



Medical Services Advisory Committee

Public Summary Document

Reference No. 35f – Positron Emission Tomography for Myocardial Viability

Sponsor: Diagnostic Services Branch
Department of Health and Ageing

Date of MSAC consideration: 48th MSAC meeting, 29-30 March 2010

1. Purpose of Application

This referral is a second phase assessment of positron emission tomography (PET) by the Department of Health and Ageing who requested the Medical Services Advisory Committee (MSAC) to review PET for public funding in relation to head and neck cancer, oesophageal gastric cancer, lymphoma, glioma, sarcoma, cervical cancer and ischaemic heart disease. The conclusion of the 2000 Review was that at that time there was 'insufficient evidence from which to draw definitive conclusions about the clinical effectiveness and cost effectiveness of PET' to warrant unrestricted Medicare Benefits Schedule (MBS) funding. As a consequence of the Review, interim funding was extended to seven PET facilities on the condition that data be collected for further evaluation of PET in Australia.

An application from the Diagnostics and Technology Branch (now Diagnostics Services Branch), Department of Health and Ageing was made to MSAC to review the value of PET using F-18 fluorodeoxyglucose (FDG) for assessing myocardial viability in patients with moderate to severe left ventricular systolic dysfunction by comparison with alternative tests:

- 1 single photon emission computed tomography (SPECT)
- 2 contrast-enhanced magnetic resonance imaging (CE-MRI)
- 3 low-dose dobutamine echocardiography (DE)

2. Current arrangements for public reimbursement

The MBS interim funding arrangement (Item number 61562), due to cease on 1 July 2010, provides reimbursement for FDG PET study of the heart, performed for the evaluation of ischaemic heart disease and impaired left ventricular function, where revascularisation surgery is being considered and standard myocardial viability tests are negative or equivocal for ischaemia.

3. Background

PET is a nuclear imaging technique using a short lived radiopharmaceutical (in this instance 2-¹⁸F-fluoro-2-deoxy-D glucose, FDG). The technique provides functional and metabolic information and current scanners incorporate CT in the same instrument.

The evaluation relates to patients with chronic coronary artery disease (CAD) and moderate to severe left ventricular (LV) systolic dysfunction. For these patients, options include medical therapy, device therapy, cardiac transplant or, if they have myocardium which is ischaemic but viable, revascularisation. However, poor LV function makes surgical revascularisation a high risk procedure, particularly for patients with other comorbidities (e.g. diabetes and impaired renal function). There is a need to determine which patients are most likely to benefit and this is done

using myocardial viability testing. This can be achieved with FDG-PET and alternative tests are: SPECT using thallium-201 (TI-201) or technetium-99m labelled agents (Tc-99m sestamibi or tetrofosmin); low-dose dobutamine echocardiography (DE); and delayed contrast-enhanced magnetic resonance imaging (DCE MRI).

FDG PET is expected to improve patient outcomes by more accurately identifying patients with viable myocardium who are most likely to benefit from revascularisation. PET is also expected to improve patient outcomes through the avoidance of surgery, and its associated morbidity and mortality, in those patients who are unlikely to benefit.

4. Clinical need

MSAC discussed the incidence of patients with moderately-to-severely impaired LV systolic function due to coronary disease, including a wide disparity between estimated disease prevalence, current demand and potential utilisation. MSAC also discussed the concept of hibernating myocardium and noted that while revascularisation improved LV systolic function in such patients, improvement in overall patient outcomes (cardiac death and major adverse cardiac events [MACE]) was unproven. MSAC noted that the use of PET/CT may avoid expensive and morbid interventions.

5. Comparator

MSAC agreed that the appropriate comparators for FDG-PET / CT to assess myocardial viability in patients with CAD and moderate to severe left ventricular systolic dysfunction were the alternative tests, SPECT, CE-MRI and DE.

MSAC noted that the evidence base is limited, and noted that PET is not in routine use for this indication in Australia at an average of only 18 scans per year. MSAC also noted that while access to PET may impose some limitation on use, the more routinely used comparators are part of existing workflows. Of the comparators, both SPECT and DE currently attract a Medicare benefit (although not specifically for myocardial viability testing) while CE-MRI does not.

6. Safety

PET and PET/CT are considered safe procedures. Patients undergoing PET/CT will be exposed to low doses of ionizing radiation, but potential benefits outweigh radiation risks.

7. Clinical effectiveness

PET/CT was considered by MSAC to have comparable accuracy to DE, SPECT and CE-MRI, with all the comparators having similar diagnostic performance.

MSAC noted that randomised controlled trial (RCT) evidence did not demonstrate a reduction in cardiac death or MACE in patients revascularised after viability testing by PET versus SPECT or conventional management, although the studies were under-powered.

MSAC noted that there was no RCT evidence that coronary revascularisation in patients with heart failure and non-contractile but viable myocardium is of greater benefit than optimal medical therapy. In the absence of such evidence, the value of viability testing by any means is unproven. MSAC also noted that two multicentre trials were currently underway to test this question, the Heart Failure Revascularisation Trial (HEART) and the Surgical Treatment for Ischemic Heart Failure (STICH) Trial.

8. Cost-effectiveness

MSAC noted that due to insufficient evidence to undertake economic evaluation, only financial estimates were made. MSAC agreed that the superiority of PET/CT over comparator tests, including existing funded tests, was not demonstrated. MSAC found that an additional area of economic uncertainty was the likely proportion of public versus private utilisation of PET if public funding were approved for this indication. MSAC noted that PET for this indication could be up to around three times more expensive per unit cost than the comparator technologies.

MSAC also noted that multiple tests were likely to be used in managing these patients – i.e. not simple PET versus CE, MRI or DE. Higher risk patients will tend to have more tests to increase the

clinician confidence when referring a patient for revascularisation.

9. Financial/budgetary impacts

MSAC considered the potential volume of use per year, as well as data that showed that during the period of interim funding (2001 to 2009) actual usage of this item was very low, and that general funding of PET for this indication was unlikely to increase utilisation substantially due to the availability and costs of the comparators. MSAC agreed there was no evidence to support continued funding.

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

MSAC considered the use of FDG PET to assess myocardial viability by comparison with alternative tests (single-photon emission computed tomography [SPECT]/contrast-enhanced magnetic resonance imaging [CE-MRI]/dobutamine echocardiography [DE]) in patients with moderate to severe left ventricular systolic dysfunction and found that considerable uncertainty remained regarding health outcome benefits attributable to PET. MSAC agreed that PET for this indication could be up to around three times more expensive per unit cost than the comparator technologies.

MSAC noted the difficulty in selecting patients with moderately to severely impaired left ventricular function who would be most likely to benefit from revascularisation, and RCT findings to date, albeit from small studies, are that the use of PET does not result in improved outcomes compared to SPECT or conventional management algorithms.

MSAC also noted that it remains to be proven whether surgical revascularisation offers outcome benefits over optimal medical therapy for patients with coronary artery disease and moderate to severely impaired left ventricular systolic function in the absence of angina – this is currently the subject of clinical trials.

11. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to safety, effectiveness and cost-effectiveness, MSAC found that PET had no advantages in diagnostic accuracy or safety, and that the unit cost was up to three times greater, compared to other modalities for assessing myocardial viability in patients with moderate to severe left ventricular systolic dysfunction.

MSAC does not support the continuation of public funding for FDG PET for assessing myocardial viability in patients with moderate to severe left ventricular systolic dysfunction.

12. 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.

13. Linkages to Other Documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.

The MSAC Assessment Report is available at <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/completed-assessments>