**Title: CEA-scan for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum, 2005**

**Agency:** Medical Services Advisory Committee (MSAC) Australian Government Department of Health and Ageing

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**Reference: MSAC Application 1062. Assessment report ISBN 0 642 82737 0**

# Aim

To assess the safety, effectiveness and cost effectiveness of CEA-scan® for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum and the circumstances under which public funding should be supported for it.

# Conclusions and results

## Safety.

The main safety concerns relating to the routine use of CEA-scan® are allergic reaction to the murine antibody, exposure to radiation and the increased risks associated with repeat tests. The reported incidence of allergic reaction to the murine antibody is less than 1%. Overall, of 453 patients receiving CEA-scan® in nine clinical trials, 3% were reported to have adverse events so severe reactions are likely to be rare events. A previous immune response to murine antibodies increases the chance of serious immune reactions or immune complex disease. The radiolabel employed in CEA-scan® emits low energy radiation with very limited destructive ability.

## Effectiveness

The comparator for the assessment of diagnostic accuracy of CEA-scan® was FDG-PET. Only two small studies directly compared CEA-scan® and FDG-PET. CEA-scan® was less accurate than FDG-PET in both these studies. Estimates of accuracy of CEA-scan® varied widely. Small study size and selection bias are likely to have strongly influenced the results in a significant number of the studies. The reported accuracy of CEA-scan® was generally low. In the single large clinical trial identified, CEA-scan® had a

reported sensitivity of 71% and specificity of 63%. Studies examining the diagnostic accuracy of FDG-PET

reported overall sensitivities of 71-100% and specificity of 43-100%. The median sensitivity and specificity of FDG-PET from 12 recent clinical studies was 97% and 94% respectively.

## Cost-effectiveness

At present there is no evidence to suggest that CEA-scan® is as accurate as the comparator FDG-PET or that it leads to an improved long term outcome for patients. A full health economic analysis was therefore not undertaken.

# Recommendations

MSAC recommended that after consideration of safety, effectiveness and cost-effectiveness,

public funding should not be supported for this procedure.

# Method

A systematic review of CEA-scan® for imaging recurrence and/or metastases in patients with histologically demonstrated carcinoma of the colon or rectum was conducted. The literature was searched up to January 2004 using Medline, Embase, Current Contents, Science Citation Index, Cochrane Library, DARE, and various website sources. Study selection criteria were stipulated and standard checklists were used to appraise study quality.

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