



## **REIMBURSEMENT UNRAVELLED: Australia's schizophrenic device coverage system**



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## REIMBURSEMENT UNRAVELLED: Australia's schizophrenic device coverage system

► By Sarah Griffin

**AUSTRALIA OFFERS PUBLIC MEDICARE INSURANCE** for its entire population of 23 million, but half of Australians also have private healthcare insurance. Sarah Griffin\* explains the many pathways for medical device reimbursement in Australia and untangles a system that is more complicated than the route to regulatory approval

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While Australia generally manages to deliver very good care to most of its citizens most of the time, like any healthcare system, there are inefficiencies, contradictions and inbuilt perverse economic incentives. Medical device reimbursement is no exception.

Device reimbursement in Australia comprises a number of Health Technology Assessment (HTA) processes and agencies, multiple pathways and variable levels of economic and clinical evidence requirements. There exist different and sometimes conflicting requirements between the public and private healthcare systems and there are differences in access to new technologies between the two systems.

Australia is a Commonwealth with six states and two territories each with its own government responsible for running the state public hospital system. The Commonwealth government has responsibility for Medicare, which is the national universal healthcare scheme. Under Medicare, Australian citizens have access to free public hospital care, subsidized pharmaceuticals and a mixture of free and subsidized medical services. The Commonwealth also provides money to the state governments that contributes to the operation of the state public hospital systems.

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A parallel private hospital system exists. This is heavily regulated and doctors are able to access Medicare payments for procedures performed within private hospitals. Nearly half of all Australians opt to have private health insurance which is primarily insurance for hospital admissions. Private health insurance is subsidized by the Commonwealth via a means tested tax rebate. More than half of all elective procedures are performed in private hospitals.

There are three Commonwealth HTA agencies in Australia. These are: the Pharmaceutical Benefits Advisory Committee (PBAC), the Medical Services Advisory Committee (MSAC), and the Prostheses List Advisory Committee (PLAC).

## **PBAC – the Pharmaceutical Benefits Advisory Committee**

Australia pioneered the use of cost-effectiveness in determining whether to publicly subsidize drugs. The PBAC has rigorous standards for both clinical and economic evidence and these have been heavily drawn upon by the other HTA committees.

## **MSAC – the Medical Services Advisory Committee**

MSAC is an independent body that provides advice to the Minister for Health on the safety, clinical and cost effectiveness of medical services and technology. MSAC makes recommendations on whether new procedures should be included on the Medical Benefits Schedule (MBS).

Inclusion on the MBS is the basis of both physician and private hospital reimbursement and hence device reimbursement. Physicians are only eligible for Medicare funding for procedures included on the MBS. Health insurers are only obliged to pay a benefit for a procedure performed in a private hospital if the procedure is included on the MBS. Therefore, if a device is dependent upon a physician procedure and a hospital admission then inclusion on the MBS is essential.

Even though the MBS is a system for subsidizing medical professionals, applications to include a new procedure on the MBS are often initiated by technology suppliers. An MSAC application is a substantial undertaking, and it may be that while physician groups are keen to have innovative procedures included on the MBS, they lack the resources to prepare a submission.

The MSAC has two subcommittees, the Economic Subcommittee (ESC) and the Protocol Advisory Subcommittee (PASC). An application must pass through all three committees and as each committee only meets three times a year, with lengthy periods between submission deadlines and actual meetings, an MSAC application may take over two years to complete.

After an initial application to determine eligibility a Decision Analytic Protocol (DAP) is developed. This is generally prepared by the applicant and outlines the clinical and economic questions that should be addressed in a submission to the MSAC. A DAP follows the PICO (Population, Intervention, Comparator and Outcome) model, and is a substantial document.

A draft DAP is submitted to the PASC for consideration and is made available for public comment. Following public consultation PASC approves the Final Protocol, which forms the basis for the submission that MSAC will assess.

The actual submission is likely to include the following:

- detailed descriptions of the proposed procedures and technologies;
- its place in the Australian healthcare system;
- descriptions of the comparator;
- clinical pathway algorithms for both the new intervention and the comparator;
- a comprehensive literature search, detailing the reasons for inclusion and exclusion;
- an assessment of the measures taken to minimize bias in the selected studies;
- a very detailed analysis of the included trials and interpretation of the results;
- an analysis of the applicability, extrapolation and translational issues of the trials to be used in the economic model;
- pre-modelling studies including hospital costs, follow-up costs, transition probabilities and health state utilities;
- a detailed economic evaluation of the proposed intervention with the comparator, including a working model. Depending on the DAP, cost-utility, cost-effectiveness and cost-minimization models may be used;
- detailed sensitivity analyses;
- a full budget impact analysis, including estimates of the likely uptake of the new procedure, impacts to the MBS and other parts of the health systems; and
- a discussion of equity and access issues.

The submission is rigorously scrutinized and critiqued, and the MSAC will make either a positive or negative recommendation. The MSAC has a preference for randomized controlled trials and the guidelines for a submission mimic those for pharmaceuticals. Single arm trials and case series receive far less credence and are therefore considered to be less reliable when building the economic model. It is acknowledged by MSAC that clinical trials of medical devices inherently face difficulties meeting the same standard of pharmaceutical trials, however, in practise, assessments of the submissions do not appear to reflect this.

It could be argued that the MSAC in its natural zeal to avoid Type I errors in the evaluation of evidence is at risk of committing Type II errors and making recommendations that lead to the rejection of procedures that may offer health benefits to Australians.

Following a positive recommendation from the MSAC, an applicant has one more hurdle to overcome. While the MSAC determines the safety, clinical and cost effectiveness of a new intervention, the Australian Department of Finance must determine whether it is affordable. As with all budget expenditures, this decision is ultimately political. It is interesting to note that the Australian health minister has just announced a comprehensive review of the MBS to identify inefficiencies and to identify services that do not reflect contemporary best clinical practice.

### PLAC – the Prostheses List Advisory Committee

The Prostheses List is a list of devices for which private health insurers are mandated to pay a specific benefit. This is over and above any case payment or DRG arrangements. While this arrangement provides a level of certainty for suppliers, hospitals and insurers, there are some inherent difficulties. Insurers often complain loudly about the increased cost of prostheses, and suppliers point out that prices are effectively decreasing year on year. In fact both claims are true. Prostheses benefits are not indexed to inflation and benefits have remained the same for many years, however utilization, and therefore overall cost, is increasing.

To be included on the Prostheses List, an applicant must demonstrate substantial clinical equivalence to a device that is already listed. If the device is considered high risk, requires long term durability or is novel in design, an applicant must provide evidence of safety and efficacy with at least two years of follow up. Applications are assessed by practicing clinicians. However, the assessment process is less than transparent with often brief and unsatisfactory reasons given for a rejection.

Prices are determined via a benefit validation process, which does not follow health economic conventions, but rather considers whether a proposed price is “fair and reasonable”. While not mandatory, applicants are encouraged to provide their marketing and distribution costs, as well as public hospital and foreign prices.

There are specific criteria to be included on the Prostheses List. A device must be approved for sale in Australia and must be delivered during a hospital episode of care and be associated with an MBS item number. However the additional requirements are that the device:

- is surgically implanted;
- replaces an anatomical part;
- combats a pathological process or modulates a physiological process; and/or
- is a single-use aid essential for implanting a prosthesis.

The very literal application of these criteria leads to some interesting anomalies and gives rise to some perverse financial incentives in care delivery. The anachronistic term “prostheses” is indicative of the inability of the current arrangements to keep pace with the less-invasive nature of new technologies.

As the cost of a prosthesis is fully reimbursed, hospitals and physicians do not need to be mindful of the cost of a device in the same way as a device not included on the Prostheses List. The table below outlines some examples:

Prostheses	Not prostheses
Radioactive beads	Tissue markers for radiotherapy
Pacemakers and ICDs	Cardiac ablation catheters
Cardiac stents	Coronary pressure wires

In the first example, radioactive beads, used in the treatment of prostate cancer are included on the Prostheses List, whereas tissue markers - often highly-sophisticated technologies that may communicate via radiofrequency to direct radiotherapy beams - are not. Regardless of the clinical outcomes, the radioactive beads will not be a cost to the hospital, whereas the price of tissue markers will be.

Similarly, while not suggesting that a pacemaker or defibrillator is interchangeable with a cardiac ablation procedure, the cost of the implantable device is not borne by the hospital whereas the cost of the ablation catheters is.

The oft quoted case of coronary pressure wires is a clear example of a perverse economic incentive. Use of coronary pressure wires is gold standard practice to determine the severity of occlusions of coronary arteries. The use of pressure wires has been unequivocally demonstrated to reduce the use of stents and significantly improve clinical outcomes and reduce costs. Cardiac stents are included on the Prostheses List, whereas coronary pressure wires are not. Their cost must be met by the hospital. Consequently the uptake of pressure wires has been slow in private hospitals compared to public hospitals despite the overall clinical and economic benefits.

### The public hospital system

As noted, Australia’s public hospital system is funded by a mixture of federal and state resources with states having the responsibility of managing hospitals. Since 2013, public hospitals have been reimbursed under Activity Based Funding (ABF, see below) using the Australian Refined Diagnosis-Related Groups (AR-DRG) scheme to reimburse episodes of care.

Unlike in the private system, no separate device reimbursement exists in the public system. Public hospitals

are free to use medical devices as soon as they registered. While the AR-DRG system is underpinned by the MBS to some extent, there is more freedom in the public sector to use innovative technologies. Public hospitals are constrained by severe budgetary concerns rather than regulatory barriers in introducing new technologies and procedures.

Typically, new technology in Australia is introduced into the public sector before being launched in the private sector. Public hospitals conduct a significant amount of clinical research and are well placed to evaluate new technologies. In some cases, a procedure or technology is available in public hospitals some years before it is available in the private system, as there is not the requirement to navigate the MSAC or be included on the Prostheses List. However the AR-DRG system is extremely slow to take into account new technologies as there is no mechanism to issue a temporary AR-DRG or similar measure. A new AR-DRG is issued based on retrospective evidence of use of a technology and can take some years. Reimbursement under ABF is always precarious for new technologies.

The future of ABF in Australia is uncertain. It is in the process of being dismantled, for reasons that are not clear. The former Labor government established the infrastructure to collect national data to begin ABF funding in the public system. This was tied to additional funding over time. However, on the change to a Conservative government about 18 months ago, the commitment to this additional funding was loosened, and this was accompanied by the dismantling of most of the infrastructure. However since so much work has been done, some states intend to continue funding their local public systems via DRGs. The situation is very much up in the air and it's a case of wait and see.

As a final thought, medical device reimbursement in Australia is complex. Differing funding models in the public and private sectors which can be dependent upon variations in the nature of a device can create different levels of access for the public, and at times facilitate perverse economic incentives.

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