Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1197.1 – Remote monitoring for patients with implanted cardiac devices

Applicants: **Biotronik Australia Pty Ltd**

Date of MSAC consideration: **MSAC 62nd Meeting, 26 – 28 November 2014**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

An application requesting Medicare Benefits Schedule (MBS) listing of remote monitoring of patients with cardiac implantable electronic devices (CIEDs) was received from Biotronik Australia Pty Ltd by the Department in March 2012.

Following the MSAC April 2014 recommendation to defer the application to request further information, a resubmission was received from the applicant in September 2014.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness, MSAC supported public funding of new MBS items for remote monitoring of implanted pacemakers and defibrillators (including cardiac resynchronisation devices) involving reviews of arrhythmias, lead and device parameters with one in-office yearly check. It was noted that patients may also access unscheduled consultations and diagnostic procedures as required.

In regards to the transmitter cost, MSAC accepted advice from the Department that exceptions for prostheses listings may be made if a non-implanted component is considered integral to the operation of an implanted device.

MSAC did not support inclusion of event monitoring in the MBS items as the evidence did not indicate that this improved health outcomes.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the proposed public funding of remote monitoring of patients with cardiac implantable electronic devices (CIEDs) had previously been deferred in April 2014 (Application 1197) to seek additional information.

MSAC reaffirmed their acceptance of the safety and effectiveness data presented at the previous meeting. Based on the overall evidence, it was concluded that remote monitoring:

- leads to a reduction in overall in-office follow-up visits; and
- is as safe as conventional follow-up, demonstrated by outcomes including adverse events, mortality, inappropriate shocks, hospitalisations and emergency department visits.

Additional data from the IN-TIME trial reported a mortality benefit for patients with ICDs/CRT-Ds receiving remote monitoring in addition to standard care compared with standard care alone (3.4% vs 8.7%). The study also showed that remote monitoring patients had an extra 0.32 office visits per year compared with the control group. MSAC commented that the intensified therapy rather than remote monitoring alone could have contributed to the mortality benefits, resulting in a potential overestimation of clinical effectiveness.

In April 2014 MSAC was concerned that current patients with a CIED do not have a transmitter, and questioned uptake given issues associated with subsidisation for the transmitter. An updated economic evaluation that included the full cost of the remote monitoring device (including the transmitter cost of $3,000) and enhanced battery longevity with remote monitoring was presented. The Department informed MSAC that while a device generally must be implanted to be listed on the Prostheses List (PL), exceptions may be made if a non-implanted component is integral to the operation of an implanted device.

MSAC considered that cost savings associated with remote monitoring may become more apparent as the CIEDs reached end of life – when they would usually require more frequent monitoring – as timing for device replacement may be extended in the setting of remote monitoring.

MSAC agreed with the Department regarding a potential implementation model for remote monitoring involving a proposed annual cycle of care that reflects current CIED guidelines.

Device	Proposed Annual Cycle of Care	Current MBS items
Pacemaker	1 annual consult (in-office) 1 annual diagnostic procedure (in-office) 2 scheduled reviews (in office or remote)	MBS 116 MBS 11718 or 11721
ICD/CRT-D	1 annual in-office consult (in-office) 1 annual diagnostic procedure (in-office) 4 scheduled reviews (in office or remote)	MBS 116 MBS 11727

MSAC also noted that evidence currently suggests that event monitoring results in faster physician response to events and increased services for patients. However, the evidence does not indicate that it leads to better patient outcomes.

4. Background

Application 1111 - Remote Monitoring Systems for Patients with Implanted Cardiac Device, was considered by MSAC in June 2008. MSAC considered that the procedure was safe, but

that clinical effectiveness had not been demonstrated and a formal economic assessment could not be performed.

MSAC considered Application 1197 in April 2014 and concluded that remote monitoring was as safe as standard care and that it was effective, however there was insufficient evidence to demonstrate a survival benefit. MSAC also concluded that remote monitoring was not cost neutral but may be cost-effective.

MSAC deferred the application to seek additional information from:

- the Prostheses Listing Advisory Committee (PLAC) regarding the suitability of the transmitter for listing on the prostheses list;
- the applicant regarding (a) the IN-TIME study results, particularly the mortality data and potential benefit when remote monitoring replaces in-office monitoring rather than supplements it; and (b) the potential need for multiple software packages associated with different brands of remote monitoring equipment; and (c) need for further economic modelling to take account of the cost of the transmitter to the healthcare system; and
- the Department regarding how best to incentivise monitoring practice through prospective and/or retrospective fees.

5. Prerequisites to implementation of any funding advice

The resubmission did not indicate any change to the TGA listing status of the remote monitoring device or any similar devices.

The PLAC secretariat advised that, in general, a device must be implanted for it to be listed on the Prostheses List. Exceptions may be made if a non-implanted component is integral to the operation of the implanted device.

The Applicant has agreed that, should the MSAC recommend public funding for this service, they will submit two applications for listing on the Prostheses List:

A. device plus transmitter, new patients, RM is integral to treatment plan.
B. transmitter, existing patients, to add RM to treatment plan.

6. Proposal for public funding

The proposed MBS item descriptors for delivering the remote monitoring service remain consistent with the original submission. The proposed intervention involves:

- an annual in-office check.
- regular remote monitoring reviews (4 for ICD/CRT patients; 2 for PM patients).
- event monitoring (18 mins per annum).
- unscheduled in-office visits for consultations and diagnostic procedures.

The proposed MBS item descriptors for delivering the remote monitoring service are described below.

Proposed MBS Item Descriptors

Category 2 – Diagnostic procedures and investigations
MBS item TBC IMPLANTED PACEMAKER, (including Cardiac Resynchronisation Pacemaker) REMOTE MONITORING involving reviews (without patient attendance) of arrhythmias, lead and device parameters and one in-office check in a period of 12 consecutive months. Fee: $192.86
MBS item TBC IMPLANTED DEFIBRILLATOR, (including Cardiac Resynchronisation Defibrillator) REMOTE MONITORING involving reviews (without patient attendance) of arrhythmias, lead and device parameters and one in-office check in a period of 12 consecutive months. Fee: $282.95
MBS item TBC IMPLANTED PACEMAKER TESTING indicated by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus including reprogramming when required, not being a service associated with a service to which item 11718 or 11721 applies. Fee: $66.86
MBS item TBC IMPLANTED DEFIBRILLATOR TESTING indicated by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus including reprogramming when required, not being a service associated with a service to which item 11718 or 11721 applies. Fee: $94.75

7. Summary of Public Consultation Feedback/Consumer Issues

For consumers, remote monitoring as a triage procedure (with reports to the patient where follow-up appointments are not required) could save time, money and concern. However, it is important that availability of remote monitoring does not become a barrier to people speaking with a specialist should they have concerns or prefer face-to-face interaction.

In particular, patients receiving remote monitoring of a CIED may benefit from reduced need for in-office visits and associated travel time and costs.

8. Proposed intervention's place in clinical management

The resubmission did not propose any change to the intervention's place in clinical management.

9. Comparator

The resubmission did not propose any change to the primary comparator (regular in-office (diagnostic) testing conducted by a technician on behalf of a cardiologist - currently MBS items 11718, 11721 and 11727). This is a private service conducted out-of-hospital. The comparator remains appropriate.

10. Comparative safety

The resubmission did not change the evidence for safety of remote monitoring which was accepted by MSAC in April 2014.

11. Comparative effectiveness

The resubmission did provide any further evidence regarding the effectiveness of remote monitoring which was accepted by MSAC in April 2014.

Further information on the IN-TIME study was presented:

Care type	Comparator	Population	RM Daily parameters	RM Event parameters
standard in-office care plus daily RM	standard in-office care	- ICD/CRT-D indication - NYHA class II (43%) or NYHA class III (57%) - LVEF ≦35% - no hypertension - no AF - use of ACE inhibitors, ARBs &/or beta blockers	<u>Heart rhythm parameters</u> - mean heart rate - mean heart rate at rest - heart rate variability - ventricular extra-systole - AT &/or AF burden - bradycardia - tachyarrhythmia - pacing impedances <u>Heart failure parameters</u> - patient activity - fluid settings <u>Technical parameters</u> - % biventricular pacing - shocks per episode - lead impedance - low battery - excessive charge time - VF detection off	All information conveyed during daily RM plus: <u>Heart rhythm parameters</u> - time & duration of episode - initial detection zone - PP/RR values - details of delivered therapy <u>Technical parameters</u> - RV lead

The all-cause mortality for the IN-TIME trial was 3.4% for the RM plus standard care group and 8.7% for standard care. The parameters for the RM plus standard care group included the annual in-office check, daily RM, event RM (responses to alerts) and in-office unscheduled visits (responses to events). The mortality benefit is attributed to the physician response to event monitoring. Each patient in the RM plus standard care group had 0.32 extra in-office visits per year compared to the control. It is suggested these are a response to events. However, the daily monitoring may also have contributed. In addition, these patients, because of their health status, are likely to visit their physician more regularly.

The resubmission indicated that for this sub-group such intensified monitoring (daily) is appropriate and the mortality benefit may accrue for a similar sub-group in Application 1197. However, the resubmission also noted that this approach to monitoring in the IN-TIME trial is different to the MBS items proposed under this application.

12. Economic evaluation

The resubmission provided a simple cost-minimisation analysis which was updated to include the cost of the remote monitoring device ($3,000) and enhanced battery longevity with remote monitoring. The resubmission did not provide cost off-sets such as travel time.

The Applicant estimated the total cost of remote monitoring for new patients with ICD/CRT-D indications to be $8,611 per patient per annum. This included the cost of the device and transmitter and resulted in an incremental save of $349 per patient per annum compared to standard care.

The resubmission indicated that the ongoing costs of remote monitoring is cost saving ($92.11) compared with traditional care, and that remote monitoring of ICD's remains cost saving once generator replacement cost (incorporating transmitter costs and difference in battery life) is included.

13. Financial/budgetary impacts

The resubmission did not specifically propose any change to the financial or budget impacts.

14. Key issues from ESC for MSAC

ESC noted that the additional information on the IN-TIME study indicated that mortality benefits could be reasonably attributed to intensified therapy rather than remote monitoring alone.

ESC noted that the requested information regarding the potential for cost offsets due to patient travel savings was not provided. ESC considered that it may be unrealistic to expect travel savings due to remote monitoring to result in commensurate savings to state based patient assisted travel programs.

ESC noted that the proposed cost savings were marginal, and that inclusion of potentially increased consultations could harm the claim of cost savings, and that it would be very easy to move into a state of increased cost.

ESC noted data indicates only 70% of patients follow-up with a cardiologist once per year.

ESC considered that the proposed fees are not necessarily reflective of the considerably lower effort required to deliver the remote monitoring service compared with face-to-face care.

ESC also considered that bundling the services may reduce the incentive to provide additional services where necessary.

15. Other significant factors

Nil.

16. Applicant's comments on MSAC's Public Summary Document

BIOTRONIK Australia would like to thank MSAC for evaluating the remote monitoring of Cardiac Implantable Electronic Devices and recommending public funding for those services. We would also like to thank the Cardiac Society of Australia and New Zealand (CSANZ), the industry and the various consumer groups who have provided valuable input and support for this application. We look forward to the publication of item codes that will provide suitable incentives for clinicians to deliver Australian patients the benefits of remote monitoring.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.