Prostheses List Advisory Committee
Cardiac ablation catheters: consideration of Prostheses List inclusion

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Executive summary

This paper provides an analysis of the comparative clinical-effectiveness and cost-effectiveness of cardiac ablation for atrial fibrillation (AF) in relation to the Minister for Health, the Hon Greg Hunt MP's request to the Prostheses List Advisory Committee (PLAC) for advice on the potential inclusion of cardiac ablation catheters on the Prostheses List (PL).

The analysis includes a two-part report: Report Part 1 is a rapid review of high-level clinical evidence (Attachment A); Report Part 2 is a focused economic evaluation and focused financial analysis (Attachment B).

The Medical Services Advisory Committee (MSAC) has reviewed these reports and found that cardiac ablation for atrial fibrillation is clinically effective for relieving AF symptoms when compared with medical treatment, noting that based on MBS data, approximately 20 per cent of patients will require a repeat cardiac ablation procedure.

MSAC does not consider that cardiac ablation catheters represent value for money at the proposed prices of: $2,300 for mapping catheters, $6,000 for radio frequency ablation catheters, and $4,065 for cryoablation catheters. MSAC recommended a more comprehensive modelled economic evaluation be undertaken to determine a cost-effective price for these items over a longer time horizon than the initial 12-month time frame on which the November 2018 economic analysis was based.

Although one stakeholder has asserted that affordable access to cardiac ablation is limited in Australia due to lack of specific funding through the PL, this review has found no compelling evidence that there is, or is not, a significant funding gap (although some patients may be denied coverage for some procedures). In addition, MBS data suggest the number of private sector services (of which there were about 4000 in 2017-18) is increasing at about 15 per cent per annum.

However, the availability of current services is not uniformly distributed across the country. That is because the service is specialised, and the upfront investment in the infrastructure to provide this type of surgery is significant. This feature of the medical service will not change – i.e. it is not a realistic prospect that every private hospital in the country will offer this type of procedure.

Cardiac ablation has been funded in a variety of forms for many years and a range of structures for private health insurer (PHI) funding of cardiac ablation catheters already exist.

Since cardiac ablation was listed on the MBS in 1998, PHIs have developed a number of mechanisms to reimburse these products, such as:

- payments as agreed in hospital contract schedules.
- bundled theatre payments
- *ex gratia* payments.

It is estimated that the inclusion of cardiac ablation catheters on the PL would increase costs to private health insurers by $18.4 million over the first five years of implementation.

The following two options are provided for the Minister's consideration:

- Option 1: Maintain existing funding arrangements
- Option 2: List cardiac ablation catheters on Part C of the PL following further consideration by MSAC and as necessary, negotiation with cardiac ablation catheter suppliers on a cost-effective price.

Introduction

On 10 October 2017, the Minister for Health, the Hon Greg Hunt MP requested advice from the PL Advisory Committee (PLAC) by 31 December 2018 regarding the inclusion of cardiac ablation catheters for atrial fibrillation on the PL. The Minister requested that the advice include an assessment of comparative clinical and cost effectiveness.

A key driver for this request was the claim by consumer groups that affordable access to cardiac ablation is limited in Australia. Including this procedure on the Prostheses List would therefore provide more certain access to appropriately insured patients. Consumer groups advocated that increasing the availability of cardiac ablation treatment would also provide savings to the health system through reduced hospitalisation rates and prevention of strokes. However, MSAC concluded that the available evidence did not support stroke reduction as an outcome from ablation.

The Prostheses List

The purpose of the PL is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs. Under the *Private Health Insurance Act 2007* (the PHI Act), PHIs are required to pay benefits for prostheses that are included on the PL:

- for which an insured person has appropriate cover
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment
- for which a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

The arrangements for including products on the PL help to ensure that benefits paid by PHIs are relative to clinical effectiveness. The purpose of clinical assessment for the PL is reimbursement, not regulation.

The PL arrangements are set out in Division 72 of the PHI Act and the *Private Health Insurance (Prostheses) Rules* (the Prostheses Rules). The Minister makes the rules under the authority of ss. 72-1, 72-10 and 333-20 of the PHI Act. The Rules may provide for different listing criteria to apply in different circumstances.

The PL is the schedule to the Prostheses Rules and is in three parts, Parts A, B and C.

Part A lists implantable medical devices and as at 21 November 2018 lists 10,786 items.

Part B lists products derived from human tissue (766 items listed), and Part C lists insulin infusion pumps, cardiac event recorders and cardiac home monitoring devices (26 items).

The criteria to list on Part A includes the requirement that the prosthesis is surgically implanted, is integral to implanting a prosthesis, or is essential to the correct functioning of a prosthesis. Cardiac ablation catheters do not meet the listing criteria for Part A.

With regard to the Minister's decision as to whether to list cardiac ablation catheters on the PL, there are several options that could be taken. It is important to consider the effects that each option may have. These effects include precedent setting for other high cost, non-implantable medical devices and the effects on the current funding settings for these devices, which may be functioning well enough when compared to the additional costs listing may impose on PHIs.

Disease and treatment overview

Atrial fibrillation

A cardiac arrhythmia is a condition where a patient's heart beats irregularly. Atrial fibrillation (AF) is one of the most common types of heart arrhythmia and is characterised by irregular and rapid contractions of the upper chambers of the heart, the atria, which interferes with normal blood flow from the atria to the lower chambers of the heart, the ventricles. AF may occur in brief episodes (paroxysmal), or it may be a longer-term or permanent condition.

AF is a major cause of ischemic stroke and is moderately associated with increased mortality from stroke, heart failure, and cardiovascular disease. Stroke prevention, therefore, is a major goal for the management of AF.

AF can be treated with antiarrhythmic drugs (AADs). However, in some patients AADs are not effective in restoring and maintaining normal heart rhythm and/or cause side effects that warrant treatment cessation.

Cardiac ablation procedure

Cardiac ablation for the treatment of AF is increasingly being performed on symptomatic patients as an alternative to medical management, or when medical management has been ineffective or not tolerated.

There are two types of cardiac ablation procedures, those that burn the heart tissue (radiofrequency ablation (RF), and those that freeze heart tissue (cryoablation)). Prior to the RF ablation procedure, a mapping catheter is used to identify the sites to be ablated.

RF cardiac ablation systems deliver RF energy at the tip of the ablation catheter. Significant resistive heating occurs only at the catheter tip-tissue interface and in a small volume of surrounding tissue.

Cryoablation involves the insertion of a catheter with a balloon into the openings where the four pulmonary veins bringing blood from the lungs join the left atrium. This is commonly the site of origin of atrial fibrillation. When the balloon is inflated the opening is closed off, which stops blood flow from the vein. The balloon is then filled with liquid coolant, which

destroys a ring of tissue. The resultant scarring prevents atrial fibrillation by blocking conduction of electrical activity across it.

A comparison of RF ablation versus cryoablation found no significant difference between the two technologies in terms of patient outcomes at 12 months' follow up.

Is there an unmet clinical need?

At present, there is little evidence to suggest that privately insured patients are paying out-of-pocket charges for cardiac ablation catheters. It appears that over the past 20 years PHIs have developed a number of ways to reimburse these items, at least in part.

A key issue identified by consumers is waiting periods for public hospital services. MBS data show that about 4000 private sector ablations for atrial fibrillation were performed in 2017/18 (MBS item 38290) and that number is rising at about 15 per cent per year. The MBS Review Cardiac Services Clinical Committee noted that this steady increase in private sector services could be attributed to the increasing number of electrophysiologists (subspecialist cardiologists) and increasing evidence supporting the benefit of cardiac ablation.

This review was unable to determine whether there is an unmet private sector demand and whether the absence of PL listing is displacing patients who could be treated in the private sector into the public hospital sector. However, it seems unlikely that listing of cardiac ablation catheters will have a significant impact on public hospital waiting lists as these waiting lists comprise patients who do not hold private health insurance or who hold private health insurance but prefer or require public hospital care.

In both sectors there are significant infrastructure costs for hospitals which will continue to limit the capacity of both private and public hospitals to provide this service.

Health Technology Assessment

The Department has commissioned an independent health technology assessment of cardiac ablation catheters. These are provided in full at Attachment A (Comparative clinical effectiveness) and Attachment B (Economic evaluation and financial analysis).

Comparative clinical effectiveness (Attachment A)

Despite the widespread use of cardiac ablation therapy to treat AF, both in Australia and internationally, clinical studies conducted to date provide limited evidence of the superiority of cardiac ablation over treatment with AADs. Nevertheless, cardiac ablation has an established place in therapy, as documented in the Australian Atrial Fibrillation Guidelines published by the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand earlier this year.

There is moderate evidence that RF ablation is superior to medical therapy for enhancing patient freedom from recurrence of atrial arrhythmias in both the short and long term.

On the other hand, studies suggest that up to 54 per cent of patients will need a repeat cardiac ablation procedure within 12 months. MBS statistics indicate that in Australia the repeat rate within 24 months is about 20 per cent.

A very recent study of patients with heart failure as well as AF indicated that cardiac ablation has a beneficial impact on all-cause mortality, but this was not apparent in studies that excluded patients with heart failure.

Evidence from observational studies suggests that cardiac ablation may decrease the risk of stroke compared with medical therapy. This would certainly be an expected outcome and may well prove to be the case with longer-term follow up, but this has not so far been clearly demonstrated in randomised clinical trials.

Hospitalisation was more frequent in patients who received medical therapy compared with cardiac ablation. However, these studies did not provide detail about reasons for hospitalisation and the extent to which hospitalisation for re-ablation procedures or crossover from medical therapy to ablation were included and must therefore be interpreted with some caution.

In summary, based on the current evidence available, in those patients with symptomatic AF, in comparison with medical treatment, cardiac ablation is likely to result in a significant reduction in symptoms and reduced likelihood of hospital admission either for electrical cardioversion or for complications of AF.

For those patients who have failed to respond to medication or cannot tolerate medication, ablation provides an option for managing symptomatic AF.

Comparative cost effectiveness (Attachment B)

A trial-based economic evaluation and financial analysis found that neither RF ablation nor cryoablation are cost-effective compared with medical therapy at the prices currently being paid in Australia for the ablation devices, which are averaged at $2,300 for mapping catheters, $6,000 for RF ablation catheters with the patches needed to use them, and $4,065 for cryoablation catheters.

These costs were developed based on an average of applications to list on the PL and current prices paid in the public and private systems. The indicative cost-effectiveness of cardiac ablation based on a 12-month economic analysis compared with medical therapy was found to be $110,321/QALY gained for RF ablation and $95,481/QALY gained for cryoablation. The cost-effectiveness of the procedures was most sensitive to the price of the devices.

However, it should be noted that, a number of simplifying assumptions were made in this economic model of short duration – 12 months, which may not fully take into account the longer-term benefit of cardiac ablation.

A search of the literature identified some published economic evaluations that claim cardiac ablation is cost-effective. However, these evaluations appear to be driven by the inclusion of outcomes in heart failure patients (who are out of scope for the current consideration) or the assumption that cardiac ablation reduces the rate of subsequent stroke and/or mortality (claims that are not supported by the available clinical evidence, though may plausibly prove to be true over time as further evidence accumulates in the future).

Medical Services Advisory Committee advice

The Medical Services Advisory Committee (MSAC) considered evidence for the clinical and cost-effectiveness of cardiac ablation for atrial fibrillation. MSAC agreed that there was sufficient clinical evidence to demonstrate the clinical effectiveness of cardiac ablation over

treatment with anti-arrhythmic medication in relieving symptoms of AF. However, MSAC concluded that the available evidence did not support stroke reduction as an outcome from ablation and hence most patients need to continue on oral anti-coagulation following ablation. MSAC also advised that a claim of better survival over anti-coagulation medication was not supported by the available data

Hence, MSAC advised that at current prices, cardiac ablation catheters (and the associated mapping catheters) for atrial fibrillation are not cost-effective.

MSAC requested a more comprehensive economic evaluation be brought back for its review, which should include a longer time horizon (5-10 years versus 12 months as modelled) and repeat rates based on actual MBS data. If the further analysis suggests that cardiac ablation remains cost ineffective then MSAC could provide a recommendation on the threshold PL benefit at which cardiac ablation catheters could be considered cost-effective.

MSAC noted the anticipated Catheter Ablation vs Antiarrhythmic Drug Therapy in Atrial Fibrillation (CABANA) trial is in the process of peer-review and subsequent publication.

That trial may shed more light on the magnitude of the clinical benefit that underpins the economic modelling, and the price reductions that might be needed.

Current reimbursement of cardiac ablation catheters by PHIs

Since cardiac ablation was listed on the MBS in 1998, PHIs have developed a number of mechanisms to reimburse these products, such as:

- payments as agreed in hospital contract schedules.
- bundled theatre payments
- *ex gratia* payments.

The benefit of this approach is that it allows parties involved in the cardiac ablation supply chain to negotiate on price. Listing ablation catheters on the PL could remove this flexibility.

Another cost control mechanism of the current approach is that PHIs are able to limit the number of catheters that they will reimburse per procedure.

Financial impact on private health insurance premiums

Impact of PL listing on demand for cardiac ablation procedures

It is unlikely that there will be a significant number of new providers of cardiac ablation services because of the infrastructure, technical expertise and clinical support services that must be available.

In general, it is expected that some private hospitals with existing catheter laboratories and which are not already offering AF ablation, would expand services to include it. This is a complex procedure and significant training is required, and given the potential complications cardiac surgical support must be available. This requirement for both subspecialist cardiac electrophysiologists and cardiac surgery support markedly limits the number of private hospitals that would be in a position to offer this service.

Cost to PHIs of listing cardiac ablation catheters on the PL

A financial analysis was undertaken to understand the impact of including cardiac ablation catheters to treat atrial fibrillation on the PL. The analysis is based on projected Medicare Benefit Schedule (MBS) item utilisation of cardiac ablation procedures to treat atrial fibrillation; the results are illustrated in Table 11, page 26 of Attachment B.

The analysis assumes a 10 per cent increase of cardiac ablation procedures if the catheters are listed. It also assumes that private health insurers are currently covering the majority of procedures in some form. It is estimated that the current cost of cardiac ablation catheters for private health insurers is about $34.4 million per year. It is also estimated that the cost of cardiac ablation catheters to private health insurers would increase to about $37.8 million in the first year, which would be a net increase to insurers of $3.4 million. The net increase to insurers over five years would be approximately $18.4 million ($3.4 million in year 1, $3.9 million in year five).

These costs were derived from a range of information sources, including prices of products supplied in the public and private health systems. Should PL listing have an inflationary effect on cardiac ablation catheter prices, then there would be a higher financial impact on PHIs.

Mitigating against increased costs to private health insurers

Risk of leakage

Cardiac ablation treatment of supraventricular tachycardia (SVT) can be achieved with simpler, and therefore, cheaper cardiac ablation catheters. In contrast, the treatment of atrial fibrillation (AF) and ventricular tachycardia (VT) requires more complex and more expensive cardiac ablation catheters.

Including cardiac ablation catheters on the PL will introduce the risk that complex catheters are used for treating SVT. This would unnecessarily increase costs to private health insurers. This risk could be mitigated by restricting the use of complex cardiac ablation catheters only to the appropriate interventions.

Item 4 of paragraph 72-1(2) of the PHI Act specifies that conditions can be placed on the PL. Therefore, a condition could be applied to specify an MBS item or surgical procedures for particular cardiac ablation catheters. The model developed for the economic evaluation was based on the assumption that 100 per cent of MBS item 38290 and 25 per cent of MBS item 38287 will be atrial fibrillation cases. When this was considered further by clinical experts, it was agreed that the utilisation of MBS item 38287 for atrial fibrillation cases is likely to be rare. Therefore, the recommendations outlined in this paper refer only to MBS item number 38290.

Given the infrastructure, technical expertise and cardiac surgical support that must be available, cardiologists have advised that it is desirable that requirements relating to operator training, facility requirements including access to cardiac surgical support and patient eligibility criteria as specified in the Australian Atrial Fibrillation Guidelines, should be linked to any funding of the catheters through the PL

In summary, should a decision be made to list these products on the PL, it would be prudent to place conditions on the listing that would ensure:

- the PL benefit is not to be claimed if there is already an existing agreement between an insurer and a hospital that provides for funding of these services and devices
- restriction of the number of cardiac ablation catheter and mapping catheters reimbursed per procedure
- any new funding for cardiac ablation catheters is limited to patients who have atrial fibrillation and who meet the current Australian guidelines that define the appropriate use of this therapy. Consideration should also be given to imposing facility and provider training requirements as noted above. These additional clinical requirements might be best implemented through changes to MBS item 38290 rather than through the PL.

We note that the private hospital representatives on PLAC expressed disagreement with the two stipulations around pre-existing contracts and restricting catheter numbers.

Precedent setting for other non-implantable devices

If cardiac ablation catheters are included on the PL, it is likely to be seen by some as setting a precedent for other non-implantable devices such as coronary artery pressure wires and drug-eluting balloon catheters.

Further, given current funding structures there is a risk of leakage, i.e. some devices may be funded more than once - through hospital-insurer arrangements and again through the PL.

Under the Government's Agreement with the MTAA, work will be undertaken throughout 2019 to review and revise the benefit setting framework for medical devices. Additionally, work is to be undertaken to review, through the PLAC, ways of listing new targeted medical devices on the PL that do not meet the current criteria for listing, but are safe, clinically effective and cost effective to support PHI reimbursement for a wider range of medical devices taking into account overall costs associated with the listing.

This work is currently ongoing, and will be not be completed by 31 December 2018, which is the date the Minister has requested advice from PLAC on just one example of such intervention, cardiac ablation catheters.

Options for funding cardiac ablation catheters for privately insured patients

Option 1: Maintain existing funding arrangements

Cardiac ablation has been funded by PHIs in some form for many years. It is a well-established procedure and is recognised as such in clinical guidelines. However, the merits of this high cost procedure in the Australian setting have never undergone health technology assessment prior to this assessment.

In addition, cardiac ablation catheters do not meet the listing criteria for Part A of the PL.

Under the Government's Agreement with the MTAA work is underway to review the benefit setting framework with a view to revising it in some form.

To list cardiac ablation catheters could lead to additional, albeit moderate, costs for private health insurers, which may translate into upward pressure to private health insurance premiums.

In the absence of any evidence that PL listing would immediately broaden patients' access or make the intervention more affordable, the Minister may wish to consider allowing the decision to be placed in the context of the broader review of medical devices that are clinically effective but do not meet the current PL listing criteria underway as part of the MTAA agreement.

Option 2: List cardiac ablation catheters on Part C of the Prostheses List following further consideration by MSAC and if necessary, negotiation with cardiac ablation catheter suppliers on a cost-effective price

Cardiac ablation for atrial fibrillation has been assessed by MSAC as not cost-effective at the current prices. Hence, any listing on Part C of the PL based on the currently available evidence would have to be at lower prices than proposed.

However, MSAC considered that a further economic modelling over a longer time horizon could be undertaken. MSAC advised that 5-10 years was a more clinically realistic time horizon and that this, along with modelling the cost of repeat procedures based on repeat rates from MBS data, would be expected to favourably change the incremental cost effectiveness ratios (ICERs). MSAC could provide this further advice at its next meeting of 28-29 March 2019. A positive recommendation on a cost-effective benefit would enable cardiac ablation catheters to be listed on the next available Prostheses List following the MSAC meeting, which would be 1 July 2019.

Hence, negotiation with industry could both inform MSAC's advice and subsequent advice to government about remaking the Prostheses Rules to include cardiac ablation catheters on Part C

Equipment needed for complex cardiac ablation procedures such as those for atrial fibrillation include:

- products not sufficiently funded by the Diagnosis Related Group (DRG) or bundling payments for these procedures – mapping catheter, ablation catheter and patches; and
- items sufficiently funded by the DRG or bundling payments – cables, diagnostic catheters, sheaths, needles and other consumables.

Any assessment of options for including cardiac ablation catheters on the PL therefore needs to specify the equipment to be included. Given there is already a mechanism to cover the cost of some equipment and consumables, consideration should be given only to funding the circular mapping catheters, ablation catheters and patches, which are specific to cardiac ablation procedures.

RF cardiac ablation procedures for treatment of atrial fibrillation require mapping catheters, ablation catheters and patches (the patches are required for the anatomical mapping and to allow ablation catheters to be visualised on the complex 3-dimensional mapping systems).

Cryoablation cardiac ablation procedures require mapping catheters and ablation balloons (Cryoballoons) but not patches.

The PL listing should take account of a number of conditions of use that are directed to ensuring services are clinically effective and cost effective. These conditions include:

1) PL funding for these items is only applicable for treating atrial fibrillation and hence use of the devices should be linked to MBS item 38290.
2) Reimbursement is limited to a maximum of two cardiac ablation catheters per procedure.
3) Reimbursement is limited to a maximum of one mapping catheter per procedure.
4) If an agreement for funding cardiac ablation catheters already exists between a hospital and private health insurer, the PL benefit cannot be claimed.
5) Funding is linked to patient eligibility criteria in accordance with the Australian Atrial Fibrillation Guidelines, including guidelines on provider training and facility requirements. This may be best achieved though changes to MBS item 38290, and other accreditation mechanisms that sit outside of Commonwealth and PHI control.

Attachments:

A: Report Part 1: Rapid Review of high-level clinical evidence: Cryo- and radiofrequency cardiac ablation catheters for the treatment of atrial fibrillation

B: Report Part 2: Focused economic evaluation, Focused financial analysis: Cryo- and radiofrequency cardiac ablation catheters for the treatment of atrial fibrillation