



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1346 – Amendment to MBS item 11820 – Capsule Endoscopy

Sponsor/Applicant/s: Given Imaging Pty Ltd

Date of MSAC consideration: 1 August 2013

1. Purpose of application

A submission based assessment (SBA) report requesting two amendments to the Medicare Benefits Schedule (MBS) listing of item 11820 for capsule endoscopy (CE) for the investigation of obscure gastrointestinal bleeding (OGIB) was received from Given Imaging Pty Ltd by the Department of Health and Ageing in February 2013. The two amendments include:

1. Change of the age restriction to allow children aged 2 and above to receive the service (i.e. change “10 years and over” to “2 years and over”); and
2. Removal of the restriction specifying the time duration since the preceding endoscopy and colonoscopy (i.e. removing part (d) of the restriction).

CE is a non-invasive diagnosis test, usually conducted in an outpatient setting, in which the gastrointestinal (GI) system is visualised via a camera inside an ingested capsule. The test visualises the GI tract mucosa and can be used to diagnose a range of conditions such as OGIB, coeliac disease, small bowel tumours and Peutz-Jeghers syndrome.

The submission is for an extension of the use of CE for OGIB.

OGIB is defined as bleeding of unknown origin that persists or recurs after a negative initial or primary endoscopy result. Small intestinal sources of bleeding, whilst uncommon, are responsible for the majority of cases of OGIB.

Clinically, patients may suffer from chronic fatigue and weariness due to persistent or recurrent anaemia. Patients may also suffer from anxiety arising from the uncertainty of the aetiology and pathology of their condition. Patients with severe bleeding may require regular hospitalisation for transfusion procedures (Source: MSAC Application 1057 Assessment Report: 2003).

2. Background

CE for investigation of OGIB in adult patients originally received interim MBS funding following consideration by MSAC in 2003 (Application 1057). In 2005, the indication was broadened to include patients aged 10 years and over, and in 2007 MSAC reconsidered this indication and recommended full MBS listing.

3. Prerequisites to implementation of any funding advice

The PillCam[®] CE system, manufactured by Given Imaging, was registered on the Australian Register of Therapeutic Goods (ARTG) in 2006. The wording of the intended purpose specified in the registration is *The PillCam Platform with a PillCam SB capsule is intended for visualisation of the small bowel. The PillCam SB capsules are intended for use in adults and children from 2 years of age*” (ARTG Identifier 130833 Class IIa). The CE device upon which the interim MSAC listing was made in 2003, the M2A[®] Capsule Endoscope, is no longer listed on the ARTG (formerly ARTG no. AUST L 78651).

The current descriptor for MBS item 11820 includes the requirement that patients have undergone both upper GI endoscopy and colonoscopy which have not identified the cause of the GI bleeding. The CE procedure is to be performed within six months of the upper GI endoscopy and colonoscopy, and provided to patients aged 10 years or over.

4. Proposal for public funding

The proposal for public funding is amendments for item 11820 to include children aged 2 years and over, and the removal of the ‘six month’ rule specifying the time restriction for the preceding endoscopy and colonoscopy.

Table 1. Proposed MBS item descriptor included in the SBA report

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
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 double balloon enteroscopy), 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 2 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
Fee: \$2,039.20 Benefit: 75% = \$1,529.40 85% = \$1,964.70

The proposal indicated that CE be restricted to patients who:

- i. Are aged 2 years or over; and
- ii. Have recurrent or persistent bleeding; and
- iii. Are anaemic or have active bleeding.

The proposal specified that an upper GI endoscopy and a colonoscopy have been performed on the patient and have not identified the cause of the bleeding.

The service is to be performed by specialists or consultant physicians with endoscopic training that is recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy.

5. Consumer Impact Statement

Nil

6. Proposed intervention's place in clinical management

The applicant indicated that, for paediatric patients, the additional diagnostic ability offered by CE means that treatment can be better targeted and these patients are not exposed to treatments with potentially harmful side effects or adverse events unnecessarily, thereby providing superior effectiveness in the clinical management of these patients.

The applicant also suggested that, by removing the 'six-month' rule, patients will avoid repeat colonoscopy and endoscopy procedures that have been shown to have a high chance of producing no clinical benefit in this particular patient population. The removal of the 'six month' rule will improve the clinical management of these patients (by avoiding unnecessary invasive tests).

The SBA report did not include a clinical management algorithm.

7. Other options for MSAC consideration

Nil

8. Comparator to the proposed intervention

The SBA report did not nominate a comparator for CE in patients aged 2-10 years. The prior assessment of CE for the evaluation of OGIB in adult patients nominated small bowel series (SBS) as the main comparator.

In regard to the removal of the 'six month' rule, the SBA report used the current requirement that CE be performed within 6 months of the upper GI endoscopy and colonoscopy as the comparator. In other words, if a patient required further investigation of OGIB over 6 months following upper GI endoscopy and colonoscopy, then these procedures would need to be repeated prior to CE.

The SBA report has been submitted without prior development of a DAP. As such, the PASC has not had the opportunity to consider the appropriate comparator for each requested amendment.

The accepted comparator is currently listed on the MBS (item 11820).

MBS item 11820 has been listed on the Schedule since 1 May 2004.

Table 2. MBS item descriptor as at 1 May 2013

Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
<p>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 double balloon enteroscopy), if:</p> <p>(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</p> <p>(b) the patient to whom the service is provided:</p> <p style="padding-left: 20px;">(i) is aged 10 years or over; and</p> <p style="padding-left: 20px;">(ii) has recurrent or persistent bleeding; and</p> <p style="padding-left: 20px;">(iii) is anaemic or has active bleeding; and</p> <p>(c) an upper gastrointestinal endoscopy and a colonoscopy have been performed on the patient and have not identified the cause of the bleeding; and</p> <p>(d) the service is performed within 6 months of the upper gastrointestinal endoscopy and colonoscopy</p> <p>(e) the service is not associated with double balloon enteroscopy</p> <p>(f) the service has not been provided to the same patient:</p> <p style="padding-left: 20px;">(i) more than once in an episode of bleeding, being bleeding occurring within 6 months of the prerequisite upper gastrointestinal endoscopy and colonoscopy (any bleeding after that time is considered to be a new episode); or</p> <p style="padding-left: 20px;">(ii) on more than 2 occasions in any 12 month period.</p> <p>Fee: \$2,039.20 Benefit: 75% = \$1,529.40 85% = \$1,964.70</p>

9. Comparative safety

Amendment 1

The SBA report used the evidence previously presented to the Federal Drug Administration, then subsequently to the Therapeutic Goods Administration (TGA). This evidence consisted of 44 abstracts, of which seven articles that were available as full text publications were included in the SBA report.

The critique noted that the seven included articles were published between November 2004 and January 2008 and that it was unclear whether these studies were identified through a systematic literature search. In response to the critique, the applicant performed a search update for citations published between 2008 and 2013. One study was considered relevant by the applicant to the current application (Fritscher-Ravens et al 2009).

Amendment 2

The SBA report used three categories of evidence to support Amendment 2:

1. Evidence included in the August 2003 assessment (application 1057);
2. Evidence on the clinical relevance of the 'six month' rule; and
3. Adverse events potentially avoided by the removal of the 'six month' rule.

The critique noted that the SBA report did not include an update of the literature search from the 2003 assessment report. In response to the critique, the applicant noted that Mekaroonkamol et al (2013) was only recently published and therefore was not identified at the time of submission.

Amendment 1

No randomised trials of CE were identified in the SBA report. In the absence of randomised trials, the SBA report included seven observational studies investigating the use of CE in paediatric patients. In response to the critique, the applicant included a further prospective study (Fritscher-Ravens 2009).

Table 3. Characteristics of the included studies

Study	Study design	Patient characteristics	Interventions
Antao 2007	Case series	Patients with suspected small bowel disease Age range 16 months – 16 years; median 11 years	N = 37
Barth 2004	Case series	Patients with GI bleeding Age range 3-18 years; median 9 years	N = 11
Cohen 2008	Retrospective	Patients with previously diagnosed inflammatory bowel disease Mean ± SD age at CE 16±3 years (Crohn's disease), 15±3 (ulcerative or indeterminate colitis)	N = 28
de' Angelis 2007	Case series	Patients with suspected small bowel disease Age range 18 months - 18 years	N = 87
Ge 2007	Case series	Patients with suspected small bowel disease Age range 3 – 18 years; median 11 years	N = 16
Rivet 2006	Case series	Patients with edema, diarrhea, chylous ascites and growth retardation Age range 6 - 17 years	N = 4
Thomson 2007	Case series	Patients with suspected or known small bowel disease. Age range 9.4 – 15.9 years; median 12.59 years	N = 28
Fritscher-Ravens 2009	Prospective	Children with occult gastrointestinal bleeding, suspected Crohn's disease, abdominal pain of unknown aetiology, protein-losing enteropathy and malabsorptive disorders Age range 1.5 – 7.9 years	N=83

Amendment 2

The SBA used three categories of evidence to support Amendment 2:

1. Evidence included in the August 2003 assessment (application 1057):

Table 4. Time restrictions on prior investigations from the August 2003 assessment report

Study	Type	Number of patients.	Time restriction on prior investigations ^a	Comments
Pivotal clinical trials included in the August 2003 assessment				
Hartmann	Full study	33	None specified	GR06 trial
Lewis	Full study	21	12 months ^b	US01 trial
Selby	CSR	40	None / 12 months	AU13 trial – restriction was site dependent
Other evidence (e.g., case reports, abstracts)				
Fleischer	Full study	1	None specified	Case report of impaction in throat
Gay	Full study	1	None specified	Patient had 3 sets of prior investigations in the previous 30 days; the reason for this is unclear.
Hollerbach	Full study	2	None specified	Case report on endoscopic placement of capsule
Scapa	Full study	1	None specified	Case report, previous colonoscopies at 6 and 18 months, previous endoscopy at 18 months, reasons for repeats is unclear
Lim	Abstract	29	None specified	Comparison with push enteroscopy
Mylonaki	Abstract	60	None specified	Comparison with push enteroscopy
Cave	Abstract	137	None specified	–
De Luca	Abstract	34	None specified	–
Enns	Abstract	259	None specified	Mostly obscure bleeding patients, some others
Fernandez-Diaz	Abstract	22	None specified	–
Girelli	Abstract	15	None specified	–
Landaeta	Abstract	19	None specified	–
Morandi	Abstract	46	None specified	Mostly obscure bleeding patients, some others
Rossini	Abstract	55	None specified	Mostly obscure bleeding patients, some others
Schulmann	Abstract	12	None Specified	–
Watson	Abstract	1	None specified	Case report, after -ve colonoscopy & endoscopy
Woods	Abstract	1	None specified	Case report, after -ve colonoscopy & endoscopy
Caunedo	Abstract	24	None specified	–
De Bona	Abstract	12	None specified	–
Lo	Abstract	37	None specified	–
Pennazio	Abstract	89	None specified	Comparison with push enteroscopy in a subset

Study	Type	Number of patients.	Time restriction on prior investigations ^a	Comments
Toth	Abstract	28	None specified	Duration of anaemia 2-144 months prior to CE
Van Gossum	Abstract	21	None specified	Comparison with push enteroscopy
Demedts	Abstract	18	None specified	–
Hartmann	Abstract	21	None specified	Comparison with intraoperative enteroscopy
Neu	Abstract	52	None specified	–
Neitsch	Abstract	27	None specified	Comparison with push enteroscopy

Source: Table 3 of the SBA, p. 20

2. Evidence on the clinical relevance of the ‘six month’ rule:
A PubMed search was presented in the SBA report which identified two relevant studies regarding the clinical relevance of the ‘six month’ rule:
 - a. Gilbert 2008, Journal of gastroenterology and hepatology, *Are repeat upper gastrointestinal endoscopy and colonoscopy necessary within six months of capsule endoscopy in patients with obscure gastrointestinal bleeding?*; and
 - b. Vlachogiannakos 2011, Digestive diseases and sciences, *Bleeding lesions within reach of conventional endoscopy in capsule endoscopy examinations for obscure gastrointestinal bleeding: is repeating endoscopy economically feasible?*

3. Adverse events potentially avoided by the removal of the ‘six month’ rule:
The SBA report provided a summary of two reports produced by the American Society for Gastrointestinal Endoscopy as evidence of the adverse events associated with colonoscopy and upper GI endoscopy.

Table 5. Rate of complications associated with repeat colonoscopy and endoscopy

Procedure	GI perforation	GI haemorrhage	Death
Colonoscopy	10/10,000	35/10,000	0.7/10,000
Endoscopy	3/10,000	“Rare”	0.4/10,000
Cumulative	13/10,000	35/10,000	1.1/10,000

Source: Table 5 of the SBA, p. 24.

No meta-analyses or systematic reviews were identified by the SBA report.

Amendment 1

The SBA report noted that the major safety concern regarding the use of CE in paediatric patients may be the perceived risk of delayed passage or capsule retention due to the size of the capsule compared with the size of the paediatric bowel. The 44 publications considered in the SBA report evidence reviewed collectively include 1128 patients, most of whom were paediatric or adolescent. Of the 1128 cases, there were no cases of capsule retention requiring extraction (and there were no cases of capsule retention in OGIB cases).

The SBA report acknowledged that while a portion of adult patients have endoscopic placement, this is not uncommon in paediatric patients. Furthermore, to minimise patient impact in paediatric patients, if CE was available, it is highly likely that endoscopic placement would occur immediately after a non-diagnostic colonoscopy and endoscopy, while the patient was still sedated.

The SBA report concluded that based on the evidence, CE for OGIB is safe in children, including paediatric patients affected by this amendment (i.e. those aged two to nine years old).

The critique noted that the safety data presented in the SBA report indicated that the rates of delayed passage and capsule retention with CE in paediatric patients are generally low and comparable to the rates observed in adult patients. The rate of endoscopic placement of the capsule ranged between 7% and 25% in the seven included studies, with a rate of 11% in the largest study (de' Angelis 2007). However, it was noted that in the more recent study (Frtischer-Raven 2009), endoscopic placement was performed in 76% of patients, however the relevance of this to Australian practice was questioned. The critique concluded that endoscopic placement could be a significant safety issue in paediatric patients, as it may involve additional anaesthesia and endoscopy procedures.

Amendment 2

The SBA report noted that some patients who were not satisfactorily diagnosed using the upper GI endoscopy and colonoscopy in the past (more than 6 months ago), are given these procedures again solely because of the 'six month' rule, rather than for clinical indications. The vast majority of repeat colonoscopies and endoscopies are futile in these patients, with a reported diagnostic yield of 4%. The SBA report concluded that the removal of the 'six month' rule would avoid adverse events potentially caused by the unnecessary colonoscopy/endoscopy procedures currently given due to the 'six month' rule.

The SBA report identified that for diagnostic colonoscopies and endoscopies, the notable complications are cardiopulmonary complications related to the administration of anaesthesia, GI perforation, haemorrhage and death.

However, the critique noted that the SBA report identified a number of key rare complications associated with colonoscopy and endoscopy. The critique concluded that as the true extent of the utilisation of repeat procedures to qualify for CE is uncertain, the impact of any potential complications of these procedures is also uncertain.

10. Comparative effectiveness

Evidence for comparative effectiveness of the two proposed amendments was derived from the same sources used to derive comparative safety.

No meta-analyses or systematic reviews were identified by the SBA report.

Amendment 1

The SBA report claimed that based on the five studies published between 2004 and 2008 that involved paediatric patients with OGIB (including two studies comparing CE with SBS), CE in paediatric patients returned a diagnostic yield rate of greater than 60% (the range was 64% to 100%). The two studies comparing CE with SBS demonstrated that CE was significantly more effective than SBS, with CE again returning a diagnostic yield greater than 60%, compared with a diagnostic yield of less than 21% for SBS (although these two studies also included non-OGIB patients). The applicant suggested that CE provides a similar, if not better, diagnostic yield in paediatric patients when compared with its use in adults. The study by Fritscher-Ravens et al (2009), the largest study involving paediatric OGIB patients, reports a diagnostic yield of 53% (16/30) for children aged 1.5 to 7 years with OGIB.

The critique noted that this claim of effectiveness relies entirely on diagnostic yield, with no evidence for the true diagnostic accuracy of CE in patients aged 2-9 years (although this was also the case in the application for listing for adults (MSAC Application 1057)).

Amendment 2

The SBA report noted that the ‘six month’ rule does not reflect the patient population represented by the clinical evidence included in the August 2003 assessment. While the pivotal clinical trials included in the assessment required patients to have undergone previously negative or non-diagnostic colonoscopy and endoscopy, no ‘six month’ rule was implemented in any of the trials.

The critique noted that there were no studies included in the 2003 assessment report that included a maximum time of six months; however, two of the key comparative studies included a maximum time period of twelve months.

The SBA report used data from an Australian study (Gilbert et al., 2008) to suggest that a high proportion of patients undergo repeat colonoscopy and endoscopy specifically to qualify for CE. The study reported that the diagnostic yield of these repeat procedures is very low, at 4%. Based on this study, the SBA assumed that 25% of patients referred for CE would need to undergo repeat endoscopy/colonoscopy, because of the 6-month rule. The critique noted that this study covers the time period immediately after the listing of item 11820 on the MBS and it is unclear whether these data are applicable to current clinical practice. Given the minimal amount of data available, the critique concluded that the true extent of the utilisation and diagnostic value of repeat colonoscopy and endoscopy procedures is highly uncertain.

Amendment 1

The SBA report noted that based on the evidence, CE provided similar, if not better, diagnostic yield (>60%) in paediatric patients when compared with its use in adults. The conclusion of the SBA was that CE is both safe and effective in patients under 10 years old. The critique summarised that, based on the evidence presented, CE is effective for the investigation of OGIB in patients aged 2-9 years. This conclusion was based on findings from observational CE studies, two of which reported limited evidence for the efficacy of CE compared with SBS.

Amendment 2

The SBA report noted that in Australian clinical practice, some patients who were not satisfactorily diagnosed using the upper GI endoscopy and colonoscopy in the past (more than 6 months ago), are currently given these procedures again solely because of the ‘six month’ rule. In summary, the evidence presented in the SBA report does not support the current ‘six month’ rule.

The critique noted that a review of the studies included in the 2003 assessment report found no studies that included a ‘six month rule’; however, two of the key comparative studies made use of a ‘twelve month rule’. In response to the critique, the applicant maintained that the presented clinical evidence supported the removal of any time restriction. The applicant also indicated that the mean time since previous colonoscopy/endoscopy in the Gilbert cohort was ~19 months (median: 14).

11. Economic evaluation

The SBA report did not present a formal economic evaluation. The applicant suggested that the cost-effectiveness of the proposed amendments is expected to be favourable or at least indifferent to the cost-effectiveness as observed with the existing MBS wording.

The applicant indicated that the amendments to item 11820 are expected to have negligible or favourable budgetary implications to the MBS. The available data suggests the use of CE in paediatric patients (Amendment 1) will be relatively rare, while it will play a valuable role in the management of a small paediatric patient population with specific clinical needs.

Amendment 2 will avoid repeat colonoscopies and/or endoscopies with uncertain clinical value (Gilbert et al 2008), thereby generating cost savings to the MBS.

Amendment 1

Using MBS statistics, the SBA report noted that between 11 and 28 claims were made per year between July 2007 and June 2012 for patients aged 5 – 14 for CE for OGIB. As per the current MBS listing, this usage is expected to be in patients aged from 10 to 14 years old. The relative population size in Australia between the 2 – 9 year old group and the 10 – 14 year old group is roughly 1.6 to 1. Assuming the incidence rate of OGIB is similar in the two age groups, the estimated number of CE procedures in the 2 – 9 year old group is 26 each year (based upon an annualised average over the last 5 years)

The SBA report included the fee for MBS item 11820 (\$2,039.20) as the only cost to estimate the financial impact of expanding the listing for item 11820 to include patients aged 2-9 years.

The critique noted that costs associated with endoscopic placement have not been included in the financial impact calculations. In response to the critique, the applicant provided evidence that 11% of patients would require endoscopic placement, indicating that, based on 26 CE procedures for this age group each year, endoscopic placements may be required for 2 to 3 patients (de' Angelis 2007). A study provided by Fritscher-Ravens indicated that 76% of patients in this age group required endoscopic placement, however the relevance of this to clinical practice in Australia was uncertain. In response to the critique, the applicant provided an estimated cost if all patients underwent endoscopic placement, noting that the cost to the MBS would be “less than \$30,000” per year.

Table6. Estimated extent of CE use for OGIB in paediatric patients aged 2 – 9 year old and associated financial implications

Variable	Estimates	Source/notes
<i>Expected Usage</i>	-	-
Current use in 10 –14 y.o., per year	16	Annual average over the past five years, MBS statistics
Relative population size between 2-9 y.o. and 10-14 y.o.	1.6	ABS 2008, 2.3 million for the 2-9 y.o. group and 1.4 million for the 10-14 y.o. group.
Estimated usage in 2-9 y.o.	26	Calculated (i.e., 16 procedures X 1.6)
<i>Estimated costs</i>	-	-
Cost per procedure	\$2,039.20	Current MBS benefit
Estimated total cost	\$53,019	Calculated (i.e., \$2,039.20 X 26)

Source: Table 6 of the SBA, p. 28

The number of patients aged 10-14 years was transformed into an estimate of the number of eligible patients aged 2-9 years using population projections from the Australian Bureau of Statistics.

Amendment 2

The SBA report presented a cost comparison of diagnostic work-up using CE with and without the ‘six month’ rule. This analysis is based on MBS statistics from the calendar year of 2012 (9,014 CE services) and estimates the cost savings that would have accrued to the health system had the ‘six-month’ rule not been in place using the data from the Gilbert study.

The SBA report assumed 25% of patients require repeat colonoscopy/endoscopy procedures due to the ‘six month’ rule and these repeat procedures give a diagnostic yield of 4%.

The SBA report uses data from the MBS and the public hospital cost weights to calculate procedure costs, and data from Gilbert et al (2008) to estimate the use and diagnostic yield of repeat colonoscopy and endoscopy procedures.

The critique noted that the SBA report did not provide any additional analyses to explore the effect of the proposed changes to MBS item 11820 such as:

- Increase in the eligible population due to removal of the ‘six month’ rule;
- Lower proportion of patients undergoing repeat colonoscopy or endoscopy; or
- Higher diagnostic yield from repeat colonoscopy or endoscopy.

In response to the critique, the applicant indicated that the removal of the ‘six month’ rule is not expected to lead to a notable expansion of the CE market.

The SBA report summarised that:

- Between May 2004 and September 2005, 25% of 198 patients referred to the Royal Prince Alfred Hospital, Sydney, received repeat colonoscopy/endoscopy procedures solely due to the ‘six month’ rule (Gilbert et al 2008);
- A diagnostic yield of 4% is reported for patients receiving repeat colonoscopies and endoscopies (Gilbert et al 2008);
- The estimated cost saving (25% repeat rate) is \$3 million per year or greater than \$1 million per year with a 10% repeat rate; and
- Avoiding these repeat procedures also offers safety and quality of life benefits.

Other comments

The SBA report requested two amendments to the current descriptor for MBS item 11820. The fee for item 11820 will remain unchanged (\$2,039.20 as at May 2013).

Expected co-payments/out of pocket costs have not been addressed in the SBA report.

As CE procedures are usually performed out of hospital, this proposal would have implications for the Medicare Safety Net and Extended Medicare Safety Net. These implications were not been addressed by the SBA report.

12. Financial/budgetary impacts

Amendment 1

As stated in the *Economic Evaluation* section, it is estimated that amendment 1 will result in an additional 26 services per year.

Amendment 2

The SBA report indicated that the removal of the ‘six month’ rule will reduce repeat colonoscopies by 2,254 per year. The number of patients presenting for CE will remain the same as when the ‘six month’ rule was in place (9,014 services).

Table 7. Cost comparison of diagnostic work-up using CE with and without the ‘six month’ rule

Comparison	With ‘six month’ rule	No ‘six month’ rule	Difference	Source/notes
Number of patients presenting for CE	9,014	9,014	-	MBS item 11820 Requested Medicare items processed from January 2012 to December 2012)
Cost of repeat colonoscopy/endoscopy				
Number of patients receiving repeat colonoscopy/endoscopy due	2,254 (9014x25%)	-	-2,254	Rate of repeat procedure due to the ‘six month’ rule (i.e., 25%; Gilbert 2008)

Comparison	With 'six month' rule	No 'six month' rule	Difference	Source/notes
to 'six month' rule				
Cost per procedure	\$1,469	-	-	Casemix, Public hospital cost weights round 14 (2009-2010), G48C – colonoscopy; similar costs for endoscopy.
Total costs	\$3,310,392 (2254x\$1469)	-	-\$3,310,392	Calculated
Cost of CE	-	-	-	-
Patients diagnosed after repeat colonoscopy/endoscopy	90 (4% of 2254)	0	-90	Diagnostic yield of repeat procedures, Gilbert et al 2008
Number of patients receiving CE	8,924	9014	90	Assumption (cohort analysis)
Cost per CE	\$2,039.20	\$2,039.20	-	Current MBS benefit
Total CE costs	\$18,197,535	\$18,381,349	\$183,813	Calculated
Summary all costs	-	-	-	-
Cost of repeat colonoscopy/endoscopy	\$3,310,392	-	-\$3,310,392	Calculated (see rows above)
Cost of CE	\$18,197,535	\$18,381,349	\$183,813	Calculated (see rows above)
Total	\$21,507,927	\$18,381,349	-\$3,126,578	Calculated
(per patient presenting for CE)	\$2,386.06	\$2,039.20	-\$347	Calculated (totals divided by the original 9014 cohort)

Source: Table 7 of the SBA, p. 31

MBS item 11820 currently requires that *'the service has not been provided to the same patient on more than 2 occasions in any 12 month period.'* As previously mentioned, the applicant indicates that the evidence supports the removal of any time restriction for the CE procedure.

For both proposed amendments, the financial impact was based on the current Schedule fee of \$2,039.20 and services for MBS item 11820.

The SBA report estimated a total cost to the MBS for the 2 – 9 year old group of approximately \$53,000 per year.

The SBA report estimated the financial impact for the removal of the 'six month' rule, by calculating:

- the fee for MBS item 11820 (\$2,039.20); and
- the costs of colonoscopy from the public hospital cost weights round 14 (\$1,469).

The total cost to the MBS had not been identified for Amendment 2 i.e. the benefit payable for MBS item 11820 and the relevant MBS items for colonoscopy and endoscopy.

The SBA report used data from Gilbert et al to estimate 2,254 patients (25% of 9,014 patients) receiving CE who would have undergone repeat colonoscopy or endoscopy due to the 'six month' rule. The patient numbers were applied to the public hospital cost weight for colonoscopy (\$1,469) to calculate a total annual cost of \$3.3 million for repeat colonoscopy or endoscopy procedures due to the 'six month' rule.

The SBA report used the diagnostic yield of 4% for repeat procedures from Gilbert et al (2008) to estimate that 90 patients will be diagnosed after repeat colonoscopy/endoscopy. These 90 patients will not require CE, so the total cost for CE is reduced by \$183,813 with

the 6-month rule in place. However, the 6-month rule incurs an additional cost of \$3,310,392 for repeat upper GI endoscopy/ colonoscopy procedures.

Based on these data, the SBA report estimated that the removal of the ‘six month’ rule would result in annual savings of approximately \$3.1 million, a figure based on the Schedule fee for 11820, the public hospital cost weight for colonoscopy and without safety net impacts.

Additionally, the critique identified that the SBA report did not include the costs associated with complications of the CE, endoscopy and colonoscopy procedures. In response to the critique, the applicant argued that the clinical benefits of avoiding repeat colonoscopies should outweigh any potential safety concern associated with CE.

The health care resources associated with the provision of CE have not been identified in the SBA report.

The total cost to the MBS, calculated by using the benefit payable for the services, had not been identified for the proposed amendments. Therefore, the net financial cost/year to the MBS is yet to be determined.

13. Key issues for MSAC from ESC

- Main issues around the proposed eligible population for public funding and/or the proposed main comparator

Amendment 1

The ESC did not have an issue with the population or comparator for amendment 1.

Amendment 2

ESC considered if the removal of the ‘six month’ rule would lead to an expansion in the market for CE. However, ESC noted that alternatively the proposed amendment may decrease the number of procedures. ESC suggested that the treating medical specialist may be more inclined to watch and wait if the time pressure of the ‘six month’ rule for endoscopy and colonoscopy was removed.

ESC considered and accepted that double balloon enteroscopy (DBE) was not a comparator for CE due to the much higher technical difficulty and greater adverse events associated with DBE.

- Main issues around the evidence and conclusions for safety

Amendment 1

ESC considered the impact on safety and costs associated with the increased proportion of patients in the 2 – 9 year age group who would require endoscopic placement of the capsule. The Fritscher-Ravens article notes that 76% of patients in this age group require endoscopic placement. ESC accepted that patients in this age group are likely to be having capsule placement concurrently with other procedures. Additionally, the applicant estimates that there would only be a maximum of 26 CE procedures in this age group per annum.

ESC accepted that there was sufficient evidence that it was safe to use in the proposed 2 - 9 year age group. However, ESC noted that it is not clear whether a systematic literature search was performed, and there were only seven peer reviewed studies among the evidence, with an additional study identified following the critique of the SBA report.

Amendment 2

ESC discussed the clinical rationale for the ‘six month’ rule and concluded that CE is a safe practice. The treating medical specialist will make a judgement call as to whether the procedure is required. ESC noted that younger patients may not require repeat endoscopies or colonoscopies.

ESC also noted that the use of MBS item 11820 has been substantially greater than predicted in 2003 and that this may be associated with an increased rate of complications with repeat colonoscopy and endoscopy, for example GI perforation, GI haemorrhage or death.

- Main issues around the evidence and conclusions for clinical effectiveness

For both of the proposed amendments, ESC noted that as only diagnostic yield is reported, the diagnostic accuracy of CE is unknown i.e. a finding may be a false negative or false positive. ESC also noted the reliance on diagnostic yield as the main outcome of CE in the MBS listing of CE in 2003.

For Amendment 1, ESC accepted that the evidence indicated that CE has a superior diagnostic yield to SBS for the 2 – 9 year age group.

- Other important clinical issues and areas of clinical uncertainty

ESC requested that the clinical rationale for the ‘six month’ rule be revisited and the reasoning as to why the ‘six month’ rule was originally included in the MBS item descriptor be presented to MSAC. ESC also requested that the GESA colonoscopy guidelines be provided to MSAC.

- Main economic issues and areas of uncertainty

ESC noted that the estimated costs and financial impact of the proposed amendments have been calculated based on the full Schedule fee for MBS item 11820. While Medicare safety net impacts have not been analysed, ESC noted that over 70% of services provided under this item are bulk-billed and the average out-of-pocket expense per service is \$141.26 This suggests that Medicare safety net impacts are unlikely to be large.

The following tables provide an estimate of the MBS cost associated with the proposed amendments.

Amendment 1

ESC noted that the cost of anaesthesia in the 2-9 year population had not been included in the estimated costs and financial impact. According to the applicant, the extension of CE for OGIB in this population will result in an additional 26 services per year. It is estimated that 76% (20 patients) will require endoscopic placement.

Table 8. CE - Total Expenditure – 2012/2013 - Amendment 1

CE with Endoscopic Placement (\$'000)

Cost	44.3
CE without Endoscopic Placement (\$'000)	
CE	11.8
Total MBS Cost of Amendment 1 (\$'000)	
Total	56.1

Amendment 2

The number of patients presenting for CE is assumed to be 9,014, of which 25% receive repeat colonoscopy/endoscopy. ESC discussed whether the 25% rate for repeat colonoscopy/endoscopy due to the 'six month' rule has been overestimated by the applicant taking into account the timing of the evidence in relation to the original listing of MBS item 11820 (in the Gilbert study).

Table 9. Without '6 month' Rule

Total CE MBS Expenditure (\$'000)	
Total CE MBS Expenditure	17,709.8

Table 10. With '6 month' Rule

Repeat Procedure MBS Expenditure (\$'000)	
Colonoscopy	868.4
Endoscopy	642.8
Colonoscopy and Endoscopy Total	1,511.2

ESC noted that the SBA report used the diagnostic yield of 4% of repeat endoscopy/colonoscopy procedures. This yields a total of 90 patients who are diagnosed following the repeat endoscopy/colonoscopy who do not have to undergo a second CE.

Table 11. MBS savings due to CE avoided

MBS savings due to CE avoided (\$'000)	
MBS savings due to CE avoided	176.8
CE MBS Expenditure following savings from repeat endoscopy/colonoscopy procedures	17,533.0

Totals (\$'000)	
Total MBS Expenditure: CE, Colonoscopy and Endoscopy	19,044.2
Total MBS Saving if '6 month' rule removed	1,334.4

Table 12. Amendment 1 and 2: summary

Summary (\$'000)	
Impact on MBS: Amendment 1	-56.1
Impact on MBS: Amendment 2	1,334.4
Total MBS Saving: Amendments 1 and 2	1,278.3

- Any other important areas of uncertainty (e.g. budget impact, translation of clinical evidence into the economic evaluation, linkage between an investigative intervention and a subsequent therapeutic intervention and outcomes)

Expected co-payments/out of pocket costs have not been addressed in the Submission. However, ESC noted that 73% of these services are bulk-billed and that the expected out of pocket cost is approximately \$141.26 per procedure.

ESC noted that the fee for item 11820 covered the procedure in addition to the capsule involved. ESC requested that the current capsule device cost be provided to MSAC.

14. Other significant factors

The proposed amendments for MBS item 11820 may have flow on effects for the patient population and associated interventions. For example, the clinical need for endoscopic placement in patients who are unable to swallow the capsule may increase with the inclusion of children aged 2 and above. Therefore, it may be appropriate for the proposed item descriptor to include "any associated endoscopic procedure". The applicant acknowledged that a greater percentage of patients in this age group may experience difficulties swallowing the capsule and thus require endoscopic placement. The applicant also noted that the included studies nonetheless did not highlight any safety concern associated with the procedure if the procedure is adequately carried out.

Item 11820 has the restriction "using a capsule endoscopy device approved by the Therapeutic Goods Administration". The applicant suggests additional wording (to the explanatory note) of "Capsule endoscopy in paediatric patients as young as two is only approved with certain devices. Benefits are not payable for procedures in paediatric patients undertaken with devices without evidence in paediatric patients, or not recommended by their manufacturers for use in those patients". The proposed wording would present complex issues for implementation. ESC did not think that an explanatory note was necessary, as the TGA restriction would cover the age appropriateness for usage of the device.

Medicare benefits are payable for clinically relevant professional services that are listed in the MBS. A clinically relevant service is one that is generally accepted in the medical profession as being necessary for the appropriate treatment of the patient. However, the submission refers to "unnecessary procedures currently given due to the six month rule". These "unnecessary procedures" would be contrary to the Health Insurance Act 1973 if included in the charge for a Medicare item.

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

MSAC noted that the applicant proposed two amendments to the current descriptor for MBS item 11820 to extend the use of capsule endoscopy (CE):

1. Change the age restriction to also allow children aged between 2 and 9 years to receive the service (i.e. change "10 years and over" to "2 years and over"); and
2. Removal of the time restriction for the service - that requires the CE procedure to be performed within six months of the upper gastrointestinal endoscopy and the colonoscopy which did not identify the cause of the gastrointestinal bleeding.

Amendment 1 – Change of age restriction

MSAC noted that Pillcam[®], which is manufactured by the applicant, is the only product currently available that has regulatory approval for use in the 2-9 year age group.

MSAC noted that, while the SBA report did not nominate a comparator for CE in patients aged 2-9 years, its 2003 assessment of CE for the evaluation of OGIB in adult patients had nominated small bowel series radiography (SBS) as the main comparator.

MSAC noted that, as with its previous assessment of CE, the main outcome to establish clinical effectiveness of CE was diagnostic yield in the absence of evidence to inform the diagnostic accuracy of CE in paediatric patients. The largest study involving paediatric OGIB patients, Fritscher-Ravens et al (2009), reported a diagnostic yield of 53% (16/30) for children aged 1.5 to 7 years with OGIB. Other studies of CE assessing paediatric patients with OGIB (including two studies by Antao et al (2007) and by Thomson et al (2007) which compared CE with other diagnostic methods including SBS) returned a diagnostic yield rate

of greater than 50-60%. MSAC agreed that the diagnostic yield results for CE in paediatric patients, including the 2-9 year age group, are superior to other diagnostic methods, including SBS, and similar to the adult population.

MSAC agreed that the safety data presented for CE in paediatric patients indicated similar rates of delayed passage and capsule retention results to adult patients. However, studies show that endoscopic placement for patients who cannot swallow the capsule is required in 7-25% (Fritscher-Ravens et al reported 76%) of paediatric cases which could require additional anaesthesia and endoscopy. MSAC accepted that, if required, endoscopic placement for paediatric patients is likely to occur concurrently with the diagnostic endoscopy procedure, therefore the impact of additional anaesthesia and endoscopy on the overall costs would be limited.

MSAC noted that no formal economic evaluation was presented for this amendment. MBS data estimated the extent of CE use for OGIB in paediatric patients aged 2-9 years old would be 26 patients per year with an estimated total cost of \$56,100. MSAC noted that this cost includes endoscopic placement costs for 20 patients (76%).

MSAC concluded that inclusion of an age restriction in the descriptor was not relevant as clinicians could judge paediatric patients suitable for CE treatment based on the size of the patient, which is a more relevant clinical factor to consider rather than be limited by the patient's age. MSAC also considered that removing any age restriction would cause negligible impact on the overall utilisation and costs of CE given the low volume of paediatric patients.

Amendment 2 – Removal of the time restriction for the service

MSAC noted the application used the current MBS requirement that CE be performed within 6 months of the non diagnostic upper GI endoscopy and colonoscopy as the comparator for this amendment.

MSAC considered that CE is likely to be safer or of similar safety compared with repeat endoscopy and colonoscopy as complication rates associated with repeat CE procedures are low.

The application relied primarily on data from Gilbert et al (2008), which reported a very low diagnostic yield (4%) for repeat colonoscopy and endoscopy procedures performed to qualify for CE, and that 50/198 (25%) of patients referred for CE required repeat procedures because their prior colonoscopy or endoscopy procedures were performed more than 6 months before the referral. MSAC noted that, although this was useful data, the study only involved one Australian centre and its timing coincided with the MBS listing of CE which may have had some influence on the population studied. Therefore it was unclear whether these data are applicable to current clinical practice.

MSAC considered that the more relevant evidence came from MBS data on the number and timing of previous colonoscopies (MBS item numbers 32072-32095) prior to the CE performed on 717 patients in July 2012 and subsequently billed as MBS item 11820. This data indicated that 77% of patients (551/717) had a prior colonoscopy in the period back to 1 July 2010, which suggests that 23% may not have been billed to the MBS. Of the 551 patients, 94% (517/551) had the prior colonoscopy performed within the previous six months in accordance with the item descriptor for CE, and 6% (34/551) had the colonoscopy performed earlier than six months before the CE. Of the 517 patients who had a colonoscopy in accordance with the item descriptor for CE, 17% (90/517) also had another colonoscopy performed earlier than six months before the CE, and 5% (25/517) also had another colonoscopy performed within the six-month period.

Therefore, MSAC agreed that removing the 6-month rule could result in savings to the MBS. The application's estimated cost savings of \$3 million per year to society based on AR-DRG cost weights (25% repeat rate) were considered uncertain. MSAC noted that ESC's estimated savings of slightly greater than \$1 million per year to the MBS, based on MBS rebates, were more realistic. MSAC further advised that reducing these from a 25% rate of repeated colonoscopies and endoscopies to a maximum of 17% reflecting the MBS data analysis would further reduce the estimated savings to the MBS.

MSAC noted that since CE was first listed on the MBS, the unit cost of the capsules has dropped and therefore the price of the capsule which is included in the fee should be reviewed. This item should also be removed from standard indexation of MBS items.

16. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of capsule endoscopy, MSAC supports public funding to amend MBS item 11820 to remove any age restriction and remove the requirement that the qualifying endoscopy and colonoscopy be performed in the preceding 6 months.

MSAC suggested the following amended item descriptor:

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, associated endoscopy procedure if required for placement, imaging, image reading and interpretation, and all attendances for providing the service on the day the capsule is administered) 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) has recurrent or persistent bleeding; and
 - (ii) 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 has not been provided to the same patient on more than 2 occasions in any 12 month period.

17. Applicant's comments on MSAC's Public Summary Document

Given Imaging are very pleased with MSAC's support for public funding to amend MBS item 11820 to remove any age restriction and remove the requirement that the qualifying endoscopy and colonoscopy be performed in the preceding 6 months. We believe the removal of age restriction will now enable young children who represent a small volume but clinically needy group of patients to benefit from capsule endoscopy. We also believe the removal of the preceding 6 month endoscopy timeline prior to Capsule Endoscopy will avoid the need for patients to undergo repeat endoscopy because of a timeline requirement, whilst simultaneously saving health care costs. For further information on capsule endoscopy, please visit www.givenimaging.com.

18. Context for decision

This advice was made under the MSAC Terms of Reference.

MSAC is to:

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

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

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

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

19. Linkages to other documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.