

<b>Title:</b>	<b>M2A® Capsule Endoscopy</b>
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### **Aim**

To assess the safety, effectiveness and cost-effectiveness of M2A® Capsule Endoscopy (CE) for the evaluation of obscure gastrointestinal bleeding (OGIB) in adult patients after upper gastrointestinal endoscopy and colonoscopy have failed to determine the bleeding source.

### **Conclusions and results**

#### **Safety**

The adverse events associated with the use of CE in patients with OGIB appear to be infrequent and mild in nature. The most commonly reported adverse events associated with CE are abdominal pain, nausea and vomiting. In isolated cases the delayed passage of CE has been associated with abdominal pain, hospitalisation, and GI obstructive symptoms. In other isolated cases the capsule has become lodged in a patient's bronchus and in a patient's throat. In both of these cases the capsule was removed without complication.

#### **Effectiveness**

**Diagnostic yield:** Due to the lack of a suitable reference standard for CE, diagnostic yield was used as the measure of diagnostic test performance in this assessment. This measure does not take into consideration the number of false positive and false negative results that may be associated with the findings of CE or small bowel series radiography (SBS, the comparator). Therefore, the diagnostic yield is likely to overestimate the diagnostic capabilities of these two procedures. The summary point estimates (median values) of diagnostic yield for these two tests were: 58% for CE and 4% for SBS, as determined by indirect comparison utilising a Bayesian analysis. These point estimates were surrounded by wide credibility intervals due to the limited quantity of SBS data available. Despite this fact, the odds ratio of diagnostic yield of CE versus SBS was statistically significant and favoured CE. In all of the published studies, patients had undergone extensive investigation prior to the administration of CE, often including prior investigation with SBS and are likely to resemble the current Australian prevalent OGIB patient population. The incremental estimates of diagnostic yield derived from these studies may overestimate the apparent benefit of CE in an incident patient population where the CE is used as a third line investigation (ie, after upper endoscopy and colonoscopy).

**Change in clinical management/clinical outcomes:** There are little available data on this technology's effect on patient management and long-term clinical outcomes. There are no head-to-head (ie, SBS versus CE) comparative studies that report changes in clinical management or clinical outcomes associated with CE.

#### **Cost-effectiveness**

A modelled economic evaluation assessing the cost-effectiveness of CE relative to SBS found that CE was associated with lower total health care costs overall, an estimated saving of \$1007 per patient. However, this result should be interpreted with respect to the key assumptions used in the economic model. The key assumptions used in the economic model were:

- The mean diagnostic yield of CE is sixty per cent.
- A positive diagnostic yield with CE will prevent all further diagnostic procedures.
- The ongoing treatment costs of OGIB are at least \$683 per patient per year.

A reduction in the uncertainty around the following key questions would improve the reliability of the results of the economic model.

#### **Recommendation**

The MSAC recommended that, on the strength of evidence pertaining to M2A® Capsule Endoscopy for use in obscure GI bleeding, interim funding should be supported for this procedure for patients with confirmed recurrent obscure gastrointestinal bleeding following previous colonoscopy and endoscopy without identifying bleeding source. The recommendation is to be reviewed no later than three years from the date of this report. The Minister for Health and Ageing accepted this recommendation on 7 September 2003.

#### **Methods**

The MSAC conducted a systematic review of the medical literature pertaining to CE. Those citations that met predefined inclusion criteria were included in the review of evidence. The cost-effectiveness of CE was evaluated using a decision-analytic economic model.