Title: Double-balloon enteroscopy – November 2006

**Agency:** Medical Services Advisory Committee (MSAC)

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http://www.msac.gov.au

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#### Aim

To assess the safety, effectiveness and cost-effectiveness of double-balloon enteroscopy (DBE) for obscure gastrointestinal bleeding or suspected small bowel disease relative to laparotomy with or without intra-operative enteroscopy.

## **Conclusions and results**

### Safety:

Fourteen uncontrolled case series and four case reports were identified which reported on the safety of DBE. Major complications such as perforation, sepsis, and ileus were reported in less than 1 per cent of patients. No deaths were reported in the studies identified and the most common cause of major complication was pancreatitis, of which the majority were resolved with conservative therapy. Minor complications such as abdominal pain, sore throat or fever (the majority of which were self-limiting) were experienced in 7.2 per cent of procedures. No studies comparing the relative safety of DBE against the comparative procedures of laparotomy with or without intra-operative enteroscopy were been identified at this time. Overall, without direct comparative safety data, it is not possible to conclude that DBE is as safe as, or safer than, the comparators. However, it is likely that, due to its much less invasive nature, fewer complications would arise as a result of using DBE.

# Effectiveness:

Effectiveness outcomes of DBE were reported in 11 uncontrolled case series. Ten case series reported the success of DBE as a therapeutic intervention, ranging from 77 to 100 per cent, with six studies reporting 100 per cent success of the treatments used. Biopsy yield or diagnostic yield was reported in all 11 case series and ranged between 68 and 93 per cent. Transfusion requirement after DBE was poorly reported, with only one study reporting a 70 per cent reduction in the number of patients requiring transfusion after treatment by DBE. As no data compared DBE with laparotomy with or without intra-operative enteroscopy, no conclusions can be drawn regarding the relative effectiveness of the procedure. However, on the basis of the evidence identified, DBE appears to be effective at providing therapies to small bowel lesions.

### Cost-effectiveness:

As there was no comparative evidence on DBE, it was not possible to determine if the procedure was as effective as, or more effective than, the comparators. As a consequence, a financial incidence analysis was performed which indicated that although performing DBE would be more costly to the Commonwealth relative to the comparators, there were likely to be savings to the Australian healthcare system overall.

## Recommendations

Double-balloon enteroscopy (DBE) is a safe, minimally invasive technique for endoscopically examining the whole of the small intestine, allowing biopsy and certain therapeutic procedures at the same time. While there is no direct comparative data, DBE is likely to be safer to perform than the most appropriate alternative, intra-operative enteroscopy. DBE is effective in allowing enteroscopic assessment and some treatment of the entire small intestine. Although more costly to Medicare than intra-operative enteroscopy, DBE is potentially cost saving for the entire health funding system. MSAC recommends public funding for DBE for the diagnosis and treatment of patients with obscure gastrointestinal bleeding.

The Minister for Health and Ageing accepted this recommendation on 5 February 2007.

#### **Methods**

Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (2001- May 2006). Specific journals were handsearched and reference lists pearled. Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised, data extracted in a standardised manner, and findings synthesised qualitatively.