachments:

- A:** Draft letter to the relevant stakeholders: update on the Protheses List reforms
- B:** Letter from the Prime Minister granted policy authority for the alternative approach and implementation timeline for the staged removal of approximately 400 general use items from the Protheses List
- C:** List of General Use Items proposed for removal from the Protheses List by Group

Election Commitments / Budget Measures:

The PL Reforms were announced as part of the 2021–22 Budget Measure: *Modernising and Improving the Private Health Insurance Protheses List*.

Sensitivities:

If funding of technical support services for CIEDs is removed, MTAA have indicated that there is a risk that companies will withdraw services which would put pressure on the public health system and may risk patient health.

The CIED revised implementation may not be supported by the cardiac companies as it transfers price reductions from one part of their cardiac portfolio to another. However, it will be difficult for them to argue against, given it addresses their stated concern about the need for an interim solution ahead of MSAC evaluation.

Of the five medical device companies who supply CIEDs, four also supply stents (Medtronic, Abbott, Biotronik and Boston Scientific). Other companies who supply cardiac stents are: BioExcel Australia; Cardinal Health Australia Pty Ltd; Intervene Medical Pty Ltd; Pyramed Pty Ltd; and Terumo Australia. These companies will be impacted by the increased reduction for stents.

Insurers have long complained about the high cost of cardiac stents so will see this as a positive measure. The Australian Medical Association (AMA) and cardiologists should be supportive as the status quo regarding services is maintained.

The modified approach to staged removal of general use items is supported by private hospitals and the AMA. MTAA oppose reducing the public/private gap from 1 July 2022 by 100% but also did not provide unconditional support for the delisting of ineligible items. Private health insurers oppose the price reduction approach arguing for removal of the general use devices from March 2022 as planned, on the grounds that previous price reductions applied to PL have proved to be insufficient to resolve structural problems with the PL.

Consultations:

The Department is continuing to undertake numerous consultations with all key stakeholder groups including consumers, the private hospital networks, private health insurance industry, clinicians and medical technology industry.

Cover Page for Ministers' Offices

Minister	Minister Hunt
PDR Number	MS22-000002
Subject	Interim funding arrangements for technical support services associated with Cardiac implantable electronic devices (CIEDs)
Critical Date	21 January 2022
Quality Assurance Check (completed by line area)	s22 [REDACTED]
Contact Officer	Elizabeth Flynn (02) 6289 s22 [REDACTED] s22 [REDACTED]
Clearance Officer	Adriana Platona (02) 6289 s22 [REDACTED] s22 [REDACTED]
Division/Branch	Health Resourcing Technology Assessment & Access/Prostheses Reform Taskforce Branch
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO Comments:

Return to
Dept for:

Redraft ☐

s22

From: DEVELIN, Sam
Sent: Wednesday, 12 January 2022 11:43 AM
To: FLYNN, Elizabeth; Minister Hunt DLO
Cc: s22
Subject: RE: Waiver request - MS22-000002 [SEC=OFFICIAL]

approved thanks

happy new year !

From: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Sent: Wednesday, 12 January 2022 10:40 AM
To: DEVELIN, Sam <Sam.Develin@health.gov.au>; Minister Hunt DLO <s22@health.gov.au>
Cc: s22@health.gov.au; s22@health.gov.au; s22@health.gov.au; s22@health.gov.au
Subject: Waiver request - MS22-000002 [SEC=OFFICIAL]

Hi Sam

I am seeking your approval to a waiver for MS22-000002 which is seeking the Minister's agreement to the CIED strategy we discussed before Christmas with you. We need the Minister to agree before we can discuss some of the elements with stakeholders. The critical date we have assigned is Fri 21 Jan and the Minsub should be in the office today or tomorrow. (I will also text you).

Elizabeth Flynn

Acting First Assistant Secretary

Technology Assessment and Access Division

Australian Government Department of Health
T: 02 6289 s22 1 | s22
E: elizabeth.flynn@health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.



Building a stronger,
healthier country
Yesterday
today and
tomorrow



Australian Government
Department of Health

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Recommendations:

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| <p>1. Agree in principle to defer price reductions for prostheses where the public/ private gap is less than or equal to 5% (noting that the gap on most PL items will be reduced by 80% over three years, with the quantum of price reduction in year 4 to be government at that time and that the proposed 5% threshold would be included in the final private adjustment factor)</p> | <p>1. Agreed in principle with the final % being a matter for consultation and agreement with the MTAA</p> |
| <p>2. Agree in principle to the proposed interim arrangement for funding technical support services associated with cardiac implantable electronic devices (CIEDs) by rebalancing price reductions for all cardiac devices</p> | <p>2. Agreed in principle – please present these <u>options</u> as a pragmatic compromise approach to the MTAA for consideration and not as a final position of government - please finalise a negotiated outcome for the CIED's that is supported by the sector noting that this is an interim solution whilst the industry presents a submission to MSAC</p> |
| <p>3. Note that subject to your agreement on Recommendation 2, the Department will use the strategy outlined in this submission to commence further negotiations with the relevant stakeholders through the distribution of the draft letter (<u>Attachment A</u>)</p> | <p>3. Noted – please finalise these letters as an outcome of further consultation with the industry on 1 and 2 and do not send prior to finalising arrangement with the MTAA</p> |

4. **Note** that subject to stakeholders supporting these proposals, policy approval will be sought through a further letter to the Prime Minister no later than 31 January 2022.

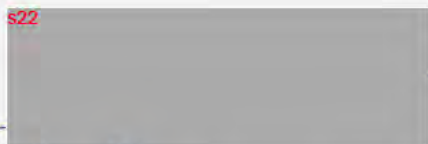
4. **Noted**

5. **Note** that the Prime Minister has granted policy authority for the alternative approach and implementation timeline for the staged removal of approximately 400 general use items from the Prostheses List (MS21-001606 and Attachments B and C refer)

5. **Noted**

Signature

s22



Date: 20/1/2022

Media Release required? YES/ NO

Comments:

Please continue to engage with the sector to finalise an agreed position on these matters by 27 January with a focus on ensuring continuity of service delivery for patients and policy clarity for the sector, noting that there are large disruptions for the sector during the Omicron outbreak including bans on elective surgery.

Contact Officer:	Elizabeth Flynn	First Assistant Secretary (A/g), Technology Assessment and Access Division	Ph: (02) 6289 s22 Mob: s22
Clearance Officer:	Adriana Platona	Deputy Secretary (A/g), Health Resourcing Group	Ph: (02) 6289 s22 Mob: s22