Technology Guidance

Intracardiac monitor

for acute coronary syndrome (ACS) event detection

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has not recommended subsidy for intracardiac monitors for acute coronary syndrome (ACS) event detection.

Funding status

Intracardiac monitors are not recommended for subsidy in patients with the abovementioned indications.

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Technology evaluation

1.1. At the December 2025 meeting, the MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of intracardiac monitors for acute coronary syndrome (ACS) event detection. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for intracardiac monitors were considered in line with its registered indication.

1.2. The evidence was used to inform the Committee's deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Overall benefit of the technology for the patient and/or the system;
- Cost-effectiveness (value for money), which considers the incremental benefit and cost of the technology compared to existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology; and
- Organisational feasibility, which covers the potential impact of adopting the technology, especially barriers for diffusion.

1.3. Additional factors, including social and value judgments, may also inform the Committee's deliberations.

Clinical need

2.1. ACS is part of the coronary artery disease spectrum. It describes a group of conditions, ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), and unstable angina (UA), that present as clinical symptoms arising from acute myocardial ischaemia. Minimising the delay between symptom onset and treatment is important in the management of ACS. However, as ACS symptoms may be non-specific, insensitive, atypical, or even silent, delays in seeking treatment remain a significant challenge to improving ACS outcomes.

2.2. The Guardian System is the only intracardiac monitor currently registered with the Health Sciences Authority (HSA). It comprises an implantable medical device (IMD) positioned in the right ventricle via a pacing lead, enabling continuous real-time monitoring of intracardiac electrograms. Significant deviations from baseline trigger alerts that prompt patients to seek medical attention. The proposed benefit is earlier detection of ACS events through objective physiological monitoring, compared with current standard of care, which relies on patient-recognised symptoms alone.

2.3. The Committee heard that the Guardian System IMD requires surgical implantation and surgical replacement after its expected battery life of six years. If the patient later requires a therapeutic device such as a pacemaker or implantable cardioverter-

defibrillator, the Guardian System will first need to be surgically removed, as these devices cannot be used together.

2.4. The Committee noted that prevailing clinical practice guidelines on the management of ACS did not publish any specific recommendation statements on the use of intracardiac monitors for ACS event detection.

Clinical effectiveness and safety

3.1. The Committee acknowledged that the evidence base comprised two studies from the pivotal randomised controlled ALERTS trial, which compared patients receiving alerts from an intracardiac monitor to patients relying on symptoms alone, and one Pre-Market Approval (PMA) submission to the US Food and Drug Agency (FDA). No health technology assessment (HTA) reports were identified. The Committee noted that the evidence base was limited by reliance on outcomes from the ALERTS trial which had significant methodological flaws (early termination, changes to the analysis plan, multiple post-hoc analyses) and a high risk of bias. These flaws introduced uncertainty to the robustness, reliability, and generalisability of findings from the evidence base.

3.2. For safety, the Committee noted that intracardiac monitors showed minimal system-related complications over a six-month period. Overall, infections, pain, erosion, and device malfunction were reported in less than 2% of the ALERTS trials population.

3.3. The Committee considered the clinical effectiveness of intracardiac monitors. Compared to patients relying on symptoms alone, improvements were shown to be limited to diagnostic performance measures and healthcare delivery metric outcomes such as positive predictive value, false positive rate, and reduced time-to-door for ACS events. However, there was no evidence that these improvements resulted in reductions in key clinical outcomes, including cardiac events or mortality. Limited quality of life (QOL) data suggested improvements in QOL using the Guardian System, although, the clinical meaningfulness of such improvements was uncertain.

3.4. The Committee acknowledged that there was only one ongoing trial on intracardiac monitors for ACS event detection, and that the clinical evidence base is not expected to change substantially.

Cost effectiveness

4.1. No local economic evaluation was identified. The Committee noted a single manufacturer-funded cost-effectiveness study conducted from a US healthcare perspective, which shared key limitations with the ALERTS trial. The results are of limited applicability to the Singapore setting.

4.2. The Committee also noted that intracardiac monitors for ACS event detection are currently not reimbursed in any overseas reference jurisdictions.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be between SG$3 million and SG$5 million. This was based on the projection of approximately 190 eligible patients in Singapore who would benefit from Government subsidy for intracardiac monitors.

Organisational feasibility

6.1. The Committee noted limited interest in adopting the technology within public healthcare institutions. Key concerns included uncertain clinical and cost effectiveness, potential implantation complications, and whether ACS event alerting leads to meaningful improvements in outcomes. Clinicians also indicated that Singapore's small geographic size, efficient emergency medical services, and low ACS recurrence rates reduce the clinical need for the device, with uptake expected to be very low in the local population.

Recommendations

7.1. Based on available evidence, the Committee recommended not listing intracardiac monitors on the MOH Implant Subsidy List (ISL) for ACS event detection, due to limited evidence of clinically meaningful benefit, lack of cost-effectiveness, and low clinical need relative to standard care.