
1206

Final Decision
Analytic Protocol
(DAP) to guide the
assessment of single
balloon enteroscopy
for obscure
gastrointestinal
bleeding

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft decision analytic protocol (DAP) that will be used to guide the assessment of single-balloon enteroscopy for the diagnosis and/or management of obscure gastrointestinal bleeding. The draft protocol will be finalised after inviting relevant stakeholders to provide input. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

- P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use;
- I**ntervention – specification of the proposed intervention;
- C**omparator – specification of the therapy most likely to be replaced by the proposed intervention; and
- O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention.

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of single-balloon enteroscopy for the diagnosis and/or management of obscure gastrointestinal bleeding was received from Olympus Australia Pty Ltd by the Department of Health and Ageing in December 2011. The proposal relates to a new procedure that has not previously been assessed by the MSAC.

Adelaide Health Technology Assessment (AHTA), in the School of Population Health, University of Adelaide, as part of its contract with the Department of Health and Ageing, has drafted this decision analytic protocol to guide the assessment of the safety, effectiveness and cost-effectiveness of the proposed intervention in order to inform MSAC's decision-making regarding public funding of the intervention.

Background

Current arrangements for public reimbursement

Single balloon enteroscopy does not currently receive any public reimbursement. A small number of Australian patients have received single-balloon enteroscopy as part of an ongoing randomised trial comparing it with double-balloon enteroscopy (Australian and New Zealand Clinical Trials Registry number 12609000917235).

Regulatory status

The devices required for single-balloon enteroscopy have been registered with the Therapeutic Goods Administration on the Australian Register of Therapeutic Goods (see Table 1). 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 1 Devices listed on the Australian Register of Therapeutic Goods

ARTG Identifier	Description	Manufacturer	Intended purpose
188394	Endotherapy overtube	Olympus Medical Systems Corporation	The overtube is designed to ensure complete positioning of the flexible endoscope for endoscopic insertions in the small intestine. By inflating the balloon on the tip of the overtube, it anchors the overtube in the small intestine, allowing the endoscope to be smoothly inserted to reach the area of diagnosis, biopsy and/or treatment of small intestine lesions.
154294	Catheter-balloon inflation system, reusable	Olympus Medical Systems Corporation	An assembly of devices used with a balloon dilatation catheter to manually inflate and regulate pressure within the catheter's balloon (e.g., by injecting and aspirating fluid or air within the balloon) and to deflate the balloon, in

			association with a medical procedure. It typically consists of a dedicated syringe/plunger, a gauge for monitoring pressure [e.g., in atmosphere (atm) or pounds per square inch (psi)], a locking mechanism, and a connecting tube. It is typically used during angiographic, angioplasty, or gastrointestinal (GI) procedures. This is a reusable device.
114377	Enteroscope, flexible, video	Olympus Medical Systems Corporation	Observation, diagnosis and treatment of small intestine during a surgical procedure

Intervention

Description

Enteroscopy has developed considerably in recent years, from the evolution of capsule endoscopy in early 2000, double-balloon enteroscopy (DBE) in 2001, spiral enteroscopy in 2005 (Akerman & Haniff 2012) and more recently single-balloon enteroscopy (SBE) in 2007 (Kaffes 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 & Domagk 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).

Both SBE and DBE provide a means for intervention as well as diagnosis. In order to be consistent with the eligibility criteria listed on the MBS for DBE, to be eligible for SBE, patients would be required to present with:

- a) A diagnosis of obscure gastrointestinal (GI) bleeding plus

- b) Recurrent or persistent bleeding; and
- c) Be anaemic or have active bleeding; and
- d) Have an upper gastrointestinal endoscopy and colonoscopy performed which did not identify the cause of the bleeding.

PASC has suggested simplifying the criteria by removing the requirement that patients be anaemic or have active bleeding.

Delivery of the intervention

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.

Currently, 41.2% of DBE procedures involve intra-procedural therapy (Medicare Australia 2012). 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-assisted enteroscopy may then be performed from the alternative approach. Expert opinion of the Advisory Panel for MSAC Assessment 1102 (Double-balloon enteroscopy) was 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-assisted 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 per cent of patients reported overt bleeding, and 35 per cent reported ongoing iron therapy and/or transfusions. However, the rate of repeat DBE was only 10 per cent (Gerson et al. 2009).

The choice of intra-procedural therapies would depend on the pathology identified. Interventions listed on the MBS items 30684 and 30686 for DBE include snare polypectomy, removal of foreign body, diathermy, heater probe and laser coagulation. Expert advice from PASC and public consultation submissions recommend that the list of interventions should be expanded to include argon plasma coagulation.

Prerequisites

Single-balloon enteroscopy would be performed by specialist gastroenterologists and specialist surgeons with appropriate approved training in endoscopic procedures. No staffing changes would be required, when compared to DBE. The Applicants have stated that there is a significant learning curve for enteroscopists performing DBE, even for experienced endoscopists, and expect that there would be the same learning curve for single-balloon enteroscopists, despite some articles claiming that SBE is easier than DBE (Manno et al. 2012). Given the small population suitable for balloon-assisted enteroscopy, it is therefore appropriate that only a small number of specialists perform this procedure, to ensure high skill levels. Credentialling, training and accreditation processes would be the same as for DBE. Retrograde balloon-assisted enteroscopy is more difficult than antegrade. It has been suggested that a minimum of 20 retrograde procedures is required to reach a basic skill level (Kaffes 2012)¹. 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).

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. SBE would be substituted 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 double-balloon enteroscopy, close to two-thirds of which were performed in a hospital setting in 2010/11 (MBS Statistics). As with other endoscopic procedures, a small number of high-risk cases may require overnight admission to the public or private facility.

Co-administered and associated interventions

Patients are only considered for balloon-assisted enteroscopies if they have obscure gastrointestinal (GI) bleeding. Obscure GI bleeding can only be diagnosed when an upper gastrointestinal endoscopy and a colonoscopy have not established the cause of the bleeding.

Whether patients will have a capsule endoscopy prior to either single- or double-balloon enteroscopy will need to be addressed at the evidence submission stage. However where it is used it would be to indicate whether there is a lesion in the small bowel, and whether it is likely to be suitable for medical management or requires immediate laparotomy with or

¹ NB: no recommendations were made regarding how many of the technically simpler antegrade procedures should be performed prior to classification of basic skill level

without intra-operative enteroscopy (if further investigation or diagnosis is not required prior to surgery for treatment).

These interventions will occur with the same frequency regardless of whether SBE received public funding, as they are also required for DBE.

The pre-procedural workup and follow-up would be consistent with those identified in the MSAC Double-Balloon Enteroscopy assessment report from 2006 since SBE would be used in exactly the same situations (see Table 2).

Table 2 Unit costs of pre-procedural workup and co-administered interventions for double-balloon or single-balloon enteroscopy.

Item	Source of estimate	Schedule fee
Pre-procedural workup		
Specialist consultation	MBS Item 104	\$84
Pre-anaesthetic consult	MBS Item 17610	\$42
Initiation of anaesthesia for upper gastrointestinal endoscopic procedures (15 minutes or less)	MBS Item 20740	\$97
Modifier (if required) , where patients are <12 months or >70 years	MBS Item 25015	\$19
Gastroscopy	MBS Item 30473	\$174
Initiation of anaesthesia for anorectal procedures (lower endoscopy)	MBS Item 20902	\$78
Time units for anaesthesia (20 - 60 minutes)	MBS Item 23021 - 23043	\$39 - \$78
Colonoscopy (flexible fiberoptic sigmoidoscopy or colonoscopy up to hepatic flexure)	MBS Item 32084	\$109
Colonoscopy (fiberoptic colonoscopy beyond hepatic flexure)	MBS Item 32090	\$328
CT scan	MBS Item 56407	\$360
Capsule endoscopy	MBS Item 11820 or 11823	\$2,001
Small bowel series, barium	MBS Item 58915	\$79
Co-administered interventions		
Fluoroscopy	MBS Items 60500 - 60504	\$15 - \$43
Initiation of anaesthesia for upper gastrointestinal endoscopic procedures	MBS Item 20740	\$97
Time units for anaesthesia, based on procedure taking 90 minutes ^a	MBS Item 23063	\$117
Modifier (if required) , where patients are <12 months or >70 years	MBS 25015	\$19
Initiation of anaesthesia for anorectal procedures	MBS Item 20902	\$78
Hospital services	AR-DRG V5.1 Private Sector G44C – Other colonoscopy, sameday service	\$713

Medicare Benefits Schedule (MBS) Items at June 2012.

^aBased on Expert Opinion of Gastroenterological Society of Australia nominee on Advisory Panel for MSAC Assessment 1102: Double-balloon enteroscopy

Listing proposed and options for MSAC consideration

Proposed MBS listing

The Applicants have proposed that the MBS item numbers for double-balloon enteroscopy 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. The proposed MBS item descriptors are shown in Table 3. MBS item numbers for capsule endoscopy would also need to be amended to cross-reference balloon-assisted enteroscopy (or the MBS item numbers), rather than double balloon enteroscopy. PASC and public consultation submissions have recommended that items 30684 and 30686 be further amended to allow for procedures involving argon plasma coagulation

Table 3: Proposed MBS item descriptor for single- and double-balloon enteroscopy

Category 3 – Therapeutic procedures
<p>MBS 30680</p> <p>BALLOON-ASSISTED 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)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"> (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. <p>(Anaes.)</p> <p>Fee: \$1,148.20 Benefit: 75% = \$861.15 85% = \$1,074.50</p>
<p>MBS 30682</p> <p>BALLOON-ASSISTED 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)</p> <p>The patient to whom the service is provided must:</p> <ul style="list-style-type: none"> (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. <p>(Anaes.)</p> <p>Fee: \$1,148.20 Benefit: 75% = \$861.15 85% = \$1,074.50</p>
<p>MBS 30684</p> <p>BALLOON-ASSISTED 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)</p>

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.)

Fee: \$1,413.00 Benefit: 75% = \$1,059.75 85% = \$1,339.30

MBS 30686

BALLOON-ASSISTED 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.

(Anaes.)

Fee: \$1,413.00 Benefit: 75% = \$1,059.75 85% = \$1,339.30

MBS item 11820

CAPSULE ENDOSCOPY to investigate an episode of obscure gastrointestinal bleeding, using a capsule endoscopy device approved by the Therapeutic Goods Administration (including administration of the capsule, imaging, image reading and interpretation, and all attendances for providing the service on the day the capsule is administered), (not being a service associated with 30680, 30682, 30684, 30686), if:

(a) the service is performed by a specialist or consultant physician with endoscopic training that is recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy; and

(b) the patient to whom the service is provided:

- (i) is aged 10 years or over; and
- (ii) has recurrent or persistent bleeding; and
- (iii) is anaemic or has active bleeding; and

(c) an upper gastrointestinal endoscopy and a colonoscopy have been performed on the patient and have not identified the cause of the bleeding; and

(d) the service is performed within 6 months of the upper gastrointestinal endoscopy and colonoscopy

Fee: \$2,001.20 Benefit: 75% = \$1,500.90 85% = \$1,927.50

MBS item 11823

CAPSULE ENDOSCOPY to conduct small bowel surveillance of a patient diagnosed with Peutz-Jeghers syndrome, using a capsule endoscopy device approved by the Therapeutic Goods Administration. The procedure includes the administration of the capsule, imaging, image reading and interpretation, and all attendances for providing the service on the day the capsule is administered (not being a service associated with 30680, 30682, 30684, 30686).

Medicare benefits are only payable for this item if:

1. the service has been performed by a specialist or consultant physician with endoscopic training that is recognised by the Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy; and
2. the patient to whom the service is provided has been conclusively diagnosed with Peutz-Jeghers syndrome (PJS)

This item is available once in any two year period.

Fee: \$2,001.20 Benefit: 75% = \$1,500.90 85% = \$1,927.50

Patients who would be eligible for single-balloon enteroscopy are those with obscure gastrointestinal bleeding. Further restrictions are that the patient must have (i) 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. These criteria are identical to double-balloon enteroscopy, and consistent with the broad approved indications listed on the ARTG (see Table 1). PASC have suggested that the criteria for eligibility should be simplified by removing the restriction that patients must be “anaemic or have active bleeding”.

Clinical place for proposed intervention

SBE is proposed as a direct substitute for a currently subsidised intervention, DBE (see Figure 1). There will be rare cases when one form of balloon-assisted 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. Here DBE may be more appropriate due the availability of both a standard enteroscope as well as a short enteroscope which is compatible with most endoscopic retrograde cholangiopancreatography (ERCP) accessories.² However, as a general rule, no changes would be expected in regards to the position of therapy, management options, or spectrum of patients treated. 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 gastrointestinal bleeding, as DBE was listed on the MBS to be used only for those with obscure gastrointestinal bleeding. It is possible that balloon-assisted enteroscopy may be useful in patients with small bowel disease who present without bleeding e.g. pain, obstruction, weight loss, diarrhoea³.

² Expert opinion of MESP, Dr M. Efthymiou, email communication, 20th August 2012.

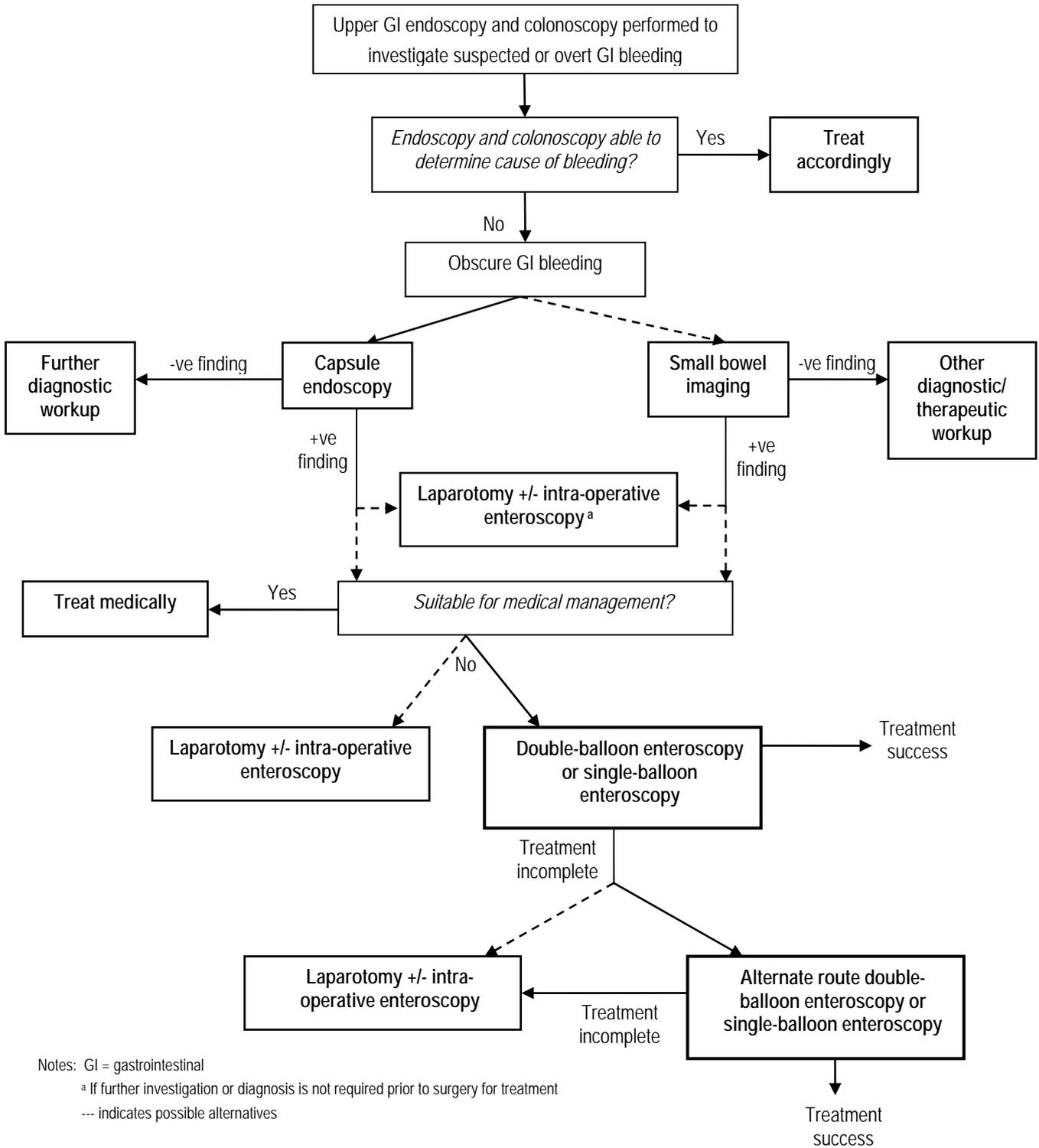
³ Expert opinion of Advisory Panel member for MSAC 1102, A/Prof W. Selby, email communication, 4th May 2006.

However, the Applicants are not requesting funding to be expanded to cover any indications not already listed for DBE.

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

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Figure 1 Management algorithm for patients with obscure GI bleeding, based on MSAC Application 1102 for Double-balloon enteroscopy



The best source of data to estimate the potential use of SBE is the current utilisation of double-balloon enteroscopy in the private health system in Australia. Since its listing on the MBS in July 2007, use of DBE has been steadily increasing (see Table 4).

Table 4 Claims made on MBS items for double-balloon enteroscopy between 2007/08 and 2010/11

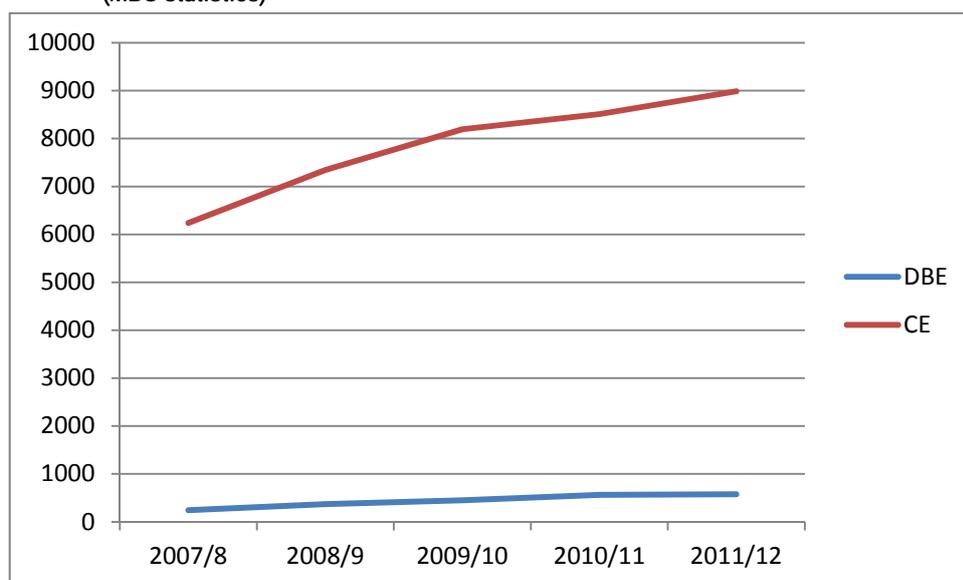
Financial year	MBS item 30680	MBS item 30682	MBS item 30684	MBS item 30686	Total
2007/08	83	56	74	30	243
2008/09	121	97	112	37	367
2009/10	148	100	153	49	450
2010/11	190	150	153	69	562
2011/12	189	166	149	71	575
Total	731	569	641	256	2197

The potential use for SBE would depend on the expected growth in use of balloon-enteroscopic techniques and market-share. The MESP expect that the introduction of SBE will not increase the overall use of balloon-assisted endoscopies, and that the important factor affecting the rate of use is the number of significant findings on capsule endoscopy. Using the assumption that 10 per cent of patients undergo two DBE procedures rather than one, in 2010/11 and 2012/11, for every 16 to 17 capsule endoscopy procedures performed, one patient went on to undergo one or more DBE. This is consistent with what has been reported from a large tertiary hospital in the United Kingdom (1 in 17 patients who received capsule endoscopy underwent DBE) (Sidhu et al. 2012).

With the growth in the use of capsule endoscopy, the absolute number of positive findings identified is expected to increase, and consequently, the use of balloon-assisted endoscopies is also expected to increase. It is unknown at what point the use of these MBS items will plateau.

Using the growth in capsule endoscopy in the last two financial years, by 2015/16, it is estimated that 636 – 675 patients will receive balloon-assisted enteroscopy (700 – 743 procedures). By 2017/18, it is estimated that 765 – 813 patients will receive balloon-assisted enteroscopy (842 – 894 procedures).

Figure 2 Number of DBE and capsule endoscopy (CE) services claimed on MBS between July 2007 and June 2102 (MBS statistics)



Comparator

The Applicants have proposed that single-balloon enteroscopy is an equivalent substitute for double-balloon enteroscopy, fulfilling the same role in the management algorithm. The MBS item numbers for double-balloon enteroscopy are outlined in Table 5. In addition to the noted DBE items in Table 5, the associated MBS item listings and fees are identified above in Table 2. The direct comparator for SBE is the currently used DBE and all procedures associated with the usage of this.

Table 5 MBS item descriptor for double-balloon enteroscopy

Category 3 – Therapeutic procedures	
MBS 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.) Fee: \$1,148.20 Benefit: 75% = \$861.15 85% = \$1,074.50
MBS 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.)

Fee: \$1,148.20 **Benefit:** 75% = \$861.15 85% = \$1,074.50

MBS 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.)

Fee: \$1,413.00 **Benefit:** 75% = \$1,059.75 85% = \$1,339.30

MBS 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.)

Fee: \$1,413.00 **Benefit:** 75% = \$1,059.75 85% = \$1,339.30

Outcomes for safety and effectiveness evaluation

The health outcomes, upon which the comparative clinical performance of single-balloon enteroscopy versus double-balloon enteroscopy in patients with obscure gastrointestinal bleeding will be measured, are:

Effectiveness

Primary: reduction of symptoms, reduction in gastrointestinal bleeding, biopsy yield/ diagnostic yield (of findings that could explain symptoms, ie arteriovenous malformations, erosions, ulcers, epithelial tumours, polyps), transfusion requirement.

Secondary: examination time, completion of procedure, length of hospital stay, re-admission, further diagnostic workup, technical (equipment) success/failure, depth of insertion, rate of total enteroscopy.

Safety

Primary: major complications such as perforation, pancreatitis, post-polyp sepsis, ileus, abscess, intestinal haematoma, haemorrhage, intussusceptions, infection (eg peritonitis), death.

Secondary: minor complications such as pain (ie sore throat, abdominal discomfort), fever, low-grade infection.

Summary of PICO to be used for assessment of evidence (systematic review)

Table 6 provides a summary of the PICO used to:

- (1) define the question for public funding,
- (2) select the evidence to assess the safety and effectiveness of single-balloon enteroscopy in patients with obscure gastrointestinal bleeding, and
- (3) provide the evidence-based inputs for any decision-analytical modelling to determine the cost-effectiveness of single-balloon enteroscopy in patients with obscure gastrointestinal bleeding.

Table 6: Summary of PICO to define research questions that assessment will investigate

Patients	Intervention	Comparator	Reference standard	Outcomes to be assessed
Patients with obscure gastrointestinal bleeding	<p><i>Diagnostic</i> Single-balloon enteroscopy (per oral or per anal-approach depending on location of identified or suspected small bowel pathology)</p> <p><i>Therapeutic</i> As above</p>	<p><i>Diagnostic</i> Double-balloon enteroscopy (per oral or per anal-approach depending on location of identified or suspected small bowel pathology)</p> <p><i>Therapeutic</i> As above</p>	<p><i>Diagnostic</i> Double-balloon enteroscopy (per oral or per anal-approach depending on location of identified or suspected small bowel pathology)</p> <p><i>Therapeutic</i> As above</p>	<p>Safety Primary: major complications such as perforation, pancreatitis, post-polyp sepsis, ileus, abscess, intestinal haematoma, haemorrhage, intussusceptions, infection (eg peritonitis), death.</p> <p>Secondary: minor complications such as pain (ie sore throat, abdominal discomfort), fever, low-grade infection.</p> <p>Effectiveness Primary: reduction of symptoms, reduction in gastrointestinal bleeding, biopsy yield/ diagnostic yield (of findings that could explain symptoms, ie arteriovenous malformations, erosions, ulcers, epithelial tumours, polyps), transfusion requirement.</p> <p>Secondary: examination time, completion of procedure, length of hospital stay, re-admission, further diagnostic workup, technical (equipment) success/failure, depth of insertion, rate of total enteroscopy.</p> <p>Cost-effectiveness Cost</p>
<p>Questions</p> <p>1. Is single-balloon enteroscopy as safe, effective and cost-effective as double-balloon enteroscopy in patients with obscure gastrointestinal bleeding?</p>				

Due to the current wording of MBS items 11820 and 11823 for capsule endoscopy, the use of this technology may not be claimed on the same day as double-balloon enteroscopy. PASC agree that this same restriction should apply to single-balloon enteroscopy.

Clinical claim

The Applicants claim that SBE is non-inferior in regards to both safety and effectiveness when compared to DBE. It is therefore expected that a cost-comparison would be performed (see Table 7). If it is proven that costs to the healthcare system (including to patients, and the costs to public hospitals etc) are identical, then no further economic analyses would be required. However, should any differences in the safety or effectiveness of the two procedures be identified, then a cost-effectiveness analysis or a cost-utility analysis would be required.

Table 7: Classification of single-balloon enteroscopy versus double-balloon enteroscopy for determination of economic evaluation to be presented

		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

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes for economic evaluation

Given that the Applicants claim that SBE is non-inferior to DBE in regards to both safety and effectiveness, the outcomes for economic evaluation are expected to be reduced to a comparison of costs. Should the costs differ in any way (i.e. a difference in the price of capital equipment or fewer referrals required given the wider availability of Olympus enteroscopy equipment etc), then a financial incidence analysis would also be required.

Health care resources

It is assumed that the costs associated with pre-procedural workup, professional fees, hospital stay and post-hospital costs would be the same for both single-balloon enteroscopy and double-balloon enteroscopy. The costs associated with these items would therefore not need to be considered. The healthcare resources which would need to be considered are the capital costs, maintenance costs and disposables associated with single- and double-balloon enteroscopy (ie the balloon control unit, small intestinal videoscope and the single use splinting tube). The Applicants have not provided any information on the costs associated with single-balloon enteroscopy, and have claimed that there would be no difference in the

healthcare resources used from double-balloon enteroscopy (including equipment and disposables). Therefore, the only information detailed in Table 8 is the capital, maintenance and disposable costs for the comparator, double-balloon enteroscopy, as provided in 2006.

Table 8 List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
Resources provided to deliver proposed intervention										
- Cost per procedure of capital costs and maintenance	Equipment costs	Private day facility	100%	Not stated						
- Associated disposables	Equipment costs	Private day facility	100%	Not stated						
Resources provided to deliver comparator 1										
- Cost per procedure of capital costs and maintenance	Equipment costs	Private day facility	100%	\$299				\$299		\$299
- Associated disposables (overtube and balloon)	Equipment costs	Private day facility	100%	\$359				\$359		\$359

* Include costs relating to both the standard and extended safety net.

Proposed structure of economic evaluation (decision-analytic)

As it is expected that single-balloon enteroscopy and double-balloon enteroscopy are non-inferior to each other in regards to safety and effectiveness, a decision-analytic model has not been created.

References

Akerman, PA & Haniff, M 2012, 'Spiral enteroscopy: Prime time or for the happy few?', *Best Pract Res Clin Gastroenterol*, vol. 26, no. 3, Jun, pp. 293-301.

Gerson, LB, Batenic, MA, Newsom, SL, Ross, A & Semrad, CE 2009, 'Long-term outcomes after double-balloon enteroscopy for obscure gastrointestinal bleeding', *Clin Gastroenterol Hepatol*, vol. 7, no. 6, Jun, pp. 664-669.

Hartmann, D, Eickhoff, A, Tamm, R & Riemann, JF 2007, 'Balloon-assisted enteroscopy using a single-balloon technique', *Endoscopy*, vol. 39 Suppl 1, Feb, p. E276.

Kaffes, AJ 2012, 'Advances in modern enteroscopy therapeutics', *Best Pract Res Clin Gastroenterol*, vol. 26, no. 3, Jun, pp. 235-246.

Khashab, MA, Lennon, AM, Dunbar, KB, Singh, VK, Chandrasekhara, V, Giday, S, Canto, MI, Buscaglia, JM, Kapoor, S, Shin, EJ, Kalloo, AN & Okolo, PI, 3rd 2010, 'A comparative evaluation of single-balloon enteroscopy and spiral enteroscopy for patients with mid-gut disorders', *Gastrointest Endosc*, vol. 72, no. 4, Oct, pp. 766-772.

Lenz, P & Domagk, D 2012, 'Double- vs. single-balloon vs. spiral enteroscopy', *Best Pract Res Clin Gastroenterol*, vol. 26, no. 3, Jun, pp. 303-313.

Manno, M, Barbera, C, Bertani, H, Manta, R, Mirante, VG, Dabizzi, E, Caruso, A, Pigo, F, Olivetti, G & Conigliaro, R 2012, 'Single balloon enteroscopy: Technical aspects and clinical applications', *World J Gastrointest Endosc*, vol. 4, no. 2, Feb 16, pp. 28-32.

Medicare Australia 2012, *MBS Item Reports: Items 30680, 30682, 30684, 30686* viewed 27th June 2012, <http://www.medicareaustralia.gov.au/providers/health_statistics/statistical_reporting/medicare.htm>.

Sidhu, R, McAlindon, ME, Drew, K, Hardcastle, S, Cameron, IC & Sanders, DS 2012, 'Evaluating the role of small-bowel endoscopy in clinical practice: the largest single-centre experience', *Eur J Gastroenterol Hepatol*, vol. 24, no. 5, May, pp. 513-519.