Single Balloon Enteroscopy System for Obscure Gastrointestinal Bleeding (Small Bowel)

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Assessment report

Assessment Report - Single Balloon Enteroscopy System for Obscure Gastrointestinal Bleeding (Small Bowel)

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EXECUTIVE SUMMARY

BACKGROUND

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 from Olympus Australia Pty Ltd by the Department of Health and Ageing in December 2011.

Medical condition

Obscure GI bleeding is generally accepted to be GI bleeding that persists or recurs without an obvious etiology 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. Obscure overt GI bleeding is defined as clinically evident bleeding that persists or recurs after negative endoscopic examinations (Lin et al 2005).

Medical procedure

Double balloon enteroscopy (DBE) is an endoscopic technique for visualising the small bowel, which was introduced into clinical practice in 2001. It involves the use of an endoscope and a flexible overtube, both of which have an inflatable balloon at the distal tip. Inflation of the balloon enables the internal surface of the small bowel to be gripped. Alternating inflation and deflation of the balloons, combined with "push-and-pull" movements of the endoscope and overtube enables deep intubation of the small bowel.

Visualisation of the entire small bowel can be achieved using DBE. This usually requires two DBE procedures – one using an oral or antegrade approach, and another using an anal or retrograde approach. During the first procedure, at the point of maximum depth of insertion, the small bowel is tattooed. If this point can be reached during the second procedure (via the alternate approach) then complete enteroscopy is confirmed.

This application relates to SBE which is an alternate technique that was introduced into clinical practice in 2008. With this system there is no balloon on the tip of the endoscope. Gripping of the small bowel by the endoscope is achieved by angulating (or hooking) the end of the instrument on a fold of bowel. Gripping of the bowel by the overtube is achieved by use of the inflatable balloon, as in DBE.

The single balloon enteroscope system (Olympus, Tokyo, Japan) was developed in 2006 and was introduced into the commercial market in 2007.

The single balloon enteroscope system consists of the enteroscope, an overtube balloon control unit and a disposable silicone splinting tube with balloon (Manno et al 2012).

It is suggested that SBE is easier to use compared to double balloon enteroscope, as attachment of the enteroscope balloon to the distal tip of the scope is not required and neither is the inflation and deflation of the two balloons (Manno et al 2012).

Providers

As with DBE, SBE would be performed by specialist gastroenterologists and specialist surgeons with appropriate approved training in endoscopic procedures. Credentialling, training and accreditation processes would be the same as for DBE.

Retrograde balloon-assisted enteroscopy has been identified as more difficult than antegrade. It has been suggested that providers perform a minimum of 20 retrograde procedures in order to reach a basic skill level (Kaffes 2012). It has also been suggested that fluoroscopy may be beneficial during an endoscopist's first 10 to 20 SBE cases to observe advancement and reduction of the endoscope (Manno et al 2012).

Facilities

Given the small population who would be eligible for SBE, only a small number of facilities would be likely to purchase the capital equipment required (the multi-use insufflations system). As with DBE, it is therefore likely only to be available in some capital cities. It is likely that SBE would be used as an alternative for DBE based on operator preference.

SBE would predominantly be performed in public and private day-stay endoscopy units. The preparation and management of these patients would be no different to other endoscopy services and DBE. As with other endoscopic procedures, a small number of high-risk cases may require overnight admission to the public or private facility. Table 1 provides the total number of services provided in and out of hospital for DBE. It is anticipated that these total numbers will remain constant with the introduction of SBE.

Table 1 MBS items for DBE - in and out of hospital services

MBS item	2007-08*	2008-09	2009-10	2010-11	2011-12	2012-13
30680 DBE – oral approach						
In hospital	64	77	84	126	113	131
Not in hospital	19	44	64	64	76	63
Total	**83**	**121**	**148**	**190**	**189**	**194**
30682 DBE – anal approach						
In hospital	34	69	58	104	110	113
Not in hospital	22	28	42	46	56	74
Total	**56**	**97**	**100**	**150**	**166**	**187**
30684 DBE – oral approach with 1 or more procedures						
In hospital	47	54	84	94	97	75
Not in hospital	27	58	69	59	52	51
Total	**74**	**112**	**153**	**153**	**149**	**126**
30686 DBE – anal approach with 1 or more procedures						
In hospital	24	21	31	46	48	34
Not in hospital	6	16	18	23	23	28
Total	**30**	**37**	**49**	**69**	**71**	**62**
TOTAL	**243**	**367**	**450**	**562**	**575**	**569**

*Data for 2007-08 is for 4 months

Indications for treatment

Both SBE and DBE provide a means for intervention as well as diagnosis. To be eligible for SBE, patients would be required to present with the following (consistent with DBE):

a) A diagnosis of obscure GI bleeding;

b) Recurrent or persistent bleeding;

c) Anaemia or active bleeding; and

d) Have had an upper GI endoscopy and colonoscopy performed which did not identify the cause of the bleeding.

Therapeutic Goods Administration

The devices required for SBE have been registered with the Therapeutic Goods Administration on the Australian Register of Therapeutic Goods (see Table 4 on Page 13). The manufacturer is Olympus Medical Systems Corporation, Japan, and the sponsor is Olympus Australia Pty Ltd. These devices are not exempt from the regulatory requirements of the Therapeutic Goods Act 1989.

Proposed MBS listing

The applicant has proposed that the MBS items for DBE (30680, 30682, 30684, and 30686) be amended to replace the term “double balloon enteroscopy” with “balloon-assisted enteroscopy”, so that the MBS items may be used for DBE or SBE.

Currently, SBE and DBE are referred to as “balloon enteroscopy” or “balloon-assisted enteroscopy” (the term proposed by the applicant). Consultation feedback provided in November 2012 by the Gastroenterological Society of Australia and the Colorectal Surgical Society of Australia and New Zealand specifically refers to the term “balloon enteroscopy. Therefore, this term has been used in the proposed MBS item descriptors presented in Table 3 on Page 12.

Additionally, PASC indicated that MBS items 30684 and 30686 should be amended to allow for procedures involving argon plasma coagulation (APC). Consultation feedback indicated that APC is used routinely at balloon enteroscopy and should be considered in this application. The review of literature identified four studies that measured the therapeutic intervention yield (including APC). The findings of the studies do not suggest that SBE is associated with inferior ability to perform therapeutic interventions compared with DBE (see Page 25). Therefore, the proposed descriptors for items 30684 and 30686 allow for the procedure of APC.

The PASC also suggested simplifying the criteria by removing the requirement that patients be anaemic or have active bleeding. However, the removal of this criteria from the item descriptors has not been a part of the submission or the evaluation of the evidence, and therefore has not been incorporated in the amendments.

It should be noted that MBS items 11820 and 11823 for capsule endoscopy (CE) have the restriction “not being a service associated with double balloon enteroscopy”. This restriction would also need to be amended to cross-reference “balloon enteroscopy” (or the MBS item numbers), rather than double balloon enteroscopy, in line with the two current MSAC applications for CE:

- MSAC 1346 *Revision of Item 11820* (considered by MSAC in August 2013); and
- MSAC 1146.1 *Resubmission of CE for the Diagnosis of Suspected Small Bowel Crohn's Disease*.

Consumer impact

DBE is already funded through the MBS and available in both the public and private healthcare systems. It is anticipated that there will be no potential advantages (or disadvantages) to consumers should SBE be funded under the MBS.

Clinical claim

The applicant claims that SBE is non-inferior in regards to both safety and effectiveness when compared to DBE.

Primary evidence

Five comparative studies were identified for inclusion in this report - four prospective, randomised controlled trials and one retrospective, non-randomised study. All five comparative studies included subjects undergoing enteroscopy for a variety of indications, not just for obscure gastrointestinal tract (GIT) bleeding. Outcomes for the specific subpopulation of patients with obscure GIT bleeding were not presented separately in any of the published papers. The stated indications (suspected or known) for enteroscopy were as follows:

- GIT bleeding;
- Inflammatory bowel disease / Crohn's disease;
- Masses / tumours;
- Diarrhoea;
- Abdominal pain;
- Diarrhoea / abdominal pain;
- Polyposis;
- Coeliac disease; and
- Other.

In the four randomised controlled studies 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. The authors suggest that a change over time in the reasons for referral for enteroscopy may explain the higher yield with SBE.

The percentage of patients in whom a therapeutic intervention (e.g. argon plasma coagulation; endoscopic haemostasis; polypectomy; or dilatation) can be undertaken during enteroscopy was measured in four studies. The findings do not suggest that SBE is associated with inferior ability to perform therapeutic interventions compared with DBE.

DISCUSSION

Is it safe?

There were no deaths related to enteroscopy reported in any of the five comparative studies.

There were no reported cases of perforation, post-polyp sepsis, ileus, abscess, intestinal haematoma, bleeding caused by the procedure, intussusception, infection or peritonitis. There were no reports of pancreatitis although there was 1 case of raised amylase with SBE.

Is it effective?

In the four randomised controlled studies there was no significant difference in diagnostic yield between DBE and SBE. In the non-randomised study by Lenz (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. The authors suggest that a change over time in the reasons for referral for enteroscopy may explain the higher yield with SBE.

Is it cost-effective?

For the purposes of the economic evaluation, the health care resources and MBS items documented for SBE are assumed to be the same as for DBE.

What are the economic considerations?

SBE has been identified as likely to be non-inferior in terms of comparative safety and effectiveness. A cost minimisation analysis is presented taking into account that SBE will be undertaken relative to that of DBE. An economic evaluation is provided at Page 33 of this report.

What are the financial considerations?

The financial analysis has been based on the estimated growth of the MBS items for DBE. It is anticipated that the healthcare setting will remain constant should MBS funding be provided for SBE.

In 2012-13 there were 567 services for the MBS items available for DBE (items 30680, 30682, 30684 and 30686). A small growth in the number of procedures for “balloon enteroscopy” has been estimated to 2017-18 (Table 40 on Page 39). The increase in total MBS cost, including items for consultation, anaesthesia, fluoroscopy and enteroscopy, is estimated at approximately $20,000 per financial year (Table 42 on Page 40).

Conclusion

The four randomised controlled trials 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 is 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 outcome.

Differences in examination time between SBE and DBE were inconsistent across the four randomised studies and may have been due to factors other than ease of use of one particular system.

The non-randomised study (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 randomised studies and therefore may have been due to imbalances between the enteroscopy groups.

In all five studies, the incidence of significant adverse events was low and comparable between SBE and DBE.

The review of literature has therefore identified that SBE is likely to be non-inferior in terms of comparative safety and effectiveness. Therefore, a cost minimisation analysis is presented for the service relative to that of DBE.

As previously mentioned, 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 findings do not suggest that SBE is associated with inferior ability to perform therapeutic interventions compared with DBE.

CONTEXT

PURPOSE OF THE ASSESSMENT REPORT

An application requesting MBS listing of SBE for the diagnosis and/or management of obscure GI bleeding was received from Olympus Australia Pty Ltd by the Department of Health and Ageing in December 2011.

This report provides information for the assessment of the safety, effectiveness and cost-effectiveness of SBE for obscure GI bleeding. The report is based on the Decision Analytic Protocol (DAP) developed during the MSAC process.

Clinical Research Questions

1. Is SBE as safe, effective and cost-effective as DBE in patients with obscure GI bleeding?

BACKGROUND

Enteroscopy has advanced considerably in recent years, from the evolution of capsule endoscopy in early 2000, DBE in 2001, spiral enteroscopy in 2005 (Akerman et al 2012) and more recently SBE in 2007 (Kaffes et al 2012).

DBE involves using two balloons in a 'push pull' fashion, whereby one latex balloon is situated on the end of an endoscope and another on an 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 in order 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. With the endoscope fully extended, the second balloon situated on the endoscope can be inflated to anchor this in place and the overtube deflated and moved forward. Performing this procedure from both retrograde and antegrade approaches allows for complete visualisation of the small intestine (Lenz et al 2012).

SBE works in a similar fashion, but differs in that it has a 'hooked tip' on the endoscope in lieu of a balloon. The overtube is pulled back to shorten the bowel and the endoscope is pushed further into the lumen, as for DBE. An alternative technique has also been described where the balloon is pulled back at the same time as the endoscope is extended. Both techniques require considerable skill (Hartmann et al 2007). SBE was developed in an attempt to reduce the considerable technical learning curve required for DBE and to avoid the difficulties arising from having two balloons, which relate to the attachment of the balloon to the endoscope and the requirement for double balloon inflation and deflation in multiple repeated steps (Manno et al 2012).

Clinical presentation of patients

The investigation of obscure GI bleeding usually begins with a history of symptoms, past medical history, medications, family history, and a physical examination, although a history may not always be helpful in suggesting a diagnosis. Careful attention should be focused on the small bowel with reference to weight loss and obstructive symptoms.

Elderly patients, patients with a history of renal disease, a connective tissue disease, or von Willebrand's disease may be at higher risk for vascular lesions. Surgical patients may be at higher risk for anastomotic bleeds or aortoenteric fistulas. Users of nonsteroidal anti-inflammatory drugs have an increased risk of small bowel ulcerations. Important family history includes a history of inflammatory bowel disease, malignancies, or hereditary telangiectasias. Additionally, history and physical examination should focus on elements likely to be active in patients with easily overlooked lesions.

Difficult to identify causes of obscure GI bleeding include the following:

- Hemosuccus pancreaticus;
- Hemobilia;
- Aortoenteric fistula;
- Dieulafoy's ulcer (stomach more than other sites);
- Meckel's diverticulum; and
- Extraesophageal varices (gastric, small bowel, colonic) (Lin et al 2005).

A key first step in the investigation is typically to localise the site of bleeding. The appearance of the stool may also be suggestive of location of the bleeding. Blood that has been in the GI tract for less than 5 hours is usually red, whereas blood present for more than 20 hours is usually melenic (dark in colour). Upper GI, small bowel, or a slow right colon bleeding usually produces melena, whereas patients passing bright red, bloody stools (hematochezia) typically have left colonic or rectal lesions. Although melena and hematochezia are typically associated with upper and lower GI tract bleeding, respectively, it should be emphasised that patients with slow oozing from the distal small bowel or cecum may have melena and occasional patients with aggressive bleeding from an upper GI source may present with hematochezia (Lin et al 2005).

Indications for treatment

Obscure GI bleeding accounts for approximately 5% of all patients with GI bleeding (Zuckerman et al 2000) and is often difficult to clinically diagnose and manage. Clinical decisions often have to be made as to whether invasive investigation is required, such as intraoperative enteroscopy, or whether a supportive ''wait and see'' approach should be adopted which may include multiple transfusions; prothrombotic agents; and hormonal agents (Kaffes et al 2007).

USAGE OF SBE

The best source of data to estimate the potential use of SBE is the current utilisation of MBS items for DBE, which were listed on the Schedule in July 2007.

Statistics indicate that the usage of the four MBS items related to DBE (30680, 30682, 30684 and 30686) have remained relatively constant. As shown in Table 2, items 30680 and 30682 (oral or anal approach without intraprocedural therapy) have gradually increased each year since introduction in 2007. In comparison items 30684 and 30686 (oral or anal approach with intraprocedural therapy) saw an initial increase followed by a plateauing since 2011-12 (with a slight decrease in the last financial year of 2012-13).

Table 2 MBS items for DBE – usage 2007-08 to 2012-13

MBS item	2007-08*	2008-09	2009-10	2010-11	2011-12	2012-13
30680 DBE – oral approach without intraprocedural therapy	83	121	148	190	189	194
30682 DBE – anal approach without intraprocedural therapy	56	97	100	150	166	187
30684 DBE – oral approach with 1 or more intraprocedural therapy	74	112	153	153	149	126
30686 DBE – anal approach with 1 or more intraprocedural therapy	30	37	49	69	71	62
TOTAL	**243**	**367**	**450**	**562**	**575**	**569**

*Data for 2007-08 is for 4 months

The potential use for SBE would depend on the expected growth in use of balloon-enteroscopic techniques and market-share. Clinical advice is that the introduction of SBE will not increase the overall use of balloon-assisted endoscopies, as SBE will be used as an alternative for DBE. An important factor affecting the rate of use of SBE is the number of significant findings on capsule endoscopy (CE). Sidhu et al (2012) reported that in 2009, for every 17 CEs performed, one patient underwent DBE locally.

TECHNIQUE FOR SBE

The work-up required for SBE would be identical to the pre-procedural work-up required for DBE. No specific bowel preparation is required for the oral approach other than 12 hours of fasting, while the retrograde approach requires 4 L of polyethylene glycol and conscious sedation (Manno et al 2012). The SBE procedure lasts approximately one hour (Khashab et al 2010).

SBE would be performed in public and private day-stay endoscopy units, by specialist gastroenterologists and specialist surgeons. The use of SBE would not impact the rate of any other investigations or interventions, other than DBE.

In 2012-13, 33% of DBE procedures involved intra-procedural therapy. It is expected that the percentage of SBE procedures which involve treatment would be the same as for DBE. The remainder of procedures are likely to be purely diagnostic, or fail to identify the source of bleeding. In this latter case, a repeat balloon enteroscopy may then be performed from the alternative approach. MSAC Assessment 1102 (2006) for DBE indicated that 10% of patients would require both an antegrade and a retrograde procedure. There is no specific restriction in the proposed item descriptor to using SBE once per approach, however, it is 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 enteroscopies by either route, to retreat lesions, or if the patient continues to bleed. Based on a follow-up study on patients who received DBE, after 12 months, 23% of patients reported overt bleeding, and 35% reported ongoing iron therapy and/or transfusions. However, the rate of repeat DBE was only 10% (Gerson et al 2009).

In most cases no bowel preparation is required for SBE by the oral approach, however a minimum of 12 hour fasting while the standard polyethylene glycol (PEG) preparation is used for the retrograde approach (Manno et al 2012).

For retrograde SBE, conscious sedation as for colonoscopy is sufficient in most cases. For anterograde approach deep monitored sedation with propofol or general anaesthesia with intubation is recommended (Manno et al 2012).

Because of length of the procedure, large volumes of air are usually insufflated that can lead to failure of the procedure. Carbon dioxide (CO2), unlike standard air, is rapidly absorbed from the bowel. A randomised, double blind trial showed that insufflation with CO2 is safe, reduces patient discomfort, and significantly improves intubation depth (Manno et al 2012).

Fluoroscopy can be helpful during the initial 10 to 20 SBE cases to observe advancement and reduction of the enteroscope and as an aid to determine when looping is present and how to solve it. In addition, for some patients with surgically modified anatomy and for those undergoing therapeutic procedures such as dilations, fluoroscopic guidance is recommended (Manno et al 2012).

PROPOSED MBS LISTING

The applicant has proposed that the MBS items for DBE be amended to replace the term “double balloon enteroscopy” with “balloon-assisted enteroscopy”, so that the MBS items may be used for DBE or SBE. Currently, SBE and DBE are referred to as “balloon enteroscopy” or “balloon-assisted enteroscopy”. 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.

Additionally, PASC indicated that MBS items 30684 and 30686 should be amended to allow for procedures involving argon plasma coagulation (APC). Consultation feedback indicated that APC is used routinely at balloon enteroscopy and should be considered in this application. The review of literature identified four studies that measured the therapeutic intervention yield (see Page 25). Therefore, the proposed descriptors for items 30684 and 30686 allow for the procedure of APC.

The PASC also suggested simplifying the criteria by removing the requirement that patients be anaemic or have active bleeding. However, the removal of this criterion from the item descriptors has not been a part of the submission or the evaluation of the evidence, and therefore has not been incorporated in the amendments.

It should be noted that MBS items 11820 and 11823 for capsule endoscopy (CE) have the restriction "not being a service associated with double balloon enteroscopy". This restriction would also need to be amended to cross-reference "balloon enteroscopy" (or the MBS item numbers), rather than double balloon enteroscopy, in line with the two current MSAC applications for CE:

- MSAC 1346 *Revision of Item 11820* (considered by MSAC in August 2013); and
- MSAC 1146.1 *Resubmission of CE for the Diagnosis of Suspected Small Bowel Crohn's Disease*.

Table 3 Proposed MBS item descriptors

Category 3 – Therapeutic procedures
30680 BALLOON ENTEROSCOPY, 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) The patient to whom the service is provided must: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.
30682 BALLOON ENTEROSCOPY, 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: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.

30684 BALLOON ENTEROSCOPY, 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 **argon plasma coagulation**), 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: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.
30686 BALLOON ENTEROSCOPY, 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 **argon plasma coagulation**), 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: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding.

THERAPEUTIC GOODS ADMINISTRATION

The devices required for SBE have been registered with the Therapeutic Goods Administration (TGA) on the Australian Register of Therapeutic Goods (ARTG). The manufacturer is Olympus Medical Systems Corporation, Japan, and the sponsor is Olympus Australia Pty Ltd. These devices are not exempt from the regulatory requirements of the Therapeutic Goods Act 1989.

Table 4 ARTG listing of devices required for SBE

ARTG NUMBER	Description	Summary of intended purpose	ARTG start date
188394	Endotherapy overtube	Ensure complete positioning of the flexible endoscope for endoscopic insertions in the small intestine	23 August 2011
154294	Catheter-balloon inflation system, reusable	Manually inflate and regulate pressure within the catheter's balloon and to deflate the balloon	4 August 2008
114377	Enteroscope, flexible, video	Observation, diagnosis and treatment of small intestine during a surgical procedure	12 November 2004

COMPARATOR FOR SBE

The applicant has proposed that SBE is an alternative procedure for DBE, fulfilling the same role in the management algorithm. The MBS items for DBE are outlined in Table 5. The direct comparator for SBE is the currently used DBE and all procedures associated with the usage of this.

Table 5 MBS items for DBE

Category 3 – Therapeutic procedures
30680 DOUBLE BALLOON ENTEROSCOPY, 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) The patient to whom the service is provided must: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding. (Anaes.) (See para T8.17 of explanatory notes to this Category) **Fee**: $1,170.00 **Benefit**: 75% = $877.50 85% = $1,095.50
30682 DOUBLE BALLOON ENTEROSCOPY, 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: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding. (Anaes.) (See para T8.17 of explanatory notes to this Category) **Fee**: $1,170.00 **Benefit**: 75% = $877.50 85% = $1,095.50
30684 DOUBLE BALLOON ENTEROSCOPY, 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 or laser coagulation), 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: (i) have recurrent or persistent bleeding; and (ii) be anaemic or have active bleeding; and (iii) have had an upper gastrointestinal endoscopy and a colonoscopy performed which did not identify the cause of the bleeding. (Anaes.) (See para T8.17 of explanatory notes to this Category) **Fee**: $1,439.85 **Benefit**: 75% = $1,079.90 85% = $1,365.35

30686 DOUBLE BALLOON ENTEROSCOPY, 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 or laser coagulation), 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:

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

(Anaes.)

(See para T8.17 of explanatory notes to this Category)

Fee: $1,439.85 Benefit: 75% = $1,079.90 85% = $1,365.35

MBS items as at 1 July 2013

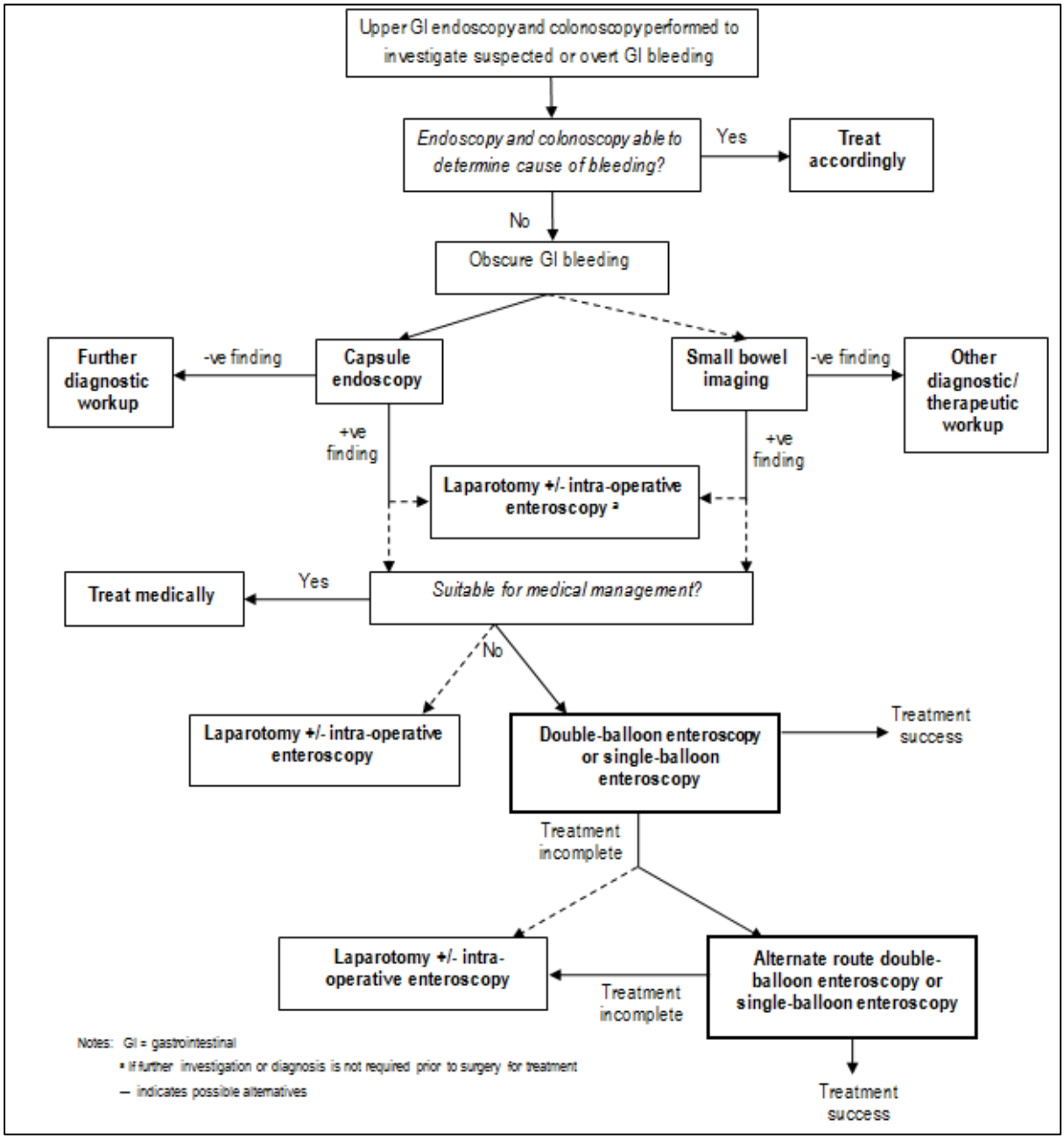
CLINICAL MANAGEMENT ALGORITHM

Figure 1 is based on the management algorithm used in MSAC Assessment 1102 of DBE. This algorithm has been amended to remove the small population of those 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.

While 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, the applicant has not requested funding to be expanded to cover any indications not already listed for DBE and therefore this population group will not be considered further.

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

Figure 1 Decision analytic pathway



DIFFERENCES BETWEEN SBE AND DBE

As a general rule, no changes would be expected in regards to the position of therapy, management options, or spectrum of patients treated. There will be rare cases when one form of balloon enteroscopy may be more appropriate than another, such as when a patient has a latex allergy (in which case SBE is more appropriate, as it is latex-free), or when a patient in a liver transplant unit with altered anatomy is undergoing an endoscopic retrograde cholangiopancreatography (DBE may be more appropriate due the availability of both a standard and short enteroscope which are compatible with most endoscopic retrograde cholangiopancreatography (ERCP) accessories).

Safety and Effectiveness

The health outcomes upon which the comparative clinical performance of SBE versus DBE in patients with obscure GI bleeding will be measured are outlined in Table 6.

Table 6 Summary of PICO to define research questions

Patients	Patients with obscure GI bleeding
Intervention	*Diagnostic / Therapeutic* SBE (per oral or per anal-approach depending on location of identified or suspected small bowel pathology)
Comparator	*Diagnostic / Therapeutic* DBE (per oral or per anal-approach depending on location of identified or suspected small bowel pathology)
Outcomes	Safety Primary: major complications include: • perforation; • pancreatitis; • post-polyp sepsis; • ileus; • abscess; • intestinal haematoma; • haemorrhage; • intussusceptions; • infection (e.g. peritonitis); and • death. Secondary: minor complications include: • pain (i.e. sore throat, abdominal discomfort); • fever; and • low-grade infection. Effectiveness Primary: • reduction of symptoms; • reduction in GI bleeding; • biopsy yield/diagnostic yield (of findings that could explain symptoms, i.e. arteriovenous malformations, erosions, ulcers, epithelial tumours, polyps); and/or • transfusion requirement. Secondary: • examination time; • completion of procedure; • length of hospital stay; • re-admission; • further diagnostic workup; • technical (equipment) success/failure; • depth of insertion; and • rate of total enteroscopy. Cost-effectiveness: Cost

CLINICAL CLAIM

The applicant claims that SBE is non-inferior in regards to both safety and effectiveness when compared to DBE.

Table 7 Method used to identify the type of analysis

		Comparative effectiveness versus comparator					
		Superior		Non-inferior	Inferior		
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA	Net clinical benefit	CEA/CUA	
					Neutral benefit	CEA/CUA*	
					Net harms	None^	
	Non-inferior	CEA/CUA		CEA/CUA*	None^		
	Inferior	Net clinical benefit	CEA/CUA	None^	None^		
		Neutral benefit	CEA/CUA*				
		Net harms	None^				

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

EVIDENCE

INTRODUCTION

A systematic method has been undertaken to identify the best available evidence for the assessment of the safety, effectiveness and cost-effectiveness of SBE relative to DBE.

SEARCH STRATEGY

The search for information on the treatment of SBE involved three approaches:

1. Search of the published literature, including reviews by the U.S. Food and Drug Administration (FDA) and the National Institute for Health and Clinical Excellence (NICE);
2. Search of registers of clinical trials, including the U.S. National Institutes of Health, the Cochrane Central Register of Controlled Trials and the Australian New Zealand Clinical Trials Registry (ANZCTR); and
3. Manual checking of the reference lists of all included articles.

Table 8 toTable 10 outline the search strategies for Medline, Embase and Cinahl respectively.

Table 8 Medline search strategy

Database	Search strategy
MEDLINE	1. Single balloon enteroscopy.mp. 2. Endoscopy, Gastrointestinal/ 3. Exp Intestine, small/ 4. 2 and 3 5. sbe.ti.ab 6. (single adj3 balloon).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]Limit 6 to (English language and humans and yr = 2002-current) 7. 4 or 5 8. 6 and 7 9. 1 or 8 10. obscure.mp 11. 9 and 10 12. exp Gastrointestinal Haemorrhage 13. 6 and 10 and 12 14. 11 or 13 15. limit 14 to (english language and humans and yr="2002 -Current") 16. limit 15 to (clinical trial, all or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline or randomised controlled trial or systematic reviews) 17. exp "Costs and Cost Analysis"/ 18. ec.fs 19. 17 or 18 20. 15 and 19

Table 9 Embase search strategy

EMBASE	1.	single balloon enteroscopy/
	2.	obscure.mp
	3.	(single adj2 balloon adj2 enteroscopy).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]transcatheter and closure
	4.	1 or 3
	5.	2 and 4
	6.	intestine endoscopy
	7.	single balloon.mp
	8.	2 and 6 and 7
	9.	5 or 8
	10.	sbe.mp
	11.	2 and 10
	12.	9 or 11
	13.	limit 12 to (human and english language and yr="2002 -Current")
	14.	limit 13 to (clinical trial or randomised controlled trial or controlled clinical trial or multicenter study or phase 1 clinical trial or phase 2 clinical trial or phase 3 clinical trial or phase 4 clinical trial)
	15.	limit 13 to (meta analysis or "systematic review")

Table 10 Cinahl search strategy

CINAHL	1.	(MH “Enterostomy+”)
	2.	(MH “Intestine,Small+”)
	3.	1 and 2
	4.	single n2 balloon
	5.	3 and 4
	6.	obscure
	7.	4 and 6
	8.	1 and 4
	9.	2 and 4
	10.	single balloon enteroscopy
	11.	5 or 7 or 8 or 9 or 10
	12.	6 and 11
	13.	Limit 12 to English Language
	14.	Limit 13 to Publication Type: Clinical Trial, Meta Analysis, Practice Guidelines, Randomised Controlled Trial, Systematic Review

SEARCH RESULTS

The search of the published literature from the Medline, Embase and Cinahl databases retrieved 57 results with a total of 56 citations excluding one duplicate.

None of the 56 citations were of studies that compared SBE with DBE. However a number of review articles on enteroscopy identified by the search were obtained and the references manually searched for comparative studies.

COMPARATIVE STUDIES

Five comparative studies were identified for inclusion in this report (four prospective, randomised controlled trials and one retrospective, non-randomised study). Table 11 toTable 15 provide an overview of these five comparative studies.

Randomised controlled trials

Table 11 Prospective trial - May et al (2010)

Title	Prospective Multicenter Trial Comparing Push-and-Pull Enteroscopy With Single- and Double-Balloon Techniques in Patients with Small-Bowel Disorders		
Location	5 centres in Germany		
Study date	October 2007 to November 2008		
Study design	Prospective, open, randomised controlled trial with parallel group design		
Study arms	1. DBE using Fujinon EN450-P5 2. SBE using Fujinon EN450-P5		
Inclusion criteria	Suspected or known small-bowel disorders for: - diagnostic balloon enteroscopy; or - therapeutic enteroscopy with argon plasma coagulation of up to 5 angiodysplasias.		
Exclusion criteria	Age < 18, pregnancy, coagulation disorders, prior surgery of small bowel and colon, patients requiring polypectomy, dilatation, coagulation of > 5 angiodysplasias or foreign body extraction.		
Primary endpoint	Complete enteroscopy rate		
	DBE	**SBE**	**P-value**
Number of patients	50	50	
Age of patients	53 years ± 18	56 years ± 18	ns
Sex (M/F)	28/22	33/17	ns

Table 12 Prospective trial - Takano et al (2011)

Title	Single-balloon versus double-balloon endoscopy for achieving total enteroscopy: a randomised controlled trial		
Location	Single centre in Tokyo, Japan		
Study dates	April 2008 to April 2010		
Study design	Prospective, open, randomised controlled trial with parallel group design		
Study arms	1. DBE using Fuji EN450-T5 2. SBE using Olympus SIF-Q180		
Inclusion criteria	Suspected small bowel disease		
Exclusion criteria	Inability to undergo both oral and anal balloon enteroscopy; previous balloon enteroscopy; age < 20 years.		
Primary endpoint	Complete enteroscopy rate		
	DBE	**SBE**	**P-value**
Number of patients	20	18	
Age of patients	62.7 years ± 16.1	64.9 years ± 14.7	0.66
Sex (M/F)	15/5	13/5	0.99

Table 13 Prospective trial - Domagk et al (2011)

Title	Single- vs. double-balloon enteroscopy in small-bowel diagnostics: a randomised multicentre trial		
Location	3 centres in Germany, Norway and the Netherlands		
Study dates	June 2008 to May 2009		
Study design	Prospective, single (patient)-blinded, randomised controlled trial with parallel group design		
Study arms	1. DBE using Fuji EN450-T5 or –P5 2. SBE using Olympus SIF-Q180		
Inclusion criteria	Subjects requiring small bowel enteroscopy, with the intention of total enteroscopy.		
Exclusion criteria	Age < 18 years, inability to understand patient information or give consent.		
Primary endpoint	Small bowel insertion depth during oral approach		
	DBE	**SBE**	**P-value**
Number of patients	65	65	
Age of patients	52 years (18-84)	53 years (21-80)	0.74
Sex (M/F)	32/33	35/30	0.73

Table 14 Prospective trial - Efthymiou et al (2012).

	SINGLE-01: a randomised, controlled trial comparing the efficacy and depth of insertion of single-and double-balloon enteroscopy by using a novel method to determine insertion depth		
Location	3 centres in Sydney and Melbourne, Australia		
Study dates	July 2008 to June 2010		
Study design	Prospective, single (patient)-blinded, randomised controlled trial with parallel group design		
Study arms	1. DBE using Fujinon ET-45 2. SBE using Olympus SIF-180		
Inclusion criteria	Proven or suspected small bowel disease		
Exclusion criteria	Inability to provide informed consent, pregnancy or lactation, high risk oesophageal or gastric varices, suspected perforation of GI tract, inability to tolerate sedation or general anaesthesia.		
Primary endpoint	Diagnostic yield for clinically significant findings.		
	DBE	**SBE**	**P-value**
Number of patients	57	50	
Age of patients (median (IQR)	61 years (49-68)	67 years (51-72)	0.055
Sex (M/F)	24/33	19/31	0.696

Non-randomised, retrospective study

Table 15 Retrospective study - Lenz et al (2013).

Title	Double- vs. single-balloon enteroscopy: single center experience with emphasis on procedural performance		
Location	Single centre in Germany		
Study dates	November 2004 to November 2011		
Study design	Non-randomised, retrospective study		
Study arms	1. DBE using Fujinon EN-450P5 or EN-450T5 2. SBE using Olympus SIF-Q180		
Inclusion criteria	All patients who had undergone diagnostic enteroscopy over the study period.		
Exclusion criteria	Not applicable		
Primary endpoint	Various endpoints with none specified as primary.		
	DBE	**SBE**	**P-value**
Number of patients	606	298	
Age of patients (median (IQR)	56 years ± 19.1	55 years ± 19.1	0.34
Sex (M/F)	316/290	152/146	0.62

All five comparative studies included subjects undergoing enteroscopy for a variety of indications, not just for obscure GI bleeding. Outcomes for the specific subpopulation of patients with obscure GI bleeding were not presented separately in any of the published papers. The stated indications (suspected or known) for enteroscopy were as follows:

Table 16 Indications for enteroscopy

	May 2010	**Takano 2011**	**Domagk 2011**	**Efthymiou 2012**	**Lenz 2013**
GIT bleeding	60	23	55	84	446
IBD / Crohn's disease	12	7	23	-	112
Masses / tumours	7	8	-	-	79
Diarrhoea	-	-	13	-	98
Abdominal pain	-	-	18	-	64
Diarrhoea / abdominal pain	19	-	-	-	-
Polyposis	-	-	5	-	43
Coeliac disease	-	-	-	-	8
Other	2	-	16	23	54
Totals	**100**	**38**	**130**	**107**	**904**

IBD = inflammatory bowel disease

The five studies differed with respect to whether or not subjects were required to undergo both oral and anal enteroscopy:

- In May et al 2010, all subjects were required to have both procedures. The oral procedure was performed first, with the anal procedure being performed one or two days later. Subjects in whom a second procedure was not performed were excluded from the analysis.
- In Takano et al 2011, subjects were scheduled to receive both procedures. The order of the procedures was decided according to the suspected site of pathology. If there was no information on site, the anal approach was used first. Subjects who were unable to undergo the second procedure were still included in the analysis.
- In Domagk et al 2011, subjects were scheduled to receive both procedures. The oral procedure was performed first, with the anal procedure being performed on the same day or the following day. Subjects who were unable to undergo the second procedure were still included in the analysis.
- In Efthymiou et al 2012, subjects generally received only one procedure, with the oral or anal route chosen based on suspected location of pathology. Only a minority of subjects underwent both procedures.
- The study by Lenz et al 2013 was a retrospective analysis of subjects from one centre who had undergone enteroscopy. The publication does not state whether there was a standard protocol for determining whether a subject received one or two procedures.

The actual numbers of patients who underwent the two procedures is summarised in Table 17.

Table 17 Subject numbers

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
Oral approach only	0	4	26	NR	188
Anal approach only	0	6	0	NR	53
Both oral and anal	100	28	104	6	663
Totals	**100**	**38**	**130**	**107**	**904**

In Efthymiou 2012, 107 subjects received 119 procedures suggesting that up to 12 subjects may have received both procedures. However, the paper states that total enteroscopy was attempted in only 6 subjects.
NR = not reported

Primary Effectiveness Outcomes

In the following tables the effectiveness results from the Lenz et al 2013 study are presented in a shaded column to emphasise that these data are from a non-randomised study.

Diagnostic yield

Diagnostic yield was measured in all five studies and refers to the percentage of patients in whom a diagnosis was established by enteroscopy.

Table 18 Diagnostic yield (% of subjects)

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
DBE	52.0%	50.0%	43.1%	53.0%	48.2%
SBE	42.0%	61.1%	36.9%	56.6%	61.7%
p-value	ns	0.53	0.59	0.70	<0.001

In the four randomised controlled studies 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. The authors suggest that a change over time in the reasons for referral for enteroscopy may explain the higher yield with SBE.

Therapeutic intervention yield

This endpoint refers the percentage of patients in whom a therapeutic intervention (e.g. argon plasma coagulation, endoscopic haemostasis, polypectomy, dilatation) can be undertaken during enteroscopy. It was measured in four studies:

Table 19 Therapeutic yield using oral approach only or anal approach only

% of subjects	Lenz 2013	
	Oral approach	Anal approach
DBE	11.1%	3.5%
SBE	14.4%	10.4%
p-value	ns	<0.001

ns = not significant

Table 20 Therapeutic yield using oral AND anal approaches

% of subjects	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
DBE	-	15.0%	9.2%	25.7%	-
SBE	-	11.1%	4.6%	30.0%	-
p-value	-	ns	0.49	0.592	-

Takano 2011 reported results for “endoscopic haemostasis” and “endoscopic polypectomy”.
ns = not significant

These findings do not suggest that SBE is associated with inferior ability to perform therapeutic interventions compared with DBE.

Biopsy yield.

One study (Efthymiou et al 2012) reported on the proportion of patients who had targeted biopsies collected during enteroscopy using oral and anal approaches.

Table 21 Therapeutic yield of targeted biopsies using oral AND anal approaches

% of subjects	Efthymiou 2012
DBE	10.6%
SBE	20.8%
p-value	NR

NR = Not reported

Other Primary Effectiveness Outcomes

None of the studies reported clinical outcomes in the subpopulation of patients who underwent enteroscopy for the indication of obscure GIT bleeding. Therefore, there was no information on reduction in symptoms or GI bleeding, or transfusion requirements in such patients.

May et al (2010) described two patients who had recurrent haematochezia after enteroscopy. One was found to have colonic diverticula and the other was found to have a fistula between the proximal jejunum and the stump of the renal artery after a nephrectomy. Both subjects had undergone DBE.

One of the randomised controlled trials (Takano et al 2011) provided limited information on subsequent clinical outcomes in patients after enteroscopy.

Table 22 Subsequent clinical outcomes in patients after enteroscopy

% of subjects (Takano 2011)	Surgery	Medication	Observation
DBE	5.0%	15.0%	65.0%
SBE	5.6%	11.1%	72.2%
p-value	0.99	0.99	0.73

Secondary Effectiveness Outcomes

Examination time

The time taken to perform enteroscopy was measured in all five comparative studies.

Table 23 Examination time (minutes) – Oral approach

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
	mean ± SD	mean ± SD			mean ± SD
DBE	66.5 ± 17.7	70.4 ± 26.5	-	-	50 ± 11.3
SBE	53.6 ± 16.7	92.8 ± 20.6	-	-	40 ± 11.5
p-value	<0.0001	0.019	-	-	<0.001

Table 24 Examination time (minutes) – Anal approach

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
	mean ± SD	mean ± SD			mean ± SD
DBE	62.0 ± 22.7	90.4 ± 13.7	-	-	55 ± 14.7
SBE	60.3 ± 19.6	93.1 ± 22.6	-	-	46 ± 16.2
p-value	ns	0.70	-	-	<0.001

ns = not significant

Table 25 Examination time (minutes) – Total for oral AND anal approaches

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
		mean ± SD	mean (range)		
DBE	-	160.7 ± 29.0	105 (40-140)	-	-
SBE	-	185.9 ± 34.9	96 (35-135)	-	-
p-value	-	0.03	0.13	-	-

Table 26 Examination time (minutes) – Oral OR anal approach

	May 2010	Takano 2011	Domagk 2011	Efthymiou 2012	Lenz 2013
				median (IQR)	
DBE	-	-	-	60 (45-70)	-
SBE	-	-	-	60 (45-67)	-
p-value	-	-	-	0.991	-

IQR = interquartile range

Significant differences in favour of either DBE or SBE were not consistently observed. A shorter examination time does not necessarily reflect greater ease of use.
A shorter time with DBE may reflect greater experience with this system on the part of the endoscopist, as DBE system was introduced and became established earlier than the SBE system. Also, in some studies the DBE system has been associated with a greater rate of complete visualisation of the small bowel (see below - complete enteroscopy rate). A shorter examination time with the SBE system may therefore reflect this procedure being aborted earlier.

Depth of insertion

The estimated depth of insertion was studied in three of the comparative studies.

Table 27 Depth of insertion (cm) – Oral approach

	Domagk 2011	Efthymiou 2012	Lenz 2013
	mean (range)	mean ± SD	mean ± SD
DBE	253 (120-450)	234.1 ± 99.3	245 ± 65.3
SBE	258 (100-560)	203.8 ± 87.6	218 ± 62.6
p-value	(a)	0.176	<0.001

Table 28 Depth of insertion (cm) – Anal approach

	Domagk 2011	Efthymiou 2012	Lenz 2013
	mean (range)	mean ± SD	mean ± SD
DBE	107 (10-250)	75.2 ± 55.2	103 ± 77.0
SBE	118 (5-300)	72.1 ± 41.1	91 ± 68.3
p-value	(a)	0.835	0.054

Table 29 Total depth of insertion (cm) – Oral AND anal approach

	Domagk 2011	Efthymiou 2012	Lenz 2013
	mean (range)		mean ± SD
DBE	360 (180-550)	-	355 ± 101.9
SBE	373 (100-620)	-	319 ± 91.2
p-value	(a)	-	<0.001

(a) Domagk 2011 was designed as a non-inferiority study, with non-inferiority being concluded if the lower 95%CI for the difference in depth of insertion (DBE minus SBE) was less than 25cm. Non-inferiority was established on all three endpoints for depth of insertion.

DBE produced significantly greater oral and total insertion depths in the non-randomised study by Lenz (2013). However, no significant differences were seen between DBE and SBE in the two randomised controlled trials.

Complete enteroscopy rate

This endpoint measures the percentage of patients in whom complete visualisation of the small bowel was achieved, usually by a combination of oral and anal approaches. In three of the randomised controlled trials subjects were scheduled to undergo both procedures. In the other randomised study (Efthymiou et al 2012) most subjects only underwent one procedure. In the non-randomised study (Lenz et al 2013), the proportion of patients who were scheduled for complete enteroscopy was not stated.

Table 30 Complete enteroscopy rate (%)

	May 2010	**Takano 2011**	**Domagk 2011**	**Efthymiou 2012** (b)	**Lenz 2013**
DBE	66.0%	57.1%	18.0%	-	5.0%
SBE	22.0%	0.0%	11.0%	-	4.0%
p-value	<0.0001	0.002	(a)	-	ns

(a) Domagk 2011 was designed as a non-inferiority study, with non-inferiority being concluded if the lower 95%CI for the difference in rate of total enteroscopy (DBE minus SBE) was no more than 10%. The lower 95% CI was calculated as -20% and therefore non-inferiority was NOT established.
(b) In Efthymiou 2012, complete enteroscopy was attempted in only 6 subjects (5 DBE and 1 SBE). It was unsuccessful in all subjects.
ns = not significant

The rate of complete enteroscopy was numerically superior in all three randomised studies and the difference was statistically significant in the first two (May et al 2010 and Takano et al 2011). These findings suggest that DBE may be superior to SBE in terms of achieving complete visualisation of the small bowel. This is possibly due to better gripping of the small bowel by a balloon than by hooking of the endoscope tip (Teshima et al 2012).

The May et al (2010) study has been criticised (e.g. Ross et al 2010, Teshima et al 2012) on the grounds that the SBE equipment used was not the dedicated Olympus SBE system, but an adaptation of the Fuji DBE system. It has also been suggested that the lower rates obtained with SBE in the first two randomised studies may have been due to operators having less experience with the SBE system compared to the well established DBE system (Ross et al 2010, Manno et al 2012). The importance of complete enteroscopy rate as an endpoint is also questionable, in the absence of evidence that an increased rate is associated with a greater diagnostic yield or improved clinical outcomes.

Failure rates

The proportion of study subjects in whom the enteroscopy procedure could not be completed was reported in two studies.

Table 31 Failure rate (%)

	Oral OR anal approach (Efthymiou 2012)	Anal approach (Lenz 2013)
DBE	9.1%	17.6%
SBE	5.7%	14.7%
p-value	0.729	ns

ns = not significant

In the Efthymiou et al (2012) study failure of the oral approach occurred in one subject in each of the SBE and DBE groups, both in subjects with previous extensive abdominal surgery. Failure of the anal approach occurred in seven subjects due to poor bowel preparation.

In the Lenz et al (2013) study failure of the anal approach was defined as an insertion depth of less than 5 cm proximal to the ileocaecal valve.

Other Secondary Effectiveness Outcomes

None of the five comparative studies provided data on hospital stay or the proportion of patients requiring readmission or further diagnostic workup.

Safety Outcomes

Serious adverse events

Lenz et al (2013), the study with the largest number of subjects, reported the incidence of serious adverse events as follows:

Table 32 Incidence of serious adverse events – Lenz 2013

	Oral approach	Anal approach
DBE	1 (0.2%)	2 (0.3%)
SBE	1 (0.3%)	1 (0.3%)
p-value	ns	ns

The publication did not identify the events. No other safety data were reported for this study.

Individual adverse events

Each of the four randomised controlled trials reported individual adverse events including abdominal pain, decreased oxygen saturation, Mallory-Weiss syndrome and hyperamylasaemia.

Table 33 summarises the incidence of individual adverse events reported in three of the four randomised controlled trials.

Table 33 Individual adverse events

		May 2010	Takano 2011	Efthymiou 2012
Abdominal pain	**DBE**	2 (4.0%)	-	1 (1.8%)
	SBE	1 (2.0%)	-	1 (2.0%)
Decreased oxygen saturation	**DBE**	1 (2.0%)	-	-
	SBE	0 (0.0%)	-	-
Mallory-Weiss syndrome	**DBE**	-	1 (5.0%)	-
	SBE	-	0 (0.0%)	-
Hyperamylasaemia	**DBE**	-	0 (0.0%)	-
	SBE	-	1 (5.6%)	-

In Domagk et al (2011), abdominal pain during and after the procedure was measured as a secondary endpoint, using a visual analogue scale (VAS) with a range of 0 (no pain) to 100 (very heavy pain). As can be seen in Table 34, the results did not indicate any significant differences between DBE and SBE.

Table 34 Abdominal pain - Domagk 2011

Visual analogue score	**DBE** (n=65)	**SBE** (n=65)	p-value
Pain during examination	33.0 ± 26	36.2 ± 33.6	0.55
Pain after 1 hour	12.2 ± 21.9	12.5 ± 24.2	0.87
Pain after 3 hours	3.9 ± 11.1	3.6 ± 12.0	0.57
Pain after 6 hours	2.3 ± 5.2	3.1 ± 8.6	0.82
Pain after 24 hours	2.4 ± 5.5	3.8 ± 9.0	0.41

mean ± SD

Other safety outcomes

There were no deaths related to enteroscopy reported in any of the five comparative studies.

There were also no reported cases of perforation, post-polyp sepsis, ileus, abscess, intestinal haematoma, bleeding caused by the procedure, intussusception, infection or peritonitis. There were no reports of pancreatitis although there was 1 case of raised amylase with SBE identified in Takano et al (2011) as shown in Table 33.

INTERPRETATION

The four randomised controlled trials 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 is 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.

Differences in examination time between SBE and DBE were inconsistent across the four randomised studies and may have been due to factors other than ease of use of one particular system.

The non-randomised study (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 randomised studies and therefore may have been due to imbalances between the enteroscopy groups. In all five studies, the incidence of significant adverse events was low and comparable between SBE and DBE.

The review of literature has therefore identified that SBE is likely to be non-inferior in terms of comparative safety and effectiveness. Therefore a cost minimisation analysis will be undertaken for the service relative to that of DBE.

Table 35 Cost-minimisation analysis to be used for the economic evaluation

Comparative safety	**Comparative effectiveness**			
	Inferior	**Uncertain**	**Non-inferior**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Non-inferior	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

b An adequate assessment of 'non-inferiority' is the preferred basis for demonstrating equivalence

ECONOMIC EVALUATION

OVERVIEW

SBE has been identified as likely to be non-inferior to DBE in terms of comparative safety and effectiveness. A cost minimisation analysis is presented taking into account that SBE will be undertaken relative to that of DBE.

TYPE OF ECONOMIC EVALUATION

The cost minimisation analysis of SBE present costs relative to the service.
The method used for the determination of a cost minimisation analysis for SBE is presented in Table 36.

Table 36 Method used to identify the type of analysis

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">Comparative effectiveness versus comparator</td></tr>
<tr><td colspan="2">Superior</td><td>Non-inferior</td><td colspan="2">Inferior</td></tr>
<tr><td rowspan="6">Comparative safety versus comparator</td><td rowspan="3">Superior</td><td colspan="2" rowspan="3">CEA/CUA</td><td rowspan="3">CEA/CUA</td><td>Net clinical benefit</td><td>CEA/CUA</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
<tr><td>Non-inferior</td><td colspan="2">CEA/CUA</td><td>CEA/CUA*</td><td colspan="2">None^</td></tr>
<tr><td rowspan="3">Inferior</td><td>Net clinical benefit</td><td>CEA/CUA</td><td rowspan="3">None^</td><td colspan="2" rowspan="3">None^</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
</table>

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

POPULATION

The current assessment is for SBE for obscure GI bleeding. The assessment has not been restricted by age group for either the proposed intervention or the comparator of DBE. This is consistent with MSAC Assessment 1102 (2006) which assessed the safety, effectiveness and cost-effectiveness of DBE for obscure GI bleeding or suspected small bowel disease relative to laparotomy with or without intra-operative enteroscopy. MSAC Assessment 1102 did not restrict by the age of the patient. Current literature indicates that there are limited studies on DBE in children which describe the procedure as safe and clinically useful, but these are mostly retrospective and include relatively small numbers.

In 2012-13, Medicare statistics for items 30680 to 30684 show nil services for the 0 to 4 age group with only one claim under item 30682 for the 5-14 year age group. Figure 2 andFigure 3 show the age breakdown of services for item 30680 (DBE oral approach) and item 30682 (DBE anal approach) in 2012-13.

Figure 2 MBS item 30680 – Services 2012-13

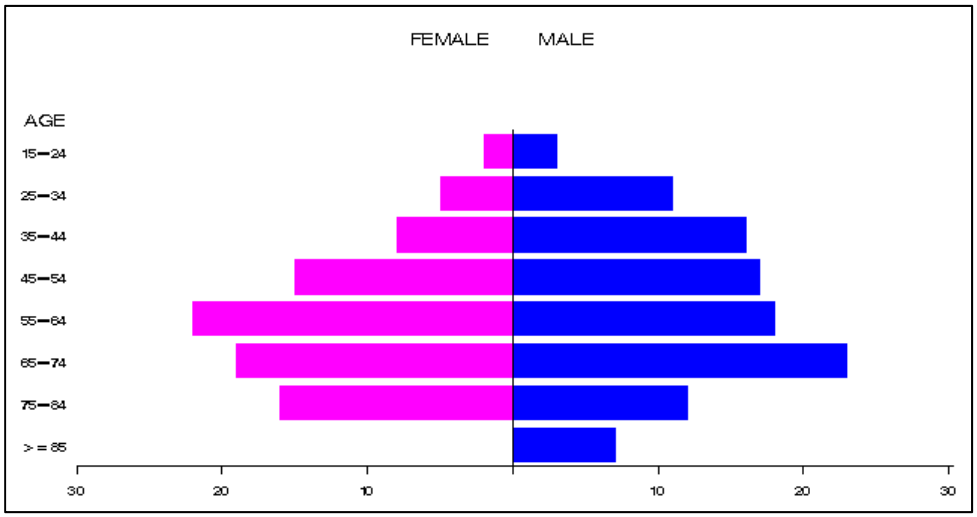
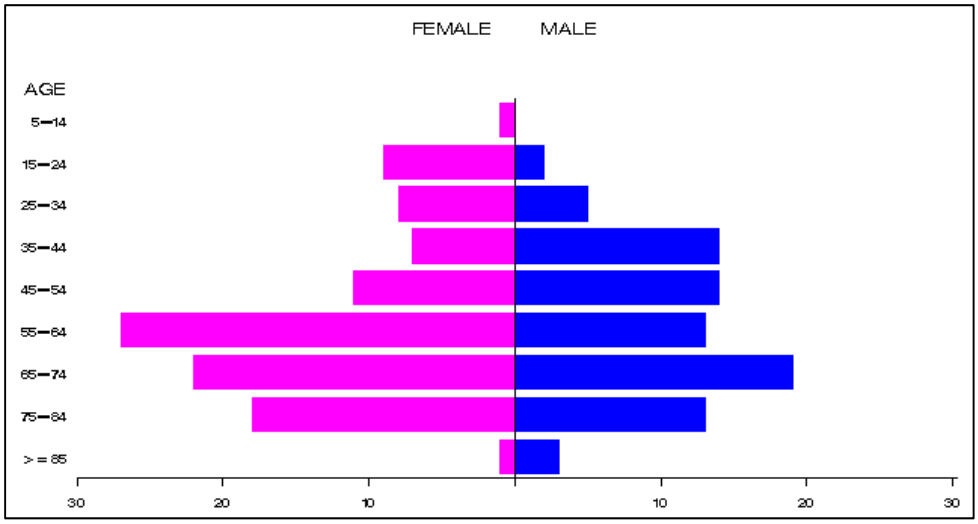


Figure 3 MBS item 30682 - Services 2012-13



CIRCUMSTANCES OF USE

Lenz et al (2013) reported that, on the background of 5 years experience in enteroscopy, the application of SBE and DBE since 2008 seems to be somehow more goal-oriented: more patients are referred to SBE to exclude a suspected diagnosis (e.g. unclear CT scan) and the differences in indications (less anaemia) and findings (more inflammatory bowel disease) between DBE and SBE may also support this argument.

However, as a general rule, it is proposed that no changes would be expected in regards to the position of therapy, management options, or spectrum of patients treated.

VARIABLES IN THE ECONOMIC EVALUATION

Variables used in the economic evaluation include health care resources and MBS items. The health care resources documented for SBE are assumed to be similar as for DBE. The list of health care resources included in the economic evaluation is presented in Table 37.

Table 37 Summary of health care resources

Resource	Type
Endoscope	Private / Government
Overtube	Private / Government
Anaesthesia	MBS
Fluoroscopy	MBS
Procedure	MBS
Endoscopy unit	Private Health Insurer / Government
Hospital stay	Private Health Insurer / Government

Direct health care resources

Information from the American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee (2007) indicates 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 in Table 38.

Table 38 Direct health care resources

	Estimated cost
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

SBE would predominantly be performed in public and private day-stay endoscopy units. The preparation and management of these patients would be no different to other endoscopy services and DBE. As with other endoscopic procedures, a small number of high-risk cases may require overnight admission to the public or private facility.

Table 1 on Page 3 provides the total number of services provided in and out of hospital for DBE. In 2012-13, Medicare statistics for items 30680, 30682, 30684 and 30686 indicate that 62% of services were provided in hospital. It is anticipated that these total numbers will remain constant with the introduction of SBE.

MBS items

MBS items listed for SBE are assumed to be similar and are therefore based on the items associated with DBE. Table 39 provides a list of MBS items that may be claimed in association with SBE.

Table 39 MBS items for SBE

	MBS item	Schedule fee	75% benefit	85% benefit
Both oral and anal approach				
Specialist initial consultation	104	$88.55	$64.20	$72.75
Pre-anaesthetic consult	17610	$43.00	$32.25	$36.55
Fluoroscopy	60500	$43.40	$32.55	$36.90
Oral approach				
Initiation of anaesthesia for upper GI endoscopic procedures	20740	$99.00	$74.25	$84.15
Time units for anaesthesia (1:01 hours to 1:05 hours)	23051	$99.00	$74.25	$84.15
DBE without intraprocedural therapy	30680	$1,170.00	$877.50	$1,095.50
DBE with intraprocedural therapy	30684	$1,439.85	$1,079.90	$1,365.35
Anal approach				
Initiation of anaesthesia for lower intestinal endoscopic procedures	20810	$79.20	$59.40	$67.35
Time units for anaesthesia (56 minutes to 1:00 hours)	23043	$79.20	$59.40	$67.35
DBE without intraprocedural therapy	30682	$1,170.00	$877.50	$1,095.50
DBE with intraprocedural therapy	30686	$1,439.85	$1,079.90	$1,365.35

Based on MBS fees and benefits as at 1 July 2013

The literature suggests that SBE has similar challenges to DBE but is conceptually less complicated, given that only 1 balloon must be inflated and deflated (ASGE 2007). Therefore, SBE may have a shorter procedure time compared to DBE.

Manno et al (2012) reported that examination time for anterograde insertion was 65.3 minutes for SBE and 74 minutes for anterograde DBE. SBE retrograde insertion averaged 57.5 minutes and 56.3 minutes for retrograde DBE. The slight difference in procedure is reflected in the MBS items used for the financial analysis in the next section.

RESULTS OF THE ECONOMIC EVALUATION

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

Minimal differences have been identified in the cost of health resources for SBE compared to DBE. The equipment cost for SBE has been 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 have not been evaluated.

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 suggests that SBE may have a shorter procedure times 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 will be reflected in the financial analysis.

FINANCIAL ANALYSIS

SBE is proposed as an alternative procedure for DBE. There are four MBS items available for DBE (items 30680, 30682, 30684 and 30686).

Complication rates reported for enteroscopy are similar for both SBE and DBE, and have not been factored into the financial analysis.

NUMBER OF PROCEDURES

The number of procedures estimated for "balloon enteroscopy" is outlined in Table 40.

Table 40 Estimated "balloon enteroscopy" procedures (DBE and SBE) 2013-14 to 2017-18

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

An increase in services of 1.2% has been included based on the two year growth from 2010-11 to 2012-13 for items 30680 to 30686 (see Table 2 on Page 10).

Frequency and duration of treatment

Patients may have one or more enteroscopy procedures. For the purposes of the economic evaluation, the number of procedures has been based on the services claimed under the MBS items associated with DBE.

The financial analysis has factored in the slight difference in examination time for versus anal approach of the enteroscopy procedure. Manno et al (2012) reported that examination time for anterograde insertion was 65.3 minutes for SBE and 74 minutes for anterograde DBE. SBE retrograde insertion averaged 57.5 minutes and 56.3 minutes for retrograde DBE.

HEALTH RESOURCE COST

The health resource cost per patient used in the financial analysis is shown in Table 41. While recognising that a small number of high-risk cases may require overnight admission, the analysis is based on a single day hospital stay.

Table 41 Health resource cost per patient for 2012-13

Resource	Cost
Endoscope overtube (disposable)	$225
Endoscopy unit (sameday service)	$265
Ward stay (one day)	$774

SBE 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

MBS COST

The MBS items used in the financial analysis is provided in Table 39 on Page 37.

The MBS cost is based on a split of 75% and 85% benefit of the MBS items as outlined in the economic evaluation. The estimated total MBS cost over 4 year for "balloon enteroscopy" is presented in Table 42.

Table 42 MBS cost for "balloon enteroscopy" procedures 2013-14 to 2016-17

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

MBS Schedule fees and benefits as at 1 July 2013

RESULTS OF THE FINANCIAL ANALYSIS

The financial analysis has been 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. As previously noted, it is anticipated that the healthcare setting will remain constant should MBS funding be provided for SBE.

Current statistics indicate 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 has been 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" is estimated at approximately 7 services per financial year.

The total MBS cost incorporates 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 is estimated at $740,048, with an annual increase of approximately $20,000 per financial year.

ABBREVIATIONS

ABS	Australian Bureau of Statistics
ASGE	American Society for Gastrointestinal endoscopy
AIHW	Australian Institute of Health and Welfare
ANAES	Anaesthetic
ANZCTR	Australian New Zealand Clinical Trials Registry
ARTG	Australian Register of Therapeutic Goods
CE	Capsule endoscopy
CEA	Cost-effectiveness Analysis
CUA	Cost-utility Analysis
DAP	Decision analytic protocol
DBE	Double balloon enteroscopy
DRG	Diagnosis related group
FDA	Food and Drug Administration
GI	Gastrointestinal
GIT	Gastrointestinal tract
ICD	International Classification of Diseases
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NICE	National Institute for Health and Clinical Excellence
PASC	Protocol Advisory Sub-Committee
PICO	Patients; Intervention; Comparator; Outcomes
SBE	Single balloon enteroscopy
TGA	Therapeutic Goods Administration

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