



Australian Government

Department of Health

Application 1555:

Endoscopic sleeve gastroplasty for the treatment of patients with Class I and II obesity with comorbidities who have failed first- and second-line treatments

Ratified PICO Confirmation

(To guide a new application to MSAC)

(Version 1.0)

Component	Description
Patients	Patients aged 18 years or over with a body mass index (BMI) of 30.0 to 39.9 kg/m ² who have one or more major medical comorbidities (including sleep apnoea, hypertension, diabetes, excessive abdominal weight, lipid abnormalities, metabolic syndrome, cardiovascular disease or liver disease) and have failed first- and second-line treatment options ^a .
Intervention	Endoscopic sleeve gastropasty plus lifestyle interventions (behavioural therapy, diet and exercise) with or without pharmacotherapy.
Comparator	<p><i>Comparator 1: patients with a BMI of 30.0 to 34.9 kg/m²</i></p> <p>Lifestyle interventions (behavioural therapy, diet and exercise) with or without pharmacotherapy.</p> <p><i>Comparator 2: patients with a BMI of 35.0 to 39.9 kg/m²</i></p> <p>Sleeve gastrectomy or laparoscopic adjustable gastric banding plus lifestyle interventions (diet, exercise and behavioural therapy) with or without pharmacotherapy.</p>
Outcomes	<p><i>Safety</i></p> <p>Incidence and severity of minor adverse events (for example, abdominal pain and chest, nausea, vomiting, reflux, pneumoperitoneum), serious adverse events (for example, gastric leaks, serous fluid collections, pulmonary embolism and pneumothorax), device-related adverse events, complications (for example, injury to gastrointestinal tract or stomach, bleeding), mortality, blood loss, length of hospital stay, revision rates, conversion rates, rates of sutures reopening and long-term other risks (for example, Barrett's oesophagus).</p> <p><i>Efficacy</i></p> <p><i>Primary outcomes:</i></p> <p>Durable (> 5 years), total body and excess weight loss, impact on metabolic comorbidities (for example, hypertension, diabetes, hyperlipidaemia, cardiovascular disease, steatohepatitis), operative success and unplanned/planned revision, reversal or conversion rates.</p> <p><i>Secondary outcomes:</i></p> <p>Health-related quality of life, percentage of sleeves intact at follow-up, function of the plicated stomach, nutritional profile, joint health, number</p>

of missed days of work/school/activity, hospitalisation (obesity-related) and frequency of obesity-related medication.

Healthcare resources:

Cost, cost per quality-adjusted life year, incremental cost-effectiveness ratio, Australian Government healthcare costs and patient costs.

Notes: a = the Applicant defined treatment failure as an inability to achieve a minimum of 5 per cent weight loss within 3 months.

Population

The Application proposed the following population for endoscopic sleeve gastroplasty:

Patients aged 18 years or over with a BMI of 30.0-39.9 kg/m² who have one or more major medical comorbidities (such as diabetes, cardiovascular disease or cancer) and have failed first- and second-line treatment options.

Obesity

Obesity is chronic, relapsing disease caused by a complex interaction between biological, environmental, individual and sociodemographic factors.^{1, 2} In brief, obesity results from a persistent state of energy imbalance where an individual's energy intake exceeds expenditure. This typically results in the accumulation of adipose tissue (body fat).³ Increased body fat is associated with an increased risk of developing cardiovascular-related comorbidities which in turn increases the risk of mortality.⁴⁻⁷

A common measurement of adiposity is the body mass index (BMI). BMI is calculated by dividing an individual's weight in kg by the square of their height in metres. In Australia, a BMI of 30 or greater is considered obese (Table 1). It is important to note that body composition and the distribution of adipose tissue varies substantially across ages and ethnic groups.⁸⁻¹¹ BMI thresholds pertaining to Caucasians may not be suitable for other ethnic groups such as Asian or Aboriginal and Torres Strait Islanders. Therefore, additional measures of adiposity such as waist circumference are used to support BMI.

Consequences of obesity

Obesity is a major cause of preventable health problems accounting for approximately seven per cent of all disease and injury burden in Australia.¹² Obesity is closely associated with the development of hypertension, hyperlipidaemia, type two diabetes and some forms of cancer.^{13, 14} These comorbidities significantly increase the likelihood of death owing to their adverse effects on multiple body systems. Longitudinal studies have shown as BMI increases, the likelihood of developing comorbidities increases, as does their severity and the rate of mortality.^{5, 15}

In Australia, the most common comorbidities diagnosed among obese individuals include; arthritis (27.7%), back problems (24.1%), hypertension (24.5%), mental health problems (22.6%), asthma (13.7%) and diabetes (12.8%) as reported in Table 2.¹⁶ Of particular noteworthiness is the link between obesity and mental health problems. Obese individuals often find it difficult to or are precluded from performing every-day tasks, thus leaving individuals feeling isolated which may further drive obesity and reduce quality of life.^{13, 17}

In addition to its adverse effects on the individual, obesity has a significant impact on the Australian economy. Patients with obesity utilise healthcare resources (such as; general practitioners, specialists, allied health professionals and pharmaceuticals) more frequently and have a lower age of retirement and death.^{18, 19} These effects contribute to the direct costs associated with obesity. Indirect costs contributing to the economic burden include loss of productivity and unpaid labour by a caregiver.¹⁹

While difficult to estimate; the financial cost attributable to overweight and obesity in Australia ranges between \$6.5 to 8.7 billion annually. Indirect costs (losses in productivity) accounted for the greatest

financial impact (\$3.6-4.4 billion), followed by direct health care costs (\$2.0-3.8 billion) and carer costs (\$1.9 billion).¹⁹⁻²¹

Prevalence of obesity

Within Australia, the prevalence of obesity is similar between males and females, and is highest among those aged 45 to 74 years.²² Obesity disproportionately affects those of lower socioeconomic status, the elderly, individuals living in regional and remote areas of Australia and Aboriginal and Torres Strait Islanders.²²⁻²⁴

The prevalence of obesity in Australia has increased from 19 to 28 per cent between 1995 to 2014-2015, and it is anticipated to rise to 35 per cent by 2025.^{25, 26} Currently, 4.9 million Australians are classified as obese, of which 4.3 million are class I or II (Table 1). Furthermore, the prevalence of comorbidities in patients with obesity ranges from 1.9 to 27.7 per cent (reflecting the type of comorbidity, Table 2).¹⁶

Table 1 The proportion of Australians within each BMI category

Classification	BMI (kg/m²)²⁷	Number of Australians (%)²⁵
Underweight	< 18.5	290,100 (1.6%)
Normal weight range	18.5 – 24.9	6,204,500 (35.0%)
Overweight	25.0 – 29.9	11,200,000 (35.5%)
Obesity I	30.0 – 34.9	3,251,000 (18.3%)
Obesity II	35.0 – 39.9	1,119,900 (6.3%)
Obesity III	≥ 40	571,700 (3.2%)
Total obese	30 - ≥ 40	4,942,600 (27.8%)

Abbreviations: BMI = body mass index; NA = not applicable.

Table 2 The number of obese Australians by comorbidity type

Comorbidity	Prevalence of comorbidities in patients who also have obesity ¹⁶	Estimated number of patients*
Arthritis	27.7%	1,369,100
Asthma	13.7%	677,136
Back problems	24.1%	119,1167
Cancer	2.8%	1,383,928
COPD	4.7%	2,323,022
Diabetes	12.8%	632,653
Heart, stroke and vascular diseases	10.0%	494,260
Hypertension	24.5%	1,210,937
Kidney disease	1.9%	93,909
Mental and behavioural problems	22.6%	1,117,028
Osteoporosis	4.8%	237,245

Abbreviations: COPD = chronic obstructive pulmonary disease.

Notes: *The estimated number of patients was determined by multiplying the number of obese Australians as informed by the Australian Bureau of Statistics, National Health Survey, 2014-15²⁵, by the prevalence of comorbidities¹⁶.

Current care and management

The treatment of obesity should follow a chronic disease model of care.²⁸ Treatments are individualised with initial interventions aiming to alter lifestyle and environmental factors using a multidisciplinary team (general practitioner, nurse, dietitian and psychologist). More intensive therapies are considered if the individual fails to respond to treatments or the burden of disease increases. Importantly, the treatment of obesity should not only focus on weight loss but a range of health outcomes such as improving quality of life and function.^{13, 28}

Lifestyle modification is the first-line treatment option for overweight and obese individuals. Lifestyle interventions broadly aim to reduce energy intake, increase physical activity, curb adverse behaviour and assist individuals in making lasting changes. Second line interventions are considered in individuals who fail to achieve target weight and maintenance with first-line treatment and have a BMI of 30 kg/m² or greater, or a BMI of 27 kg/m² or greater with comorbidities.¹³ Second-line interventions are used in conjunction with first-line treatments and include: very low energy diets (VLEDs), pharmacotherapy or bariatric surgery. Bariatric surgery is considered in individuals who have failed to reduce weight and/or maintained weight loss following lifestyle interventions, VLEDs and/or pharmacotherapy. Further suggested eligibility criteria for bariatric surgery include a BMI of 40 kg/m² or more, or a BMI of 35 kg/m² or more plus one or more major medical comorbidities.

Rationale

In determining the appropriate population for endoscopic sleeve gastroplasty, the following should be considered: the populations with the greatest clinical need and populations in which it has been trialled.

Clinical need

A common theme among non-surgical treatments for obesity is that of short-term weight loss, followed by gradual weight re-gain. Bariatric surgery is the only intervention which generally results

in short- and long-term weight loss.²⁹⁻³¹ As such, the National Health and Medical Research Council (NHMRC) obesity clinical practice guidelines and the Diabetes Society guidelines recommend bariatric surgery is considered after first- and other second-line interventions have failed to reduce weight or maintain weight loss.^{13, 32}

In Australia, the Medicare Benefits Schedule (MBS) guidelines suggest bariatric procedures are reimbursable for patients with “a BMI of 40 kg/m² or more, or a patient with a BMI of 35 kg/m² or more with other major medical comorbidities (such as diabetes, cardiovascular disease, cancer)”.³³ Thus, for these individuals, long-term weight loss can be achieved through bariatric surgery.²⁹⁻³¹ However, some individuals are contraindicated for bariatric surgery (owing to cardiac or pulmonary disease) or do not wish to undergo the available procedures. These individuals have an unmet medical need as they are still at a heightened risk of mortality. Therefore, endoscopic sleeve gastroplasty may be a viable therapeutic option in this patient population.

Class I obese individuals (BMI 30.0 - 34.9 kg/m²) with one or more comorbidities are generally not recommended for bariatric surgery in Australia, and do not meet MBS reimbursement guidelines. Clinical feedback from surgeons questions the need to extend bariatric interventions to patients with a BMI of 30.0 - 34.9 kg/m², given the risks may outweigh benefits of the procedure. This is supported by feedback from the Australian and New Zealand Metabolic and Obesity Surgery Society, which suggests there is insufficient evidence to recommend any bariatric procedure in this obesity group.

However, patients in this group may have a heightened risk of mortality and an unmet medical need once all non-surgical treatments for weight loss have been exhausted.⁴⁻⁷ Therefore, endoscopic sleeve gastroplasty may be a viable therapeutic option for this patient group. This intervention is supported by clinical feedback from a gastroenterologist who suggests this procedure should be considered in these patients as it is only a matter of time before their BMI exceeds 35 kg/m². Early intervention may prevent significant obesity-related co-morbidities.

In support of this, the American Society for Metabolic and Bariatric Surgery, the International Federation for Surgery of Obesity and Metabolic Disorders, a conglomerate of International Diabetes Organisations and the Australian Diabetes Society recommend bariatric procedures could be offered to patients with a BMI of 30-35 kg/m² and obesity-related co-morbidities who have not achieved or sustained weight loss using non-surgical methods.^{32, 34-36}

Patients with a BMI of 40 kg/m² or greater are at an increased risk of mortality and are recommended to undergo bariatric surgery to promote weight loss.¹³ These patients are currently eligible for all bariatric procedures in Australia (unless contraindicated). Clinical feedback suggests these patients are theoretically eligible for endoscopic sleeve gastroplasty. However, other bariatric procedures such as sleeve gastrectomy are preferred in patients who can tolerate surgery. Therefore, endoscopic sleeve gastroplasty may act as a bridging procedure in patients who are currently unsuitable for surgery.³⁷ Patients with a BMI of 40 kg/m² or greater are outside the scope of this Application.

The Applicant proposed that the service is restricted to patients aged 18 and over. Clinical feedback supports this position, as they suggest the procedure is not as durable and is technically complex in younger patients. However, other clinical feedback suggests bariatric procedures can be, under some circumstances, performed in adolescents, and current MBS bariatric surgery items are not age restricted.

The Applicant and PICO Advisory Sub-committee (PASC) suggested the following comorbidities be considered when determining eligibility to endoscopic sleeve gastroplasty:

- sleep apnoea (STOP-BANG questionnaire and polysomnography);
- hypertension defined by blood pressure $\geq 130/80$ mm/Hg or patient taking hypertension medication;
- prediabetes, defined by HbA1c levels between 5.7 and 6.5%, fasting plasma glucose between 5.6 and 6.9 mmol/L or 2-hour glucose plasma level on oral glucose tolerance test (OGTT) between 7.8 and 11.1 mmol/L;
- diabetes, defined by HbA1c $> 6.5\%$, fasting plasma glucose ≥ 7.0 mmol/L or 2-hour glucose level ≥ 11.1 mmol/L on OGTT;
- excessive abdominal weight, waist circumference >102 cm (males) or >80 cm (females);
- lipid abnormalities, defined by triglycerides >1.7 mmol/L or HDL-C <1.3 mmol/L or <1.0 mmol/L for women and men respectively;
- metabolic syndrome (including elevated blood pressure, elevated waist circumference, lipid abnormalities, and elevated glucose levels);
- cardiovascular disease; and,
- liver disease.

PASC recommended that lifestyle modification and treatment failure be appropriately defined. The NHMRC guidelines propose lifestyle interventions encompass nutrition (diet), physical activity (exercise) and behavioural changes. They include low and VLEDs, increased physical activity and behavioural counselling.

Broadly, treatment failure for lifestyle and pharmacotherapy interventions is defined as failure to lose weight (less than 1% body weight or no change in waist circumference) after three months of active management. However, treatment failure often differs according to the type of intervention. For example, treatment failure for Orlistat, a pharmacotherapy for obesity is defined as failure to lose $\geq 5\%$ body weight within 12 weeks of starting therapy. By contrast, treatment failure with VLEDs would be failure to lose 1kg of body weight within 4 weeks of treatment.^{13, 32}

Clinical feedback suggests given patient's typically cycle through multiple lifestyle and/or pharmacotherapies before considering bariatric surgery. Treatment failure should be considered in a broader context rather than considering treatment failure for one specific intervention. Thus, treatment failure, could be defined as a failure to lose weight or maintain weight loss following several lifestyle interventions and pharmacotherapies over a specified period of active management.

The Applicant proposed the following definition of treatment failure: "*an inability to achieve a minimum 5 per cent weight loss within 3 months*". The definition was derived from the NHMRC guidelines on obesity which suggest a weight loss of 5 per cent reduces health risks by lowering blood pressure and reducing the risk of, or delaying the progression of, type two diabetes.

Trial populations

An important consideration when determining eligibility for endoscopic sleeve gastroplasty is whether there is an evidence base to support the intervention for the intended population.

Case series

Several case series utilising endoscopic sleeve gastroplasty have been published. In general, patient inclusion in the studies was restricted to overweight (BMI of 27 kg/m² or over) or obese (BMI of 30 kg/m² or over) individuals, with one or more comorbidities.^{38, 39} However, the enrolled participants generally had BMIs of 35 to 45 kg/m². Further, not all enrolled patients had comorbidities. For example, the prevalence of hypertension and diabetes among trial participants ranged from 20 to 30 per cent, and 3 to 20 per cent, respectively.³⁸⁻⁴¹

Comparative trials

Two retrospective comparative trials evaluating endoscopic sleeve gastroplasty to sleeve gastrectomy or adjustable gastric banding have been published. The mean BMI of patients enrolled in the endoscopic sleeve gastroplasty arms of the two studies were 38.6 and 43.0 kg/m². The presence of comorbidities such as diabetes and hypertension ranged from 3 to 20 per cent.^{42, 43}

Current clinical trials

Six ongoing clinical trials were identified evaluating endoscopic sleeve gastroplasty include patients with class I and II obesity. Three trials require patients to have one or more comorbidities. Three trials do not specify the type of comorbidities required for inclusion.

Intervention

The proposed intervention is endoscopic sleeve gastroplasty plus lifestyle interventions (behavioural therapy, diet and exercise) with or without pharmacotherapy.

Registration of the device

The OverStitch™ Endoscopic Suturing System and the OverStitch™ Endoscopic Suturing System 2.0 Suture (Emergo Asia Pacific Pty Ltd) are listed on the Prosthesis List (billing codes: ER279 and ER280) and the Australian Register of Therapeutic Goods (item number 237773, 237774, 236906, 245894). The intended purpose of the OverStitch™ system is for endoscopic placement of suture(s) and approximation of soft tissue.

The OverStitch™ is mounted onto a double-channel endoscope, for example, the GIF-2T160 (Olympus Medical Systems Corp., Tokyo, Japan).

General information

Endoscopic sleeve gastroplasty reduces gastric volume by modifying the shape of the stomach to resemble a sleeve (a tubular lumen).^{44, 45} The procedure facilitates weight loss by limiting the volume of food consumed and delaying gastric emptying. It is intended to be used in conjunction with lifestyle modifications (behavioural therapy, diet and exercise). Applicant feedback suggests that due to use of full-thickness sutures and consequential scarring the procedure is intended to change the configuration of the stomach permanently. Clinical feedback suggests that the suture anchors will stay embedded in the stomach permanently increasing the risks associated with future gastric surgeries. Furthermore; clinical feedback reflects a concern with the long-term (up to five-year) durability of the procedure given the history of other stomach partitioning procedures.

Endoscopic sleeve gastroplasty is performed by gastroenterologists and general, bariatric or upper gastrointestinal tract surgeons familiar with endoscopic procedures. 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. For example, access to specialised general anaesthesia for overweight and obese patients, appropriately weighted examination couches, operating tables and ward beds, scales that weigh above 150kg, toilets that are not wall suspended, long surgical instruments and imaging equipment able to cope with patients who weigh over 150kg. The Applicant indicated the procedure is technically demanding and is usually performed in tertiary hospitals with appropriate bariatric equipment and clinical backup. However, follow-up can be performed using telehealth, which increases accessibility for rural and remote patients.

The Applicant indicated the training required for endoscopic sleeve gastropasty includes, courses, peer to peer site visits, proctoring and preceptorship programs and ongoing support by REDACTED.⁴⁶

The Applicant indicated the procedure is not currently funded or reimbursed in private or public setting in Australia for the same or another clinical indication. However, there is some evidence to suggest the procedure is currently being performed in Australia without reimbursement.⁴⁷

The Applicant indicated this procedure could be considered as an intermediate step before considering bariatric surgery. That is, it could occur after failing pharmacotherapy but before bariatric surgery (see clinical management algorithm).

Pre-operative

The Applicant stated (Application Form, page 24) *“upon referral to a bariatric surgeon or gastroenterologist, patients will be assessed for their suitability for endoscopic sleeve gastropasty. Patients may be excluded from the procedure if a contraindication is confirmed during the pre-procedure assessment”*. The Applicant and published trials suggest contraindications to endoscopic sleeve gastropasty include: family history of stomach cancer; cirrhosis, pregnancy, prior gastric surgery; gastric ulceration; anticoagulation; coagulopathies; vascular abnormalities; hiatus hernia; psychiatric disorders; or, any condition that would preclude a safe endoscopic suturing procedure or sedation.^{48, 49} Further, the patient must be able to understand and comply with strict post-operative nutritional demands.

The Applicant indicated (Application Form, page 24): *“Patients deemed suitable for the procedure are instructed to begin a course of proton pump inhibitors one week preceding the procedure. On the day preceding the procedure, a liquid diet is prescribed with patients advised to fast from midnight. Patients are prescribed Emend (Aprepitant) to be taken on the day of the procedure as well as the day after.”*

Peri-operative

Based on the Applicant’s description (Application Form, page 24); the procedure is performed under general anaesthesia, with patients in the left lateral position. An oesophageal overtube is inserted to facilitate atraumatic passage of the endoscope, with suturing device (OverStitch™). Following placement of the overtube, the gastric lumen is distended using CO₂ insufflation and evaluated to assess the presence of any contraindications. The anterior and the posterior walls of greater curvature (the larger side of the stomach) are subsequently marked using an argon plasma coagulator (APC).^{44, 45, 50} The Applicant suggested: *“the use of APC may be eliminated in future procedures as the physician becomes more proficient in endoscopic suturing and gains more familiarity with the procedure”*.

Within the stomach, suturing begins distally (near the incisura angularis/lower gastric body) and moves progressively more proximal, finishing in or near the fundus. Full-thickness sutures are typically placed in a triangular pattern; however, variations have been reported.^{51, 52} Full-thickness sutures are first passed into the anterior wall followed by the greater curvature and then the posterior wall. The suturing pattern is then repeated backwards (posterior, greater curvature, anterior) slightly more proximal, using the argon markings as a guide to ensure correct orientation of the stomach.

The Applicant suggested, *“five to six bites of tissues are taken per suture”*. However, published trials report up to nine.⁴⁸ Importantly, full-thickness bites are taken between each point to avoid the formation of two long gastric pockets.

The sutures are subsequently brought together into a plication (a fold) using a cinching device. The Applicant suggests *“the number of sutures and cinches vary according to each patient’s anatomy as well as physician preference and experience”*. Published trials range from 4 to 8 plications per patient.^{44, 45, 50}

The Applicant suggests *“the fundus should be left un-sutured and sutures should be placed until the endoscope begins to retroflex uncomfortably”*.

Following the procedure, an endoscopy may be performed to assess for bleeding and completeness of the sleeve. The procedure reduces gastric volume by approximately 70 per cent.⁴⁵

Total procedure time varies and is primarily determined by a physician’s experience level with the endoscopic suturing system. The learning curve ranges from 7 to 38 cases resulting in an average procedure time between 60 to 120 minutes.^{38, 48, 50, 53, 54}

Post-operative

The Applicant and clinical feedback from a gastroenterologist indicated this procedure might take place in an outpatient clinic. However, early published trials and clinical feedback from a surgeon recommend monitoring patients overnight.⁵⁰

The Applicant stated that patients must adhere to a strict post-procedure diet (transition from liquids to pureed to solids foods over 4 to 8 weeks) and require visits from dietitians, exercise physiologists and psychologists.⁵³ The post-operative care programs vary slightly reflecting the location of the intervention. However, all care programs are designed to implement lifestyle changes.

Medications are also prescribed to manage pain, nausea, and heartburn.

If the sleeve loses integrity, patients may receive a repeat procedure (where additional endoscopic stitches are made to return the sleeve to its original volume). Alternatively, patients may undergo a different bariatric procedure. Clinical feedback suggests technical (size and length of the sleeve), and patient aspects (compliance to eating small size meals) influence the integrity of the sleeve. Further, clinical feedback from a surgeon suggests the sleeve is unlikely to maintain integrity beyond 3 to 5 years.

Potential adverse events

Minor adverse events reported in published trials included: nausea, abdominal pain, chest/epigastric pain, asymptomatic pneumoperitoneum and gastro-oesophageal reflux. All minor adverse events were successfully managed using conservative treatments.⁴⁰

Major adverse events reported in published trials include; perigastric leak, perigastric inflammatory serous fluid collection, pulmonary embolism and pneumoperitoneum with pneumothorax.^{53, 55} All patients recovered without surgical intervention.

To decrease the risk of major adverse events, the following precautions are implemented during the surgical procedure: intermittent pneumatic compression devices; prophylactic subcutaneous heparin; minimal CO₂ insufflation during suturing; and increased monitoring of the abdomen. Furthermore, the reduction of the posterior aspect of the fundus was stopped, owing to its predisposition for leakage.⁴⁰

Anticipated utilisation

The Applicant provided estimates regarding the anticipated utilisation of the procedure over the first four years based on the usage of MBS item 31758 (gastroplasty) and the number of procedures expected to be performed based on the number of trained physicians (Table 3).

Table 3 Estimated number of procedures

	Percentage of bariatric procedures	Number of potential patients	Source of data
Year 1 lower procedure limit estimate	3.5%	739	25 trained physicians
Year 2 lower procedure limit estimate	5%	1,056	35 trained physicians
Year 3 lower procedure limit estimate	7.5%	1,591	50 trained physicians
Year 4 lower procedure limit estimate	10%	2,121	75 trained physicians

Rationale

No alternative uses of the intervention have been identified.

Comparator

The comparators relevant to endoscopic sleeve gastroplasty are:

1. For patients aged 18 years or over with a BMI of 30.0 to 34.9 kg/m² who have one or more major medical comorbidities, the proposed comparator is lifestyle modification (behavioural therapy, diet and exercise), with or without pharmacotherapy.
2. For patients aged 18 years or over with a BMI of 35.0 to 39.9 kg/m² who have one or more major medical comorbidities, the proposed comparator is sleeve gastrectomy or laparoscopic adjustable gastric banding, plus lifestyle modification, with or without pharmacotherapy.

Current care and management

The management of obesity is complex and requires a personalised approach addressing modifiable causes of weight gain such as sedentary behaviour and inappropriate diet. Adequately addressing these causes necessitates a multidisciplinary team consisting of a general practitioner, nurse, dietitian, psychologist and/or an exercise physiologist. These individuals aim to assist the individual in implementing changes that alter behaviour, improve health and promote weight loss via behavioural training, dietary change, physical activity and pharmacotherapy.^{13, 28}

Lifestyle interventions are first-line treatment for obesity. Failure to lose weight or maintain weight loss or the development or worsening of co-morbidities requires implementation of second-line interventions. If the individual still fails to lose weight, has increased disease burden, and has a BMI greater than 40 kg/m² or 35 kg/m² with one or more comorbidities, they are eligible for bariatric surgery.

First-line interventions

Lifestyle

Lifestyle interventions encompass three areas: nutrition, physical activity and behaviour. Lifestyle interventions broadly aim to reduce energy intake, increase physical activity, curb adverse behaviour and assist individuals in making lasting changes. Treatment strategies that include two or three interventions are more effective than those including one.^{56, 57} However, there is significant heterogeneity regarding how each individual respond to any given treatment. Individuals may cycle through multiple interventions before finding one which works. Thus, lifestyle interventions must be tailored to the individual.

Diet and exercise are the first options for patients who present with weight-related comorbidities. Lifestyle interventions are effective in producing short-term weight loss. However, long-term, the patient's typically exhibit minor weight loss (range 1-10kg) or weight re-gain.^{58, 59}

Second-line interventions

Individuals with a BMI of 30 kg/m² or greater, or a BMI of 27 kg/m² or greater, with comorbidities, who have unsuccessfully reduced or maintained weight loss following lifestyle interventions (first-line treatments) are eligible for second-line interventions.¹³ Second-line interventions are used in conjunction with first-line treatments and include; VLEDs, pharmacotherapy and bariatric surgery.

Very low energy diet

Very low energy diets are a weight loss strategy that restricts energy intake to 3400 kilojoules (kJ) per day (the average adult daily consumption is 8,700kJ). The diet consists of three formulate meal replacement products that are consumed at specific times throughout the day. The diet typically lasts 8 to 16 weeks; however, the duration can be extended if required.^{60, 61} In the short-term, VLEDs are effective in reducing weight and improving blood pressure, insulin and cholesterol levels.^{62, 63} However, VLEDs are less successful in achieving and maintaining long-term weight loss.^{64, 65}

Pharmacotherapy

Anti-obesity medications are utilised in patients who do not respond to or have regained weight following VLEDs. While each drug acts differently, they broadly aim to alter processes governing energy regulation in the body, which reduces appetite and promotes satiety following meals.⁶⁶ Like VLEDs, pharmacotherapies successfully promote short-term weight loss. However, their long-term efficacy is poor owing to adverse side effects.⁶⁶⁻⁶⁸ In Australia, only Orlistat (Xenical®) is listed on the Pharmaceutical Benefits Scheme (PBS).

Bariatric surgery

Bariatric surgery is considered in individuals who have failed to reduce weight and/or maintained weight loss following lifestyle interventions, VLEDs and/or pharmacotherapy.¹³ Clinical feedback suggests individuals do not need to fail both first- and second-line interventions in a clinical scenario to be eligible for bariatric surgery. Additional guidelines for bariatric surgery eligibility include a BMI of 40 kg/m² or more, or a BMI of 35 kg/m² or more plus one or more major medical comorbidities such as diabetes or obstructive sleep apnoea.³³

In Australia, sleeve gastrectomy, gastric bypass and gastric banding are the most commonly performed procedures (Figure 1, Table 4) (see Appendix for a summary of bariatric surgery items listed on the MBS). These procedures aim to reduce food intake by limiting gastric capacity or reducing the amount of food absorbed.¹⁴ Bariatric surgery results in short- and long-term weight loss, improves or resolves comorbidities associated with obesity and increases the quality of life.²⁹⁻³¹

Table 4 Summary of the most common bariatric procedures performed in Australia

	Adjustable gastric band	Sleeve gastrectomy	Gastric bypass
Description	An adjustable silicone band is placed below the gastroesophageal junction. The band gently applies pressure to the region which in turn, suppresses hunger.	Surgical removal of part of the stomach along the greater curvature. The volume of the stomach is reduced by approximately 80 %.	A small stomach pouch is created and joined to the jejunum. This limits the amount of food ingested and absorbed.
MBS utilisation 2017 – 2018	1,170	21,109	3,660*

Abbreviation: MBS = Medicare benefit schedule.

Notes: * = Roux-en-Y gastric bypass.

Number of bariatric procedures in Australia

The number of procedures performed, attributable to a principal diagnosis of obesity, has increased substantially over the past 20 years (Figure 1). Correspondingly, the number of bariatric services claimed on the MBS (and recorded by the Australian Institute of Health and Welfare) has increased. Given approximately 90-95% of bariatric procedures occur in private hospitals, using MBS items to capture usage is appropriate.^{14, 69}

In the 2017-2018 financial year, there were approximately 27,000 bariatric procedures performed in Australia, of which laparoscopic sleeve gastrectomy was the most frequently claimed (Figure 1). Its utilisation has increased from 64 to 80 per cent over the past five years.

PASC noted that the device (OverStitch™ Endoscopic Suturing System) is listed on the Prosthesis List, and that insurers paid benefits for 200 endoscopic sleeve gastroplasty procedures in 2016-17.

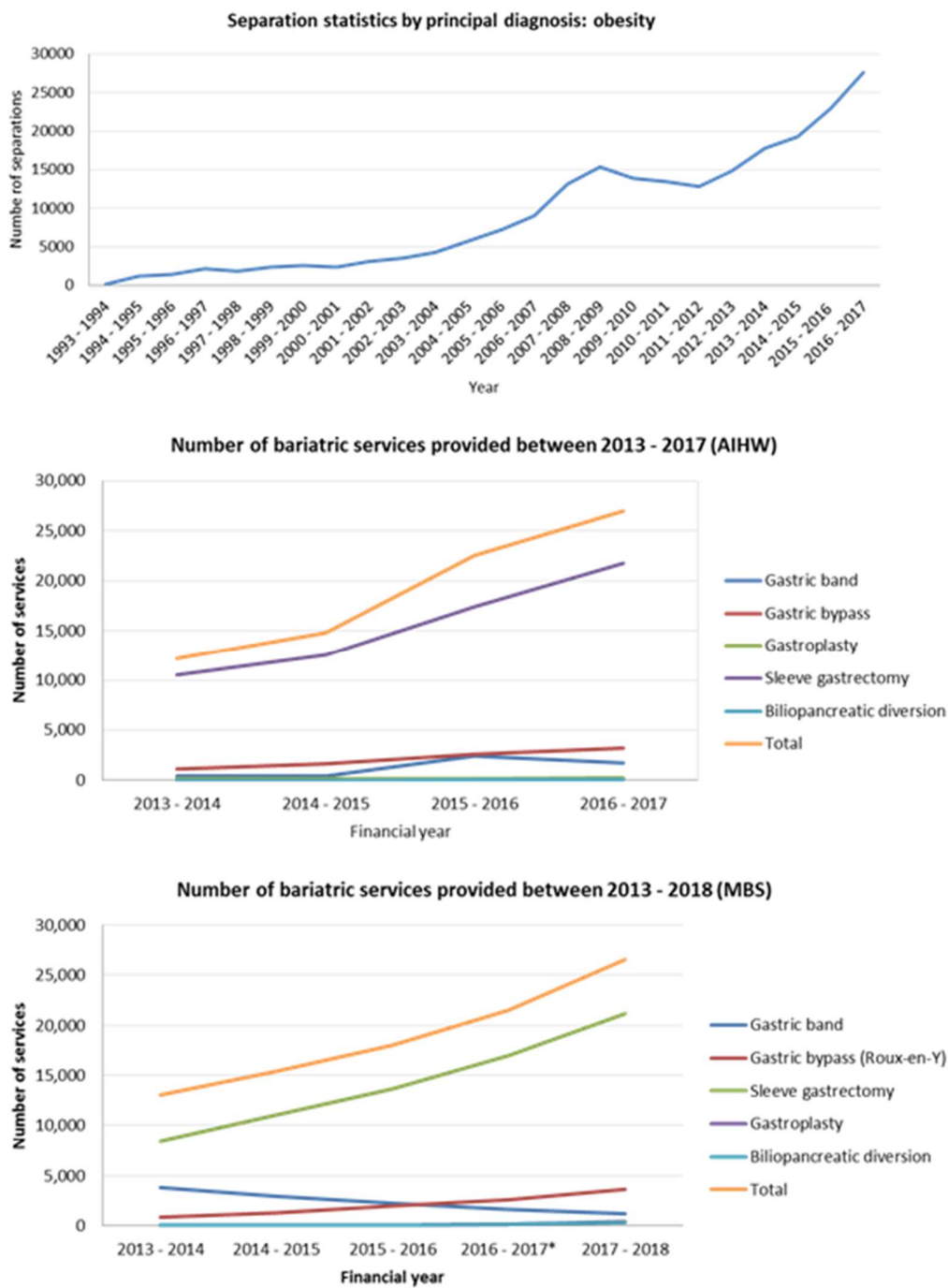


Figure 1 The number of procedures related to obesity in Australia^{16, 70, 71}

Rational

Comparator 1

For patients with a BMI of 30.0 to 34.9 kg/m², who have one or more major medical comorbidities, the proposed comparator is lifestyle modification (behavioural therapy, diet and exercise) with or without pharmacotherapy.

Obese patients with comorbidities are at an increased risk of cardiovascular-related morbidity and mortality.⁴⁻⁷ Diet and exercise are the first options for patients who present with weight-related

comorbidities. Lifestyle interventions are effective in producing short-term weight loss. Long-term; however, patient's exhibit minor weight loss (range 1 to 10kg) or weight regain.^{58, 59} Patients with a BMI of 30.0 to 34.9 kg/m² are currently not recommended for surgery and must continue to cycle through lifestyle treatment options despite being at a heightened risk of morbidity and mortality.

Endoscopic sleeve gastroplasty is intended to be used in adjunct to lifestyle modification. Patients who undergo this procedure will still need to implement lifestyle changes (diet, exercise and behavioural change) with or without pharmacotherapy. Once weight loss stabilises and the patient reaches target weights, the type of diet, exercise and pharmacotherapy will be modified.

Comparator 2

For patients with a BMI of 35.0 to 39.9 kg/m², who have one or more major medical comorbidities, the proposed comparators are laparoscopic adjustable gastric banding and sleeve gastrectomy.

Patients with a BMI of 35.0 to 39.9 kg/m², plus one or more comorbidities, are deemed at an elevated risk of mortality, and consequently are eligible for all bariatric procedures in Australia. Adjustable gastric banding is one of the most studied procedures in terms of safety and effectiveness. Australian trials evaluating adjustable gastric banding (laparoscopic or open approach) have shown an improvement in quality of life and a reduction BMI, excess body weight and the presence of comorbidities five years post-surgery.⁷² Endoscopic sleeve gastroplasty may replace this intervention.

Feedback from a gastroenterologist suggests the appropriate comparators should be comparable with the level of risk and hospital length of stay, not just about weight loss outcomes. ANZMOSS notes, *"Regarding the safety of endoscopic procedures, there is significant "assumption bias" prevalent in the language of many who describe/promote this procedure as being safer than surgery because it is 'non-surgical'. The statement that an endoscopically delivered operation is safer than one delivered by other means is not supported by current data. The risks of a procedure are related to the procedure itself, not the method of delivery."*

Clinical feedback from surgeons suggests the appropriate comparators in this population are gastric bypass or sleeve gastrectomy. Further, feedback suggests that gastric banding is not a good comparator due to a high complication rate and decreasing use worldwide. This is supported by MBS utilisation statistics that show claims for gastric band (Item 31569) have been decreasing since 2013 (Figure 1).

PASC confirmed the appropriate comparators for endoscopic sleeve gastroplasty, in patients with a BMI of 35.0 to 39.9kg/m², who have one or more major medical comorbidities, are sleeve gastrectomy or adjustable gastric banding, plus lifestyle interventions.

Outcomes

The Applicant proposed the following outcomes for all comparators:

Safety

- Adverse event rates (primary adverse events are abdominal pain, nausea, vomiting and device-related adverse events).

- Complications (primary complications are injury to gastrointestinal tract or stomach, bleeding).
- PASC proposed the inclusion of additional safety-related outcomes: mortality; immediate device-related complications; blood loss; length of stay; revision and conversion rates; rates of sutures reopening.

Primary effectiveness

- Total body and excess weight loss. PASC further specified that the weight loss must be durable and sustained (≥ 5 years for health benefit) and should be measured using mean absolute weight loss and mean excess weight loss.
- Impact on metabolic co-morbidities (systolic blood pressure, diabetes, hyperlipidaemia, cardiovascular disease, steatohepatitis).
- Unplanned/planned revision, reversal or conversion rates.
- Operative success.

Secondary effectiveness

- Impact on quality of life.
- Percentage of intact sleeves at follow-up.
- Function of the plicated stomach.
- Nutritional profile (i.e. malnourishment), joint health.
- Number of missed days of work/school/activity.
- Hospitalisation (obesity-related).
- Use of obesity-related medication.

Minimum clinically important differences (MCIDs)

A brief search for MCIDs, correlating health-related outcomes to weight loss, was performed. Two MCIDs correlating quality of life to weight loss were found. No MCIDs were found for sleep apnoea, blood pressure, blood lipids and blood glucose. However, in the absence of MCIDs, clinically meaningful outcomes regarding comorbidities can still be approximated using trial data (Table 5).

Table 5 Summary of the impact of weight loss on comorbidities

Outcome	Target weight loss	Result	Rationale
Blood pressure	2 – 5kg	Reduction in systolic BP by 2 – 5mm/Hg	Reduction in cardiovascular mortality by 12 – 13 per cent ⁷⁴
HbA _{1c}	> 5kg	Reduction in HbA _{1c} by 0.5 – 1 %	1.8 per cent decrease in HbA _{1c} corresponds to a diabetes remission rate of 71 per cent ^{31, 75}
Quality of life	9 – 30 per cent of baseline weight	Increase SF-36 score by 2.83 to 6.81	Notable improvements in physical health and function respectively
HDL/LDL	5 kg/m ²	20 per cent decrease in the prevalence of hyperlipidaemia	Reduction in coronary heart disease by 50 – 64 per cent ^{31, 76, 77}

Abbreviations: BP = blood pressure, HbA_{1c} = glycated haemoglobin, HDL = high-density lipoprotein, LDL = low-density lipoprotein, kg = kilogram, mm/Hg = millimetres of mercury, SF-36 = 36-item short form survey.

The clinical relevance of any literature-reported outcome should be examined during the assessment phase.

Healthcare system

PASC proposed the inclusion of the following cost-effectiveness outcomes: cost, cost per quality-adjusted life year, incremental cost-effectiveness ratio, Australian Government healthcare costs and patient costs.

The Applicant provided the healthcare costs associated with performing endoscopic sleeve gastroplasty in Table 6.

Additional healthcare costs associated with endoscopic sleeve gastroplasty and the comparators may include:

Surgery cost and provision

- The proposed fee of endoscopic sleeve gastroplasty (\$849.55, benefit 75% = \$637.20). Costs pertinent to the procedure include pre-operative assessment, device costs, surgical implantation, anaesthetics and post-operative care. The Applicant has estimated the total cost associated with the proposed service at \$6354.63. Additional costs relating to imaging and revision may need to be considered.
- Training costs for the primary healthcare team (surgeon, assistant, anaesthetist, nurse).
- Costs associated with the post-operative diet for bariatric surgery patients.
- Costs associated with monitoring the compliance of the procedure.

Resources provided in association with bariatric surgery

- Management of weight will require the engagement of general practitioner, dietitian, psychologist and pharmacist and other allied health professionals.
- Patients located in rural regions of Australia will incur greater costs associated with transport, lodging and days missed at work owing to specific sites at which the service is delivered.
- Hospitalisation costs associated with adverse events due to surgery or weight-related comorbidities.

Resources and costs required to deliver comparator

Comparator 1: Lifestyle interventions

- Management of weight will require the engagement of general practitioner, dietitian, psychologist and pharmacist and other allied health professionals.
- As weight is not adequately controlled, weight-related comorbidities may require the additional engagement of healthcare professionals including hospitalisation costs associated with adverse events due to weight-related comorbidities.

Comparator 2: Adjustable gastric banding and sleeve gastrectomy

- Cost to provide the comparator surgery (surgery and associated costs).

- Ambulance transport/emergency department visits/hospitalisation cost associated with adverse events related to the surgery or weight-related comorbidities.
- Costs associated with the post-operative diet for bariatric surgery patients.
- Costs associated with monitoring the compliance of the procedure.
- Management of weight post-operative will require the engagement of general practitioner, dietitian, psychologist and pharmacist and other allied health professionals.

Table 6 Procedures and costs associated with endoscopic sleeve gastroplasty

Resource item	Applicant Unit cost	Source/notes
Pre-operative^a		
Pre-operative assessment for complex medical problems	\$86.85	MBS 17615 [#]
Device costs		
Endoscopic Suturing System	REDACTED	Manufacturer- REDACTED
Tissue Helix	REDACTED	Manufacturer- REDACTED
Overtube	REDACTED	Manufacturer- REDACTED
Polypropylene Suture (8 units)*	REDACTED	Manufacturer- REDACTED
Suture Cinch (8 units)*	REDACTED	Manufacturer- REDACTED
Subtotal (devices)	REDACTED	Calculated
Surgical implantation^a		
Endoscopic Sleeve Gastroplasty	\$849.55	Proposed fee
Assistance	\$209.08	MBS item 51303 for bariatric surgery assistance
Subtotal (surgery)	\$1058.63	Calculated
Anaesthetics^a		
Pre-anaesthesia consultation	\$43.65	MBS 17610 [#]
Initiation of anaesthesia for bariatric surgery in a patient with clinically severe obesity	\$198.00	MBS 20791 [#]
Anaesthesia time units	\$158.40	MBS item 23083 [#] ; Anaesthesia time units; 1:56 hours to 2:00 hours
Subtotal (anaesthetics)	\$400.05	Calculated
Post-operative		
Post-operative gastroscopy	\$177.10	MBS 30473 [#]
Est. total per procedure	\$6354.63	
Overnight private hospital stay ^c	\$394.55 (0.5 days)	NSW government State Insurance Regulatory Authority
Consultant appointment ^c	\$402.30 (3 visits)	MBS 133
Allied health^b		
Dietitian appointment	\$373.50 (6 visits)	MBS 10954
Psychologist appointment	\$62.25 (1 visit)	MBS 10968
Exercise physiology appointment	\$62.25 (1 visit)	MBS 10953
Blood tests	\$16.95 (1 test)	MBS 65070
Renal test	\$84.95 (1 test)	MBS 12527
Est. Allied health costs	\$599.90	
Total costs	\$7,751.38	

Notes: As provided by the Applicant. a = Adjusted as on September 2018; b = adjusted as on January 2019; c = additional costs identified by the Applicant post-2018 PASC.

The Applicant noted the listed healthcare costs are designed to reflect the cost of ESG, compared to lifestyle interventions. The Applicant further stated that the use of allied health professionals in patients undergoing ESG and bariatric surgery is similar. As such, the cost incurred is assumed to be the same.

The Applicant provided an example cost of the procedure and associated care in the private sector (\$15,000). The cost encompasses the pre and post-operative follow-up, the procedure, and support from dietitians, exercise physiologists and psychologists. It is unclear whether this cost is representative of all endoscopic sleeve gastroplasty procedures and/or care plans.

Rationale

Alternative outcomes

The following additional outcomes are suggested, based on a review of the literature:

Safety: mortality. Mortality should be considered as an additional outcome, as the mortality rate following adjustable gastric banding ranges from less than 0.1 to 0.5 per cent.^{78, 79}

The function of the plicated stomach should be considered. Clinical and Applicant feedback suggested the plicated stomach results in a delay in gastric emptying, which may improve satiety.

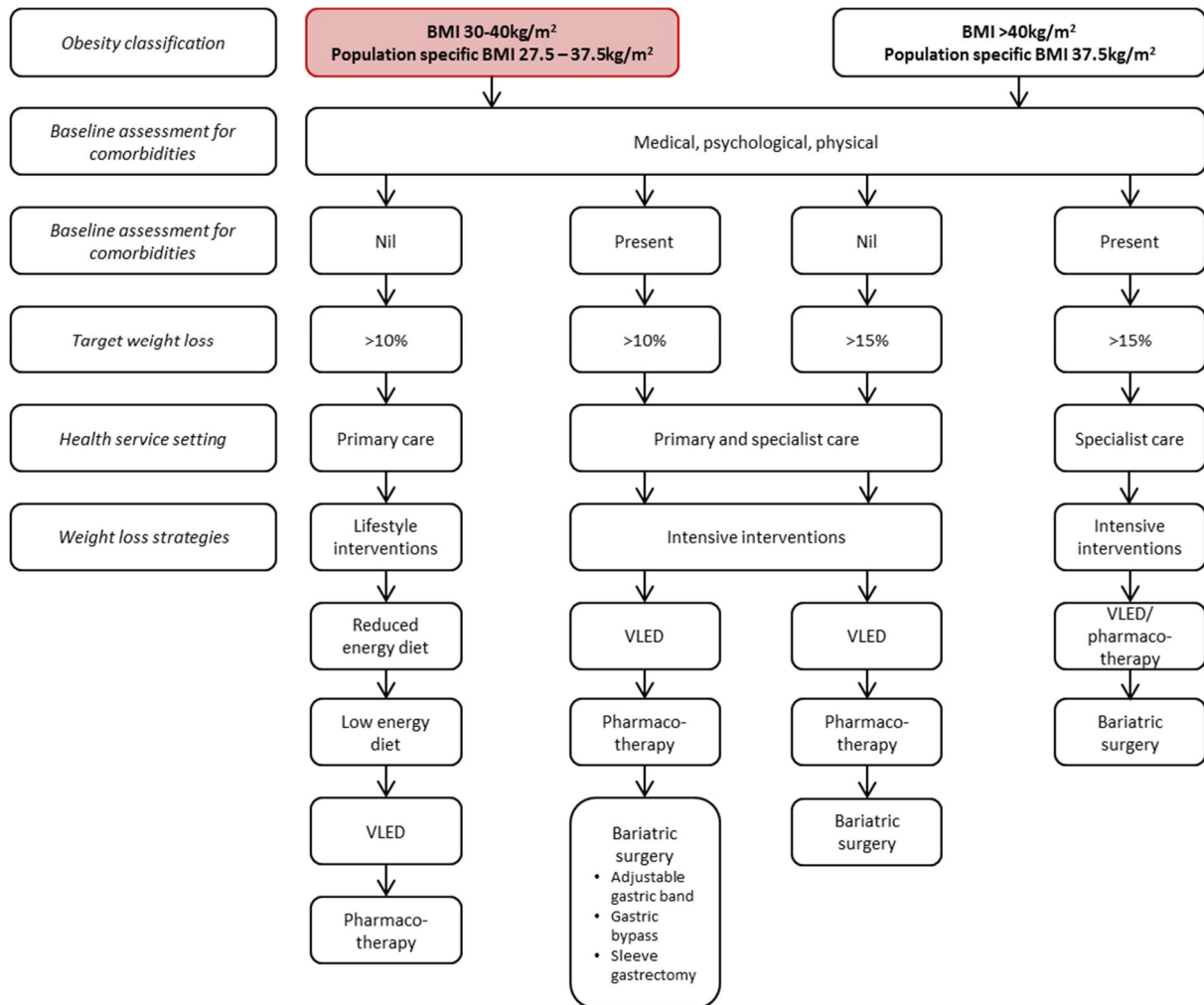
Joint health, number of missed days and hospitalisation are all important indirect measures of quality of life.

Clinical management algorithm: BMI of 30 to 39.9 kg/m², plus one or more comorbidities

The current and proposed clinical management are presented in Figure 2 and Figure 3 respectively. In line with feedback from the Applicant and PASC, the clinical management algorithm is designed to reflect a singular population (patients who have a BMI of 30.0 – 39.9kg/m² plus one or more comorbidities).

Individuals who fail to achieve their weight loss goals continue to cycle through diet, exercise, behavioural modification and pharmacotherapy options. After failing multiple cycles, individuals often give up trying to lose weight. To be eligible for endoscopic sleeve gastroplasty, individuals must have failed these first and second-line treatment options.

Figure 2 The current clinical management algorithm for patients with a BMI between 30 and 40 kg/m² plus one or more comorbidities



Notes:

Comorbidities may include T2DM, cardiovascular disease, hypertension, dyslipidaemia, kidney disease, sleep apnoea or osteoarthritis. Diet may include reduced, low and very low energy diets.

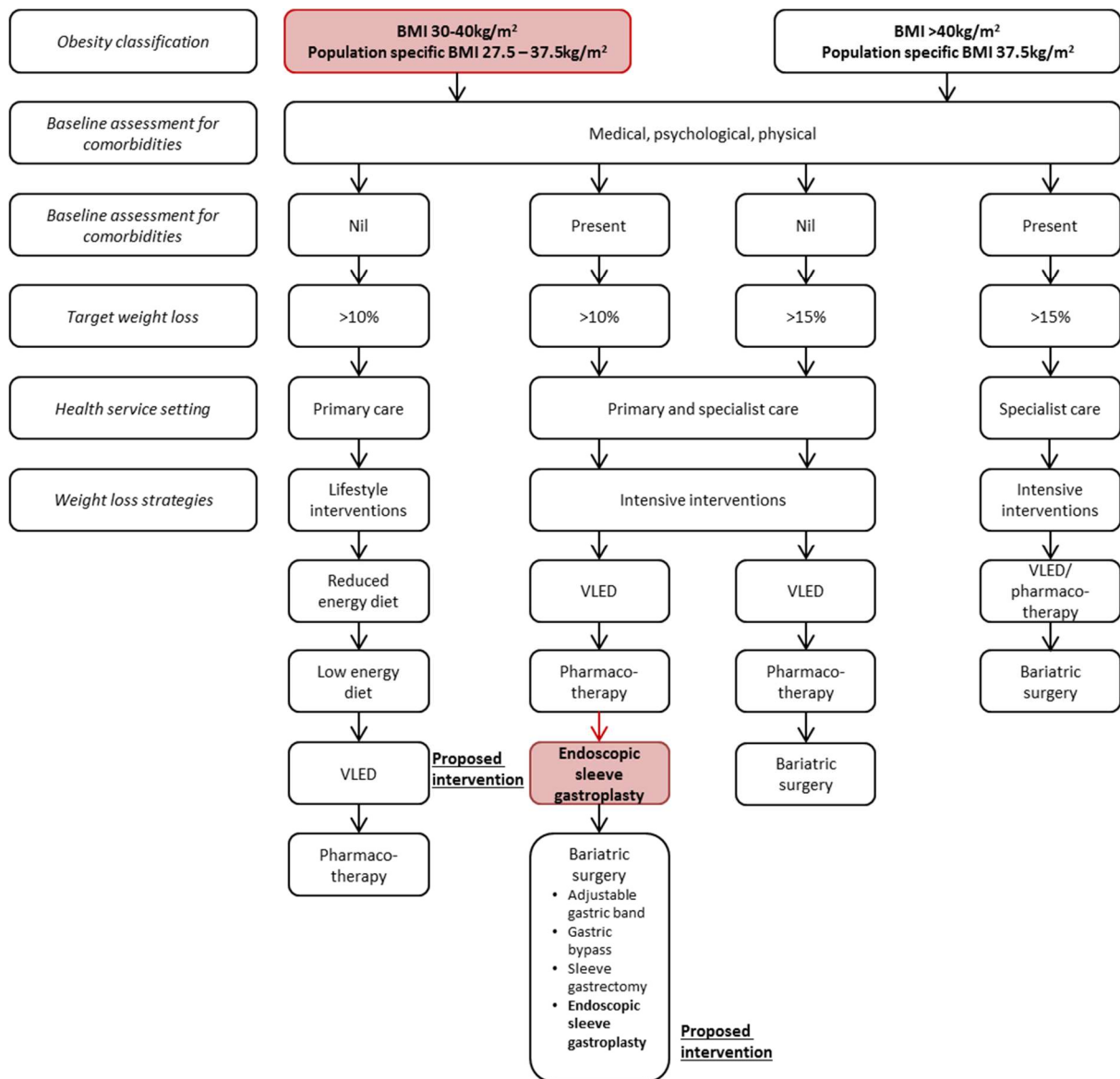
Drugs currently registered in the Therapeutic Goods Administration (TGA) for the treatment of obesity are Phentermine (Duromine® and Metermine®), Orlistat (Xenical®) and Liraglutide (Saxenda®). Out of them, only Orlistat (Xenical®) is supported by PBS.

Dietitians, Clinical Psychologists, General Practitioners, Physiotherapists, Surgeons, Gastroenterologists, Endocrinologists and Nurses play an essential role as a multidisciplinary team.

Highlighted red box = proposed population.

Source: Australian and New Zealand Obesity Society and Australian Diabetes Society (2016).

Figure 3 The proposed clinical management algorithm for patients with a BMI of 30 to 40 kg/m² plus one or more comorbidities



Notes:

Comorbidities may include T2DM, cardiovascular disease, hypertension, dyslipidaemia, kidney disease, sleep apnoea or osteoarthritis. Diet may include reduced, low and very low energy diets.

Drugs currently registered in the TGA for the treatment of obesity are Phentermine (Duromine® and Metermine®), Orlistat (Xenical®) and Liraglutide (Saxenda®). Out of them, only Orlistat (Xenical®) is listed on the PBS.

Dietitians, Clinical Psychologists, General Practitioners, Physiotherapists, Surgeons, Gastroenterologists, Endocrinologists and Nurses play an essential role as a multidisciplinary team.

Highlighted red box = proposed population or intervention.

Source: Australian and New Zealand Obesity Society and Australian Diabetes Society (2016).

Proposed economic evaluation

Comparator 1: lifestyle modification (behavioural therapy, diet and exercise) with or without pharmacotherapy.

The Applicant has stated the following clinical claim: endoscopic sleeve gastroplasty has superior efficacy and inferior safety compared to lifestyle modification. Therefore, cost-effectiveness or a cost-utility analysis would be appropriate.

Comparator 2: adjustable gastric banding and sleeve gastrectomy.

The Applicant has stated the following clinical claim: endoscopic sleeve gastroplasty has non-inferior efficacy and safety compared to adjustable gastric banding or sleeve gastrectomy. Therefore, a cost-minimisation analysis may be appropriate

Proposed item descriptor

The item descriptor proposed in this Application (Table 7) is based on the existing item for placement of an adjustable gastric band.

Restrictions

Patients eligible for the procedure should be restricted to those with a BMI of 30 kg/m² or greater, with the presence of one or more comorbidities, who can understand and adhere to, strict post-operative nutrition.

Table 7 Proposed MBS item

Category 3 – THERAPEUTIC PROCEDURES
XXXXX
Endoscopic Sleeve Gastroplasty for patients 18 years of age or over with a BMI 30.0-39.9 kg/m ² and comorbidities.
Multiple Services Rule
(Anaes.) (Assist.)
Fee: \$849.55 Benefit: 75% = \$637.20
(See para TN.8.29 of explanatory notes for this Category)

Existing explanatory note TN.8.29 may need to be amended to include this new intended population, specifically in relation to ESG. The existing explanatory note specifies “*The term clinically severe obesity generally refers to a patient with a BMI of 40 kg/m² or more, or a patient with a BMI of 35 kg/m² or more with other major medical co-morbidities (such as diabetes, cardiovascular disease, cancer).*”³³ However, the proposed item descriptor for ESG clearly states the BMI range, which is clear for patients, practitioners and the Department of Human Services (who administer MBS billing).

PASC proposed incorporating a timeframe into the MBS item (e.g. 90 minutes or less).

PASC noted an MBS item for procedural reversal was not required.

However, if it is identified during the assessment phase that an item for revision or repair is warranted, a proposed descriptor is in Table 8.

Table 8 Proposed MBS item descriptor for repair or revision of endoscopic sleeve gastroplasty

Category 3 – THERAPEUTIC PROCEDURES
xxxx
Surgical repair or revision of endoscopic sleeve gastroplasty.
Multiple Services Rule
(Anaes.) (Assist.)
Fee: \$xxxx Benefit: 75% = \$xxx
(See para TN.8.30 of explanatory notes for this Category)

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Appendix A

Table 9 MBS item descriptors and their usage pertaining to bariatric surgery

Procedure	Description	MBS item number	Claims 2017 - 2018
Anaesthesia	Initiation of the management of anaesthesia for bariatric surgery in a patient with clinically severe obesity	20791	27,700
Bariatric surgery			
Adjustable gastric band	Adjustable gastric band, placement of, with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity	31569	1,170
Roux-en-Y gastric bypass	Gastric bypass by Roux-en-Y including associated anastomoses, with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity not being associated with a service to which item 30515 applies	31572	3,660
Sleeve gastrectomy (laparoscopic and open?)	Sleeve gastrectomy, with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity	31575	21,109
Gastroplasty	Gastroplasty (excluding by gastric plication), with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity	31578	354
Biliopancreatic diversion	Gastric bypass by biliopancreatic diversion with or without duodenal switch including gastric resection and anastomoses, with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity	31581	272
Modification, revision or removal			
Reversal of bariatric procedure	Surgical reversal of adjustable gastric banding (removal or replacement of gastric band), gastric bypass, gastroplasty (excluding by gastric plication) or biliopancreatic diversion being services to which items 31569 to 31581 apply	31584	3,777
Adjustment to gastric band	Adjustment of gastric band as an independent procedure including any associated consultation	31887	59,079
	Adjustment of gastric band reservoir, repair, revision or replacement of	31590	387