Australian Government

Department of Health

Application 1555.1

Endoscopic sleeve gastroplasty for the treatment of patients with Class I and II obesity who have failed first line (lifestyle modification) and second line (pharmacotherapy) treatments

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):
Corporation name: Apollo Endosurgery Australia Pty Ltd
ABN: 20 169 23 845
Business trading name:

Primary contact name: REDACTED

Primary contact numbers
Business **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☒ Yes
☐ No

(b) If yes, are you listed on the Register of Lobbyists?

☒ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Endoscopic sleeve gastroplasty for the treatment of patients with Class I and II obesity who have failed first line (lifestyle modification) and second line (pharmacotherapy) treatments.

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Overweight and obesity refers to excess body weight. Obesity can be measured using the body mass index (BMI). Class I obesity refers to patients who have a body mass index (BMI) 30 ≤ 35kg/m². Class II obesity refers to patients who have a BMI 35 ≥ 40 kg/m². Obesity is associated with an increased risk of variety of significant comorbidities which may include diabetes, cardiovascular disease and liver disease which may have a significant impact on quality of life.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Endoscopic sleeve gastroplasty (ESG) is a bariatric surgical procedure. ESG is an incisionless transoral endoscopic procedure that uses a full-thickness endoscopic suturing system to reduce the stomach volume into a tubular gastric cavity[1]. The gastroplasty is created using an endoscopic suturing device fitted to an endoscope. The ESG procedure will shorten the length of a stomach by up to 50% and reduce its volume by 75%[2]. 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.

(a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☐ Amendment to existing MBS item(s)
☒ New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

[1] Endoscopic sleeve gastroplasty for the treatment of obesity.*Lopez-Nava G, Galvão MP, da Bautista-Castaño I, Jimenez A, De Grado T, Fernandez-Corbelle JP. Endoscopy. 2015 May; 47(5):449-52.*

[2] The BMI Clinic. https://bmiclinic.com.au/endoscopic-sleeve-gastroplasty/

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

N/A

6. What is the type of service:

☒ Therapeutic medical service
☐ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

7. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☐ Assists in establishing a diagnosis in symptomatic patients
iii. ☐ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

8. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ No

9. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

N/A

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

N/A

10. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☒ Yes
☐ No

(b) If yes, please provide the following information (where relevant):

Billing code(s): ER279
Trade name of prostheses: OverStitchTM Endoscopic Suturing System
Clinical name of prostheses: Endoscopic Suturing System including needle driver, Anchor exchange and tissue helix device.

Billing code(s): ER280
Trade name of prostheses: OverStitchTM Endoscopic Suturing System – 2.0 Suture
Clinical name of prostheses: Endoscopic polyproprylene suture with cinch

Other device components delivered as part of the service:

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

N/A

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☒ No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

11. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables:

- Examination gloves
- Mouth guard
- Gel lubricant

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

12. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Medical Device Included Class IIa
Manufacturer's name: Apollo Endosurgery
Sponsor's name: Emergo Australia

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A

13. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☒ Yes (if yes, please provide details below)
☐ No

ARTG number:	Registered item	TGA approved indication(s)	TGA approved purpose(s), if applicable:
237774	Endoscopic suturing unit, single-use	N/A	The device is intended for endoscopic placement of sutures and approximation of soft tissue
237773	Endotherapy forceps, grasping, flexible	N/A	A device used in combination with a dedicated endoscope during endotherapy. It is used for mechanical work, e.g. grasping tissue or foreign bodies. It functions without electricity, including e.g. high frequency, electromagnetic, ultrasonic or laser energy. It is disposable.
245894	Suture, polypropylene monofilament	N/A	The DemeTECH non-absorbable polypropylene suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures. Product is intended for use over 30 days. The product is not intended to be used on the heart or with the central circulatory and central nervous system.
236906	Suture retention device	N/A	The OverStitch Suture Cinch is intended to secure suture(s). The OverStitch Suture Cinch is part of the OverStitch Endoscopic Suturing System (ESS), which is intended for endoscopic placement of suture(s) and approximation of soft tissue.
236427	Endotherapy overtube, single-use.	N/A	The overtube is intended to be used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the lower or upper gastrointestinal tract. Single use.

14. **If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

    N/A

15. **If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

    N/A

PART 4 – SUMMARY OF EVIDENCE

16. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design	**Title of journal article or research project**	**Short description of research**	**Website link to journal article or research**	**Date of publication**
1.	Retrospective, multi-centre study	Badurdeen D et al ***'Endoscopic sleeve gastroplasty plus liraglutide versus endoscopic sleeve gastroplasty alone for weight loss'*** Gastrointest Endosc. 202 June; 93(6):1316-1324	This study aimed to evaluate the efficacy of ESG and liraglutide (ESG-L) compared to ESG alone. Not randomised. Patient population BMI > 27	https://pubmed.ncbi.nlm.nih.gov/33075366/	June, 2021
2.	Prospective, single-centre review	Hajifathalian K et al ***'Improvement in Insulin Resistance and Estimated Hepatic Steatosis and Fibrosis after Endoscopic Sleeve Gastroplasty'*** Gastro Endosc. 2021 May:93 (5):1110-1118	An evaluation of the change in insulin resistance (IR) and estimated hepatic steatosis and fibrosis after ESG. BMI >30 2 year follow-up	https://pubmed.ncbi.nlm.nih.gov/32861753/	May, 2021

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
3.	A prospective cohort study.	Sharaiha R Z et al ***'Five-year outcomes of endoscopic sleeve gastroplasty for the treatment of obesity'*** Clin Gastroenterol Hepatol 2021 May:19(5): 1051-1057	A study of the long-term safety and efficacy of ESG for the treatment of obesity. The primary outcome measure was weight loss at 5 years after the procedure (%TBWL). 216 patients with a mean BMI of 39 underwent ESG. At 5 years, the mean TBWL was 15.9%. There was a rate of 1.3% moderate adverse events (AEs), without any severe or fatal AEs. Results suggest that ESG is safe and effective.	https://pubmed.ncbi.nlm.nih.gov/33011292/	May, 2021
4	Retrospective patient review	Lopez-Naza G et al ***Endoscopic Sleeve Gastroplasty (ESG), Laparoscopic Sleeve Gastroplasty (LSG), and Laparoscopic Greater Curve Plication (LGCP): Do They Differ at 2-years?*** Endoscopy 2021 Mar;53(3):235-243	A study comparing the effectiveness and safety of ESG to laparoscopic sleeve gastrectomy (LSG) and laparoscopic greater curve plication (LGCP). Mean BMI: ESG: 39.4 (5.4) LSG: 40.1 (3.7) LGCP: 40.2 (3)	https://pubmed.ncbi.nlm.nih.gov/32698234/	March, 2021

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
5	Systematic review and meta-analysis	Marincola G et al ***'Laparoscopic sleeve gastrectomy versus endoscopic sleeve gastroplasty: a systematic review and meta-analysis'*** Endosc Int Open. 2021 Jan; 9(1):E87-E95	Systematic review comparing the efficacy and safety of the surgical and endoscopic bariatric approaches to understand if these two interventions are interchangeable for the same obese population. BMI 30-40	https://pubmed.ncbi.nlm.nih.gov/33403240/	Jan, 2021
6.	Systematic review	Due-Petersson R Et al ***'Effect and safety of endoscopic sleeve gastroplasty for treating obesity – a systematic review'*** Dan Med J 2020 Oct 16; 67(11)	A systematic review evaluating the effectiveness and safety of ESG for the treatment of obesity. Mean BMI > 34.9 Median follow-up was 6 months	https://pubmed.ncbi.nlm.nih.gov/33215606/	Oct, 2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7.	Prospective, multicentre	Neto MG et al ***'Safety and short-term effectiveness of endoscopic sleeve gastroplasty using overstitch: preliminary report from a multicentre study'*** Surg Endosc. 2020 Oct;34(10):4388-4394	A prospective study of ESG in four bariatric centres in Brazil. The aim of the study was to demonstrate the short-term outcome after primary ESG and to compare the effectiveness of weight loss between Class I and Class II obesity patients. ESG performed using Overstitch. Not randomised. Included patients with BMI 30-39.9	https://pubmed.ncbi.nlm.nih.gov/31624939/	Oct, 2020
8.	Systematic review and meta-analysis	Jalal MA et al ***'Systematic Review and Meta-Analysis of Endoscopic Sleeve Gastroplasty with Comparison to Laparoscopic Sleeve Gastrectomy'*** Obes Surg. 2020 Jul;30 (7):2754-2762	Review of the safety and weight loss outcomes of ESG compared to LSG. BMI range 33±5 - 47±8	https://pubmed.ncbi.nlm.nih.gov/32304011/	July, 2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
9.	Systematic review and meta-analysis	Hedjoudje A et al '***Efficacy and Safety of Endoscopic Sleeve Gastroplasty: a Systematic Review and Meta-Analysis'*** Clin Gastroenterol Hepatol. 2020 May;18(5):1043-1053	A systematic review and meta-analysis to evaluate the efficacy and safety of ESG in adults. Investigated outcomes included total body weight loss (TBWL), body mass index reduction, percent excess weight loss (EWL), adverse events.	https://pubmed.ncbi.nlm.nih.gov/31442601/	May, 2020
10.	Systematic review and meta-analysis	De Miranda Neto AA et al ***'Efficacy and Safety of Endoscopic Sleeve Gastroplasty at Mid Term in the Management of Overweight and Obese Patients: a Systematic Review and Meta-Analysis'*** Obes Surg. 2020 May;30(5):1972-1987	A systematic review and meta-analysis to update on the efficacy and safety of ESG.	https://pubmed.ncbi.nlm.nih.gov/32107706/	May, 2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
11.	Quality of Life (QoL) study	Fiorillo Cet al ***'6-Month Gastrointestinal Quality of Life (QoL) Results after Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: A Propensity Score Analysis'*** Obes Surg. 2020 May;30(5):1944-1951	Compared QoL after ESG and LSG using a propensity score analysis. QoL was evaluated by means of Gastrointestinal Quality of Life Index (GIQLI) questionnaire before and 6 months after the procedure. BMI > 40	https://pubmed.ncbi.nlm.nih.gov/31965488/	May, 2020
12.	Systematic Review and Meta-Analysis	Mohan B P et al ***'Outcomes of endoscopic sleeve gastroplasty; how does it compare to laparoscopic sleeve gastrectomy? A systematic review and meta-analysis'*** Endosc Int Open 2020 Apr; 8(4) E558-E565	A comprehensive literature search and meta-analysis to evaluate the efficacy and safety of ESG in patients with moderate to severe obesity. Compared 12-month outcomes with ESG to those of LSG.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7089787/	Apr, 2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
13.	Systematic review and meta-analysis	Singh S et al ***'Safety and Efficacy of Endoscopic Sleeve Gastroplasty Worldwide for Treatment of Obesity: A Systematic Review and Meta-analysis'*** Surg Obes Relat Dis 2020 Feb: 16(2):340-351	A comprehensive systematic review and meta-analysis of studies to evaluate the efficacy, safety, and procedural technique of ESG. No controlled or randomised studies. Mean BMI before ESG 35.8	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7009311/	Feb 2020
14.	Retrospective, Randomised, Multi-centre analysis of prospectively collected data.	Barrichello S et al ***'Endoscopic sleeve gastroplasty in the management of overweight and obesity: an international multicentre study'*** Gastrointest Endosc 2019 Nov:90(5):770-780	Multicentre analysis of prospectively collected data from 7 centres including patients with overweight and obesity who underwent ESG. No comparator. Mean BMI 34.11.	https://pubmed.ncbi.nlm.nih.gov/31228432/	Nov 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
15.	Prospectively collected and retrospectively analysed	Lopez-Nava G et al ***'Bariatric endoscopy procedure type or follow-up: What predicted success at 1 year in 962 obese patients?'*** Endoscop Inter Open 2019;07:E1691-E1698	The study compared 1 year weight loss outcomes of four different endoscopic bariatric therapies (EBTs) at a single centre with a standardized multi-disciplinary team (MDT) follow up. ESG N = 247 Mean BMI = 38.3 BMI > 40 = 36.4% Apollo ESG demonstrated significantly higher mean TBWL (19.5kg), %TBWL (17.4%).	https://www.thieme-connect.com/products/ejournals/pdf/10.1055/a-1007-1769.pdf	Dec, 2019
16.	Systematic review and meta-analysis	Khan Z et al ***'Efficacy of Endoscopic Interventions for the Management of Obesity: a Meta-analysis to Compare Endoscopic Sleeve Gastroplasty, Aspire Assist, and Primary Obesity Surgery Endolumenal'*** Obes Surg 2019 Jul:29(7) 2287-2298	A meta-analysis of 12 studies of ESG, Aspire, and POSE. Main outcomes evaluated were excess weight loss and total body weight loss. ESG and AA were found to have no difference in EWL% and ESG was found to have a significant amount more sustained weight loss than POSE.	https://www.giejournal.org/article/S0016-5107(18)30328-6/fulltext	June 2018

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
17.	Single centre Retrospective analysis	Morales ***'Modified endoscopic gastroplasty for the treatment of obesity'.*** Surgical Endoscopy 32, 3936-3942 (2018)	A retrospective study of 148 patients who underwent ESG. %TWL was 17.53 in 12 months and 18.5 in 18 months indicating durability of the procedure.	https://link.springer.com/article/10.1007%2Fs00464-018-6133-0	February 2018
18.	Multi-centre, retrospective,	Lopez-Nava et al ***'Endoscopic Sleeve Gastroplasty for Obesity: a Multicenter Study of 248 Patients with 24 Months Follow-Up'*** Obes Surg DOI 10.1007/s11695-017-2693-7	Patients who underwent ESG between Jan 2013-Dec 2015 in 3 centres were retrospectively analysed. Procedures performed using the Apollo OverStitch device. N= 248 Baseline BMI 37.8 6 months %TBWL: 15.2% 12 months %TBWL: 18.6% 24 months % of patients achieving ≥ 10% TBWL was 84.2%	https://www.nwls.com.au/pdf/endoscopic-sleeve-gastroplasty.pdf	April 2017

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
19.	Single-centre prospective study	Sharaiha et al. ***'Endoscopic Sleeve Gastroplsty Significantly rEduces Body Mass Index and Metabolic Complications in Obese Patients'*** Clinical Gastroenterology and Hepatology 2017, Apr; 15(4):504-510	ESG was performed on 91 patients. All patients had a BMI greater than 30 kg/m2 and had failed non-invasive weight loss measures, or had a BMI greater than 40 kg/m2 and were not considered as surgical candidates or refused surgery. At 12 months post-ESG, patients had lost 17.6% total body weight and showed statistically significant reductions in haemoglobin A1c, systolic blood pressure, waist circumference, and serum triglycerides.	https://pubmed.ncbi.nlm.nih.gov/28017845/	April 2017
20.	Single-centre prospective study	Dayyeh et al. ***'Endosopic Sleeve Gastroplasty Alters Gastric Physiology and Induces Loss of Body Weight in Obese Individuals'*** Clinical Gastroenterology and Hepatology 2017; 15:37-43*'*	Prospective study of patients undergoing ESG between Sep 2012-March 2015 using OverStitch. N= 25 BMI 30-40	https://www.cghjournal.org/action/showPdf?pii=S1542-3565%2815%2901714-0	January 2017

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
21.	Prospective, single-centre study	Lopez-Nava et al ***'Endoscopic Sleeve Gastroplasty for Obesity Treatment: Two Years of Experience'*** ABCD Arq Bras Cir Dig 2017;30(10:18-20	A prospective study of 154 patients to evaluate ESG for effectiveness, safety, weight evolution, and two-year outcomes. N= 154 Baseline BMI: 38.3 28 completed the 24-month assessment: mean BMI at 24 months 30.8, mean TBWL 21.3kg No major adverse events	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5424680/pdf/0102-6720-abcd-30-01-00018.pdf	2017
22.	Single-centre prospective study	Lopez-Nava et al ***'Endoscopic sleeve gastroplasty with 1-year follow-up: factors predictive of success'*** Endoscopy International Open 2016; 04: E222–E227	25 patients underwent flexible endoscopic suturing for endoluminal gastric volume reduction. Baseline Mean BMI: 38.5 1 year follow-up: BMI loss: 7.3 Mean %TBWL: 18.7	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4751018/	February 2016
23.	Single-centre prospective study	Lopez-Nava et al ***Endoscopic Sleeve Gastroplasty: How I Do It?*** *OBES SURG* **25,** 1534–1538	50 patients treated with ESG and details given regarding procedural time as well as post-procedure outpatient care. At one year, 100% of sleeves were intact and patients experienced mean %TBWL of 19.0. there was a reduction in BMI from 37.7 to 30.9.	https://link.springer.com/article/10.1007%2Fs11695-015-1714-7#citeas	August 2015

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
24.	Single-centre prospective study	Lopez-Nava et al ***'Endoscopic Sleeve Gastroplasty for the Treatment of Obesity'*** Endoscopy 2015; 47(05): 449-452	20 obese patients were treated with endoscopic sleeve gastroplasty to reduce gastric volume endoluminally. Patient outcomes recorded at baseline, 1, 3 and 6 months. There were no adverse events and all patients were discharged in less than 24 hours. At 6 months, mean body weight was reduced by 17.8%.	https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0034-1390766	1 May 2015
25.	Single-centre prospective study	Sharaiha et al ***'Initial Experience with Endoscopic Sleeve Gastroplasty: Technical Success and Reproducibility in the Bariatric Population'*** Endoscopy 2015; 47(02): 164-166	10 patients were treated for obesity with ESG. At 6 months post-procedure, excess weight loss of 30% was observed and mean loss was recorded as 33 kg.	https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0034-1390773	2 September 2014

17. **Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

Type of study design	Title of research	Description of research	Website link to research	Date of available results
Single-centre prospective randomised case study	Safety, Tolerability, and Sustained Weight Loss of Endoscopic Sleeve Gastroplasty with Diet Modification and Exercise **NCT03206905**	On-going clinical trial enrolling 34 participants to compare the effect of ESG with diet and exercise, to diet and exercise alone, to see which is better in weight loss reduction. A comparison of resolution or improvements in comorbidities will also be studied between the two cohorts. Patients are currently being recruited for this trial.	https://clinicaltrials.gov/ct2/show/NCT03206905	Study start date July 2017 Estimated completion date December 2022 Last update November 2020 **No further results posted as of 14th July 2021**
Randomised, multi-centre, prospective study	Efficacy and Results of Endoscopic Gastroplasty Using Overstitch in Patients with Class I and II Obesity **NCT03493620**	The primary objective of this research is to make a gastric tube similar to that obtained by surgical gastroplication but using endoscopic intragastric sutures. The secondary objective will be to correlate demographic, endoscopic and laboratory data with the outcomes. Primary outcome measure: • Weight loss (measured over 2 years) Secondary outcome measure: • Weight maintenance (over 2 years) • Surgical related complications (over 2 years) • Comorbidities (over. 2 years)	https://clinicaltrials.gov/ct2/show/study/NCT03493620	Expected date was August 2020. Last update made in May, 2019. **No further results posted as of 14th July 1st 2021**

Type of study design	Title of research	Description of research	Website link to research	Date of available results
		Patients included (N=60) • > 18 years • BMI > 30 and < 36 with or without comorbidities • BMI > 36 and < 40 without comorbidities		

Type of study design	Title of research	Description of research	Website link to research	Date of available results
Randomised, multi-centre, interventional, crossover study	Multicentre ESG Trial **(MERIT Trial)** **NCT03406975**	The investigators are completing this study to compare how effective ESG is for achieving long-term weight loss when compared to lifestyle modification only, as well as to evaluate the long-term safety and durability of the procedure and its impact on quality of life. Primary outcome measure: • % EWL at 12 months from randomisation (over 12 months) Secondary outcome measures: • Change in hypertension in treatment group compared to control (lifestyle) only (over 24 months) Other outcome measures: • Change in type II diabetes in the treatment group compared to control (lifestyle) only (over 24 months) Patients included (N = 200) • 21-65 years • BMI ≥30 and ≤40 kg/m^2 • A minimum of 50 patients with hypertension and 50 patients with type II diabetes will be included. The cohort of 200 will have 3 groups: obesity, obesity HTH and obesity DM. This combined group will be randomised. No more than 50 patients without comorbidities will be enrolled in the trial. • The study does not distinguish between Class I and Class II obesity	https://clinicaltrials.gov/ct2/show/study/NCT03406975	Last update posted December 19, 2020. Estimated completion date December 2021. **No results posted as of 14th July 2021**

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

18. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Australian & New Zealand Metabolic and Obesity Surgery Society (ANZMOSS).

19. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    Australian & New Zealand Metabolic and Obesity Surgery Society (ANZMOSS)

20. **List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    None could be identified.

21. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    None

22. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**.

    Name of expert 2: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

23. Define the medical condition, including providing information on the natural history of the condition and a high-level summary of associated burden of disease in terms of both morbidity and mortality:

Overweight and obesity are defined by the World Health Organisation as abnormal or excessive fat accumulation that may impair health[3]. Obesity is defined by a body mass index (BMI) over 30kg/m². Class I Obesity is defined as a BMI of 30.0-35kg/m². Class II is defined as 35.0-40 kg/m ². In 2017 31% of Australians were considered obese. Of these 21.7% of males and 17.7% of females had Class I obesity, 7.6% of males and 7.8% of females had Class II obesity[4].

Obesity is associated with an increased prevalence of comorbidities including but not limited to arthritis, diabetes mellitus (DM) and cardiovascular conditions. Figure 1 demonstrates the difference in prevalence between people of normal weight and those people who suffer from obesity.

Figure 1

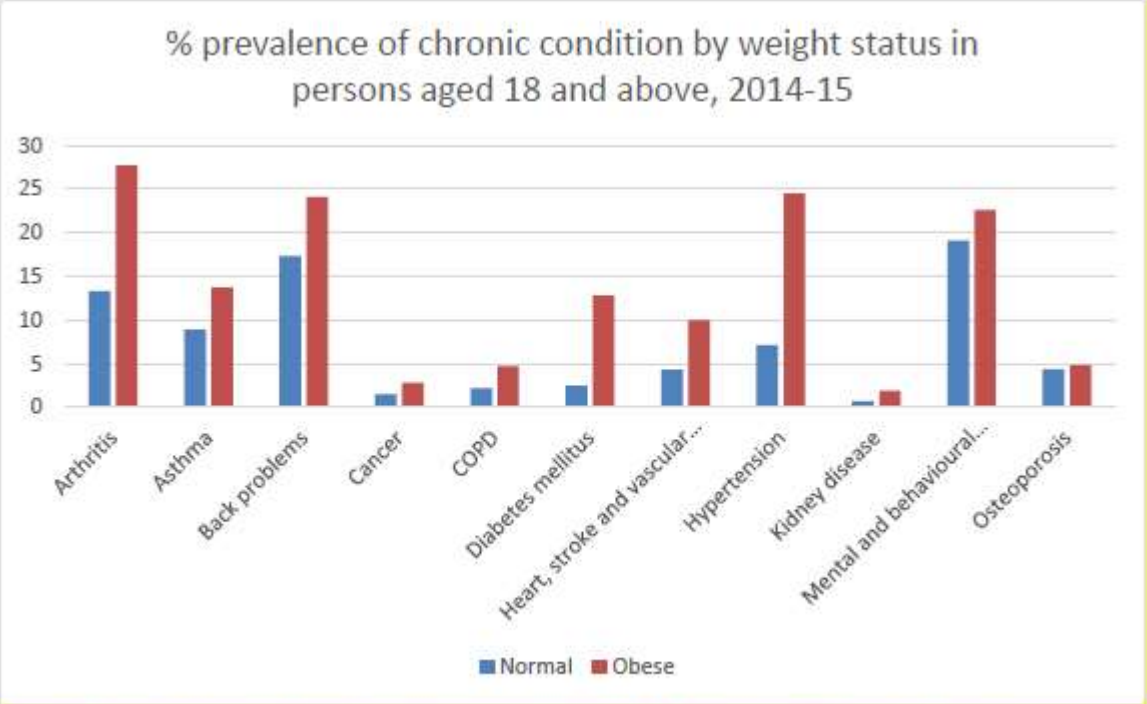

Figure 1: Source: ABS (Australian Bureau of Statistics) 2015. National Health Survey: first results, 2014–15. ABS cat no. 4364.0.55.001. Canberra: ABS

Overweight and obesity were identified as the leading contributor to non-fatal disease burden and second only to tobacco in overall burden[5]. This includes 54% of the type 2 diabetes burden, 44% of the

[3] World Health Organisation Obesity and Overweight Fact Sheet June 9 2021, https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight

[4] AIHW Overweight and Obesity: an interactive insight 27 Nov 2020, https://www.aihw.gov.au/reports/overweight-obesity/overweight-and-obesity-an-interactive-insight/contents/what-is-overweight-and-obesity#BMI

[5] AIHW Australian Burden of Disease Study, 2015

osteoarthritis burden, 40% of chronic kidney disease burden, 25% of coronary heart disease burden, 24% of the asthma burden and 21% of the stroke burden[6]. Increasing BMI is associated with an increasing hazard ration (HR) for all-cause mortality[7].

The economic cost to Australia was estimated to be $5.4 billion in direct health costs and $6.4 billion in indirect costs, which do not include quality of life impacts.[8]

24. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Patients 18 years of age or over who have Class I or Class II obesity (BMI between 30 and 40 kg/m²) who have failed first- and second-line weight loss therapies. Conventional therapies include serious efforts to reduce weight though diet modification and exercise, or pharmacology interventions. If these measures consistently fail, then referral to a bariatric surgeon or interventional gastroenterologist may be considered. ESG is intended for patients for whom laparoscopic or open surgery is unpalatable due to its invasive nature and the comparatively long hospital stay or who would otherwise not consider bariatric surgery. Patients may be contraindicated for ESG due to 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.[9]

25. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

There are two main treatment options, and the choice should be guided by the patient's history of any previous weight loss efforts and the response to those efforts. These are:

1. A Very Low Energy Diet (VLED) is an initial option for individuals who have not tried this previously and are willing to use meal replacements. If effective in achieving adequate weight loss, the meal replacements can be reduced, and the diet can be replaced with a weight maintenance diet. If weight is regained the VLED can be reintroduced.
2. Pharmacotherapy can be considered in individuals who do not have an adequate response to VLED or who regain weight once the VLED is relaxed.

Physiological reasons behind failure to achieve and maintain weight loss are complex and not fully understood[10]. Therefore, surgical intervention may be a viable option for some patients.

Please see Figure 2 which demonstrates the clinical management prior to eligibility for surgery.

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[6] *The Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015*. Australian Institute of Health and Welfare, June 2019 . https://www.aihw.gov.au/reports-data/health-conditions-disability-deaths/burden-of-disease/overview

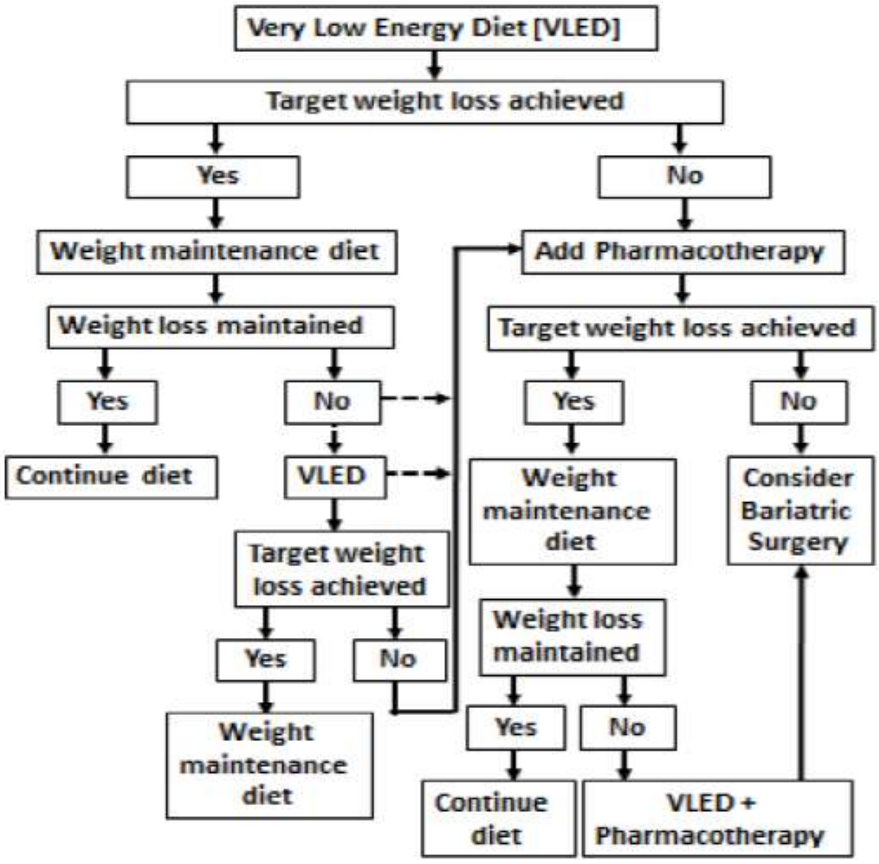
[7] di Angelantonio E, Bhupathiraju SN, Wormser D, Gao P, Kaptoge S, de Gonzalez AB et al '*Body-mass index and all-cause mortality :individual-participant-data meta-analysis of 239 prospective studies in four continents'* The Lancet, 2016, 388:766-86

[8] The Obesity Collective *'Weighing in: 'Australia's growing obesity epidemic'* 2019.

[9] Hill C et al '*Endoscopic sleeve gastroplasty: the learning curve'* Endosc Int Open. 2017 Sep; 5(9):E900-E904

[10] Ghanemi A et al *Broken Energy Homeostasis and Obesity Pathogenesis: The Surrounding Concepts'* J Clin Med. 2018 Nov; 7(11):453

Figure 2: Clinical Pathway



Source: The Australian Obesity Management Algorithm – Australian and New Zealand Obesity Society. *https://www.anzos.com/publications*

PART 6b – INFORMATION ABOUT THE INTERVENTION

26. Describe the key components and clinical steps involved in delivering the proposed medical service:

Once determined to be an appropriate candidate for ESG by a bariatric surgeon or gastroenterologist, the patient is prescribed a protein pump inhibitor (PPI) for one week prior to the procedure.

The procedure is performed under general anaesthesia with the patient placed in the left lateral position. An overtube is placed with a diagnostic scope during the initial evaluation of the pylorus and to obtain gastroesophageal (GE) junction measurements. Argon plasma coagulation (APC) may be used to mark the anterior wall and posterior wall of the greater curvature. 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 cinching 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 are taken to avoid the creation of gastric pockets[11]. A tissue grasper or helix may be

[11] Hill, C, et al. "*Endoscopic Sleeve Gastroplasty: The Learning Curve*". 13 September 2017. Endoscopy International Open. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5597932/

used to maximise the amount of tissue sutured in each bite. The numbers 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 retroflex uncomfortably [8]. Following 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 to check for completeness of the sleeve. Upon completion, stomach volume is reduced by up to 75%[12]

Post-procedure, ESG patients are instructed to follow a standard post-bariatric procedure diet, including a transition from liquids to pureed foods then to solids foods over the course of several weeks. Medications are also prescribed to manage pain, nausea, and heartburn.

27. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

OverStitch Endoscopic Suturing System is a trademarked device involving the placement of full-thickness sutures using an endoscopic curved needle arm and anchor exchange device.

28. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Endoscopic Sleeve Gastrectomy is a new approach in that it is a transoral, incisionless and less invasive procedure than other bariatric surgeries such as sleeve gastrectomy or laparoscopic adjustable gastric banding. It may be a more desirable alternative for some patients who may be unwilling or unsuitable for open or laparoscopic procedures.

29. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

ESG is intended to be performed once in a lifetime. Similarly, to other bariatric interventions, it is possible that some patients may require a revision procedure. Bariatric surgery is likely to be more available through the private hospital system with resource constraints limiting access in the public sector. It is also likely that the procedure will be more accessible in the urban areas where there is a higher concentration of specialists who are able to perform the procedure.

30. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

Patients will require the services of an anaesthetist. These services are detailed below.

31. If applicable, advise which health professionals will primarily deliver the proposed service:

- Gastroenterologists who are qualified in endoscopic interventions
- General, bariatric or upper GI surgeons

32. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

The service cannot be delegated.

33. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

General Practitioners or other appropriate specialist medical practitioners may refer for the service.

34. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

[12] The BMI Clinic. https://bmiclinic.com.au/endoscopic-sleeve-gastroplasty/

General, bariatric or upper GI surgeons who have fulfilled the requirements to become a Fellow of the Royal Australasian College of Physicians, General Surgery specialty or who are otherwise qualified to practice in Australia.

Physicians who have fulfilled the requirements to become a Fellow of the Royal Australasian College of Physicians who have completed advanced training in Gastroenterology or who are otherwise qualified to practice in Australia and who are suitably experienced in endoscopic interventions.

Additionally, 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 a preceptor.

35. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- ☒ Inpatient private hospital
- ☒ Inpatient public hospital
- ☐ Outpatient clinic
- ☐ Emergency Department
- ☐ Consulting rooms
- ☒ Day surgery centre
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The service is able to be provided on a day only basis and requires an endoscopy suite. It is therefore suitable for either public or private hospitals and day surgeries.

36. Is the proposed medical service intended to be entirely rendered in Australia?

- ☒ Yes
- ☐ No

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

37. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The comparator is moderate intensity lifestyle interventions which may include VLED, behavioural interventions and/or pharmacotherapy. Health care resources may include general practitioners, dieticians, exercise physiologists, and psychologists.

38. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

There are not specific item numbers related to lifestyle interventions, but patients may access a variety of services through their general practitioner (GP) and allied health services. These services include standard GP consultations, health assessments for people at risk of developing diabetes or at risk of developing chronic disease, chronic disease management plans and chronic disease management by allied health professionals. The item numbers are listed below with links to the MBS

☒ Yes (please provide all relevant MBS item numbers below)
☐ No

GP Attendances - MBS 3, 23, 36, 44

GP Health Assessments – 701, 703, 705, 707

Chronic Disease/Complex Care Management – 721, 723, 732, 729

Allied Health – 10951, 10953, 10954 10956, 10960, 10968

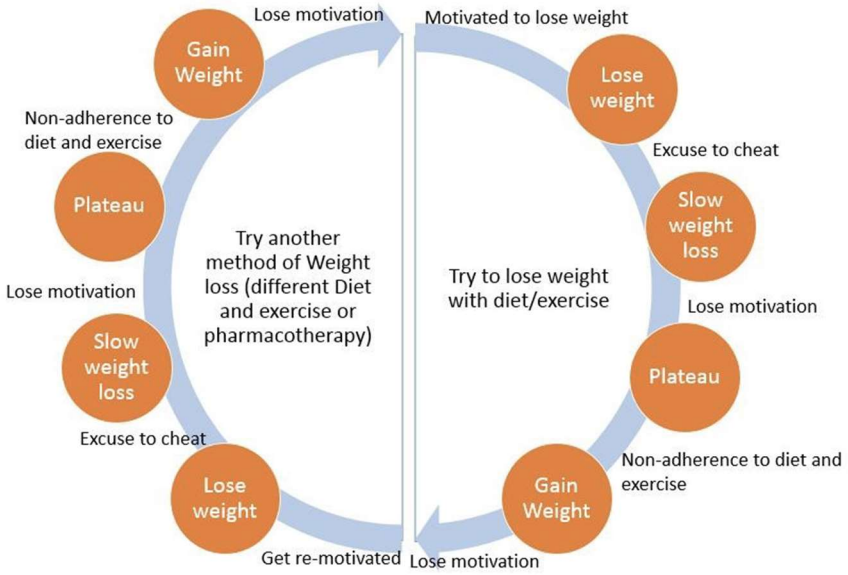
39. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

Lifestyle interventions to support weight loss in patients with BMI ≥30 and <40 kgm² include very-low energy diets and weight loss medication. These items are most commonly used consecutively, starting with a VLED then using medication to help counter hormone changes and increased hunger that follow weight loss. The treatment algorithm for is depicted in

Figure 3: Clinical pathway moderate intensity lifestyle interventions

. The cycle of weight loss, maintaining motivation and ultimately non-adherence allow for high rates of relapse and weight gain. Please see Figure 3

Figure 3: Clinical pathway moderate intensity lifestyle interventions



Source: https://sciatica.clinic/understanding-weight-fat-loss/

40. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☒ Yes
☐ No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

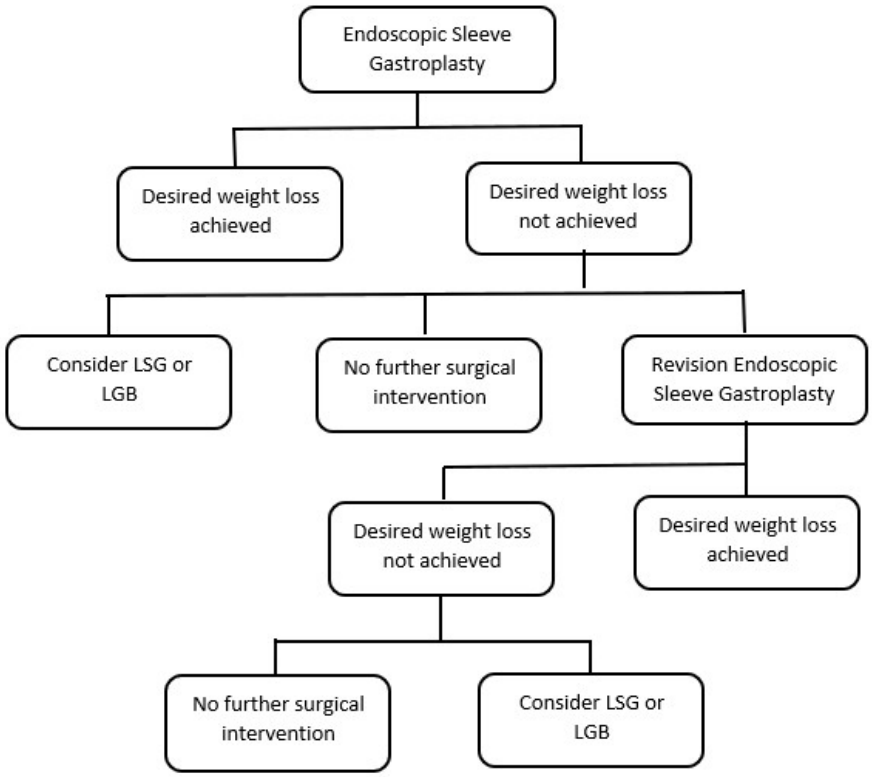
ESG will be used in addition to moderate intensity lifestyle interventions

41. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

The ESG is typically performed in a day hospital setting under general anaesthesia. Patients who fail first and second-line treatment options of diet, exercise, behavioural modification and pharmacotherapy options may then be eligible for ESG. Some patients with a BMI are eligible for Medicare funded bariatric surgery. ESG is intended for patients for whom laparoscopic or open surgery is unpalatable due to its invasive nature and the comparatively long hospital stay or who would otherwise not consider bariatric surgery.

Following ESG, patients will follow a post-procedure diet and will require the services of allied health professionals which may include dieticians, exercise physiologists or psychologists. A small percentage of patients may not experience sufficient weight loss or experience a loss of satiety. This can be improved by an endoscopic procedure to tighten the sutures. Should weight loss not be maintained, some patients may consider more invasive surgery such as laparoscopic banding or sleeve gastrectomy.

Figure 1 Proposed Australian algorithm for the management of obese patients with BMI 30 to 40kg/m²



PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

42. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

ESG has superior effectiveness compared to moderate intensity life style interventions in patients with BMI ≥ 30 <40 kgm² and inferior safety

43. Please advise if the overall clinical claim is for:

☒ Superiority
☐ Non-inferiority

44. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Adverse events which may include abdominal pain, nausea, vomiting and device-related adverse events or surgical complications which may include injury to the gastrointestinal tract or bleeding**.**

Mortality

Clinical Effectiveness Outcomes:

Primary Outcomes: Total body and excess weight loss, changes in metabolic comorbidities which may include systolic blood pressure, diabetes (as measured by HbA1c) and hyperlipidaemia, cardiovascular disease and steatohepatitis

Revision, reversal, or conversion rates

Secondary Outcomes: Health Related Quality of Life

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

45. Estimate the prevalence and/or incidence of the proposed population:

In 2021 31.3% of Australians are obese, approximately 12.5 million adults[13].

- Obese Class I = BMI 30 < 35: 17.7% of adult females; 21.7% of adult males
- Obese Class II = BMI 35 < 40: 7.8% of adult females; 7.6% of adult males

46. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The proposed medical service would be delivered to a patient no more than once per year.

47. How many years would the proposed medical service(s) be required for the patient?

Endoscopic sleeve gastroplasty is a single procedure delivered in one surgical appointment. In rare cases, a follow-up endoscopy may be required to apply additional sutures should patients lose satiety or begin to regain weight.

48. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

While the population who may be eligible to receive ESG is extremely large, the capacity to deliver the service is highly constrained. In 2016 following inclusion on the Prostheses List, the Overstitch device was used in ESG procedures, prior to a determination that the existing item numbers did not encompass the use of ESG. This period of ultilisation of ESG provides a real-world experience of the likely uptake, albeit for only 1 year.

In the year that ESG was performed, there were approximately 720 procedures. This is the basis of the current projections where it is estimated that there would be the same uptake in the first year. The uptake of ESG is constrained primarily by the number of gastroenterologists or bariatric surgeons who have the appropriate endoscopic skills and the time and resources required for adequate training to use the Overstich device. Proceduralists must have sufficient skill to be able to perform interventional endoscopic procedures. Additionally, training provided by the applicant can take up to 4 or 5 days. There are further constraints in that proceduralists should either be proctored when performing their first cases, or alternatively attend cases with a preceptor.

49. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

It is estimated that there will be a comparatively large increase in uptake in the first 2-4 years as the new service is diffused which will then plateau. There is likely to be l uptake of ESG in patients in the proposed BMI range in patients who regard an ESG endoscopic procedure more palatable and who may not consider the more invasive laparoscopic alternatives. Nevertheless, the main constraint will be the availability of qualified practitioners and is the basis of the projections. It is anticipated that surgeons will increase the number of ESG procedures after the first year of practice. Please see Table 2

[13] AIHW 'Overweight and Obesity' 2020. https://www.aihw.gov.au/reports/australias-health/overweight-and-obesity

Table 2: Projected utilisation of ESG

	Number of Surgeons	Number of Procedures Calculation	Average number of Procedures per Surgeon
Year 1	20*	720	36
Year 2	35	20 surgeons at 50 per year - 1000 15 surgeons at 36 per year -540 Total =1,540	44
Year 3	50	35 Surgeons at 50 per year -1750 15 surgeons at 36 per year -540 Total = 2290	46
Year 4	65	50 surgeons at 50 per year -2500 15 surgeons at 36 per year -540 Total = 3040	47

* Actual number of surgeons performing ESG in 2016.

There is potential for leakage outside of the proposed population, however there is no evidence to suggest that this will be greater than with other bariatric surgeries.

PART 8 – COST INFORMATION

50. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

Resource item	Unit cost	Source / notes
Pre-operative		
Pre-operative 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 surgery in a patient with clinically severe obesity	$154.50	MBS 20791, 75% Benefit
Anaesthesia time units	$164.80	MBS item 23085; Anaesthesia time units; 1:46 hours to 2:00 hours, 75% Benefit
Subtotal (anaesthetics)	**$387.1**	Calculated
Post-operative		
Post-operative gastroscopy	138.25	MBS 30473, 75% Benefit
Est. total per procedure	**REDACTED**	

51. Specify how long the proposed medical service typically takes to perform:

Total procedure time varies from physician to physician and is based on experience level with the endoscopic suturing system. However, for an experienced physician, the procedure typically takes between under 90 minutes to complete.

52. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 3 – Therapeutic Procedures -
XXXX Endoscopic Sleeve Gastroplasty for patients 18 years or over with Class I or Class II obesity. Multiple Services Rule (Anaes.) (Assist.) Fee: $884.00 Benefit: 75% = 663.00