



Medical Services Advisory Committee Public Summary Document

Application No. 1117 – Doppler Cardiac Output Measurement Without Imaging

Sponsor: USCOM Ltd

Date of MSAC consideration: 45th MSAC meeting, 5 June 2009, Sydney

1. Purpose of Application

Cardiac continuous wave Doppler ultrasound without imaging is a non-invasive tool for real-time monitoring and measurement of cardiac output and other cardiac flow parameters. This technology measures cardiac output by detecting and measuring blood flow velocity and direction. The Doppler shift is dependent on the velocity of blood movement and the angle between the sound beam and direction of moving blood. Information from reflected sound waves can be computer analysed to represent blood flow through vessels.

The application referred to the use of the USCOM device (manufactured by USCOM Limited), which is a non-invasive device that uses continuous wave Doppler ultrasound technology for haemodynamic monitoring. It is designed and intended for use in a number of clinical settings for patients who may require cardiac output measurement for haemodynamic monitoring.

The applicant requested that three separate MBS items (for each of the indications represented by items 55113, 55114 and 55115) be established for the professional service of cardiac continuous wave Doppler ultrasound without imaging, at a fee of \$150.07 which is lower than the comparator service.

2. Background

Applications to MSAC undergo an eligibility step that includes an assessment of the application's compliance with any required Therapeutic Goods Administration (TGA) listing, conformity with MSAC's Terms of Reference, and consistency with Government policy.

MSAC receives a report from expert independent evaluators on the strength of the evidence of the safety, effectiveness and cost-effectiveness of the requested procedure and related technology, which is produced under the guidance of an Advisory Panel consisting of MSAC members, clinical experts, and consumer representatives. The applicant is consulted at the initial research protocol stage and at the final draft report stage of the production of this report.

The comparator proposed in the research protocol and subsequently used in the report was Pulmonary Artery Catheterisation (PAC). The literature review identified only studies comparing the use of the USCOM device with PAC in adult intensive care and intraoperative settings.

At its 45th MSAC meeting, MSAC considered the strength of the evidence for the safety, effectiveness and cost-effectiveness for Doppler Cardiac Output Measurement Without Imaging compared with PAC. Members considered the final report of the evaluation of the evidence (as endorsed by the Advisory Panel), the applicant's response and evaluator's rejoinder, as well as presentations/input from the 1st discussant (independent MSAC member), 2nd discussant (MSAC Advisory Panel Chair), and the MSAC Economics Sub Committee.

3. Safety

On the basis of the evidence presented, MSAC was satisfied there are no known safety concerns relating to the use of continuous wave Doppler ultrasound with a non-imaging probe. In terms of complications associated with the technique itself, MSAC acknowledged that Doppler ultrasound was safer than PAC.

4. Clinical effectiveness

No evidence was found that continuous wave Doppler ultrasound has an impact on management or patient outcome.

- The review identified 6 comparative studies of USCOM vs PAC in adult intensive care or intraoperative settings. All included studies were Level III-3 and of fair (N=5) or poor (N=1) quality based on the NHMRC hierarchy for levels of evidence.
- The technique is operator-dependent, but no measures of intra-observer or inter-observer reproducibility were identified in the assessment report.
- Agreement with PAC measurements was assessed by Bland-Altman analysis of differences between pairs of measurements. Acceptable limits of agreement were considered to be a bias of < 0.5 L/min and a 95% precision of +/- 1.0 L/min.
- The identified studies evaluating the level of agreement between USCOM and PAC estimates of cardiac output revealed inconsistent findings and it was therefore not possible to conclude equivalence with PAC.

5. Cost effectiveness

An economic analysis was not conducted in view of the findings that:

- (i) equivalence could not be concluded between USCOM and PAC as regards measurement of cardiac output; and
- (ii) impact on patient management and patient outcomes was not demonstrated.

6. Rationale for MSAC's Advice

MSAC found great uncertainty in the evidence relating to this application, including the clinical value of haemodynamic monitoring by means of the proposed new service and its comparator. Members also noted evolving trends towards less invasive cardiac output monitoring.

MSAC discussed the differences in technology and noted that PAC provided additional information not provided by non-imaging continuous wave Doppler ultrasound (PAC allows monitoring of filling pressures), although the proposed non-invasive service was safer than PAC as well as being less expensive compared to PAC monitoring.

However, MSAC agreed that on the basis of available evidence relating to clinical efficacy, it could not support public funding, despite the fact that Doppler was safer and less expensive than PAC.

Furthermore, MSAC suggests that the Minister may care to re-assess the MBS listing of PAC in view of concerns about its safety, effectiveness and cost effectiveness found in the literature review.

16 of the 17 MSAC members present for this discussion were in favour and one member abstained when the motion was put to not support public funding for this service.

MSAC advises that it does not support public funding for cardiac continuous wave Doppler ultrasound without imaging.

7. Context for Decision

This advice was made under the MSAC Terms of Reference:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

8. Linkages to Other Documents

The MSAC Advisory Panel Report is available at
<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSACCompletedAssessments1101-1119>