

The policy and politics of reimbursement of medical devices in Australia – Cook Medical perspective

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Outline

- Cook Medical Australia
- How does the current criteria for Prostheses Listing impact us?
 - Standard devices
 - Custom made devices
- Thoughts on benefit setting proposals
 - Public system comparisons
 - International reference pricing

Cook Medical Australia

- Cook is one of the few multi-nationals that manufactures in Australia for both local and international markets.
- Our Brisbane facility serves as Cook Medical's APAC headquarters and employs over 500 people. It has 50 research engineers and laboratory staff committed to creating innovative healthcare treatments.



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Sales in 2016

Local production

- Manufactured more than 13,000 endovascular stent grafts and 920,000 IVF needles – exporting >90% to 64 countries at a value >US\$100 million

Local sales

- >\$A100 million in Australia. Majority of Cook products were imported into Australia from our other manufacturing sites (in USA and Europe)

How does the current criteria for listing effect Cook Medical in Australia?

Legislatively based criteria:

Private Health Insurance Act

- Medicare Benefits Schedule (MBS) number associated with the device
- Product provided as part of hospital treatment

Therapeutic Goods Act and regulations

- **ARTG number**

As per Prostheses List guidelines:

- Surgically implanted or essential to implanting/maintaining an implanted product
- Product needs to be compared to alternative products/ treatments and have at least similar clinical effectiveness and the cost of the product should be relative to its clinical effectiveness

Custom made devices (CMDs)

- Cook manufactures custom made endovascular grafts for patients whose anatomy or disease progression precludes treatment with standard off-the-shelf grafts and who are deemed “unfit” for open surgical repair.
- Under the Therapeutic Goods Act, CMDs are exempt from inclusion on the register. Therefore, they don’t receive an ARTG number but can be lawfully supplied. However, without the ARTG number, they are ineligible for the PL.
- Uncertainty of private health insurance coverage for CMDs
 - Funding is at the discretion of the insurer
 - Securing ex gratia payments from health insurers is administratively burdensome for doctors/hospitals and is anxiety inducing for patients due to the potentially life threatening delay in treatment
 - This is not an issue faced by public patients

Review criteria for listing

- The Prostheses List Advisory Committee (PLAC) Reform Work Plan includes reviewing the criteria for listing. We are hopeful that the issue of CMDs can be considered.

Issues for Consideration	Desired Outcome	Proposed Activities
Review the criteria for listing	<p>Privately insured Australians have access to medical devices that meet their healthcare needs through their private health insurance.</p> <p>Evidence requirements for listing on the Prostheses List are appropriate and defensible.</p>	<ul style="list-style-type: none">• Consider the current definition with other comparable processes internationally and definitions in relevant regulatory arrangements.• Consultation – seek views on any proposed change to the existing definition including impacts and transition requirements.• Refine the criteria, including evidence requirements, publish revised guidelines, and communicate the timelines, transition and implementation arrangements.

Benefit reviews

- The reform work plan also includes targeted benefit reviews.

Issues for Consideration	Desired Outcome	Proposed Activities
Targeted benefits and category review	The Prostheses List lists medical devices that are clinically effective and cost effective.	<ul style="list-style-type: none">• Develop a proposed Prostheses List Category and Benefit Review Framework.• Consultation – seek feedback from sponsors on impacts and transition requirements outlined in the Review Framework.• Refine the Review Framework, publish the process, and communicate the timelines, transition and implementation arrangements.

- The Department of Health recently released their Draft Proposed Approach for these reviews. The will use pricing data from a variety of available sources to inform the level of benefit.

Public vs private sector pricing

- Cook offers the same service to both public and private hospitals in Australia. Therefore, utilizing public price information to adjust Prostheses List benefits seems like a reasonable approach to us.
- However, other suppliers may differ in their service offering, so blunt comparisons may not be appropriate.
- Audit / reporting of Prices to a control body – ok with us.

International reference pricing

- Need to account for the high costs in Australia
 - Wages/benefits are generally higher in Australia. Particularly when super, payroll tax, leave entitlements, fringe benefits tax etc. are factored in
 - High utilities (electricity, water etc.) and facility costs
 - Market size – small population and small hospitals, geographical spread and high service expectations. Smaller markets also have higher product write-offs as the turnover will not be as frequent.
 - Logistics – hospitals expect consignment stock management. Air freight is expensive
 - Regulatory burden – high given size of market (staff cost + fees)
 - Cost of currency fluctuations

International reference pricing

- Health Systems are different
 - Countries where whole cost base is different
 - Reimbursement prices, adjusted for FX movement, mandatory
 - Hospitals can make on margin on reimbursed products
 - No hospital / insurance companies making products in the system
- If they are going forward with international reference pricing, Japan is probably the best model as they recognize high costs in their own system and utilize pricing from 5 comparable countries.
- The supplier needs to submit price information or at least verify accuracy. Often products get mixed up and sometimes analysts do not make fair comparisons (e.g. compare different components of a system). (procedure based pricing)

Conclusion

- Broadly supportive of the Prostheses List as it gives access to devices without out of pocket costs to patients
- As both an Australian manufacturer and importer we welcome the evidence based approach that is currently being discussed
- International reference pricing needs to be considered with caution
- Support balanced reviews of medical costs in Australia, devices are one component