



Australian Government

Medical Services Advisory Committee

## Public Summary Document

### *Application 1206 – Single balloon enteroscopy for obscure gastrointestinal bleeding*

**Sponsor/Applicant/s:** Olympus Australia Pty Ltd

**Date of MSAC consideration:** 28 November 2013

#### **1. Purpose of application**

An application requesting Medicare Benefits Schedule (MBS) listing of single balloon enteroscopy (SBE) for the diagnosis and/or management of obscure gastrointestinal (GI) bleeding was received by the Department of Health from Olympus Australia Pty Ltd in December 2011.

SBE can be performed by either the antegrade (oral) or retrograde (anal) route and needs the same preparation as a standard endoscopy.

For SBE, a 200-centimetre-long flexible endoscope is fitted with an over-tube that slides over the endoscope. The tip of the over-tube has a balloon. When the balloon is inflated against the bowel wall it anchors the over-tube within the small bowel and allows the enteroscope to be inserted more deeply, while withdrawing the anchored over-tube makes the bowel shorter and straighter, allowing the endoscope to progress through the lumen. With the balloon deflated, the over-tube can be inserted further and the endoscope advanced again. The enteroscope is similar to a standard fiberoptic endoscope, allowing the intestine to be fully viewed, inflated with air, rinsed with water, and biopsies or therapeutic procedures to be performed.

Double balloon enteroscopy (DBE) is listed on the MBS for the evaluation of obscure gastrointestinal bleeding (items 30680, 30682, 30684, 30686). It involves the sequential use of two balloons in a 'push-pull' fashion, whereby one latex balloon is situated at the end of the endoscope and another on the overtube. Both are inserted as far as possible into the bowel (via an antegrade [oral] approach or retrograde [anal] approach), and the overtube balloon is then inflated to anchor it in place. Pulling gently, the small intestine is pleated behind the balloon and straightened in front of the balloon allowing for the endoscope to be pushed further into the lumen.

SBE differs from DBE in that it has a 'hooked tip' on the endoscope in lieu of a second balloon, and has been suggested by the applicant as a non-inferior alternative technique to DBE. Both techniques require considerable skill. SBE was developed in an attempt to reduce the additional technical difficulty associated with using two balloons.

Patients are only considered for balloon enteroscopy if they have obscure GI bleeding and an upper GI endoscopy and a colonoscopy have not established the cause of the bleeding.

Obscure GI bleeding is generally accepted to be GI bleeding that persists or recurs without an obvious aetiology after standard endoscopic examination (routine upper endoscopy and colonoscopy). Obscure GI bleeding may be categorised into two groups: obscure occult and obscure overt bleeding. Obscure occult GI bleeding is defined as persistently positive faecal occult blood testing with or without iron deficiency and without frank blood loss recognisable to the patient or the physician.

Other less common diseases of the small bowel can also be diagnosed and/or managed using balloon enteroscopy.

Both SBE and DBE are used for intervention as well as diagnosis.

## **2. Background**

MSAC has not previously considered SBE.

MBS items 30680, 30682, 30684 and 30686 were introduced on the Schedule in July 2007 following an assessment by MSAC (Application 1102) of DBE for the diagnosis and treatment of patients with obscure GI bleeding.

## **3. Prerequisites to implementation of any funding advice**

Devices for SBE are registered with the Therapeutic Goods Administration (TGA) on the Australian Register of Therapeutic Goods (ARTG). At the time of the application four SBE products were known by MSAC to be listed on the ARTG. Interested parties can review the TGA website for current SBE products listed in the ARTG.

## **4. Proposal for public funding**

The application proposed that the MBS items numbers for DBE be amended to replace the term 'double balloon enteroscopy' with 'balloon-assisted enteroscopy' so that the same MBS items may be used for either DBE or SBE.

Consultation feedback provided in November 2012 by the Gastroenterological Society of Australia and the Colorectal Surgical Society of Australia and New Zealand refers to the term "balloon enteroscopy". Therefore, this term has been used in the proposed item descriptors.

MBS items for capsule endoscopy (CE) would also need to be amended to cross-reference balloon enteroscopy (or the MBS item numbers) rather than DBE. The Protocol Advisory Sub-Committee (PASC) of MSAC and public consultation submissions recommended that items 30684 and 30686 be further amended to allow for procedures involving argon plasma coagulation.

## Applicant's Proposed MBS item descriptors amendments for balloon enteroscopy

Category 3 – Therapeutic procedures
<p><b>30680 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del></b>, examination of the small bowel (oral approach), with or without biopsy, WITHOUT intraprocedural therapy, for diagnosis of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30682 or 30686)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"><li>(i) have recurrent or persistent bleeding; and</li><li>(ii) be anaemic or have active bleeding; and</li><li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li></ul>
<p><b>30682 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del></b>, examination of the small bowel (anal approach), with or without biopsy, WITHOUT intraprocedural therapy, for diagnosis of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30680 or 30684)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"><li>(i) have recurrent or persistent bleeding; and</li><li>(ii) be anaemic or have active bleeding; and</li><li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li></ul>
<p><b>30684 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del></b>, examination of the small bowel (oral approach), with or without biopsy, WITH 1 or more of the following procedures (snare polypectomy, removal of foreign body, diathermy, heater probe, laser coagulation or <b>argon plasma coagulation</b>), for diagnosis and management of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30682 or 30686)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"><li>(i) have recurrent or persistent bleeding; and</li><li>(ii) be anaemic or have active bleeding; and</li><li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li></ul>
<p><b>30686 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del></b>, examination of the small bowel (anal approach), with or without biopsy, WITH 1 or more of the following procedures (snare polypectomy, removal of foreign body, diathermy, heater probe, laser coagulation or <b>argon plasma coagulation</b>), for diagnosis and management of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30680 or 30684)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"><li>(i) have recurrent or persistent bleeding; and</li><li>(ii) be anaemic or have active bleeding; and</li><li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li></ul>

Eligibility for SBE would be limited to patients with obscure GI bleeding. The patient would also be required to present with the following symptoms:

- i) recurrent or persistent bleeding; and
- ii) be anaemic or have active bleeding; and
- iii) have an upper GI endoscopy and colonoscopy performed which did not identify the cause of the bleeding.

This patient population is the same for those patients suitable for DBE.

It was expected that the majority of patients would receive balloon enteroscopy a maximum of twice (once per approach). However, some patients may require more than two balloon enteroscopy procedures by either route, to re-treat lesions, or if the patient continues to bleed.

The application indicated that as with DBE, SBE would be performed in public and private day-stay endoscopy units by specialist gastroenterologists and specialist surgeons with

appropriate approved training in endoscopic procedures. Credentialing, training and accreditation processes would be the same as for DBE, with retrograde balloon enteroscopy considered more difficult than antegrade.

## **5. Consumer Impact Statement**

The application indicated that given the small population which would be eligible for SBE, only a small number of facilities would be likely to purchase the capital equipment required. As with DBE, it is likely therefore only to be available in some capital cities. SBE would be used as a substitute for DBE based on operator preference.

Feedback from a specialist to the consultation Decision Analytic Protocol (DAP) identified that the waiting time for DBE is significant as its availability is limited. SBE would be more widely available, so that patients should have better access and be treated more promptly.

## **6. Proposed intervention's place in clinical management**

The use of SBE would not impact the rate of any other investigations or interventions, other than DBE.

The majority of patients would have a CE prior to either SBE or DBE, to indicate whether there is a lesion in the small bowel, and whether it is likely to be suitable for enteroscopic intervention or requires surgery with or without intra-operative enteroscopy (if further investigation or diagnosis is not required prior to surgery for treatment).

SBE was proposed as an alternative service for the currently subsidised intervention, DBE. There would be rare cases when one form of balloon enteroscopy may be more appropriate than another, such as when a patient has a latex allergy (the DBE system has latex balloons whereas the SBE system has a silicon balloon), or when a patient in a liver transplant unit with altered anatomy is undergoing an endoscopic retrograde cholangiopancreatography (ERCP). In that situation, DBE may be more appropriate due the availability of both a standard enteroscope as well as a short enteroscope which is compatible with most ERCP accessories.

However, as a general rule, no changes would be expected using SBE in place of DBE in regards to the position of therapy, management options, or spectrum of patients treated.

The algorithm used was based on the management algorithm used in MSAC Assessment 1102 of DBE. The algorithm was amended to remove the small population of patients with small bowel pathology, without obscure GI bleeding, as DBE was listed on the MBS to be used only for those with obscure GI bleeding. It is possible that balloon enteroscopy may be useful in patients with small bowel disease who present without bleeding e.g. pain, obstruction, weight loss, diarrhoea. However, the application did not seek funding to be expanded to cover any indications not already listed for DBE.

The algorithm was also amended to specify that patients are required to have an upper GI endoscopy and a colonoscopy, prior to being classified as having obscure GI bleeding.

## **7. Other options for MSAC consideration**

Nil.

## **8. Comparator to the proposed intervention**

The application proposed that SBE is an alternative procedure for DBE. Therefore, the direct comparator for SBE is the currently used DBE and all procedures associated with its usage.

MSAC agreed that DBE is the appropriate comparator.

MBS items 30680, 30682, 30684 and 30686 for DBE were introduced on the Schedule from 1 July 2007.

## **9. Comparative safety**

Five comparative studies were identified for inclusion in the evaluation of the safety and effectiveness of SBE (four prospective, randomised controlled trials (RCTs) - May *et al* 2010, Takano *et al* 2011, Domagk *et al* 2011 and Efthymiou *et al* 2012; and one retrospective, non-randomised study - Lenz *et al* 2013).

In all five studies, the incidence of significant adverse events was low and comparable between SBE and DBE. There were no deaths related to enteroscopy reported in any of the five studies.

There were no reported cases of perforation, post-polypectomy sepsis, ileus, abscess, intestinal haematoma, bleeding, intussusception, infection or peritonitis caused by the procedure. There were no reports of pancreatitis, although there was one case of raised amylase with SBE.

MSAC noted that the patients included in the five comparative studies presented were undergoing enteroscopy for a number of reasons, not only for obscure gastrointestinal tract bleeding. In all five studies, the incidence of significant adverse events was low and comparable between SBE and DBE.

Overall, MSAC considered that SBE is likely to be non-inferior to DBE in terms of comparative safety.

## **10. Comparative effectiveness**

MSAC noted that in the four RCTs there was no significant difference in diagnostic yield between DBE and SBE. In the non-randomised study by Lenz *et al* (2013) a significant difference in diagnostic yield in favour of SBE was found. However, in this study DBE was performed over the period 2004 to 2011, whereas SBE was performed from 2008 to 2011. MSAC agreed that a change over time in the reasons for referral for enteroscopy or preference for the latter technique could account for the higher yield with SBE.

The non-randomised study by Lenz *et al* (2013) suggested increased effectiveness for one system or the other on various outcomes. However, such findings were generally not consistent with the findings of the RCTs and therefore may have been due to imbalances between the enteroscopy groups.

Four studies measured the percentage of patients in whom a therapeutic intervention (e.g. argon plasma coagulation, endoscopic haemostasis, polypectomy, dilatation) can be undertaken during enteroscopy. The results did not suggest that SBE is associated with inferior ability to perform therapeutic interventions compared with DBE.

The results of the four RCTs suggest that SBE has comparable effectiveness to DBE. The only effectiveness outcome that suggested an advantage for DBE was the complete enteroscopy rate. However, even if this was a real difference, the higher rate of complete visualisation of the small bowel did not translate into an improvement in diagnostic yield or other clinical outcomes.

Overall, MSAC considered that SBE is likely to be non-inferior to DBE in terms of comparative effectiveness.

## 11. Economic evaluation

A cost-minimisation analysis was presented taking into account that SBE will be undertaken relative to DBE.

Minimal differences were identified in the cost of health resources for SBE compared to DBE. The economic evaluation identified that all enteroscopic procedures can be done with the processing units used for standard endoscopy.

However, special accessories must be purchased for enteroscopes. DBE and SBE require a specific endoscope/overtube combination, and may require additional personnel during the procedure and fluoroscopy suites with associated costs. The estimated theatre and hospital costs are presented below.

### Direct health care resources

	Estimated cost - from Contracted Assessment (CA)
SBE endoscope (equipment cost)	\$37,500
SBE overtube (disposable i.e. single use)	\$225
Endoscopy unit	\$265
Ward	\$774 (per day)

SBE endoscope and overtube cost from ASGE (2007)

Endoscopy unit cost from AR-DRG V5.1 Private Sector G44C – Other colonoscopy, sameday service

Ward costs sourced from the Victorian Government guide to fees for admitted patients 2012/13

The equipment cost for SBE was noted in the economic evaluation. Taking into account the specialised nature of both SBE and DBE, and that the facilities for both procedures are currently available in the healthcare system, further capital and maintenance costs were not evaluated.

The economic evaluation listed the health resources and MBS items that may be associated with the procedure of SBE for obscure GI bleeding. The evaluation did not restrict the procedure of SBE by age group which is consistent for the currently funded intervention of DBE.

SBE would predominantly be performed in public and private day-stay endoscopy units which is consistent with the procedure of DBE. MBS statistics indicate that for 2012-13, 62% of services associated with DBE were provided in hospital. It is anticipated that the healthcare setting will remain constant with the introduction of SBE to the MBS.

Literature suggested that SBE may have a shorter procedure time compared to DBE. The list of MBS items associated with SBE is consistent with the items reported in MSAC Assessment 1102 (2006) for DBE. The slight differences in anaesthesia time for oral versus anal approach of the procedure were reflected in the financial analysis.

The application proposed the same Schedule fee for SBE as DBE.

### MBS items for DBE

MBS item	Schedule fee	Benefit
<b>30680</b> DBE – oral approach without intraprocedural therapy	\$1,170.00	75% = \$877.50
<b>30682</b> DBE – anal approach without intraprocedural therapy		85% = \$1,095.50
<b>30684</b> DBE – oral approach with 1 or more intraprocedural therapy	\$1,439.85	75% = \$1,079.90
<b>30686</b> DBE – anal approach with 1 or more intraprocedural therapy		85% = \$1,365.35

*MBS Schedule fees and benefits as at 1 July 2013*

## 12. Financial/budgetary impacts

MBS data indicated that the overall growth rate of the MBS items for DBE has been plateauing following introduction on the Schedule in July 2007. The services for 30684 and 30686 have shown a decrease from 2011-12 to 2012-13. To be consistent with the current slowdown of services for DBE, a 1.2% growth factor was estimated for the financial analysis based on the two year growth from 2010-11 to 2012-13.

Overall, the annual growth of MBS items for balloon enteroscopy was estimated at approximately seven services per financial year. The following table outlines the estimated service numbers for balloon enteroscopy procedures (DBE and SBE) for 2013-14 to 2017-18.

### Estimated services for balloon enteroscopy – 2013-14 to 2017-18 – from CA

MBS item	2013-14	2014-15	2015-16	2016-17	2017-18
<b>30680</b> oral approach	196	199	201	203	206
<b>30682</b> anal approach	189	192	194	196	198
<b>30684</b> oral approach with 1 or more procedures	128	129	131	132	134
<b>30686</b> anal approach with 1 or more procedures	63	63	64	65	66
<b>Total</b>	<b>576</b>	<b>583</b>	<b>590</b>	<b>597</b>	<b>604</b>

Patients may require one or more enteroscopy procedures (it is expected that the majority of patients would receive balloon enteroscopy a maximum of twice – once per approach). The financial analysis was based on the estimated growth of the MBS items for DBE. In 2012-13, there were \$584,759 benefits paid for items 30680 to 30686.

The total MBS cost incorporated a split of Medicare benefits for in-hospital and not-in-hospital services of the MBS items for:

- Initial consultation;
- Anaesthesia;
- Fluoroscopy for a specified proportion of the procedures; and
- The procedure based on DBE.

In 2013-14, the total MBS cost was estimated at \$740,048, with an annual increase of approximately \$20,000 per financial year as presented in the following table.

**Estimated total MBS cost – 2013-14 to 2017-18 – from CA**

	2013-14	2014-15	2015-16	2016-17	2017-18
<b>30680</b> Oral approach without intraprocedural therapy	\$239,855	\$247,345	\$255,069	\$263,034	\$271,248
<b>30682</b> Anal approach without intraprocedural therapy	\$226,076	\$233,136	\$240,416	\$247,924	\$255,666
<b>30684</b> Oral approach with intraprocedural therapy	\$184,855	\$190,628	\$196,581	\$202,720	\$209,050
<b>30686</b> Anal approach with intraprocedural therapy	\$89,262	\$92,049	\$94,924	\$97,888	\$100,945
<b>Total MBS cost</b>	<b>\$740,048</b>	<b>\$763,158</b>	<b>\$786,990</b>	<b>\$811,566</b>	<b>\$836,910</b>

*MBS Schedule fees and benefits as at 1 July 2013*

MSAC was satisfied that the addition of the SBE technique to the MBS was unlikely to expand the population and accepted that the financial and budgetary implications of including SBE on the MBS will be minimal.

**13. Key issues for MSAC from ESC**

ESC considered it was unclear where BE sits on the clinical management algorithm i.e. does BE replace capsule endoscopy (CE) and magnetic resonance imaging (MRI).

ESC suggested some restriction of the imaging modalities. ESC considered that it was inefficient to allow capsule endoscopy, CT imaging and MRI imaging all on the same person. However, ESC agreed it was reasonable to allow one of these services along with balloon endoscopy since the latter allows biopsy or intervention.

ESC suggested that expertise and credentialing were essential to keep the number of adverse events (AEs) low.

**14. Other significant factors**

Nil.

**15. Summary of consideration and rationale for MSAC's advice**

MSAC considered the application for an amendment of the current MBS items for DBE to include single balloon enteroscopy SBE. MSAC agreed that DBE is the appropriate comparator.

MSAC noted that the patients included in the five comparative studies presented were undergoing enteroscopy for a number of reasons, not only for obscure gastrointestinal tract bleeding. In all five studies, the incidence of significant adverse events was low and comparable between SBE and DBE.

In the four randomised controlled trials comparing the effectiveness of SBE with DBE, there was no significant difference in diagnostic yield, even with a reported higher complete enteroscopy rate for DBE. In the non-randomised, retrospective study by Lenz et al (2013) a significant difference in diagnostic yield in favour of SBE was found. However, in this study DBE was performed over the period 2004 to 2011, whereas SBE was performed from 2008 to

2011, and the proportion of patients referred for GI bleeding was significantly lower for SBE than for DBE. MSAC agreed that a change over time in the reasons for referral for enteroscopy or preference for the latter technique could account for the higher yield with SBE.

Overall, MSAC considered that SBE is likely to be non-inferior to DBE in terms of comparative safety and effectiveness.

MSAC noted that the MBS data for items 30680, 30682, 30684 and 30686 indicated that the growth rate of DBE appeared to be plateauing since its introduction on the Schedule in July 2007. MSAC was satisfied that noting current utility of DBE, the addition of the SBE technique to the MBS was unlikely to expand the population.

MSAC noted that SBE may be perceived by practitioners as being easier to perform than DBE which might increase utilisation. However, MSAC accepted that this risk was no more than for other endoscopic procedures and that the single balloon technique would be performed by a limited number of skilled practitioners. Based on MBS data from 2012/13, there were 30 providers performing DBE procedures, six providers claimed for one service and three providers claimed for 40 or more services. To reinforce the importance of credentialing, training and accreditation processes associated with this technique, MSAC requested that a letter be sent to the Gastroenterological Society of Australia (GESA) to highlight the number of practitioners performing only one procedure per year.

MSAC accepted that the financial and budgetary implications of including SBE on the MBS were expected to be minimal. The number of balloon enteroscopy procedures performed in Australia is projected to increase to 604 in 2017/18. Based on these figures, the estimated increase of MBS expenditure for balloon enteroscopy over 4 years will be less than \$100,000.

MSAC noted that argon plasma coagulation (APC) is an additional therapeutic option which is used routinely with balloon enteroscopy and agreed that the list of allowed procedures under the relevant MBS items should be updated to include APC.

### **Lay summary**

Patients with obscure gastrointestinal (GI) bleeding – that is, bleeding where the cause is not determined from initial medical procedures examining the GI tract – may be further investigated with balloon enteroscopy. A balloon enteroscope allows for a detailed investigation of the small bowel. Currently, MBS items are available for procedures using a double balloon technique. The application requested that a single balloon technique be included on the MBS.

The available evidence suggested that the single balloon technique is as effective and safe as the double balloon technique. MSAC noted that both double and single balloon techniques require a high level of skill to perform. MSAC supported public funding of SBE.

### **16. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of single balloon enteroscopy for obscure gastrointestinal bleeding, MSAC supports public funding by:

- amending current MBS items 30680, 30682, 30684 and 30686 to include the term 'balloon enteroscopy' to encompass both single and double balloon enteroscopy;
- amending current MBS items 30684 and 30686 to include argon plasma coagulation in the therapeutic interventions listed; and

- amending current MBS items 11820 and 11823 (for capsule endoscopy) to include the term ‘balloon enteroscopy’ for consistency.

Category 3 – Therapeutic procedures
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<p>30682 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del>  Examination of the small bowel (anal approach), with or without biopsy, WITHOUT intraprocedural therapy, for diagnosis of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30680 or 30684)  The patient to whom the service is provided must:</p> <ul style="list-style-type: none"> <li>(i) have recurrent or persistent bleeding; and</li> <li>(ii) be anaemic or have active bleeding; and</li> <li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li> </ul>
<p>30684 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del>  Examination of the small bowel (oral approach), with or without biopsy, WITH 1 or more of the following procedures (snare polypectomy, removal of foreign body, diathermy, heater probe, laser coagulation or <b>argon plasma coagulation</b>) for diagnosis and management of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30682 or 30686)  The patient to whom the service is provided must:</p> <ul style="list-style-type: none"> <li>(i) have recurrent or persistent bleeding; and</li> <li>(ii) be anaemic or have active bleeding; and</li> <li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li> </ul>
<p>30686 BALLOON ENTEROSCOPY <del>DOUBLE BALLOON ENTEROSCOPY</del>  Examination of the small bowel (anal approach), with or without biopsy, WITH 1 or more of the following procedures (snare polypectomy, removal of foreign body, diathermy, heater probe, laser coagulation or <b>argon plasma coagulation</b>) for diagnosis and management of patients with obscure gastrointestinal bleeding, not in association with another item in this subgroup (with the exception of item 30680 or 30684)  The patient to whom the service is provided must:</p> <ul style="list-style-type: none"> <li>(i) have recurrent or persistent bleeding; and</li> <li>(ii) be anaemic or have active bleeding; and</li> <li>(iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.</li> </ul>

### 17. Applicant’s comments on MSAC’s Public Summary Document

No comment.

## **18. Context for decision**

This advice was made under the MSAC Terms of Reference.

MSAC is to:

Advise the Minister for Health on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
- the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
- other matters related to the public funding of health services referred by the Minister.

Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

## **19. Linkages to other documents**

MSAC's processes are detailed on the MSAC Website at: [www.msac.gov.au](http://www.msac.gov.au).