Australian Government

Department of Health

MSAC Application 1555.1:

Endoscopic sleeve gastroplasty for the treatment of patients with Class I and II obesity with/without comorbidities who have failed first-line (lifestyle modification) and second-line (VLED/pharmacotherapy) treatments.

Ratified

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for endoscopic sleeve gastroplasty in patients with Class I or II obesity (body mass index 30–40 kg/m^2) who have failed first- and second-line obesity treatments: PICO Set 1

Component	Description
Population	Patients 18 years of age or over who have Class I or Class II obesity (body mass index [BMI] of 30–40 kg/m2) with/without comorbidities who have failed first- and second-line weight-loss therapies.
Intervention	Endoscopic sleeve gastroplasty (ESG)
Comparator/s	Moderate intensity lifestyle interventions including very-low energy diets (VLED), behavioural intervention, and/or pharmacotherapy. For patients with a BMI of 35-40 kg/m^2 who have comorbidities, bariatric surgery is a comparator.
Outcomes	Relevant safety outcomes include: • mortality • perioperative adverse events • procedure-related complications • hospital stays longer than anticipated • long-term adverse events – for example, sutures reopening • side effects of comparator medications • revision procedures or conversion to gastric sleeve or gastric bypass caused by adverse events • any additional safety outcomes reported in the literature, which should also be reported in the assessment phase. Primary effectiveness outcomes are: • weight loss (this can be reported as absolute weight loss [kg], change in BMI, percentage total weight loss, percentage excess weight loss, percentage BMI loss or percentage excess BMI loss) • maintenance of target weight • revision required – for example, due to failure to maintain target weight or loss of sleeve integrity • conversion to bariatric surgery (sleeve gastrectomy or gastric bypass) • additional treatment required – for example, pharmacotherapy. Secondary effectiveness outcomes are: • changes in comorbidity markers • quality of life and wellbeing. Healthcare system outcomes • costs associated with the intervention • costs associated with the comparator • costs associated with adverse events for the intervention and comparator.
Assessment questions	What is the safety, effectiveness, and cost-effectiveness of ESG versus moderate intensity lifestyle interventions and/or pharmacotherapy or bariatric surgery in the treatment of Class I and II obesity?

Source: Constructed during the development of the PICO based on the application form and PASC advice (see below)

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of endoscopic sleeve gastroplasty (ESG) for the treatment of patients with Class I and II obesity who have failed first-line (lifestyle modification) and/or second-line (very-low energy diet [VLED]) pharmacotherapy treatments and who are not suitable for bariatric surgery[1] was received from Apollo Endosurgery Australia Pty Ltd by the Department of Health.

The applicants claim that use of ESG in this population results in superior effectiveness outcomes and inferior safety outcomes compared to the comparator weight-loss technologies of lifestyle modification, VLEDs and/or pharmacotherapy (Applicant 2021a).

Background

An application for MBS listing of ESG was previously considered by MSAC in 2019. MSAC did not support public funding at that time because of uncertain clinical safety and effectiveness evidence. However, MSAC did note that a considerable body of evidence would soon be published (MSAC 2019a).

The applicant has advised that a pivotal randomised controlled trial (RCT), the MERIT trial, is now complete and results will be available for the assessment phase; therefore, the applicant has resubmitted an application for the assessment of ESG (Applicant 2021a, Applicant 2021c).

The current application differs from the previous one in two key areas:

- The population definition (and MBS item) no longer requires patients to have a comorbidity/ies (expanded to now included those without comorbidities i.e. with or without comorbidities)
- The population is now restricted to patients who are ineligible for bariatric surgery or who would not consider bariatric procedures if eligible. A consequence of this change is that the application no longer considers bariatric surgery a relevant comparator.

In addition, a revision item for ESG has been proposed in the PICO (Applicant 2021c). Gastrointestinal surgeons have noted that the procedure is not reversible, but may fail, and therefore needs a revision item (MSAC 2019a).

PICO criteria

Population

The applicant proposed the following population for ESG:

Patients 18 years of age or over who have Class I or Class II obesity (body mass index [BMI] of 30–40 kg/m^2) and who have failed first- and second-line[2,3] weight-loss therapies and who are not suitable[4] for bariatric surgery.

[1] Patients who are 'not suitable for bariatric surgery' are those who are not eligible or are contraindicated for bariatric surgical procedures. The definition also includes patients who are eligible for bariatric surgery but who would not consider or have refused to undergo the procedure(s).
[2] Lifestyle modifications
[3] VLED alone, VLED and pharmacotherapy, or pharmacotherapy alone
[4] Patients who are 'not suitable for bariatric surgery' are those who are not eligible or are contraindicated for bariatric surgical procedures. The definition also includes patients who are eligible for bariatric surgery but who would not consider or have refused to undergo the procedure(s).

In the previous assessment of ESG, the applicant proposed treatment failure be defined as: an inability to achieve a minimum 5 per cent weight loss within 3 months.' The definition was derived from the National Health and Medical Research Council (NHMRC) guidelines on obesity, which suggest a weight loss of 5% reduces health risks by lowering blood pressure and reducing the risk of, or delaying the progression of, type 2 diabetes (MSAC 2019b).

PASC discussed the proposed population in the context of the available evidence, the opinion of the expert who attended the meeting and the current Australian guidelines on procedural interventions for obesity (NHMRC 2013).

PASC noted that the current guidance for reimbursement of bariatric procedures in Australia is for clinically severe obesity generally described as a BMI > 40 kg/m^2 or a BMI of 35-40 kg/m^2 for patients with comorbidities taking into account the individual situation and clinical judgement of the surgeon (see explanatory note TN.8.29) (DoH 2013, NHMRC 2013).

PASC noted that patients with Class I obesity (BMI 30-35 kg/m^2) without comorbidities (who are not typically recommended for bariatric procedures in the clinical guidelines) are a relatively low-risk group and it is unclear whether the benefits of ESG (another invasive intervention) in this group would outweigh the risks of the procedure. The applicant advised that the population in the application was chosen to align with the MERIT trial and that obesity was reported to be a progressive disease and an individual who is metabolically well can become unwell and that is the rationale for the inclusion of the 30-35 kg/m^2 BMI reference group.

PASC noted the applicant's proposal to expand the proposed population to include the BMI>40kg/m^2 subgroup (consistent with the population defined for bariatric procedures in Australian guidelines); however, it was discussed that these patients were not included in the MERIT trial of ESG. After consideration, PASC advised that this population (excluded in the application form) is out of scope for this assessment. (see "Clinical management algorithms").

PASC noted there is a subgroup in the MERIT trial population which overlaps with the recommendations in the Australian clinical guidelines for bariatric surgery and established population on the MBS for bariatric procedures (BMI 35-40 kg/m^2 with comorbidities), but the proposed population in the PICO is defined differently, excluding bariatric surgery as a comparator due to contraindications and by virtue of patient choice. Although, PASC considered the contraindications appear the same for ESG vs. bariatric surgery and thus considered it was unclear whether there is a patient population with a medical condition that would render patients ineligible for bariatric surgery but eligible for ESG. PASC advised that this subpopulation should align with the Australian guidelines for bariatric procedures and proposed bariatric surgery as an additional comparator (see 'Comparator' below). This advice was accepted by the expert gastroenterologist present at the meeting.

PASC advised that individuals need to have failed both VLED and pharmacotherapy to be eligible.

PASC advised that a 12-month time frame to define treatment-failure is more appropriate than 3 months.

Overall, PASC advised that the applicant should consider revising the proposed population in line with the above advice before the application was progressed. In particular, the population should include those eligible for bariatric surgery as it is currently defined in Australia. Should the applicant wish to pursue public funding of ESG for this subpopulation 'who are not suitable for bariatric surgery', then where the cost-effectiveness of the comparator has not been established in the proposed population, the assessment

would need to demonstrate the cost effectiveness of both the intervention and comparator in the proposed population (see "Comparator" below).

Obesity

Obesity is broadly defined as an excess of body fat mass. The most widely accepted definition uses BMI, which is the ratio of body weight (in kg) to body height squared (in m^2). BMI is used as a surrogate measure of body fatness (it measures excess weight rather than excess fat) (Schwartz et al. 2017). The degree of obesity can be categorised into Class I (BMI of 30–35 kg/m^2), Class II (BMI of 35–40 kg/m^2), and Class III (BMI ≥40 kg/m^2) (Schwartz et al. 2017). Obesity is a complex disease, with the basic principle of pathogenesis being that the individual is consuming energy in amounts that exceed ongoing energy expenditure (Schwartz et al. 2017). There is, however, a growing body of evidence showing that obesity pathogenesis involves processes more complex than the passive consumption and accumulation of excess energy (Schwartz et al. 2017).

The BMI scale currently satisfies the need to estimate body fat mass at a population level and is used as a gauge of susceptibility to obesity-related complications (Schwartz et al. 2017). However, BMI is not the most reliable tool for assessing body fatness. Variations in skeletal muscle mass and lean body mass can create significant variations in total body mass. There are also significant racial, ethnic, and age differences in how BMI is associated with adverse medical consequences (Schwartz et al. 2017, Bray et al. 2018). BMI thresholds developed for Caucasians may not be suitable for Asian or Aboriginal and Torres Strait Islander individuals – other measures of adiposity, including waist-to-hip ratio, waist-to-height ratio, and waist circumference may be more suitable (Lear et al. 2007, Snehalatha et al. 2003, Daniels 2009, Bray et al. 2018).

Aboriginal individuals tend to have a relatively high limb-to-trunk ratio, so a lower BMI threshold to flag health complications may be useful (NHMRC 2013). Torres Strait Islander peoples tend to have a higher proportion of lean body mass, so they may benefit from a higher BMI threshold for health considerations (NHMRC 2013).

Prevalence in Australia

Within Australia, the prevalence of obesity in 2017–18 was reported to be 31.3%, which was an increase from 2014–15 where the rate was 27.9% (ABS 2018). Table 2 shows the detailed breakdown of prevalence by BMI category. Of note, in 2018 19.7% and 7.7% of Australians were in obesity classes I and II respectively – around 5.1 million people. Furthermore, the Indigenous and Torres Strait Islander Health Survey reported the prevalence of obesity (any class) among the Indigenous population to be 47.2% during the 2018–19 year, which is significantly higher than the nonindigenous population (ABS 2019).

Table 2 Prevalence of obesity in Australia 2017–18

Measured body mass index	Number of Australians	Percentage of Australians
Underweight (<18.50)	244,900	1.3
Normal Range (18.50–24.99)	5,920,100	31.7
Overweight (25.00–29.99)	6,643,900	35.6
Obesity Class I (30.00–34.99)	3,670,300	19.7
Obesity Class II (35.00–39.99)	1,431,700	7.7
Obesity Class III (>40.00)	742,200	4.0
Total obese (>30.00)	*5,844,200*	*31.4*

Source: ABS 2018

Burden of disease

Within Australia, excess weight obesity are the largest contributors to nonfatal burden of disease (AIHW 2017a). Compared with adults in a health BMI range, patients with obesity are at a greater risk of morbidity than for many conditions, including dyslipidaemia, insulin resistance, type 2 diabetes mellitus, hypertension, coronary heart disease, stroke, gallbladder disease, respiratory problems, sleep apnoea, osteoarthritis, dementia, gout, rheumatoid arthritis, major depressive disorder, and some cancers (Apovian 2016, Andolfi and Fisichella 2018, AIHW 2017a).

The severity of morbidity associated with some chronic conditions rises as BMI increases (National Institute of Health 1998). Table 3 presents the prevalence of chronic conditions by weight status in Australia.

Table 3 Prevalence of chronic conditions by weight status, person aged 18 and over, 2014 – 2015. (AIHW 2017b)

Chronic condition	Obese (%)	BMI 20-25 kg/m^2 (%)
Arthritis	27.7	13.4
Asthma	13.7	8.9
Back problems	24.1	17.3
Cancer	2.8	1.5
COPD	4.7	2.2
Diabetes mellitus	12.8	2.5
Heart, stroke and vascular disease	10.0	4.3
Hypertension	24.5	7.1
Kidney disease	1.9	0.7
Mental and behavioural problems	22.6	19.1
Osteoporosis	4.8	4.4

COPD = chronic obstructive pulmonary disease.
Source: AIHW 2017b

Economic impact

The cost of obesity to the Australian economy was estimated to be $8.6 billion in 2011–12 (in 2014–15 dollars). This figure was broken down into direct costs of $3.8 billion (including general practice, allied health and specialist services, hospital care, pharmaceuticals, and weight-loss interventions) and indirect costs of $4.8 billion (including absenteeism, presenteeism, Government subsidies). The report did not consider the cost of reduced wellbeing and quality of life, and loss of income (PwC 2015).

Current management

General practitioners are often the initial healthcare providers to identify that an individual is overweight or obese (Grima and Dixon 2013). The optimal management of obesity requires a team care approach involving primary and allied health physicians specifically trained and experienced in obesity management. These individuals may include dietitians, practice nurses, exercise physiologists and psychologists (NHMRC 2013). Lifestyle interventions are the first-line treatment (Grima and Dixon 2013). Lifestyle approaches are based on physical activity, nutrition and behavioural change, and focus on creating an energy deficit, through reducing energy intake, increasing energy expenditure, or both (NHMRC 2013). If first-line treatments are unsuccessful, second-line weight managements must be considered, especially when a person is obese and risk factors or comorbidities are present (NHMRC 2013).

Second-line weight management techniques include VLEDs and pharmacological interventions. Second-line treatments may be considered when the individual has a BMI ≥30 kg/m^2, or a BMI ≥27kg/m^2 with risk

factors or comorbidities, or if the individual has been unsuccessful in reducing weight or preventing weight gain using first-line lifestyle approaches (NHMRC 2013). Second-line treatment options are generally used sequentially; for example, starting with a VLED, then using medication to further assist weight loss and to help counter hormonal changes and the increased hunger that follows weight loss.

It is known that long-term weight management is challenging and there are many physiological responses that increase hunger and encourage weight regain. The individual must also resist a return to the lifestyle habits that originally caused weight gain (NHMRC 2013). Weight regain is especially common after weight loss that was been achieved by lifestyle interventions (Cooper et al. 2010, Dansinger et al. 2007, Martin et al. 2008). Bariatric surgery is the most effective treatment for weight loss and reduction of comorbidities for both short- and long-term outcomes (Kushner and Sorensen 2015, Lindekilde et al. 2015).

If first- and second-line treatments have failed, the NHMRC clinical practice recommends bariatric surgery for individuals with a BMI ≥40 kg/m^2 or adults with a BMI ≥35 kg/m^2 and with comorbidities that would improve with weight loss (NHMRC 2013). Bariatric surgery under the MBS is offered to individuals with 'clinically severe obesity', which refers to a patient with 'a BMI of 40 kg/m^2 or more, or a patient with a BMI of 35 kg/m^2 or more with major medical comorbidities (such as diabetes, cardiovascular disease, cancer)' (DoH 2013). However, the decision to undertake surgery remains a matter for the clinical judgement of the surgeon (DoH 2013, NHMRC 2013).

Despite the well-documented effectiveness of bariatric surgery, only a small proportion of eligible patients undergo these procedures (Expert Gastroenterologist #1 2021, Expert Gastroenterologist #2 2021). The reasons for this include concerns about the risks, recovery, side effects and stigma associated with these procedures (Wharton et al. 2016, Ju et al. 2019). Advice from two gastroenterologists is that reluctance to undergo bariatric surgery is a significant barrier to treating obesity (Expert Gastroenterologist #1 2021, Expert Gastroenterologist #2 2021).

Rationale

When determining the appropriate BMI criteria for ESG, the populations with the greatest clinical need and populations for which it has been trialled must be considered.

Clinical need

For this application, the population can be broken down into three subgroups:

- adults with a BMI of 30–35 kg/m^2 (with and without comorbidities)
- adults with a BMI of 35–40 kg/m^2 without comorbidities
- adults with a BMI of 35–40 kg/m^2 with comorbidities.

Individuals with Class I obesity (BMI 30–35 kg/m^2) with or without comorbidities are generally not recommended for bariatric surgery and do not qualify for MBS reimbursement. There is evidence that Class I obesity is not associated with significantly increased mortality, and the risks of the procedure may outweigh the benefits (Flegal et al. 2013). Obesity is associated with significantly higher all-cause mortality, though the relationship between obesity and higher all-cause mortality is stronger for Class II and III obesity. Therefore, if first- and second-line therapies do not work, there may be an unmet need for intervention as a preventative measure for individuals with progressive obesity (e.g. increasing weight) (Bray et al. 2017). That is, failing to intervene successfully when a patient is in obesity Class I may lead to progression to Class II and III obesity which is associated with significantly increased morality.

Expert advice was sought on whether there was a clinical need for ESG in the groups who are currently ineligible for bariatric procedures. Advice from a general surgeon was that offering bariatric interventions

to patients with a BMI of 30–35 kg/m^2 was potentially controversial, and that in their opinion ESG should only be offered to patients who are eligible for other bariatric procedures. The rationale for this was that ESG is an invasive procedure and patients with Class I obesity are at a low risk of developing obesity-related comorbidities (Expert General Surgeon 2021).

Conversely, advice from two gastroenterologists was that the proposed population (BMI 30–40 kg/m^2) was appropriate due to the risk of developing obesity-related comorbidities and the burden of disease associated with obesity of any class (Expert Gastroenterologist #1 2021, Expert Gastroenterologist #2 2021).

Individuals with a BMI of 35–40 kg/m^2 and who are without comorbidities are generally not eligible for MBS reimbursement of bariatric procedures. However, as noted, obesity is associated with significantly higher all-cause mortality, so there may be benefits for individuals in this category if first- and second-line treatments have been tried and have failed (Flegal et al. 2013).

Even though individuals with a BMI of 35–40 kg/m^2 who have comorbidities are eligible for reimbursement of bariatric procedures, there may be an unmet need for patients who are at a heightened risk of mortality, or who are also apprehensive of bariatric surgery. ESG may be a therapeutic option for this subpopulation.

All three experts consulted agreed that the use of invasive procedures to treat Class II obesity was justified (Expert Gastroenterologist #1 2021, Expert Gastroenterologist #2 2021, Expert General Surgeon 2021).

It is proposed that the service be restricted to patients aged 18 and over. This is consistent with the previous application for ESG. The rationale for this age limit presented for the previous assessment was that clinical feedback suggested that the procedure is not as durable and is technically complex in younger patients (MSAC 2019b).

Trial populations

An important consideration when determining eligibility for ESG is whether there is an evidence base to support the intervention for the intended population. Numerous studies have been published regarding this intervention and the summary of the observed population is included below.

- Randomised controlled trials: The MERIT trial is a multicentre RCT comparing ESG to lifestyle interventions in patients with a BMI between 30 and 40 kg/m^2 who had failed nonsurgical weight-loss methods. Patients both with (approximately 75%) and without (approximately 25%) comorbidities were enrolled in the trial (U.S National Library of Medicine 2021). The comorbid conditions included a quota of patients with hypertension who were on one or more antihypertensive medicines, and patients with type 2 diabetes mellitus with HbA1c ≤9% who were taking oral agents only. While not yet published, the applicant has advised that results from this trial will be available for the assessment phase (Applicant 2021c).
- Comparative studies: One recent retrospective study recruited individuals over the age of 18 with a BMI of ≥27 kg/m^2 who were unable to achieve weight loss through first-line treatments. These patients either had ESG or a combination of ESG and liraglutide (ESG-L) (Badurdeen et al. 2021).
- Case series: Hajifathalian et al. (2021) recruited individuals with a BMI 30–40 kg/m^2 with nonalcoholic fatty liver disease (NAFLD), who failed first- or second-line weight-loss measures, including pharmacotherapy (Hajifathalian et al. 2021). This study also included patients with a BMI of ≥40 kg/m^2 with NAFLD, if they refused to undergo bariatric surgery or were deemed unsuitable candidates for bariatric surgery. Sharaiha et al. (2021) reported on populations with BMI >30kg/m^2

and with BMI 27–30 kg/m^2 with comorbidities, who also failed first- and second-line treatments (Sharaiha et al. 2021). Two further studies included individuals with a BMI >30 kg/m^2 and individuals with a BMI range of 30–39.99 kg/m^2 respectively (Lopez-Nava et al. 2021, Neto et al. 2020). One case study recruited individuals with a BMI >40 kg/m^2 and individuals with a BMI >35 kg/m^2 with obesity-related comorbidities (Fiorillo et al. 2020). A further case study recruited all individuals who were overweight or obese for whom failed diet and lifestyle modifications and had no contraindications to ESG (Barrichello et al. 2019).

The proposed population of this application aligns with that of the MERIT RCT; however, ESG has also been studied in a wider patient population, albeit with nonrandomised comparative or single-arm study designs.

Intervention

The proposed intervention is endoscopic sleeve gastroplasty.

Registration

The Overstitch Endoscopic Suturing System and the Overstitch Endoscopic Suturing System 2.0 Suture (Emego Asia Pacific Pty Ltd) are listed on the Protheses List (billing codes: ER279 and ER280) and the Australian Register of Therapeutic Goods (item numbers 237773, 237774, 236906, 245894) (Applicant 2021a). The intended purpose of the Overstitch System is for endoscopic placement of suture(s) (Applicant 2021a).

The Overstitch is mounted onto a double-channel endoscope; for example, the GIF-2T160 (Olympus Medical System Corp, Tokyo, Japan) (Applicant 2021a).

General information

ESG is a transoral incisionless, minimally invasive surgery that reduces the size of the stomach by remodelling of the greater curvature of the stomach (Badurdeen et al. 2021). The procedure was first described in 2013 and its principle is that ESG reduces gastric capacity by creating a restrictive sleeve via an endoluminal suturing system, using full-thickness sutures along the corpus of the stomach (Li et al. 2020). The procedure limits food intake and delays gastric emptying and is meant to be combined with lifestyle modifications (physical activity and diet modifications). Animal and human studies have demonstrated post-eating increases in the gut neurohormones, plasma glucagon-like peptide, and peptide YY (Abu Dayyeh et al. 2013). The procedure can also result in further physiological responses, such as fewer physical fluctuations and more attenuation in plasma ghrelin, which can reduce hunger levels (Peterli et al. 2012). This results in physiological changes to regulation of caloric intake, appetite and satiation, glucose metabolism, and energy expenditure (Abu Dayyeh et al. 2013). The applicants report that the ESG procedure will shorten the length of a stomach by up to 50% and reduce its volume by 75%, but they have also stated that 'this reduction in stomach size will restrict the quantity of food a person can eat as well as initiate physiologic alterations that assist in weight loss and maintenance of weight loss' (Applicant 2021a).

The applicant has stated that general practitioners and other medical specialists may refer for the service and that the appropriate candidates for ESG are determined by a bariatric surgeon or a gastroenterologist. Qualified gastroenterologists, and general, bariatric, or upper gastrointestinal surgeons will usually conduct the procedure. The applicant states "the applicant runs wet lab training and certification prior to doctors being able to use the Overstitch in their practices. The attendee must complete the training which is both 'hands on' and didactic. Additionally, proceduralists should be proctored during their initial cases or else attend cases conducted by the preceptor"(Applicant 2021a).

PASC discussed the training requirements to perform the procedure and noted that the applicant runs wet lab training and certification; however, there are no defined standards or training accreditation.

PASC discussed if individuals should only be trained to perform ESG if they have had experience with advanced endoscopies and endoscopy techniques. It was queried if the procedure should be restricted to trained physicians that perform other endobariatric procedures and trained surgeons as these practitioners can maintain and manage healthcare for bariatric patients. Expert advice was that a practitioner should have some experience, but doesn't necessarily require credentialling in, ERCP or ERSS (for example).

PASC advised that the item descriptor should limit the procedure to "specialists".

PASC noted there needs to be further clarification of training and certification requirements.

The applicant has stated that ESG is typically performed in a day hospital setting under general anaesthesia. Advice from a general surgeon is that patients are likely to be offered an overnight stay following ESG (Expert General Surgeon 2021). The intervention can be performed in a day surgery centre or a full-service hospital that has facilities specific to the needs of overweight and obese patients (Applicant 2021a).

While ESG is not currently funded or reimbursed in private or public settings in Australia, the service is being advertised and presumably performed without reimbursement (The BMI Clinic 2021, Keyhole Obesity Surgery Centre 2021, Healthy Weight Australia 2021).

PASC noted concerns regarding the availability of the service and associated after care requirements but also noted that these concerns were for all bariatric services (not unique to ESG). The advice from clinical experts and the applicant is that ESG may be more accessible to rural and remote patients as the procedure requires only a short stay in an urban centre and aftercare (eg dietitian appointments) can be delivered via telehealth.

Preoperative

Upon referral to a bariatric surgeon or gastroenterologist, patients will be assessed for their suitability for ESG. Patients may be excluded from the procedure if a contraindication is confirmed during the pre-procedure assessment. The applicant has advised that contraindications to ESG include 'prior gastric surgery, gastric ulceration, acute gastritis, anticoagulation, pregnancy, or psychiatric/psychological disorders that pose a risk of patients being able to make the recommended life-style adjustments following surgery' (Applicant 2021a).

The applicant has stated that once an individual has been deemed an appropriate candidate for ESG, the patient is prescribed a protein pump inhibitor for one week prior to the procedure. On the day preceding the procedure, a liquid diet is prescribed, and patients are advised to fast from midnight (Lopez-Nava et al. 2015). In the previous PICO Confirmation for ESG, the applicant also stated that 'Patients are prescribed Emend (aprepitant) to be taken on the day of the procedure as well as the day after' (MSAC 2019b).

Perioperative

The procedure is conducted under general anaesthesia with the patient in the left lateral decubitus position with endotracheal intubation. Pre-procedure antibiotics are given to the patient via IV (cefataxima 2g). The surgeon uses an oesophageal overtube to facilitate both atraumatic passage of the endoscope with the suturing device and repeated intubation with a second endoscope when needed. Carbon dioxide gas insufflation can be used to distend the gastric lumen. An argon plasma coagulator is used to mark the stitch sites along the anterior wall, greater curvature, and posterior wall (Lopez-Nava et

al. 2015). The applicant states 'a full-thickness endoscopic suturing system is then inserted via a therapeutic gastroscope. An initial row of sutures is placed distally to and proximally from the anterior wall to the greater curve to the posterior wall in a triangular pattern. Five to six bites of tissue are taken with the suturing device before the suture needle, or anchor, is released. Upon release of the anchor, a clinching device is used to cut the suture and proximate the tissue by releasing a secondary T tag. A second row of sutures is placed in the opposite direction from anterior to posterior, ensuring that full-thickness bites retaken to avoid the creation of gastric pockets. A tissue grasper of helix may be used to maximise the amount of tissue sutured in each bite. The number of sutures and cinches will vary in each procedure based on patient anatomy, as well as physician preference and experience. The fundus should be left un-sutured, and sutures should be placed until the endoscope begins to reflex uncomfortably. Following the completion of the procedure, the endoscopic suturing device should be removed from the endoscope and a quick endoscopy performed to ensure there is no bleeding and the check for completeness of the sleeve' (Applicant 2021a).

Postoperative

The applicant has stated 'post-procedure, ESG patients are instructed to follow a standard post-bariatric procedure diet, including a transition from liquid to pureed foods then to solid foods over the course of several weeks. Medications are also prescribed to manage pain, nausea and heartburn' (Applicant 2021a).

Further details have been published by Lopez-Nava et al. (2015), who advise that a liquid diet be initiated on the day before the procedure and continued for at least 2 weeks following. The patient will then progress from hypocaloric liquids to small semi-solid meals over 4 weeks (Lopez-Nava et al. 2015).

The applicant has advised that if patients fail to achieve or maintain a target weight following ESG they can be treated with pharmacotherapy, undergo a revision ESG procedure or undergo another bariatric procedure such as laparoscopic sleeve gastrectomy or gastric bypass (Applicant 2021a).

PASC noted that ESG procedures should be included on the bariatric surgery register.

Comparator(s)

The proposed comparator is moderate intensity lifestyle interventions including VLEDs, behavioural intervention, and/or pharmacotherapy. Pharmacotherapy includes both PBS listed medications (Orlistat) as well as non-PBS listed obesity treatments (Phentermine, Liraglutide, Topiramate, combination phentermine and topiramate, Contrave and Semaglutide).

For patients with a BMI of 35-40 kg/m^2 who have comorbidities, bariatric surgery is a comparator.

PASC noted the type of behavioural interventions should be defined e.g. weight loss guided by a GP or weight loss guided by a dietitian.

PASC noted the issue that the only proposed comparator (moderate intensity lifestyle interventions including VLEDs, behavioural intervention, and/or pharmacotherapy) has been failed by definition.

PASC discussed the exclusion of bariatric surgery as a comparator with the applicant. The applicant advised that the real life comparator is not bariatric surgery as almost 98% of patients eligible for surgery prefer not to have it, with cost being a factor but also other factors such as the safety of the procedure and irreversible nature of some bariatric procedures. However, PASC advised that it is reasonable to include bariatric surgery as an additional comparator for the BMI 35-40 kg/m^2 with comorbidities group based on Australian guidelines (NHMRC 2013).

PASC noted that it is reasonable to include all the listed pharmaceutical obesity treatments as comparators given their widespread use in current practice.

PASC noted that if pharmaceutical obesity treatments are to be treated as comparators, as per 2021 MSAC Guidelines (p36), the cost effectiveness of the treatments which are non-PBS listed may need to be established for the population insofar as this is still unknown.

PASC noted that the new pharmacotherapy agent, semaglutide, raised in consultation feedback (STEP trial population: mean BMI 37.9 kg/m^2; 75% had at least 1 comorbidity), may be a relevant near market comparator. An application for PBS listing of semaglutide is also expected soon (Semaglutide Stakeholder Meeting August 2021).

First-Line interventions

There are three core components of lifestyle that are related to obesity, these being nutrition/diet, physical activity, and behaviour (NHMRC 2013). Each one of these factors can be targeted individually during lifestyle interventions but multicomponent interventions have been found to be more effective than interventions that just target one or two of the factors (Kirk et al. 2012). Lifestyle interventions are cyclical and may involve trialling different combinations of interventions to find the one most suitable, sustainable and efficacious for the individual (NHMRC 2013).

The main goal of the dietary approach is reducing energy intake to create an energy deficit. This approach should be tuned to suit the needs and preferences of the individual and can be undertaken under the guidance of a general practitioner, but including a dietitian in this management strategy may be advisable (NHMRC 2013).

The main goal of the physical activity approach is to increase the energy expended by the body, including during one's occupation, leisure activities (including organised sport and exercise), and travel. Health benefits can be achieved with approximately 150–300 minutes of moderate intensity activity or 75–150 minutes of vigorous activity (or a combination of the two) weekly (NHMRC 2013). It should be noted that physical activity has little effect on weight unless it is combined with dietary changes (Shaw et al. 2006, Shea et al. 2010, Thomas et al. 2006, Witham and Avenell 2010). Maintaining high levels of physical activity in combination with other behavioural strategies may reduce weight gain (Wing and Phelan 2005).

The main goal of behavioural change is education about weight loss and lifestyle changes, including weight management and weight loss strategies. These strategies can include goal setting, self-monitoring of behaviour and progress, stimulus control, cognitive restructuring, and problem-solving (NHMRC 2013). Psychological interventions can also be included, and these involve individual or group-based intervention that may significantly increase weight loss (Shaw et al. 2005, NHMRC). It has been reported that intensive psychological interventions may be required if a person is having difficulty with their behavioural change, or if they have mental health comorbidities. In this situation, a referral to a mental health specialist with relevant expertise may be required (NHMRC 2013).

Second-Line interventions

Individuals who have a BMI >30 kg/m^2, or a BMI >27 kg/m^2 with risk factors and/or comorbidities and have been unsuccessful in reducing weight or preventing weight gain using lifestyle approaches are eligible for second-line interventions (unless contraindicated) (NHMRC 2013). These include VLEDs and pharmacotherapy interventions. The choice of intervention will vary depending on the individual's presentation and situation. The interventions are also likely to be used sequentially, usually beginning with

a VLED and then progressing to medications to help counter the associated hormone changes and increased hunger associated with weight loss (NHMRC 2013).

Very-low energy diets

VLEDs involve replacing one or more meals with foods or formulas that ensure a specified number of kilojoules are consumed per day, typically between 1845 and 3280 kJ (Delbridge and Proietto 2006, NHMRC 2013). Treatment frequency and duration varies but is usually 8–16 weeks (Mustajoki and Pekkarinen 2001). There is evidence that, under close supervision, select obese individuals may safely be on a VLED for an extended time – up to 12 months (Sumithran and Proietto 2008). VLEDs have been associated with weight loss and improvements in other comorbidities such as sleep apnoea and glycaemic control in adults with type 2 diabetes (Nield et al. 2007, Norris et al. 2005, Tuomilehto et al. 2009). VLEDs are contraindicated in pregnancy or advanced age, and for people with porphyria, recent myocardial infarction or unstable angina, severe renal failure, liver failure or a history of severe psychological disturbances, alcoholism or drug abuse (Delbridge and Proietto 2006). Care must be taken in patients with diabetes treated with insulin or sulphonylureas due to the risk of hypoglycaemia occurring without a reduction in medication (Delbridge and Proietto 2006).

Pharmacology

Pharmacological intervention (in addition to lifestyle changes) for obesity has been found to increase weight loss when compared to diet alone (Franz et al. 2007). In Australia, the following medications are listed on the Australian Register of Therapeutic Goods ARTG for weight loss, or are reported to be used off-label for this indication (Lee and Dixon 2017):

- Phentermine (Duromine) is listed by the Therapeutic Goods Administration (TGA) as an 'anorectic agent indicated in the management of obesity as a short-term adjunct in a medically monitored comprehensive regimen of weight reduction based, for example, on exercise, diet (caloric/kilojoule restriction) and behaviour modification in obese patients with a body mass index of ≥30 kg/m^2'. Treatment using Duromine can be initiated in overweight patients with a lower BMI (25–29.9 kg/m^2) with an increased risk of morbidity from a number of disorders (TGA 2000a). Duromine is registered for short-term use (e.g. 3 months) in combination with lifestyle modifications (NHMRC 2013). Duromine is currently not listed on the PBS.
- Orlistat (Xenical) is indicated for the treatment of obese patients with a BMI ≥30 kg/m^2, and overweight patients with a BMI >27 kg/m^2 in the presence of other risk factors (TGA 2000b). Orlistat reduces the absorption of energy-dense fat by inhibiting pancreatic and gastric lipases (NHMRC 2013). This medication is contraindicated in women who are pregnant or breast feeding, and in adults with malabsorption or hypersensitivity to orlistat (Hauptman et al. 2000). Reduced gallbladder function is a relative contraindication and caution is advised with individuals with an obstructed bile duct, impaired liver function or pancreatic disease. Orlistat is currently listed on the PBS.
- Liraglutide (Saxenda) is indicated as an adjunct pharmacology intervention to a hypocaloric diet and increased physical activity for weight management in adult patients with a BMI ≥ 30 kg/m^2 or 27–29.99 kg/m^2 in the presence of at least one weight-related comorbidity. It is recommended that treatment is discontinued after 12 weeks on a 3.0 mg/day dose if a patient has not lost at least 5% of their initial body weight (TGA 2015).
- Topiramate is an anticonvulsant used to treat seizures and for migraine prophylaxis. It has also been used in Australia off-label to treat obesity due its side effect of weight loss (Lee and Dixon 2017). The doses with effect range from 25–100 mg daily. Several meta-analyses have estimated that a 3.4–5 kg weight loss can be expected (Kramer et al. 2011, Paravattil et al. 2016).

- Fixed dose combinations of phentermine and topiramate have been approved in the US to treat obesity (Lee and Dixon 2017). An Australian study used 15 mg of phentermine and 25 mg of topiramate for weight maintenance following weight loss using a VLED, but there was a high rate of side effects in the study, and many participants were unable to tolerate the combination. Even so, there was a 5% weight reduction in the individuals who could tolerate it (Neoh et al. 2014). This intervention may be used by some individuals off-label.
- Contrave is indicated as an adjunct pharmacology intervention to a hypocaloric diet and increased physical activity, for the management of weight in individuals over the age of 18 with a BMI ≥30 kg/m^2, or 27–29.99 kg/m^2 in the presence of one or more weight-related comorbidities (e.g. type 2 diabetes, dyslipidaemia, or controlled hypertension). It has been advised that this treatment regimen should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight (TGA 2018).
- There are numerous antidiabetic drugs that can have a weight-loss effect on overweight and obese individuals; these include metformin, glucagon-like peptide-1 (GLP-1) receptor agonist – this is liraglutide but can also include exenatide, and sodium-glucose cotransporter 2 (SGLT-2) inhibitors (e.g. canagliflozin, dapagliflozin, empagliflozin) (Lee and Dixon 2017).

Rationale

For patients with a BMI of 30–35 kg/m^2 (with or without comorbidities) and with a BMI of 35–40 kg/m^2 without comorbidities, the proposed comparator of moderate intensity lifestyle interventions (VLED and pharmacotherapy) appears to be appropriate, because those patients are not usually eligible for bariatric surgery.

For patients with a BMI of 35–40 kg/m^2 who have comorbidities, bariatric surgery is a treatment option and MBS funded. Therefore, the exclusion of bariatric surgery as a comparator in this application is due to the requirement that the population is defined as patients who are not eligible or indicated for bariatric surgery or patients who would not consider or would refuse to undergo bariatric surgery. Advice from a general surgeon is that bariatric surgery should be included as a comparator for this application (Expert General Surgeon 2021).

Outcomes

Patient relevant

Relevant safety outcomes include:

- mortality
- perioperative adverse events
- procedure-related complications
- length of hospital stay longer than anticipated
- long-term adverse events – for example, sutures reopening
- side effects of comparator medications
- revision procedures or conversion to gastric sleeve or gastric bypass due to adverse events.

Any additional safety outcomes reported in the literature should also be reported in the assessment phase.

Primary effectiveness outcomes are:

- weight loss – this can be reported as absolute weight loss (kg), change in BMI, percentage total weight loss or percentage excess weight loss[5], percentage BMI loss, percentage excess BMI loss
- maintenance of target weight
- revision required – for example, due to dehiscence, failure to maintain target weight or due to loss of integrity (stiches may open up at 2 years which can lead to gastric dilation and weight gain as a consequence)
- conversion to bariatric surgery
- additional treatment required – for example, pharmacotherapy.

Secondary effectiveness outcomes are

- changes in comorbidity markers[6]
- quality of life and wellbeing.

Healthcare system outcomes

These include:

- costs associated with the intervention, including costs of
  - appointments
  - the pre-procedure workup
  - the procedure
  - consumables
  - the hospital stay
  - follow-up
  - monitoring
  - any subsequent interventions required
- costs associated with the comparator, including costs of
  - appointments
  - pharmacotherapy
  - monitoring
  - any subsequent treatment required
- costs associated with adverse events for the intervention and comparator.

PASC noted the outcomes of dehiscence (as a surrogate for failure) should be included and discussed that sutures may open up around 2 years which can lead to gastric dilation and weight gain as a consequence.

Rationale

When evaluating the above outcomes, the type of outcome, timeframe of measurement and minimum clinically important difference (MCID) should also be considered (when relevant).

Outcomes reporting standards for metabolic and bariatric surgery (American Society for Metabolic and Bariatric Surgery [ASMBS]) recommend that total weight loss (percentage of total weight loss, %TWL), the percentage excess weight loss (%EWL) and change in BMI should be included when reporting weight-loss outcomes following bariatric surgery (Brethauer et al. 2015).

The assessment should include short- and long-term outcome measures. For weight loss, short-term is considered ≤3 years and long-term is considered beyond 5 years (Brethauer et al. 2015). Clinical advice on

[5] Percentage excess weight loss at 12 months randomisation is the primary outcome in MERIT trial.

[6] These are secondary outcomes in MERIT trial.

the previous PICO Confirmation for ESG was that it is important to also look at revision rates at medium- (3–5 year) and long-term timepoints (MSAC 2019b).

PASC noted that the outcomes need to be analysed at both short- and long-term time points out to 5 years.

The MCID for weight loss: The American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS) guidelines recommend that lifestyle modification resulting in weight loss of 5– 10% of initial weight should be considered successful weight reduction. This change in weight results in decreased cardiovascular risk factors and a decreased risk of developing obesity-related medical conditions for most patients. This degree of weight loss is also associated with meaningful improvement in sleep apnoea and gastroesophageal reflux (Jensen et al. 2014).

Similarly, the European Practical and Patient-Centred Guidelines for Adult Obesity Management in Primary Care recommend that 5–10% weight loss is sufficient to confer meaningful health benefits due to decreased risk of comorbidities (Durrer Schutz et al. 2019).

PASC noted that only a small subgroup of patients (n=50) without comorbidities were included in the MERIT trial, which may impact statistical power.

Clinical management algorithms

The current and proposed clinical management algorithms are presented below. Late in the drafting of this PICO confirmation, the applicant proposed an additional place for ESG in the pathway; that is, for patients with a BMI >40 kg/m^2 who are not suitable for bariatric surgery (Applicant 2021b). Inclusion of this usage of ESG would expand the proposed population for the assessment beyond the proposed BMI of 30–40 kg/m^2.

PASC noted that the current algorithm doesn't allow for cycling between first- and second-line therapies.

PASC queried the justification of the late proposal to include a population with a BMI > 40 kg/m^2 which was not included in the application form and new evidence from the pivotal MERIT trial. PASC considered that this new population could be included in a separate application to MSAC if the applicant wishes to pursue this.

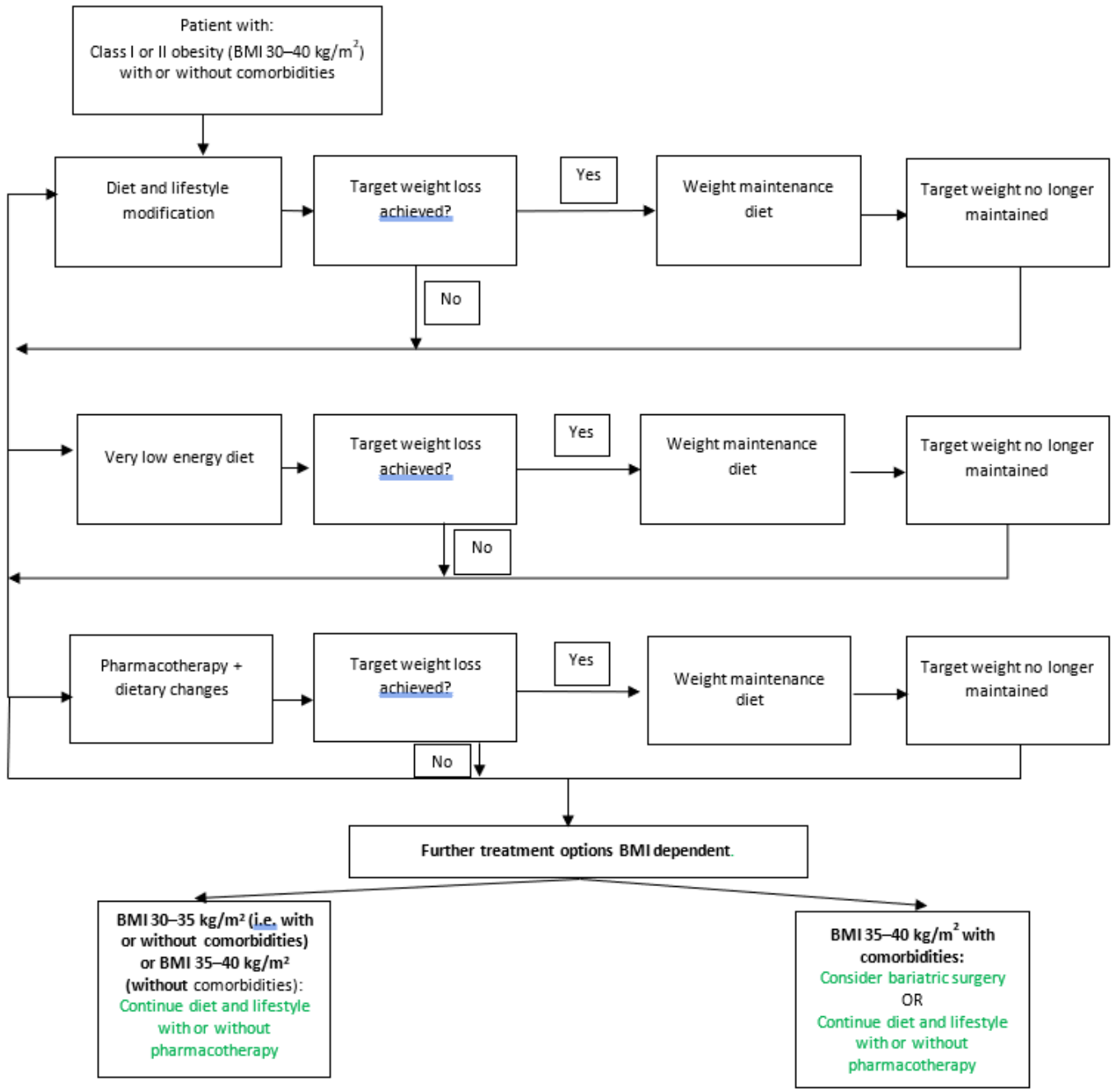

Figure 1: Current clinical management algorithm

Abbreviation: BMI = body mass index

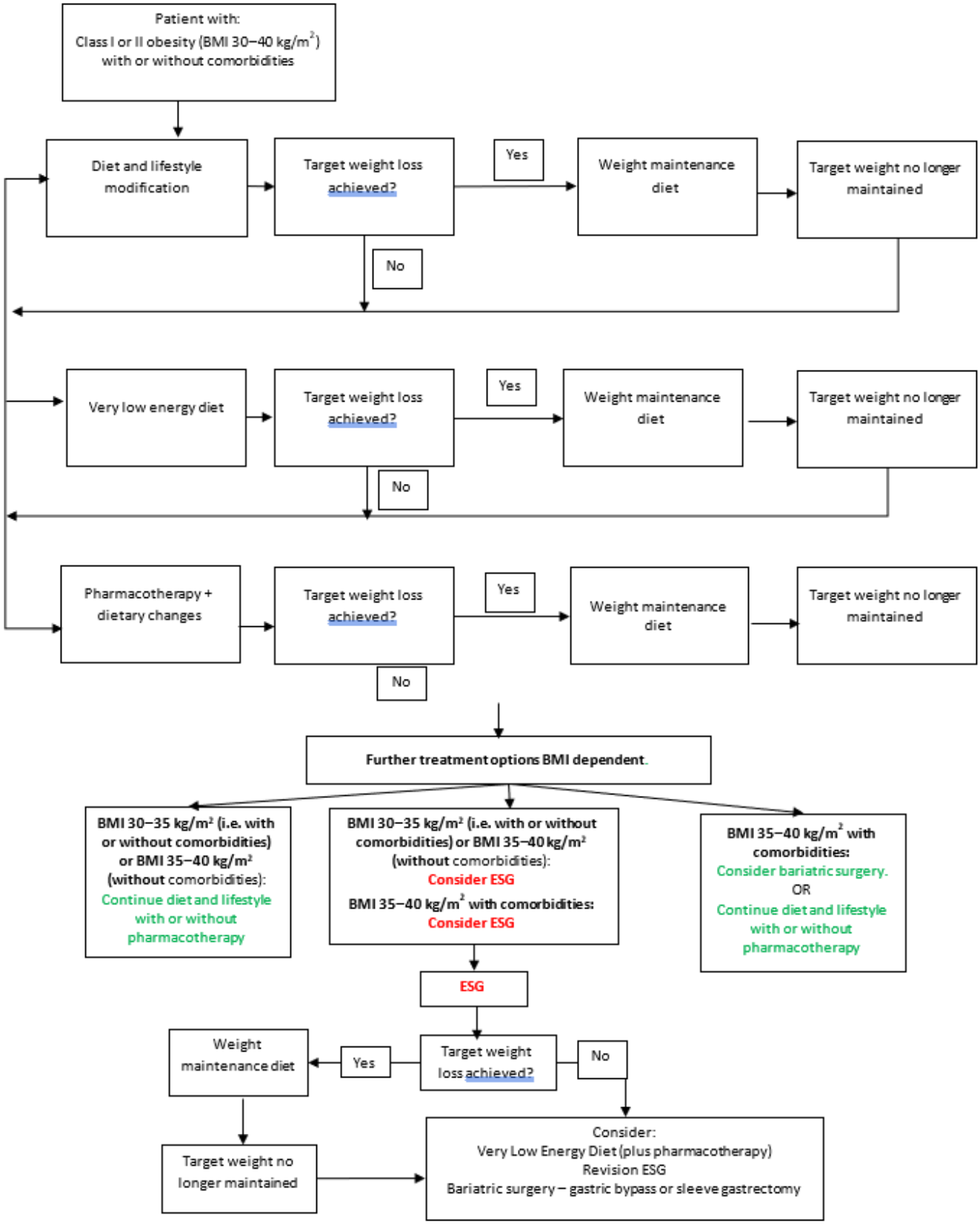

Figure 2: Proposed clinical management algorithm

Abbreviation: BMI = body mass index, ESG = endoscopic sleeve gastroplasty

Proposed economic evaluation

Based on the clinical claim and considering the matrix in Table 4; it is likely that a cost-utility analysis (CUA) is required for the assessment.

PASC noted that cost utility analysis was the most appropriate choice of economic evaluation.

Table 4 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

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

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

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

[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

Proposal for public funding

The applicant has proposed the following MBS item for ESG.

PASC noted that there is no requirement in the item descriptor that the patients need to fail first-and second-line therapies and advised that this should be defined. In addition, PASC advised that the descriptor should state that individuals should have failed both VLED and pharmacotherapies.

PASC advised that the item descriptor includes that this procedure is once per lifetime.

PASC advised that the descriptor include that the procedure is restricted to specialists.

PASC advised stating in the item descriptor a requirement for provision of data to the bariatric surgery registry in an effort to improve outcomes for this group of patients.

The assessment group has amended the item as shown in red to reflect PASC advice.

Category 3 THERAPEUTIC PROCEDURES
MBS item *XXXX Endoscopic Sleeve Gastroplasty by a specialist, for patients 18 years or over with Class I or Class II obesity (BMI 30-39.99 kg/m^2) who have failed both very low energy diet therapy and pharmacotherapy. Applicable only once per lifetime Multiple Services Rule (Anaes.) (Assist.)
Fee: $884.00 Benefit: 75% = 663.00

Explanatory note: Data from procedures using this item are required to be provided to the Bariatric Surgery Registry
Source: Constructed during the development of the PICO based on the application form and PASC advice

The applicant has not proposed a justification for the proposed fee; however, this is the same fee as for bariatric surgery items 31569 (Adjustable gastric band), 31575 (Sleeve gastrectomy) and 31578 (Gastroplasty). These items all contain a time frame of 45minutes or less.

The applicant has advised that revision ESG is sometimes required, therefore the assessment group has drafted the following MBS item for this procedure. The applicant has not suggested a fee for the revision item but has indicated the procedure is less complex than the initial ESG procedure (Applicant 2021c).

Category 3 THERAPEUTIC PROCEDURES
MBS item *XXXX Surgical repair or revision of endoscopic sleeve gastroplasty. <*Specify any relevant explanatory notes>
Fee: TBA

PASC has noted that that proposed item for the revision procedure needs to be drafted, including proposing a fee.

The applicant has provided the following costs associated with ESG (Table 5).

Table 5 Costs associated with ESG

Resource item	Unit cost	Source / notes
Preoperative		
Preoperative assessment for complex medical problems	$76.80	MBS 17615, 85% Benefit
Device costs		
Endoscopic suturing system	$1,853	Prostheses List ER279
Overtube each	$358	
Polypropylene suture (8 units)*	**REDACTED**	
Suture cinch (8 units)*	$2,120	Prostheses List ER280 ($265 X 8)
Subtotal (devices)	**REDACTED**	
Surgical implantation		
Endoscopic sleeve gastroplasty	$663.00	Proposed fee of $884.00, 75% Benefit
Assistance	$132.60	MBS item 51303 for bariatric surgery assistance, 75% Benefit

Subtotal (surgery)	$795.60	
Anaesthetics		
Pre-anaesthesia consultation	$67.80	MBS 17615, 75% Benefit
Initiation of anaesthesia for bariatric surgeryin a patient with clinically severe obesity	$154.50	MBS 20791, 75% Benefit
Anaesthesia time units	~~$164.80~~ $123.60	MBS item 23085; Anaesthesia time units; 1:46 hours to 2:00 hours, 75% Benefit
Subtotal (anaesthetics)	~~$387.1~~ $345.90	Calculated
Post-operative		
Post-operative gastroscopy	138.25	MBS 30473, 75% Benefit
Estimated total per procedure	**~~$7,024.75~~ REDACTED**	

Source: Reproduced from application documents (Applicant 2021a). A change has been made by the assessment group, shown in red, to update the anaesthesia time units to reflect the 75% fee and the corresponding change to the total cost.

Compared to the previous assessment of ESG, the costs listed in Table 5 do not include a tissue helix, an overnight hospital stay, allied health appointments and a consultant appointment. The costs associated with ESG should be clarified with the applicant and clinical experts in the assessment phase.

PASC noted that there is a substantial out of pocket cost to patients currently undergoing an ESG procedure. The expert advice was that these costs represent the entire package of care required for ESG, including 2-year follow up with allied health practitioners and a bariatric GP for privately insured patients only. Patients who are not privately insured may incur even higher costs, which will result in inequity of access.

PASC advised that the applicant clarify the costs of the procedure including in the following aspects:

a. *the preoperative assessment may have already been performed outside of the procedure*
b. *the requirement for an assistant is not clear, and ESG is presumably performed by a single endoscopist*
c. *the initiation of anaesthesia with clinically severe obesity is listed, however an individual with clinically severe obesity is not consistent with a population of BMI 30-40 kg/m^2 without co-morbidities (a population with BMI>40 kg/m^2 or BMI >35 kg/m^2 with co-morbidities would represent clinically severe obesity)*
d. *reintubation with the scope during the same gastroscopy under the same anaesthetic should not incur an additional charge of a second gastroscopy*
e. *some patients will also incur the additional costs associated with a revision procedure.*

The application notes that the population who may be eligible to receive ESG is extremely large, but the capacity to deliver the service is highly constrained. The applicant has provided an estimate of expected utilisation, with 720 procedures anticipated in the first year should an item for ESG be listed on the MBS, rising to 3,040 procedures by year 4 (Table 6). The basis for this estimate is data from 2016 (albeit only 1 year), when the applicant states ESG was being performed under existing MBS items. The applicant has used the 2016 figure as the first-year estimate with projections beyond this based on the number of gastroenterologists and surgeons who are able to be trained in the procedure.

Table 6 Expected utilisation of ESG

Year	Number of surgeons	Number of procedures	Average number of procedures per surgeon
1	20[a]	720	36
2	35	20 surgeons at 50 per year – 1000 15 surgeons at 36 per year – 540 *Total* *1,540*	44
3	50	35 surgeons at 50 per year – 1750 15 surgeons at 36 per year – 540 *Total* *2290*	46
4	65	50 surgeons at 50 per year – 2500 15 surgeons at 36 per year – 540 *Total* *3040*	47

Source: Applicant 2021a

[a] Actual number of surgeons performing ESG in 2016

Expert advice is that they expect 10–20% of eligible patients to be willing to undergo ESG (as opposed to 1% who would consider bariatric surgery) (Expert Gastroenterologist #1 2021, Expert Gastroenterologist #2 2021, Expert General Surgeon 2021). This is consistent with the previous assessment of ESG (MSAC 2019a).

PASC noted that the expected utilisation is uncertain and may be higher than estimated.

Summary of public consultation input

Consultation feedback for application 1555.1 was received from the following three (3) organisations and one (1) individual:

- The Gastroenterology Society of Australia (GESA)
- HAES Australia (HAES)
- General Surgeons Australia (GSA)

The consultation feedback was not supportive of the application.

Benefits

The consultation feedback noted that current literature shows benefits of bariatric surgical interventions in glycaemic control in type 2 diabetes, liver fibrosis risk, fatty liver disease including NAFLD, sleep apnoea, and hypertension management, and metabolic disease. GSA stated that the proposed intervention may have merit for candidates who are unfit for general anaesthesia and surgery and encouraged the use of ESG in academic centres to obtain immediate and long-term data.

Disadvantages

HAES and GESA stated that ESG technique is still being refined and long-term data demonstrating sustained benefits is lacking, particularly data from randomized controlled trials. HAES further stated that it had been reported that there is the potential for sutures to completely dehisce by 2-years post-procedure leading to gastric dilation and that there was limited data on adverse events (AEs) and screening criteria of potential patients. HAES further expressed concern regarding the cited studies, noting potential conflicts of interest. GESA expressed concern over the skill level of proceduralists described by the applicant indicating that inadequate skill level could result in ineffective or failed procedures or significant complications.

HAES noted that AEs associated with bariatric surgery include vomiting, intolerance of healthy foods, weight regain, dumping syndrome, mental health issues, loss of social life, relationship strain, and difficulty fighting off life threatening illnesses.

A final disadvantage stated by HAES was that the public funding of weight loss procedures such as ESG may contribute to societal weight stigma and pathologizing of larger bodies.

Other comments

The feedback considered that services required for the proposed service would be psychologists, dietitian, obesity physicians/general physicians, hepatologists, endocrinologists, exercise physiologists, occupational therapists, and social workers.

HAES and The individual did not agree with the population; HAES stated that including those with a BMI of down to 30 was bracket creep and The individual stated that the population should be limited to those with comorbidities. HAES went on to say that failure of first- and second-line treatments was not adequately defined.

GESA and The individual disagreed with the comparator stating that pharmacotherapy is evolving with new agents and that different treatment options for patients with class I and II obesity are not reflected in the application. HAES considered that the clinical management algorithm misrepresented the weight loss/regain cycle.

The individual stated that the clinical claim when compared to moderate intensity lifestyle interventions should be one of non-inferiority. HAES noted that there is no revision item, and GESA stated that the proposed service fees are too low for the expertise required.

PASC noted the concerns raised in the consultation feedback.

PASC noted for consideration the feedback of GESA that ESG should be undertaken in hospitals with overnight facilities.

Next steps

PASC recommended that the applicant revise the proposed population to align with current Australian guidelines for reimbursement of bariatric procedures (NHMRC 2013). Further, PASC also recommended that the population should include a requirement that patients have failed both lifestyle modification and pharmacotherapy, monitored over a 12-month period, before becoming eligible for ESG.

PASC recommended further consideration of the comparator and indicated bariatric surgery should be included.

PASC recommended the applicant provide clarification around the procedure costs.

PASC recommended clarification of training and accreditation requirements before a practitioner can perform ESG.

PASC recommended updating the proposed item descriptor and including an item for procedure revision.

PASC noted that this will be an applicant developed assessment report (ADAR).

Applicant Comments on the Ratified PICO Confirmation

Nil.

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