



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1150 – Insertion of colonic stents for the management of malignant large bowel obstructions

Sponsor/Applicant/s: **Colorectal Surgical Society of Australia and New Zealand**

Date of MSAC Meeting: **29 – 30 November 2012**

1. Purpose of application

In October 2010, the Department of Health and Ageing received an application from the Colorectal Surgical Society of Australia and New Zealand (CSSANZ) requesting Medicare Benefit Schedule (MBS) listing of colonic stents for the management of large bowel obstruction.

The intervention involves the placement of colonic stents for patients who suffer colonic obstruction, stricture or stenosis of a known or unknown diagnosis. Stents can be metallic or non-metallic (eg plastic). A self-expanding metallic stent (SEMS), the colonic stent most commonly used in Australia, is an expandable tube used for the relief of malignant colorectal obstruction as an alternative to open surgical techniques. All stents have a mesh design and are available in covered (full or partial) or uncovered compositions. The majority of stents used in Australia are of the uncovered type. A SEMS self-expands due to radial force following deployment with a delivery catheter (Small and Baron 2008; Watt et al 2007).

For the purpose of the current assessment, SEMS is indicated:

- as a bridge to surgery where an emergency resection of the obstructed colon could lead to serious complications, such as patients who are frail and/or suffering from significant comorbidities (allowing for management of the emergency and time to plan elective surgery); and
- for the palliative management of a colonic obstruction in patients who suffer from incurable metastatic disease and/or are medically unfit for surgery.

A SEMS can obviate the need for stoma or resection and may be effective for over a year, potentially providing palliation until death. Even though these patient populations are distinct in terms of their baseline morbidity, it is possible that some patients who initially receive a SEMS for palliative purposes improve over time as a result of chemotherapy and, accordingly, become eligible for resection. Conversely, some patients who initially received a SEMS as a bridge to surgery may unexpectedly deteriorate in condition and die, rendering the inserted SEMS as palliative. Based on this, four patient populations are indicated for the placement of SEMS.

The proposed medical services are not currently funded under the MBS. However, self-expanding stents are used widely to treat malignant colorectal obstruction in both the public and private sector in Australia. In the private sector, the SEMS procedure is currently paid for out-of-pocket by the patient.

Colorectal cancer is one of the most common cancers in the world. Intestinal obstruction is a common complication and medical emergency among patients with colorectal cancer. If colonic obstruction is not treated early, it can lead to ischaemia, perforation, peritonitis and even death (Winslet 2004).

Cancer is the second most common cause of intestinal obstruction in adults. Colorectal and ovarian cancers are the most common causes of malignant colorectal obstructions (Davis and Nouneh 2001; Watt et al 2007).

2. Background

This is the first time MSAC has considered the MBS listing for insertion of colonic stents for the management of malignant large bowel obstructions.

3. Prerequisites to implementation of any funding advice

A range of colonic stents is approved for use in Australia by the TGA. The SEMS which is the subject of the current submission is based on the Ultraflex™, Wallstent® and WallFlex® stents manufactured by Boston Scientific Pty Ltd (ARTG 119517). These stents are estimated to have 85 per cent of the Australian market share. Expert clinical opinion suggests that there is little difference between the stents available on the Australian market. While some stents may be used for obstruction caused by unspecified malignancy (ARTG 119517, 157191), other stents are specifically restricted for use with obstructions caused by colorectal cancer (ARTG 139317, 144564, 167223).

4. Proposal for public funding

Category 3 – Therapeutic procedures

MBS [item number]

Endoscopic insertion of stent or stents for large bowel obstruction, stricture or stenosis, where cause of the obstruction is due to:

- a pre-diagnosed colorectal cancer, or cancer of an organ adjacent to the bowel
- an unknown diagnosis.

(Anaes.)

Fee: \$650.00

Explanatory notes:

- The fee for the insertion of a colonic stent covers the colonoscopy to the point of obstruction, stricture or stenosis, passage of a guide wire under fluoroscopy and deployment of a colonic stent.
 - The procedure is undertaken by a colorectal surgeon or gastroenterologist appropriately trained in this procedure and certified by the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy.
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For the purposes of the current assessment, SEMS placement was not advocated for the treatment of benign obstructions caused by conditions such as diverticulitis and Crohn's disease. SEMS is contraindicated when the obstruction is suspected to be associated with bowel perforation, intestinal ischemia or intra-abdominal infections such as abscesses or peritonitis (Watt et al 2007). Stenting should be cautiously considered when the obstruction is

complete and the structure does not allow passage of a guide-wire, as forceful attempts could lead to bowel perforation.

The applicant suggested that the MBS item descriptor not limit repeat use of stents. One stent may be placed within another (re-stenting) if the initial stent has become obstructed by granulation tissue or tumour. Expert clinical advice suggested re-stenting is usually attempted only twice; after two or more unsuccessful attempts, an alternative approach would likely be taken. However, it may be that stents need to be inserted in separate locations in the same individual. If an obstruction or stenosis becomes reduced in size, a stent will simply fall out, as stents generally require an obstruction to stay in place. This may also occur in the case of stent migration, where re-intervention involving the removal of the migrated stent and the deployment of a new SEMS is required. Therefore, there is no need to have a specific MBS item number for stent removal.

In the case of a failed attempt at stent insertion, existing MBS item 30001 (abandoned surgery), where 50 per cent of the usual fee is paid, may be claimed for the procedure.

Procedures are to be undertaken by a colorectal surgeon or gastroenterologist appropriately trained in this procedure and certified by the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy.

5. Consumer Impact Statement

No access and equity issues were identified.

No input has been received from external craft or consumer groups addressing potential advantages (or disadvantages) to consumers if treatment with SEMS becomes available through the public healthcare system.

6. Proposed intervention's place in clinical management

In the management of malignant colorectal obstruction, SEMS may be used as an alternative modality in addition to the current management procedures.

For patients who are medically fit for surgery, SEMS can serve as:

- a bridge to surgery, which would avoid the need for emergency surgery and allow time to plan appropriate elective surgery;
- an alternative to surgery for palliative purposes in patients suffering from incurable metastatic disease.

For patients who are medically unfit for surgery, SEMS provides an additional palliation option; otherwise, best supportive care is the only treatment available.

7. Other options for MSAC consideration

Not applicable.

8. Comparator to the proposed intervention

SEMS insertion is proposed as an extension of the current management of malignant colorectal obstruction which is at present surgical management.

Two comparators are relevant to the assessment of SEMS, surgical management and best supportive care.

Surgery is indicated for patients who are medically fit and are able to tolerate general anaesthesia. It can be used as a curative and non-curative measure.

Best supportive care is the alternative intervention for patients who are in terminal stages of the underlying cancer and medically unfit for surgery, including those with comorbidities which would prevent the use of general anaesthesia.

Surgical management

The following table shows current MBS items related to resection and management of colorectal obstruction. Clinical expert opinion indicates that these may apply to both single-stage and multi-stage resection procedures.

MBS item no	Type of resection procedure
30375	Caecostomy, Enterostomy, Colostomy, Enterotomy, Colotomy, Cholecystostomy, Gastrostomy, Gastrotomy, Reduction of intussusception, Removal of Meckel's diverticulum, Suture of perforated peptic ulcer, Simple repair of ruptured viscus, Reduction of volvulus, Pyloroplasty (adult) or Drainage of pancreas Fee: \$501.50 Benefit: 75% = \$376.15
32009	TOTAL COLECTOMY AND ILEOSTOMY Fee: \$1,312.90 Benefit: 75% = \$984.70
32024	RECTUM, HIGH RESTORATIVE ANTERIOR RESECTION WITH INTRAPERITONEAL ANASTOMOSIS (of the rectum) greater than 10 centimetres from the anal verge excluding resection of sigmoid colon alone not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: \$1,312.90 Benefit: 75% = \$984.70
32025	RECTUM, LOW RESTORATIVE ANTERIOR RESECTION WITH EXTRAPERITONEAL ANASTOMOSIS (of the rectum) less than 10 centimetres from the anal verge, with or without covering stoma not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: \$1,756.15 Benefit: 75% = \$1,317.15
32026	RECTUM, ULTRA LOW RESTORATIVE RESECTION, with or without covering stoma, where the anastomosis is sited in the anorectal region and is 6 cm or less from the anal verge Fee: \$1,891.20 Benefit: 75% = \$1,418.40
32033	RESTORATION OF BOWEL following Hartmann's or similar operation, including dismantling of the stoma Fee: \$1,450.30 Benefit: 75% = \$1,087.75

MBS: Medicare Benefits Schedule. Note: All fees as of April 2011.

9. Comparative safety

All primary studies included in this assessment were reviewed for data related to adverse events occurring after treatment with SEMS. No studies that compared stents to best supportive care were retrieved. Therefore no assessment or comparison of the relative safety for these two treatments was made.

Six studies comparing SEMS placement to multi-stage surgical treatment, including one randomised controlled trial (RCT), reported on procedure-related mortalities occurring within their patient cohort.

With regard to comparative evidence, six RCTs comparing SEMS placement to multi-stage surgical treatment (including two RCTs) reported on procedure-related adverse events occurring within their patient cohorts.

Mortality

In the studies comparing SEMS placement to multi-stage surgical treatment, there was little apparent difference between treatments.

Adverse events

Adverse events arising as an outcome of SEMS placement and as a result of surgical resection vary considerably in nature and severity, complicating the direct comparison of the relative safety of SEMS and multi-stage resection. Potential adverse events following the SEMS procedure were commonly stent-related or tumour-related. Adverse events following surgery were generally stoma-related or infection-related.

One comparative study, comparing SEMS placement to multi-stage surgical treatment, identified a statistically significant difference with respect to a higher rate of patient readmission for complications after multi-stage surgical treatment.

In terms of severity, the most severe stent-related adverse event was likely to be bowel perforation. Due to the potential for serious pelvic infection and peritonitis, this outcome can be considered a life-threatening emergency, requiring immediate hospital admission as well as multi-stage surgical resection of the bowel.

The majority of information on safety outcomes after SEMS placement was obtained from level IV evidence which reported:

- Bowel perforation in >4% of SEMS patients (perforation may be higher when dilators are used);
- Adverse events related to tumour growth in 7 to 9% of patients. Tumour ingrowth/overgrowth increases the likelihood that treatment for re-obstruction will be required in the future;
- Re-obstruction and stent migration in 6 to 7% of patients (rates may be inflated by studies that used stents not specifically designed for the colon).
- Other minor adverse events in <5% of patients.

Based on the evidence, SEMS placement appears to be approximately equivalent to multi-stage surgical resection in terms of safety, albeit with the prospect of severe medical consequences arising from issues such as bowel perforation and tumour growth-related events.

10. Comparative effectiveness

No studies that compared stents to best supportive care were retrieved. Therefore no assessment of the relative effectiveness of stents versus best supportive care could be made.

Seven comparative studies, including two RCTs, were used to determine the relative effectiveness of SEMS compared to multi-stage surgical resection. However, these studies were subject to significant confounders and sources of bias in their methodology, such as inconsistency in reporting of clinical outcomes, heterogeneous patient populations, lack of statistical comparisons and small sample size.

The evidence showed few significant differences between SEMS placement and multi-stage surgery, with the potential exception of post-procedural hospital and ICU stay, where patients who received SEMS commonly experienced significantly better outcomes than those who underwent surgical resection. However, an adverse event, such as stent migration, may often require readmission.

A single study showed that patients who received SEMS as a bridge to surgery may be able to undergo planned surgery significantly sooner and require a shorter hospital stay after planned surgery than those who initially underwent surgery with temporary stoma.

Relative quality of life following treatment, the primary effectiveness outcome of interest to the present assessment, could not be determined based on the available evidence. The one

comparative study which assessed this outcome did not show any benefit for SEMs placement over surgical resection.

With respect to relative effectiveness, SEMs placement appeared to be non-inferior to multi-stage surgical resection. However, this conclusion was based on a small number of studies with considerable methodological deficiencies and should be accepted with caution.

11. Economic evaluation

A cost-effectiveness economic evaluation was undertaken.

For the purpose of conducting the economic evaluation, it was assumed that colonic stents are suitable for two groups of patients (both of whom are ineligible for single-stage bowel resection) with an obstruction caused by either pre-diagnosed cancer or unknown diagnosis:

- patients medically fit for multi-stage surgery; and
- patients medically unfit for multi-stage surgery.

These two patient populations were modelled separately as the comparator(s) differed based on the baseline risk for multi-stage surgery.

Patients fit for multi-stage surgery

Patients who were fit to undergo multi-stage surgery to resolve malignant colonic obstruction could receive such surgery (eg colostomy) for palliation or with an intention for re-anastomosis (eg second stage of two-stage surgery) at a later date.

Accordingly for the purpose of determining cost-effectiveness:

- The patients who received palliative or definitive SEMs were compared with patients who were not medically fit for re-anastomosis, which included colostomy for palliative purposes; and
- The patients who received SEMs as a bridge to surgery were compared with patients who were medically fit for a second stage of two-stage surgery. The comparative multi-stage surgeries included colostomy or Hartmann's procedure.

Patients unfit for multi-stage surgery

There was insufficient published evidence regarding patients considered unfit to receive any type of emergency surgery to resolve the obstruction. Therefore, the incremental cost of treating these patients with a SEMs compared to palliation alone (resembling best supportive care) was estimated.

Rationale for cost-effectiveness

There were only two RCTs that measured the effectiveness of SEMs relative to colostomy for colonic obstruction for palliative purpose. Both compared palliation with SEMs versus stoma creation for the management of inoperable malignant colonic obstruction. The results were:

- 14 out of 15 patients (93.3%) had successful SEMs placement without serious complications (Xinopoulos et al (2004));
- 100 per cent technical and clinical success in the 11 patients that had SEMs placed and for the 11 patients who underwent colostomy (Fiori et al (2004)).

Given the low number of patients in both RCTs and the lack of follow-up data regarding outcomes after SEMs insertion, a systematic review of clinical studies and case series by Khot et al (2002) was used to form the basis of the transitions through the model. Both models adopted a cost-utility analysis framework. Decision trees were developed to estimate the costs and benefits of SEMs versus the comparators over a one-year time period. The

decision trees incorporated all pre-procedural, surgical, hospital, ICU, post-procedural, palliative and procedure failure costs. Quality of life was also incorporated into the model based on the estimated survival. A cost per QALY for both models was estimated.

For patients requiring palliation

- SEMS for malignant bowel obstruction for palliation was cost saving (\$2,707) when compared to palliative colostomy.
- The SEMS group was estimated to gain an additional 0.01 QALYs when compared to the colostomy group.

For patients requiring a bridge to surgery

- SEMS for malignant bowel obstruction followed by multi-stage surgery was cost saving when compared to colostomy or Hartmann's procedure (\$440).
- The SEMS group was estimated to gain an additional 0.52 QALYs when compared to the colostomy group.

The financial analyses suggested that SEMS insertion was cost saving versus the comparators for both palliation and bridge to surgery. Estimated cost savings ranged from:

- \$363,981 to \$1,319,430 in the palliation group; and
- \$138,045 to \$500,412 in the bridge to surgery group.

Patients unfit for multi-stage surgery

For patients who were unfit for surgery, where SEMS would have replaced best supportive care, the incremental cost of providing the stent procedure rather than palliation alone was estimated to be \$9,659. The financial analyses suggested that if all patients received SEMS rather than best supportive care, the overall additional cost would be between \$1,294,105 and \$4,703,201.

The proposed MBS fee of \$650 was suggested by the CSSANZ.

In the base-case scenario analysis the co-payment was estimated to be 25% of the MBS fee. Under this scenario SEMS is cost saving. Higher co-payment fees were tested in the sensitivity analysis.

For patients requiring SEMS for palliation

If the total cost of the MBS schedule benefit and co-payment is over \$3058, SEMS is no longer cost-saving, relative to colostomy.

For patients requiring SEMS as a bridge to surgery

If the total cost of the MBS schedule benefit and co-payment is over \$1249, SEMS is no longer cost-saving, relative to multi-stage surgery.

There is unlikely to be an extended Medicare safety net impact because the majority of these services would be provided in an inpatient setting.

12. Financial/budgetary impacts

The estimated number of patients eligible for SEMS:

- for palliation ranged between 134 and 487;
- as a bridge to surgery ranged between 314 and 1,137.

It was estimated that most patients would only receive one SEMS procedure. A small proportion of patients (<10%) could require re-stenting because of stent failure, re-obstruction or migration of the initial stent.

The estimated volume of use for the intervention is between 493 and 1786 services per year. This figure is derived from the range of patient numbers provided, including 10% re-stenting.

Table 1 presents the total cost of a SEMS insertion compared to a colostomy, excluding the costs of palliation, stent failures or complications. The table includes pre-operative costs, surgical costs, hospitalisation costs and post-operative costs. A SEMS insertion has much higher surgical costs compared to a colostomy. However, overall the colostomy costs are higher due to the hospital costs incurred because of increased length of stay. Table 1 has been corrected to reflect an error in the total costs of SEMS.

Table 1 Estimated costs of SEMS versus colostomy (palliation)

	SEMS	Colostomy
Consumables	\$0	\$0
MBS fees	\$963	\$963
Patient/insurer costs	\$719	\$719
Total pre-operative	\$1,683	\$1,683
Consumables	\$3,535	\$5
MBS fees and theatre costs	\$1,840	\$2,360
Patient/insurer costs	\$593	\$781
Total surgical	\$5,968	\$3,146
Consumables	\$0	\$0
MBS fees	\$0	\$267
Patient/insurer costs	\$1,746	\$8,774
Total hospital stay	\$1,746	\$9,041
Consumables	\$0	\$779
MBS fees	\$185	\$105
Patient/insurer costs	\$147	\$7
Total post-operative	\$333	\$891
Total costs	\$9,730	\$14,760

MBS: Medicare Benefits Schedule; SEMS: self-expanding metallic stents

Note: Numbers may not sum to total due to rounding.

Once stent failures, complications and palliation costs are accounted for, the overall average cost of a SEMS versus a colostomy still favours stenting (Table 2).

Table 2 Estimated total costs of SEMS versus colostomy (palliation)

	SEMS	Colostomy
Consumables	\$3,902	\$690
MBS fees	\$9,659	\$11,285
Patient/insurer costs	\$4,248	\$8,541
Total post-operative	\$17,809	\$20,516

MBS: Medicare Benefits Schedule; SEMS: self-expanding metallic stents

Table 3 summarises the total average costs for SEMS versus multi-stage surgery. The costs include those patients who would receive a resection with primary anastomosis after a bridge to surgery and also any re-stenting or multi-stage surgeries due to a SEMS failure. The costs also include a proportion of patients who receive palliation. The overall cost savings are

driven by lower costs in the MBS fees and costs to the patient and private health insurance. If SEMS were to replace multi-stage surgery, there would be an increased cost in consumables, given the high costs of the SEMS itself.

Table 3 Estimated total costs of SEMS versus multi-stage surgery

	SEMS	Multi-stage surgery
Consumables	\$5,211	\$1,908
MBS items	\$9,848	\$11,852
Patient/insurer costs	\$14,670	\$16,409
Total post-operative	\$29,729	\$30,169

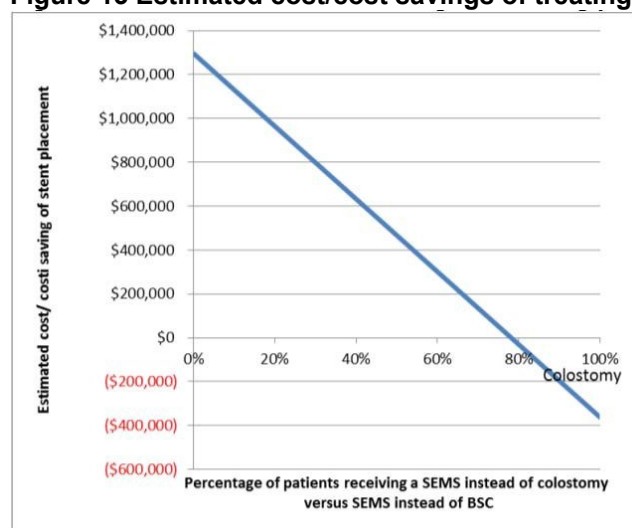
MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Patients unfit for multi-stage surgery

No evidence was identified regarding the number of patients who currently receive best supportive care for malignant bowel obstruction. It is likely that a proportion of those treated for palliative purposes would receive best supportive care. In the analysis the low and high estimates from the fit for surgery (palliation group) were used. If all patients received SEMS rather than best supportive care, the overall additional cost would be between \$1,294,105 and \$4,703,201.

The proportion of patients who receive best supportive care only is unknown. Figure 13 represents the trade-off between replacing colostomy with SEMS versus replacing best supportive care only with SEMS. The figure demonstrates that if the majority of patients received best supportive care only (<80%) there would be an increased cost to the health system, if SEMS was used instead of best supportive care. However, if >80 per cent of palliative patients were offered a (palliative) colostomy instead of best supportive care only, then there would be a cost saving if SEMS was used for these patients.

Figure 13 Estimated cost/cost savings of treating palliative patients



BSC: Best supportive care; SEMS: Self-expanding metallic stent.

The proportion of patients that would have SEMS placement in the private sector relative to the public sector is unknown. Using AR-DRGs G01B, G02B and G05B as references, the percentage of private patients was 64 per cent, 67 per cent and 36 per cent respectively.

Assuming this range of private patients, the total cost savings (SEMS versus colostomy or bridge to surgery) or total cost (SEMS versus best supportive care), would be lower than previously estimated.

The total cost savings for using a SEMS instead of colostomy:

- For palliation - the total cost savings range from:
 - \$131,033 to \$474,994 with 36 per cent private patients, or
 - \$243,867 to \$884,018 with 67 per cent private patients.

- For bridge to surgery - the total cost savings range from:
 - \$49,696 to \$180,148 with 36 per cent private patients; or
 - \$92,490 to \$335,276 with 67 per cent private patients.

The total cost increases if all patients receive SEMS instead of best supportive care and ranges from:

- \$465,877 to \$1,693,153 with 36 percentage private patients;
- \$867,050 to \$3,151,145 with 67 per cent private patients.

According to the CSSANZ, colonic stenting would replace emergency abdominal surgery (though the specific abdominal surgery MBS items were not identified) in 90 per cent of cases. After stenting, about 10 per cent of patients would require surgery for failed stent placement, while a further 10 per cent will return for definitive surgery after initial decompression. Assuming a technical success rate of 90 per cent, it is estimated that there would be 550 fewer emergency abdominal procedures performed for large bowel obstruction per year. Approximately 10 per cent of the stents currently deployed are used as a bridge to surgery; these patients will ultimately return for single-stage resection. Previously, the majority of these patients would have required two separate surgeries.

The proposed MBS fee provided by the applicant is \$650. MBS costs are based on 75% of the Schedule fee for inpatient procedures and 85% for outpatient consultation services. It is considered unlikely that there will be any effect on extended Medicare safety net accruals as the majority of MBS services are to be provided in an inpatient setting.

Based on the assessment report, MBS costs per patient (Table 63), excluding theatre costs and co-payments, have been estimated at \$1,901 per procedure (\$963 pre-operative; \$753 SEMS insertion; \$185 post-procedural).

The number of patients eligible to receive SEMS insertion:

- versus colostomy (palliation) ranges between 134 and 487 with a net financial cost/year to the MBS estimated at \$254,734 to \$925,787;
- as a bridge to surgery, ranges between 314 and 1,137 with a net financial cost/year to the MBS estimated at \$596,914 to \$2,161,437.

13. Key issues for MSAC from ESC

ESC noted that there was a level of uncertainty in the clinical analysis and that further information was requested from the Assessment Group, the responses are below:

Which was the specific clinical data on which the economic assumptions and analysis have been made compared to the clinical data presented?

The clinical data underpinning the economic models can be found in Table 57 (palliation) and Table 60 (bridge to surgery). All of the data sources used in the model are sourced in these tables. Also see page 95 for a more detailed description. The results from the two RCTs (Fiori and Xinopolous) were used to inform the palliation model and expert advice used to inform the bridge to surgery model, given the difference in length of stay is the main driver in the

models. The low number of patients in the RCTs, the transitional probabilities concerning the clinical and technical success were derived from a meta-analysis (Khot 2002) with 596 patients. The data from the meta-analysis coincided with the results from the RCTs, but were used to inform the models as they were estimated on a larger sample and provided a more concise breakdown of the patients to derive all the necessary transition probabilities.

What is the rationale for the large confidence interval?

A large confidence interval was used around the clinical and technical success rates, as these transition probabilities were derived from the literature, as detailed above. Overall, the point estimates were used in the model and the confidence interval was used only in the tornado diagram to show the robustness of the ICER when a range of values for clinical and technical success tested.

What was the method of the quality assurance used for the evidence base due to the lack of connection between the clinical effectiveness evidence and the cost effectiveness analysis?

As mentioned above, the data informing the palliation model was taken from the two RCTs (Fiori and Xinopoulos) identified in the clinical effectiveness section of the report and expert opinion used to inform the bridge to surgery in regards to length of hospital stay. All other data were sourced from the literature and tested in a sensitivity analysis to show the robustness of the results.

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

ESC noted that for those patients who are fit for surgery, SEMS compared to surgery is cost saving due to shorter procedure times, and shorter hospital and ICU stays. However, when compared to best supportive care, the quality of life had not been analysed and the focus had been on cost.

ESC observed that procedures using this technology were currently being performed and sought further information on current public and private usage split in Australia. ESC noted that colonic stent devices are listed on the Prostheses List and would remain there pending the outcome from the MSAC assessment.

Main issues around the evidence and conclusions for safety?

ESC noted that the evidence (age and illness) suggested that the primary cause of death of patients may not be the SEMS insertion or surgery and agreed that the evidence demonstrated, in terms of mortality and adverse events, that SEMS was approximately equivalent to multi-stage surgery.

Main issues around the evidence and conclusions for clinical effectiveness?

ESC noted that the evidence demonstrated that the QALY outcomes between SEMS and multi-stage surgery are comparable but the hospital and ICU stay outcomes favour SEMS. ESC concluded that the evidence demonstrated no substantive comparative effectiveness benefit for SEMS recipients over surgery, as the economic model estimated only a small gain (0.01 QALYs) in favour of SEMS.

ESC noted that the current descriptor is wider than just SEMS to allow for any stent not just SEMS. ESC discussed if it should remain broad or if as the evidence is only for SEMS it should be restricted to that type of stent.

ESC discussed the use of SEMS versus best supportive care and agreed that a model which addressed the effects of palliation would have been valuable.

Other important clinical issues and areas of clinical uncertainty?

ESC agreed that based on the evidence:

- there was no benefit to patients receiving SEMS placement over multi-stage surgical resection with regards to clinical outcomes or quality of life; and
- in patients receiving SEMS as a bridge to surgery, it may be more likely they will avoid multi-stage resection. However, the evidence for this is limited to one study;

ESC discussed the lack of evidence in relation to SEMS for patients unfit for surgery and agreed that it may be appropriate to apply the ‘rule of rescue’.

ESC noted that:

- it was likely that stenting would improve quality of life for patients for whom the only other treatment option was best supportive care;
- QALYs were not calculated for this group. ESC is of the view that the QALYs for this group are likely to be significant; and
- it would be difficult to approve SEMS for the other patient groups but not approve its use in this group of patients.

Main economic issues and areas of uncertainty?

ESC agreed that:

- in patients fit for surgery, the case for SEMS can be made on the basis of a cost-minimisation analysis, as there would be a cost-saving, gained largely from reduced hospital and ICU stay;
- in patients unfit for surgery, SEMS adds to cost compared with best supportive care. However, ESC noted that the QALYs had not been calculated for this group and that the ‘rule of rescue’ was likely to apply; and
- the economic model was highly sensitive to technical success but noted that it appears that the technical success is likely to be higher than the lower range built into the sensitivity model.

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?)

ESC noted that the proposed item descriptor:

- allows the treatment of patients presenting in an emergency situation with an unknown diagnosis;
- does not restrict the procedure to the use of SEMS, but allows the use of any stent;
- that SEMS account for 85% of the market share in Australia but that the evidence for this application is limited to SEMS devices.

ESC noted that the current comparator is colorectal surgery, an open surgical procedure, and noted that it may be more appropriate to base the fee for SEMS insertion on similar stenting procedures such as the insertion of oesophageal stents.

ESC indicated a greater breakdown of the inputs to this fee would assist their understanding of the rationale for this fee being higher compared to surgery i.e. colostomy for both time and technical skills required.

14. Other significant factors

Table 61: ‘colostomy’ should be replaced with ‘multi-stage surgery’.

Table 67: the total costs for SEMS are \$9,730 not \$9,790 as stated in report.

Page 2 and 3, In the description of the MBS item, a line of material has been redacted, due to departmental confidentiality requirements, this redaction would appear in the published final report.

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

MSAC noted that the clinical management for malignant colorectal obstruction includes patients medically fit for surgery and patients who are medically unfit for surgery. For the second group of patients, self-expanding metallic stent (SEMS) insertion provides an additional palliation option with MSAC acknowledging that colostomy may be an alternative intervention if a patient is medically unfit for major surgery.

MSAC noted that there are no comparative data with best supportive care for either safety or clinical effectiveness. SEMS insertion compared with surgery was also limited to two randomised controlled trials. The major stent related risk relates to bowel perforation. MSAC concluded that SEMS insertion is equivalent to multi-stage surgery in comparative safety.

MSAC noted that clinical effectiveness outcomes for surgery included a shorter hospital stay with SEMS, although the clinical relief was higher in the emergency surgery group and the QALY was not determined. However, MSAC acknowledged that while there is limited evidence, the procedure is already being performed in Australia and that local evidence indicates that the proposal would be cost saving.

MSAC noted that the estimated number of services per year provided by the Colorectal Surgical Society of Australia and New Zealand (CSSANZ) was within the range provided in the economic evaluation. MSAC also noted that it is difficult to account for all clinical presentations and acknowledged that the CSSANZ has indicated that it is only in exceptional circumstances where patients are near death on presentation that palliation without relief of the obstruction would be an acceptable standard of clinical care.

MSAC noted that an important benefit of SEMS insertion as a bridge to surgery is that a patient can progress to timely and well planned elective surgery and/or systemic cancer treatment. MSAC also noted that there is also a steep learning curve for a surgeon to be able to perform SEMS insertion.

MSAC agreed that, if public funding is approved, the MBS item descriptor does not need to include a more specific description of the stent such as 'metallic' or 'mesh' stent. MSAC also agreed that a similar comparator in terms of time and complexity for SEMS insertion is the insertion of a biliary stent.

Noting the shortage of evidence, MSAC agreed that there is an area of need for colonic stents and there is a patient population identified as benefiting from the procedure. MSAC agreed that the MBS fee based on the time and complexity should be the same as for insertion of a biliary stent, which is currently \$555.35.

16. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of the insertion of colonic stents, MSAC supports public funding for endoscopic stenting for large bowel obstruction, stricture or stenosis due to a pre-diagnosed colorectal cancer, or cancer of an organ adjacent to the bowel or an unknown diagnosis.

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

Nil

18. Context for decision

This advice was made in accordance with 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.