

# Medical Services Advisory Committee (MSAC) Public Summary Document

## ***Application No. 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***

**Applicant:** Boston Scientific Pty Ltd

**Date of MSAC consideration:** 3-4 April 2025

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

### **1. Purpose of application**

A re-application requesting MBS listing of endoscopic sleeve gastroplasty (ESG) as a treatment for patients aged 18 years and over, diagnosed with obesity (BMI  $\geq 30$  kg/m<sup>2</sup>), who have failed first- and second-line treatments and/or who are unsuitable for bariatric surgery, was received from Boston Scientific Pty Ltd by the Department of Health and Aged Care. Currently, ESG is not MBS-funded.

The Applicant-Developed Assessment Report (ADAR) for the re-application presented two PICO sets:

- PICO set 1: Patients with class I or class II obesity (BMI 30–39.9 kg/m<sup>2</sup>) with or without comorbidities who have failed first- and second-line weight loss therapies (lifestyle intervention delivered with or without pharmacotherapy).
- PICO set 2: Patients with class II obesity (BMI 35-39.9 kg/m<sup>2</sup>), comorbidities, or class III obesity (BMI  $\geq 40$  kg/m<sup>2</sup>).

The population of patients in PICO set 2 are currently eligible for MBS-funded bariatric procedures.

The ADAR proposed that the ESG procedure be conducted using the Apollo ESG NXT system, which is TGA-registered, but not on the Prescribed List for Medical Devices and Human Tissues Products (the PL). The applicant reported its intention to submit a PL application following assessment of the MSAC application.

## 2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC did not support public funding of endoscopic sleeve gastroplasty (ESG) for the treatment of obesity in adults with body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> and who have failed first-line (lifestyle modification) and second-line (pharmacotherapy) treatments. MSAC considered that the comparative evidence presented was limited with only 12 months of clinical trial data for patients with a BMI 30-40 kg/m<sup>2</sup>. No comparative data was presented for the populations with a higher BMI. MSAC considered the clinical evidence did not adequately support long-term comparative effectiveness and safety of ESG including the need for reintervention and whether weight loss following ESG would lead to improvements in clinically important outcomes (e.g., cardiovascular disease, diabetes, chronic kidney disease). MSAC noted that 25% of patients in the MERIT trial did not complete assessment at 1 year, and 26.5% of patients in the ESG group who completed 1 year follow-up were considered to require retightening suggesting the benefit was not durable. MSAC noted that ESG is expected to have similar costs to bariatric surgery but appeared to result in lower levels of weight reduction and did not have longer term evidence for other clinical outcomes. MSAC considered the limitations in the clinical evidence supporting ESG meant the cost-effectiveness of ESG could not be established. MSAC considered that obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) with associated comorbidities is very common and robust evidence of comparative effectiveness, safety and cost-effectiveness is needed to support the likely substantial financial implications. MSAC considered a resubmission for ESG should also consider the place of glucagon-like peptide-1 (GLP-1) therapies, and other pharmacologic and surgical interventions and the new draft Clinical Practice Guidelines for the Management of Overweight and Obesity for Adults, Adolescents and Children in Australia (November 2024).

### Consumer summary

This is an application from Boston Scientific requesting Medicare Benefits Schedule (MBS) funding for endoscopic sleeve gastroplasty (ESG) as a treatment for individuals with class I to III obesity who have not lost weight following diet or lifestyle modifications, and after taking weight-loss medications, and who have declined bariatric surgery. This is the second time that MSAC has considered this application.

Obesity is when a person has excess body weight. It can be measured using the body mass index (BMI), a measure calculated from a person's weight and height. The healthy BMI range is 18.5 to 25 kg/m<sup>2</sup>. Individuals with a BMI of 30–34.9 kg/m<sup>2</sup> is classified as having class I obesity, while a BMI of 35–39.9 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> and over is class II and class III obesity, respectively. Obesity can increase the risk of a variety of health problems including diabetes, heart disease and liver disease, and may significantly decrease quality of life.

Individuals with obesity can try to lose weight by modifying their lifestyle (such as changing their diet and being more active) or taking weight-loss medication. If that does not work, the person may be able to have weight-loss surgery, called bariatric surgery. One type of bariatric surgery currently performed is called laparoscopic sleeve gastrectomy. This is a type of keyhole surgery where a large part of the stomach is removed, leaving behind a small tube-shaped stomach.

ESG is another type of weight-loss procedure. It does not involve any surgical incision. Instead, a stitching device is inserted through the patient's mouth and fed down to the stomach. The size of the stomach is reduced, and it is changed into a sleeve shape using the stitching device. The smaller stomach size means that the person cannot eat as much food and they feel less hungry, making it easier for them to lose weight.

MSAC did not support public subsidy of ESG on the MBS. MSAC was not convinced by the evidence presented that ESG is as effective or safe as other treatments, especially in the long term. This included inadequate evidence that ESG has the ability to reduce the risk of long-term health problems commonly associated with obesity (such as diabetes, heart, liver and kidney disease). MSAC considered that the main trial informing the evidence was limited in its applicability to the Australian population proposed to use the service. MSAC was also not convinced that there is a high clinical need for the procedure, as other effective treatments are available. MSAC noted that weight-loss medications have advanced since it first considered this application, and that the effectiveness and safety of ESG versus these new medications had not been investigated.

#### **MSAC's advice to the Commonwealth Minister for Health and Aged Care**

MSAC did not support MBS listing of ESG as a treatment for individuals with class I–III obesity who have failed non-surgical treatments and who have declined other types of weight-loss surgery. MSAC was not convinced that ESG is as effective or safe as other treatments, especially in the long term, and did not consider that individuals would choose this treatment over effective alternatives. MSAC also considered the financial impact to health budgets to be very high and likely underestimated.

### **3. Summary of consideration and rationale for MSAC's advice**

MSAC noted that this was a reapplication from Boston Scientific Pty Ltd requesting Medicare Benefits Schedule (MBS) listing of endoscopic sleeve gastroplasty (ESG) as a treatment for individuals with class I–III obesity, with and without comorbidities, who have failed first-line (1L) and second-line (2L) treatments.

MSAC recalled that it first considered this application at its November 2019 meeting. At the time, the application requested MBS listing for ESG in patients with class I and II obesity with comorbidities who had failed 1L treatments such as lifestyle changes and 2L treatments such as pharmacotherapy. MSAC had not supported public funding for ESG, as it considered the evidence base to be weak and limited, resulting in highly uncertain effectiveness and safety, particularly in the long term. A reapplication was submitted in 2021 following the completion of a pivotal randomised trial (the MERIT trial) and a new PICO Confirmation was developed (December 2021 PASC meeting). The current applicant-developed assessment report (ADAR) was submitted in November 2024.

MSAC noted that there was limited consultation feedback. Of the 7 responses received, only one was from a patient who had experience with the proposed service. Organisations including the Gastroenterological Society of Australia (GESA) and Medtronic were supportive of the application, however Private Healthcare Australia (PHA) was not. The perceived advantages of the proposed procedure were its less invasive nature, shorter recovery time and that it may improve equity, while the disadvantages were mainly its uncertain clinical effectiveness, high likelihood of regression in previously achieved weight loss in the longer term and high rate of adverse effects. MSAC noted that the single consumer input had noted severe adverse effects immediately after the procedure and a subsequent revision after the treatment had not been effective. MSAC also noted the significant out of pocket costs which the consumer paid for the treatment, noting it is not currently listed on the MBS.

MSAC noted that the ADAR presented 2 PICO sets:

- PICO set 1: people with class I obesity (body mass index [BMI] 30–34.9 kg/m<sup>2</sup>) or class II obesity (BMI 35–39.9 kg/m<sup>2</sup>), with or without comorbidities (diabetes, ischaemic heart disease, etc.), who have failed 1L and 2L treatments, such as lifestyle/diet modifications and pharmacotherapy respectively.
- PICO set 2: people with class II obesity (BMI 35–39.9 kg/m<sup>2</sup>) with comorbidities, or class III obesity (BMI ≥40 kg/m<sup>2</sup>), with or without comorbidities, who are eligible for bariatric surgery.

MSAC noted that class III obesity patients were not included in the pivotal MERIT trial and were outside the PASC-ratified PICO Confirmation. MSAC noted that the ADAR considered PICO set 2 as an extension of the PICO set ratified by PASC in December 2021 and therefore no further PASC consideration would be required as the comparator and outcomes were the same. The ADAR also added that the inclusion of the second population was guided by expert clinical feedback and that limiting the use of ESG to patients with BMI <40 kg/m<sup>2</sup> would not be clinically justified. MSAC noted that the pre-MSAC response reiterated that not allowing access to ESG for this patient group would present an equity issue. MSAC however, considered that this group should be excluded from this application to align with the presented evidence base and the PASC-ratified PICO Confirmation.

MSAC noted the comparators for the two PICO sets. For PICO set 1, the ADAR nominated lifestyle/diet modification as the primary comparator. For PICO set 2, the nominated comparator was laparoscopic sleeve gastrectomy (LSG). MSAC noted that LSG represents 80% of bariatric surgical procedures performed in Australia, based on the Bariatric Surgery Registry data.

MSAC discussed the relevance of pharmacological interventions for the proposed population. MSAC noted that there has been an increase in the availability and extent of use of pharmacotherapy in weight management since PASC considered the re-application in December 2021. Consultation feedback from PHA highlighted that new weight-loss medications may reduce the need for bariatric procedures. MSAC noted that several drugs (e.g., semaglutide (Wegovy),

tirzepatide) are now registered with the Therapeutic Goods Administration (TGA) for chronic weight management and that while currently none<sup>1</sup> are PBS-listed for treatment of obesity or weight management, pharmacological therapy is used in Australian clinical practice for the treatment of obesity. MSAC noted the emerging landscape in obesity treatments (for further information, please see Section 15- 'Other relevant information') and advised that a resubmission for ESG should also consider the place of glucagon-like peptide-1 (GLP-1) therapies and other pharmacologic and surgical interventions as per MSAC Guidance on the selection of comparator(s) (MSAC Guidelines TG 2.3).

MSAC noted that for both PICO sets, the primary efficacy outcome was percentage total body weight loss (%TBWL), and the secondary efficacy outcomes were, percentage excess weight loss (%EWL), durability of weight loss (3–5 years), impact on comorbidities (e.g., improvement of diabetes, hypertension, metabolic syndrome from baseline) and the rates of revision or conversion to further surgery. The primary safety outcome was the rate of serious events, while the secondary safety outcome was long-term adverse events (persisting or new gastro-oesophageal reflux disease [GORD]).

MSAC noted that the ADAR reported improvements in weight-related comorbidities in terms of significantly more patients in the ESG group with “improving” diabetes, hypertension and metabolic syndrome at 52-weeks compared with baseline than patients in the control group (Table 19). However, MSAC considered interpretation of results difficult as the ADAR did not report endpoint data (i.e., end-organ impacts) on obesity-related comorbidities, including cardiovascular disease, stroke, kidney disease, and diabetes, which MSAC considers more relevant for public subsidy.

MSAC noted that both the current and proposed clinical management algorithms were based on the Australian Diabetes Society's Australian Obesity Management Algorithm<sup>2</sup> (2022). MSAC considered the clinical place of ESG to be uncertain due to the presence of effective alternative treatments. MSAC considered that ESG would likely only be used in patients with class I–III obesity who do not want to have bariatric surgery, given that selection of ESG also requires physical fitness for bariatric surgery.

MSAC noted the new draft clinical practice guidelines for the management of overweight and obesity for adults, adolescents and children in Australia<sup>18</sup> (November 2024), commissioned by the Department and currently undergoing public consultation. MSAC noted that for adults aged 18 to <65 years, the draft 2024 guidelines provided

- a) a strong recommendation for TGA-approved weight management pharmacological interventions;
- b) a conditional recommendation for bariatric surgery intervention, when offered as part of a comprehensive approach to weight-related health management, versus medical treatment alone; and
- c) a consensus statement for some endoscopic therapies, as part of a comprehensive approach to weight-related health management, versus medical treatment alone. MSAC noted that a consensus statement is made when there is very low certainty evidence, or where evidence is absent or insufficient, and/or if there is an unclear balance between benefits and harms.

MSAC noted that for older adults aged >65 years, the draft guidelines did not provide any recommendation on pharmacological, bariatric or endoscopic surgery interventions, due to lack of available data for this population and intervention type. MSAC considered that the proposed

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<sup>1</sup> One pharmacotherapy (orlistat) specifically intended for weight loss is listed on the Repatriation Pharmaceutical Benefits Scheme (RPBS).

<sup>2</sup> Australian Obesity Management Algorithm 2024. Available from: <https://www.diabetessociety.com.au/guideline/obesity/>

use of ESG, in patients aged 18 years and over, for PICO set 1 only partially aligns with the draft guidelines.

MSAC noted that the safety claim for PICO set 1 is that ESG has inferior short-term safety and non-inferior long-term safety compared to lifestyle modifications.

- MSAC noted that comparative safety evidence from the MERIT trial showed that 2% of ESG patients had a device- or procedure-related serious adverse event (AE) and 92% of ESG patients had some type of procedure-related AEs. However, AEs were not reported in patients undertaking lifestyle modifications only.
- MSAC noted that the long-term (5-year) safety data was from a single-arm, uncontrolled cohort study which showed that 1.3% of ESG patients reported moderate AEs, with one patient undergoing surgical reversal. MSAC also noted that both the MERIT trial and the longer-term single arm study (used to show AEs up to 5 years) had a loss to follow up of around 20% of study participants.

MSAC noted the pre-MSAC response maintained that serious AEs were rare (pooled rate 1.25%<sup>3</sup>). MSAC agreed with ESC that while the claim of inferiority in the short-term was supported, the claim of non-inferior safety in the long-term was not, due to uncertainty from high loss to follow up in the presented evidence.

For PICO set 2, MSAC noted the ADAR's claim of superior safety of ESG compared to bariatric surgery.

- MSAC noted that the safety evidence came from non-randomised controlled trials (non-RCTs), with one study providing data for up to 3 years. MSAC noted that similar to the evidence base for PICO set 1, there was a high rate of loss to follow-up.
- MSAC noted that there were lower rates of GORD identified in ESG patients than in LSG patients, however, the results were not statistically significant.

MSAC agreed with ESC that although there appears a trend towards superior safety, compared with LSG for the PICO set 2 population, superior safety was not fully supported by the limited evidence presented. MSAC also noted that there were no data presented comparing safety between ESG and non-LSG bariatric surgery.

MSAC also considered that decision regret for having ESG may be possible, as have been observed with sleeve gastrectomy<sup>4</sup> and gastric banding.<sup>5</sup> However, no evidence had been presented on this.

MSAC noted that the clinical effectiveness evidence for PICO set 1 came from the MERIT trial and 3 single-arm studies.

- MSAC noted that compared with lifestyle modifications, %TBWL at 1 year was greater for ESG patients (17-18%).
- MSAC considered that effectiveness data at 2–5 years was uncertain as a high percentage of patients were lost to follow-up (up to 80% in the single-arm study utilised for 5-year follow up data).
- MSAC noted that ESG may result in greater improvements in quality of life (QoL) and weight-related comorbidity but comparative effectiveness results were limited to 1 year.

Overall,

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<sup>3</sup> Dayyeh BKA, et al. IFSO Bariatric Endoscopy Committee Evidence-Based Review and Position Statement on Endoscopic Sleeve Gastroplasty for Obesity Management. *Obes Surg.* 2024;34(12):4318-48.

<sup>4</sup> Zoumpou T, Fleishman A, Jones DB, Wee CC. Decision regret up to 6 years after sleeve gastrectomy. *Surg Endosc.* 2023 Dec;37(12):9381-9392. doi: 10.1007/s00464-023-10364-8. Epub 2023 Aug 31.

<sup>5</sup> Wee CC, Fleishman A, McCarthy AC, Hess DT, Apovian C, Jones DB. Decision Regret up to 4 Years After Gastric Bypass and Gastric Banding. *Obes Surg.* 2019 May;29(5):1624-1631. doi: 10.1007/s11695-019-03772-0.

- MSAC considered that the evidence base beyond 12 months was limited due to significant uncertainty in the longer-term data, and while ESG appears to have superior effectiveness compared with lifestyle modifications, this was only supported when assessed at 1-year post-procedure.
- MSAC noted the 10-year follow-up data from a single-arm, single-surgeon, prospective US cohort study, presented as a conference abstract (Lahooti 2024), suggested that 15.8% mean %TBWL was sustained at 10 years.<sup>6</sup> However, conference abstracts would only be accepted as evidence under exceptional circumstances (MSAC Guidelines, Appendix 2). In addition, MSAC noted that the abstract was not peer-reviewed and the study had substantial loss to follow-up (only 27.2% of the cohort were eligible for 10-year follow-up and of these only 61.8% completed the follow-up assessment). Therefore, MSAC considered that the research study on which the abstract represented may not add substantially to the evidence base.

Regarding the key MERIT trial, MSAC noted ESC's concerns regarding the uncertainty around the applicability of the MERIT trial to the Australian population.

- This was due to concerns around the low proportion of men (12%), young mean age (47 years) and mean BMI of the study population, which were not likely to reflect the proposed Australian population. This was likely to affect the validity of the economic model inputs.
- ESC also had concerns about whether patients in the MERIT trial had failed 12 months of both lifestyle modifications and pharmacotherapy, which is a proposed requirement for access to ESG. MSAC noted that the pre-MSAC response stated that the MERIT trial inclusion criteria required patients to have a 'history of failure with non-surgical weight-loss methods'. However, MSAC considered the definition for 'failure' in the trial and the duration of time that patients needed to have trialled and failed lifestyle modifications and pharmacotherapy to be uncertain.

MSAC noted that the primary clinical effectiveness outcome for PICO set 2 was %TBWL at 1 year.

- MSAC noted that to support the claim of ESG being non-inferior effectiveness to LSG, a non-inferiority margin of 10% TBWL was proposed by the applicant. It was stated that the margin was supported by clinicians and included in one publication by Alqahtani et al. (2022). However, MSAC considered that the basis on which this margin was set was unclear. MSAC noted that %TBWL at 1 year was less for ESG than LSG (average mean difference in %TBWL, ESG minus LSG, -9.95%, 95% CI -10.0% to -9.19%), and included the 10% non-inferiority margin set by the applicant when assessing the 95% confidence interval. MSAC noted that the pre-MSAC response maintained that ESG and LSG are clinically comparable procedures and that any difference in absolute %TBWL between the two procedures was not considered clinically relevant.
- Evidence from a non-randomised observational study<sup>7</sup> showed that QoL outcomes improved, although not significantly, for ESG patients, but improved significantly for LSG patients.

Due to the presented evidence, MSAC considered that the claim of non-inferiority of ESG to LSG was not supported.

MSAC noted that the pre-MSAC response acknowledged that the non-inferiority evidence was not supported, but asked MSAC to consider a broader set of potential health benefits with even small %TBWL of 5–10%. MSAC considered that the broader health benefits referred to in the pre-MSAC

<sup>6</sup> Lahooti et al. (2024), 'Ten-year outcomes of endoscopic sleeve gastroplasty for the treatment of obesity' [conference abstract], *The American Journal of Gastroenterology*, 119(10S):S1473–4, doi:10.14309/01.ajg.0001037620.30740.d4.

<sup>7</sup> Carr, et al. (2022), Efficacy and safety of endoscopic sleeve gastroplasty and laparoscopic sleeve gastrectomy with 12+ months of adjuvant multidisciplinary support, *BMC primary care*, 23(1), 26. <https://doi.org/10.1186/s12875-022-01629-7>

response should have been defined and presented within the ADAR. MSAC noted that cardiometabolic benefits, which were referred to in the pre-MSAC response, are mostly seen for people with class I obesity, and not for those with class II or III obesity who may require a greater %TBWL to achieve cardiometabolic benefits.<sup>8,9</sup>

MSAC discussed the lack of long-term data and high loss to follow-up in the studies presented in the ADAR. MSAC noted that the pre-MSAC response stated that this was typical of observational studies and in line with the evidence available for bariatric surgery studies. However, MSAC considered that this did not address uncertainty in benefit beyond 12 months and noted that most of the single-arm trials informing 5-year outcomes did not require prior failure of pharmacotherapy, which is not aligned with the population presented in the ADAR.

MSAC noted that a cost-utility analysis was presented for PICO set 1, which MSAC considered appropriate given that ESG appears to be superior to lifestyle modifications in the short-term.

- MSAC noted that over a 40-year time horizon, the base case incremental cost-effectiveness ratios (ICERs) were \$7,553 per quality-adjusted life year (QALY) gained for class I obesity patients, and \$12,591/QALY gained for class II obesity patients.
- MSAC noted that the model assumed that >60% of class I and class II obesity patients would achieve a lower obesity class in the first 6 months and maintain it for up to 40 years, while around 20% would return to their original weight. MSAC queried the assumption of >60% of patients sustaining long-term benefit and considered that the model may be optimistic based on the limited evidence provided in the ADAR to support longer term weight outcomes.
- MSAC also noted ESC's concerns regarding the uncertainty in the model assumptions, especially regarding key AEs and patient adherence (20% loss to follow-up). MSAC noted that the pre-MSAC response maintained that the rate of serious AEs was low, and that rare AEs (where the incidence rate is <0.25%) could be excluded from the economic model. However, MSAC considered it inappropriate and that all reported AEs should be included in the model.
- MSAC noted that the pre-MSAC response provided sensitivity analyses with some revised assumptions, including a 6% revision rate at 2 years post-procedure and a 2.7% conversion rate to LSG at 3 years post-procedure (Table 27). MSAC noted the ICERs increased further to \$13,467 and \$18,454 per QALY gained for class I and II obesity, respectively, when assuming reintervention was applicable up to 15 years post-procedure. The pre-MSAC response also stated that within the model, the 20% of patients lost to follow-up were assumed to return to their baseline weight over 5–10 years (representing a worst-case assumption). MSAC considered that while the sensitivity analyses helped address some model issues, there were still significant issues around the uncertainty on the inputs and health state transition probability assumptions.

For PICO set 2, MSAC noted that a cost-minimisation analysis was used.

- MSAC agreed with ESC that this was inappropriate given that the clinical claim of non-inferiority versus LSG was not established by the evidence presented.
- The model showed that, over a 30-day time horizon, ESG results in a cost saving of \$5,658 per patient compared with LSG (\$14,932 for ESG versus \$20,590 for LSG). MSAC noted that the pre-ESC response provided an updated sensitivity analysis, following evaluation feedback, incorporating the costs of additional AEs from reoperation and

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<sup>8</sup> Tahrani AA, Morton J. Benefits of weight loss of 10% or more in patients with overweight or obesity: A review. *Obesity* (Silver Spring). 2022 Apr;30(4):802-840. doi: 10.1002/oby.23371.

<sup>9</sup> Warkentin LM, Majumdar SR, Johnson JA, et al. Weight loss required by the severely obese to achieve clinically important differences in health-related quality of life: two-year prospective cohort study. *BMC Med*. 2014 Oct 15;12:175. doi: 10.1186/s12916-014-0175-5.

readmission, and extending the time horizon to 12 months, resulting in a slightly reduced cost-savings with ESG (Table 32).

- MSAC noted that the key drivers of the models were the time horizon, hospital costs, health state utilities, reintervention rates, equipment costs and success rates.

The proposed MBS fee for ESG (\$967.90) was based on the MBS fee for LSG under MBS item 31575<sup>10</sup>. MSAC noted that feedback from GESA disagreed with the ADAR's proposed fee, stating that ESG was a more complex procedure so should attract a higher fee. MSAC considered that the complexity of ESG in relation to LSG was uncertain and more information would be required to determine an appropriate fee.

MSAC noted other costs included are pre-surgery costs (haematology, renal function test, professional attendance items with a consultant physician and anaesthetist, general practitioner [GP] and allied health services) and anaesthesia costs (based on MBS item 23035<sup>11</sup>). MSAC noted that MBS item 23035 provides for 31–45 minutes of anaesthesia time, which MSAC considered optimistic for the ESG procedure. Regarding the costs for revisions and removals, MSAC noted that the pre-MSAC response suggested fees of \$967.90 per revision and \$279.80 for removal. MSAC also noted that the intervention requires an endoscopy suite and anaesthetist, an OverStitch™ device (\$9,626), an overtube device (\$511) and 8 sutures (\$2,120). MSAC considered that these issues added uncertainty around the model inputs, and ultimately overall cost-effectiveness.

Regarding the financial analysis, MSAC noted that the estimated net financial impact to the MBS at 75% benefits was \$1.07 million in year 1 to \$2.90 million in year 5. At 100% benefits, the impact was estimated to be \$1.43 million in year 1 to \$3.87 million in year 5. The total budget impact to the MBS and Prescribed List (PL) was estimated as \$5.79 million in year 1 to \$19.15 million in year 5 at 75% benefits, and \$6.16 million in year 1 to \$20.12 million in year 5 at 100% benefits. MSAC noted that estimated savings and offsets depended on ESG replacing LSG, estimated to represent 48% and 35% of total ESG procedures in Year 1 and Year 5, respectively. However, MSAC considered this uncertain and noted that replacement of LSG with ESG also depends on the availability of trained providers.

MSAC noted that the ADAR used a market share approach to estimate the financial impact, using the number of claims for MBS item 31575 to estimate the market size. Utilisation was estimated to be 1,230 patients in year 1, increasing to 2,726 in year 5. MSAC noted the ADAR assumed various market growth rates (redacted%- redacted% for class I/II and redacted% for class III obesity) and ESG uptake rates for patients with class I/II/III obesity (redacted%/redacted%- redacted%/redacted%). MSAC noted that around 30% of adult Australians have obesity.<sup>12</sup> MSAC considered the estimated utilisation to be uncertain given the potential population could be large and little justification was provided for who within the population would seek access to this service. MSAC considered that it would be more appropriate to estimate utilisation using item statistics for MBS item 20791<sup>13</sup>, which pertains to the initiation of the anaesthesia management for bariatric surgery in patients with clinically severe obesity and is relevant to all bariatric surgery procedures. MSAC noted that a sensitivity analysis performed during the evaluation showed that

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<sup>10</sup> Medicare Benefits Schedule – Item 31575, MBS Online, Australian Government, Department of Health and Aged care, <https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=31575&qt=item&criteria=31575>

<sup>11</sup> Medicare Benefits Schedule – Item 23035, MBS Online, Australian Government, Department of Health and Aged care, <https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23035&qt=item&criteria=23035>

<sup>12</sup> Age-standardised rate 31.1% of adults living with obesity in 2022 (Figure 3, Overweight and obesity, AIHW, web-report, last updated: 17 June 2024) [available: <https://www.aihw.gov.au/reports/overweight-obesity/overweight-and-obesity/contents/summary>].

<sup>13</sup> Medicare Benefits Schedule – Item 20791, MBS Online, Australian Government, Department of Health and Aged care, <https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=20791&qt=item&criteria=20791>

using claims for MBS item 20791 resulted in a total budget impact that was 36% higher than the base-case estimates.

MSAC noted that the pre-MSAC response maintained it was appropriate to estimate utilisation based on MBS item 31575. The applicant claimed that LSG is the best comparator, ESG is unlikely to be substituted for other procedures, and that basing utilisation on the anaesthesia item will overestimate the size of the ESG market. The pre-MSAC response provided a sensitivity analysis incorporating revisions resulting in greater estimated net cost of \$4.2 million to MBS and \$22.7 million to the health budget at Year 5 of listing (Table 35).

MSAC considered that, if the applicant has not already done so, it should apply to have ESG as part of the Bariatric Surgery Registry. This would enable data collection and facilitate comparison with other surgical treatments, and would be useful to inform more accurate estimates around utilisation.

MSAC noted that the ADAR proposed 2 new MBS item numbers, one for patients with class I or II obesity and another for patients with class III obesity, to monitor usage across different obesity classes. The applicant has proposed in the ADAR that they are open to a single combined listing for simplicity.

MSAC advised that the MBS item descriptors should stipulate that patients must be aged 18 years and over, and that the descriptors should be agnostic to the endoscopic suturing device. MSAC agreed with the feedback from GESA that a multidisciplinary team approach is essential for assessment and post-treatment care but noted that this was not mentioned in the ADAR's proposed item descriptors. The procedure itself would involve gastroenterologists and surgeons, and the applicant proposed that it is restricted to trained interventionalists. MSAC agreed that training was required, but questioned who would define and enforce credentialing, as such MSAC considered that further advice was needed. MSAC also noted ESC advice on BMI and considered that basing the 'class' of obesity on BMI was not always appropriate, particularly for some ethnic groups.

MSAC noted potential equity issues associated with the application including the requirement of pharmacology for weight loss, which is not PBS listed, resulting in potential out-of-pocket costs to the patient. MSAC also noted that specialists who can provide the service are located in metropolitan areas, which may create an access barrier for patients in rural and remote areas.

Based on considerations of the ADAR's proposed broad population, uncertain clinical place, limited clinical evidence, and major uncertainty in the economic and financial analyses, MSAC did not support the public funding of ESG as a treatment for individuals with class I–III obesity, with and without comorbidities, who have failed 1L and 2L treatments. MSAC advised that all aspects of the reapplication would need to be reassessed, including reconsideration by PASC (to clarify clinical positioning, comparator issue, etc), and new evidence (including a comparison with drug treatments) would need to be included as a part of any reapplication. MSAC also advised that further long-term outcomes, including end-point data (i.e., end-organ impacts) on weight-related comorbidities (cardiovascular disease, stroke, kidney disease and diabetes), would also need to be provided as a part of any reapplication.

## **4. Background**

In November 2019, MSAC first considered ESG in Application 1555, which sought MBS listing for ESG to treat adults with class I and II obesity (BMI 30.0–39.9 kg/m<sup>2</sup>) and comorbidities, who had failed first-line treatments such as lifestyle changes and/or pharmacotherapy. MSAC did not support public funding for ESG and considered the evidence base (2 non-randomised

retrospective comparative studies and 6 case series) for ESG to be weak, with limited applicability to the proposed population and highly uncertain safety, comparative clinical and cost-effectiveness.<sup>14</sup> Following the completion of a pivotal randomised trial (MERIT), a re-application (Application 1555.1) was submitted and considered by PASC in December 2021.

A summary of the key matters of concern from the previous consideration is presented below (Table 1).

**Table 1 Summary of key matters of concern from Application 1555**

| Component                     | Application 1555 (November 2019 MSAC meeting)<br>Matter of concern                                                                                                                                                                                                                   | How the current assessment report addresses it                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Efficacy of ESG               | Relative to comparator 1 (first- and second-line interventions), ESG has unclear short-term and unknown long-term effectiveness.                                                                                                                                                     | <b>Partially addressed</b><br>The ADAR reports comparative evidence from the MERIT trial that supports the effectiveness of ESG compared to lifestyle modifications up to 12 months.<br>The long-term clinical effectiveness of ESG beyond the 12 months is based on single-arm, uncontrolled cohort studies with high rates of loss to follow-up. This high loss to follow-up reduces the validity of the findings, as patients who do not complete the study often have different prognoses than those who do. Consequently, the long-term effectiveness of ESG treatment remains uncertain based on the current evidence.                                                                                                                             |
| Safety of ESG                 | ESG is not associated with any serious safety concerns over the reported follow-up duration. However, the safety data obtained are limited and relatively short-term. The safety profile of ESG is inferior compared to standard care and non-inferior to other bariatric surgeries. | <b>Partially addressed</b><br>Data from MERIT supports relative safety of ESG compared to lifestyle modification up to 12 months. While ESG is associated with few procedure-related AEs (2%), it is inherently inferior in short-term safety to standard of care, which involves no active intervention.<br>The long-term safety of ESG is based on single-arm, uncontrolled cohort studies up to 5 years, with high rates of loss to follow-up. This high loss to follow-up reduces the validity of the findings, as patients who do not complete the study often have different prognoses than those who do. Further long-term studies are needed to substantiate this claim accurately. Consequently, the long-term safety of ESG remains uncertain. |
| ESG vs LSG<br>Efficacy of ESG | Relative to comparator 2 (SG and AGB), ESG is likely to have non-inferior short-term and unknown long-term effectiveness.                                                                                                                                                            | <b>Partially addressed</b><br>A total of 7 non-randomised controlled studies investigated the efficacy of ESG compared to LSG. The results of the meta-analyses for the primary outcome of %TBWL do not support a finding of non-inferior effectiveness for ESG compared to LSG at 12 months, as the confidence interval of the pooled effect overlaps with the 10% MCID for non-inferiority (-9.95 [-10.70, -9.19]).<br>One non-randomised controlled study with a moderate risk of bias reported non-inferior efficacy based on %TBWL (-4.8 [-8.7, 1.5]) at 36 months.                                                                                                                                                                                 |
| ESG vs LSG<br>Safety of ESG   | ESG is not associated with any serious safety concerns over the reported follow-up duration. However, the safety data obtained are limited and relatively short-term. The                                                                                                            | <b>Addressed</b><br>Nine non-randomised controlled studies report the safety of ESG up to 3 years. This evidence demonstrates the non-statistically significant improved rates of severe AEs of ESG compared to LSG (OR 0.80 [0.48, 1.32]). Excluding studies with a high risk of bias, the results demonstrated a more favourable                                                                                                                                                                                                                                                                                                                                                                                                                       |

<sup>14</sup> Medical Services Advisory Committee 2019, 'Public Summary Document: Application No. 1555 – Endoscopic Sleeve Gastroplasty (ESG) for the treatment of patients with class I and class II obesity with comorbidities who have failed first-time treatments', viewed 4 Dec 2024, [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/15C072BAEE7A6F9CCA258330001AB3F7/\\$File/1555%20-%20Final%20PSD\\_redacted.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/15C072BAEE7A6F9CCA258330001AB3F7/$File/1555%20-%20Final%20PSD_redacted.pdf).

| Component                              | Application 1555 (November 2019 MSAC meeting)<br>Matter of concern                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | How the current assessment report addresses it                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                        | safety profile of ESG is non-inferior to other bariatric surgeries.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | non-significant safety profile for ESG compared to LSG (OR 0.40 [0.15, 1.06]).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| MBS Item Descriptor                    | The clinical evidence provided is limited to ESG performed with OverStitch™. MSAC may want to consider whether it would list an item number for OverStitch™ only or consider a more generic item.                                                                                                                                                                                                                                                                                                                                                                                | <b>For noting</b><br>The Overstich™ endoscopic suturing device is a proprietary system (Apollo Endosurgery, USA). Evidence from the ADAR comes from studies on the Overstitch device™. The proposed MBS item descriptors are generic. MSAC may wish to include generic ESG systems.                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Low Quality Clinical Evidence          | Evidence on comparative effectiveness is limited to case series and 2 retrospective comparative studies that have significant risk of biases across included studies from open-label designs, short durations of follow-up, high attrition rates, and indirect comparisons (2 RCTs currently ongoing)                                                                                                                                                                                                                                                                            | <b>Partially addressed</b><br>Direct RCT evidence from the MERIT trial with 1- and 2-year follow-up supporting the use of ESG in patients with obesity is now available and presented in this ADAR. Additional real-world studies are presented as supportive evidence for both the short- and long-term efficacy and safety of ESG. The additional evidence for longer-term follow-up is obtained from single-arm studies with high rates of loss to follow-up. This high loss to follow-up reduces the validity of the findings, as patients who do not complete the study often have different prognoses than those who do. Consequently, the long-term effectiveness of ESG treatment remains uncertain based on the current evidence. |
| Uncertain Applicability Issues         | The populations included in the ESG and comparator evidence bases generally do not align with the proposed population in the PICO Confirmation: study populations had higher baseline BMIs vs proposed MBS populations. As patients with higher baseline BMIs have a higher capacity to lose weight, the clinical effectiveness results (e.g. BMI reductions) may be subject to overestimation. In addition, the comorbidity and treatment failure status of patients in the evidence base was often unclear. These uncertainties have flow-on effects to the economic analyses. | <b>Partially addressed</b><br>The MERIT trial provides largely applicable data supporting the efficacy and safety of ESG in people with class I and class II obesity, with or without comorbidities. The MERIT trial and the single-arm studies did not report that patients had experienced 12 months of treatment failure including pharmacotherapy before enrolment. The implications of this disparity with the PASC guidance and applicability with the proposed patient group are unclear. Moreover, there is uncertainty in applying MERIT trial data to the Australian context. There are discrepancies in gender, age, and BMI between the MERIT trials and the Australian Bariatric Surgery registry.                            |
| Cost Implications and Possible Offsets | The base case of the CUA assumes weight loss is sustained over the lifetime of the patient (40 years). The long-term clinical effectiveness of ESG is uncertain and concerns regarding the durability of the sleeve have been raised by clinicians.                                                                                                                                                                                                                                                                                                                              | <b>This concern remains</b><br>The CUA models patient transitions through the various obesity classes according to MERIT trial data in the initial 2 years following ESG. In years 3 to 5 it was assumed that 80% of individuals would remain in the health state they were in at the end of year 2, while 20% would regress back to their baseline BMI. The model assumed that TBWL would be maintained for at least 80% of patients up to 5 years. Conservatively, it was assumed that 20% would return to baseline weight. However, for patients that gained weight during the first 2 years it was assumed that all patients (100%) would remain in the higher obesity class.                                                          |

| Component                                                          | Application 1555 (November 2019 MSAC meeting)<br>Matter of concern                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | How the current assessment report addresses it                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | The long-term effectiveness of ESG is not explicitly addressed as treatment failure is not captured.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Highly Uncertain Model-Based Economic Evaluation (vs comparator 1) | There is a high level of uncertainty in the model-based CUA arising from:<br>uncertain applicability issues (patient characteristics and baseline BMI)<br>highly uncertain model inputs (baseline and treatment effect BMI trajectory component), informed from low-quality clinical evidence<br>highly uncertain structural assumptions including oversimplifications, and duration of treatment effect (continuing effect), given short duration of follow-up and the model time horizon (lifetime)<br>uncertain impact of revision/repair (which is highly likely to be needed). | <b>Partially addressed</b><br>The baseline population (sourced from the MERIT trial and validated with Australian clinicians and with the Bariatric Surgery Registry) is applicable to the proposed MBS population. The evidence was from the MERIT trial (direct comparative trial comparing ESG to lifestyle modification), which is appropriate. However, there is uncertainty related to treatment allocation and transition probabilities extracted from the MERIT trial. The duration of treatment effects is supported by a single-arm study. However, oversimplifications are made on continuing effects beyond the 5-year time horizon, and short-term follow-up.<br>The impact of revision surgery and repair is not accurately captured in the CUA or the cost-minimisation analysis. Neither model considers ESG conversion to other forms bariatric surgery. Costs associated with revision and repair surgeries would likely be high in patients who received ESG. Alquahtani, Elamedi et al (2022) reported that within 10 months of receiving ESG, 2.7% of patients (n = 80) underwent conversion to LSG after not achieving %TBWL of 5%. Similarly, within 19 months, 0.9% (n = 28) of ESG recipients had to undergo a subsequent ESG due to insufficient weight loss. No LSG patients had to undergo conversion surgery due to weight regain over 5% TBWL within 10 months; however, 3 LSG recipients had to undergo Roux-en-Y gastric bypass and 1 underwent endoscopic stenting, due to suffering staple-line leaks. |
| Uncertain Financial Impact                                         | Potential for net cost to be overestimated due to overestimated eligible population (uptake rate, comorbidities derived from population with BMI >35 kg/m <sup>2</sup> ). Also, the cost of ESG revision/repair was not included and potential leakage may be possible (particularly in patients without comorbidities).                                                                                                                                                                                                                                                            | <b>Partially addressed</b><br>The financial analysis used a market share approach, defining the market based on the number of patients currently accessing LSG through the MBS (item 31575). The analysis considered that a proportion of these patients would substitute to ESG should it be listed. In addition, a market growth rate percentage was applied to account for uptake of ESG among patients who would otherwise not have opted to undergo bariatric surgery. This approach differs to the epidemiological approach used in the prior application (Application 1555).<br>Expert advice provided in the PICO for Application 1555.1 was that 10–20% of eligible patients may be willing to undergo ESG, as opposed to 1% who would consider bariatric surgery. Presumably, estimating service numbers as a percentage of MBS item 31575 utilisation risks underestimating ESG uptake. The cost of ESG repairs and revisions are still lacking in the analysis, indicating underestimation of net cost. The estimation was based on the cost of the initial procedure only, which indicates uncertainties on the budget estimation including the pattern of healthcare utilisation and cost-saving.                                                                                                                                                                                                                                                                                                                          |

Abbreviations: AE: adverse event; AGB: adjustable gastric banding; BMI: body mass index; CUA: cost-utility analysis; ESC: Evaluation Sub-Committee; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy; MBS: Medicare Benefits Schedule; MSAC: Medical Services Advisory Committee; PICO: Population, Intervention, Comparator, Outcome; RCT: randomised controlled trial; SG: sleeve gastrectomy; %TBWL: total body weight loss

Source: Public Summary Document for MSAC Application 1555; Table 1-2 from ADAR

## 5. Prerequisites to implementation of any funding advice

ESG is a minimally invasive weight loss intervention performed with an incisionless transoral endoscopic procedure that uses a full-thickness endoscopic suturing system to reduce the stomach volume into a tubular gastric cavity. The gastropasty is created using an endoscopic suturing device fitted to an endoscope.

The ADAR reported that ESG is performed using the Apollo ESG NXT system, which was registered with the Therapeutic Goods Administration (TGA) under ARTG 461292 in August 2024, with ongoing approval, but not listed on the Prescribed List (PL). The intended purpose of the Apollo ESG NXT system is:<sup>15</sup>

*“The Device is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastropasty in adult patients with obesity with BMI between 30–50 kg/m<sup>2</sup> who have not been able to lose weight, or maintain weight loss, through more conservative measures.”*

The Apollo ESG NXT system is to be used in conjunction with the Endotherapy Overtube device (also registered with the TGA under ARTG 236427 as of April 2015). The applicant reported its intention to submit a PL application to list the Apollo ESG NXT system following assessment of the MSAC application.

The application for 1555.1 proposed the use of ESG with two devices, the QQ015 OverStitch™ Endoscopic Suturing System (\$redacted) and the QQ107 OverStitch™ Endoscopic Suturing System – 2.0 Suture (\$redacted = \$redacted x redacted). The ADAR reported that the Apollo ESG NXT system is the next generation of the OverStitch™ family of products and comprises the following devices: OverStitch™ NXT Handle (1 unit), Tissue Helix (1 unit), Suture-Anchors (8 units) and Suture Cinch device (8 units).

## 6. Proposal for public funding

The ADAR proposed that patients would be eligible for ESG treatment by a specialist if they meet the following criteria:

- age 18 years or older with class I or II obesity with or without comorbidities, and do not have an adequate response to very low energy diet (VLED) and pharmacotherapy
- age 18 years or older with class III obesity with or without comorbidities and:
  - do not have an adequate response to VLED or pharmacotherapy
  - are ineligible or refusing alternative bariatric surgery

The ADAR proposed 2 new MBS item numbers, one for patients with class I or II obesity, and another for patients with class III obesity. It proposed this will allow for monitoring of the use of the intervention between the different classes of obesity. The ADAR states that the applicant is open to working with the Department of Health and Aged Care to agree the proposed descriptors and use of the proposed items, including a single combined item across all classes of obesity if a streamlined listing is preferred.

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<sup>15</sup> Therapeutic Goods Administration 2024, 'Boston Scientific Pty Ltd - Apollo ESG NXT System - Suture/needle passer, single-use (461292)', viewed 4 Dec 2024, <https://www.tga.gov.au/resources/artg/461292>.

The ADAR proposes using the Apollo ESG NXT system, an upgraded version of the OverStitch™ system, for performing ESG. The TGA-registered Apollo ESG NXT system is intended for use by gastroenterologists or bariatric surgeons to aid patient weight loss by reducing stomach volume in adults with a BMI of 30–50 kg/m<sup>2</sup> who have not succeeded with conservative methods. The proposed MBS items are listed in Table 2 and Table 3.

**Table 2: Proposed new item descriptor for ESG in class I–II obesity in the ADAR**

| <b>Category 3 – Therapeutic Procedures</b>                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MBS item xxxx<br>Endoscopic sleeve gastropasty, by a specialist, for patients aged 18 years or over with class I or class II obesity* without adequate and/or sustained response to very low energy diet therapy delivered with or without pharmacotherapy.<br>Applicable once per <b>24-month period</b> **<br>Multiple Operation Rule<br>(Anaes.) (Assist.) |
| <b>Fee: \$967.90 Benefit: 75% = \$725.95</b>                                                                                                                                                                                                                                                                                                                  |

Notes: Red text added by assessment group in line with proposed item descriptor in the ratified PICO Confirmation for Application 1555.1 (p.20)<sup>17</sup>.

\* BMI thresholds developed for Caucasians may not be suitable for Asian or Aboriginal and Torres Strait Islander individuals.<sup>17</sup>

Explanatory Note TN 8.29 details that different ethnic groups may experience major health risks at a BMI that is below the 35–40 kg/m<sup>2</sup>, and that the decision to undertake obesity surgery remains a matter for the clinical judgment of the surgeon. This explanatory note may need to be expanded to include the new MBS items, should the application be approved.

\*\*The proposed item descriptor in the ratified PICO Confirmation specified the proposed item would be applicable once per lifetime. However, the applicant revised this to 'once per 24-month period' in the ADAR to account for the need for revision procedures. This represents a difference relative to the proposed item ratified by PASC.

Source: Table ES 3 pg. 24 from ADAR.

**Table 3: Proposed new item descriptor for ESG in class III obesity in the ADAR**

| <b>Category 3 – Therapeutic Procedures</b>                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MBS item xxxx<br>Endoscopic sleeve gastropasty, by a specialist, for patients aged 18 years or over with class III obesity: <ul style="list-style-type: none"> <li>without adequate and/or sustained response to very low energy diet therapy delivered with or without pharmacotherapy, OR</li> <li>who are unsuitable for or would refuse to undergo bariatric surgery</li> </ul> Applicable once per <b>24-month period</b> *<br>Multiple Operation Rule<br>(Anaes.) (Assist.) |
| <b>Fee: \$967.90 Benefit: 75% = \$725.95</b>                                                                                                                                                                                                                                                                                                                                                                                                                                      |

Notes: Red text added by assessment group in line with proposed item descriptor in the ratified PICO Confirmation for Application 1555.1 (p.20)<sup>17</sup>.

\*The proposed item descriptor in the ratified PICO Confirmation specified the proposed item would be applicable once per lifetime.

However, the applicant revised this to 'once per 24-month period' in the ADAR to account for the need for revision procedures. This represents a difference relative to the proposed item ratified by PASC.

Source: Table ES 4 pg. 25 from ADAR

The ESG procedure is conducted during an inpatient hospital admission—either as a day surgery or overnight admission—by a multidisciplinary team including gastroenterologists qualified in endoscopic interventions or general, bariatric or upper gastrointestinal (GI) surgeons and anaesthesiologists. The proposed MBS item and fee are for the proceduralist conducting the ESG procedure. Existing MBS items would be used for the anaesthetist as the ESG procedure is performed under general anaesthesia.

The ADAR stated that the proposed MBS fees are the same as those suggested for MBS bariatric surgery item 31575. It is noted that MBS item 31575 states: 'Sleeve gastrectomy, with or without crural repair taking 45 minutes or less, for a patient with clinically severe obesity'. The ADAR claims that the ESG procedure takes less than 90 minutes if a proceduralist is

experienced. Other surgical centres suggest the procedure can take 60–90 minutes.<sup>16</sup> MBS item 31575 does not impose a restriction on the time taken to complete a sleeve gastrectomy. The timeframe in 31575 refers to a crural repair done in addition to the sleeve gastrectomy. In the event that a crural repair is undertaken with ESG the draft item descriptors would result in a separate MBS item being claimed. The current draft items would be consistent with the situation where an alternative surgical route (laparoscopic/open) was used.

PASC (December 2021) previously advised that an MBS item for post-ESG revision was required due to the potential for intervention failure (Table 4). The ADAR did not propose any MBS item for revision surgery to an alternate bariatric procedure, and it is unclear how these services would be funded and covered under MBS listings, if required.

**Table 4: Presentation of a proposed MBS item for revision or repair (proposed during the commentary)**

|                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------|
| <b>Category 3 – Therapeutic Procedures</b>                                                                                    |
| MBS item *XXXX<br>Surgical repair or revision of endoscopic sleeve gastroplasty.<br><*Specify any relevant explanatory notes> |
| Fee: TBA                                                                                                                      |

Source: Ratified PICO Confirmation Application 1555.1 (p.20)<sup>17</sup>

In the PSD for MSAC assessment 1555, MSAC considered that the ESG procedure is not reversible but is highly likely to fail and therefore needs a revision item. However, the ADAR reported that total removal of ESG could be completed using an existing MBS item for removal of a foreign body, but it is unclear which specific item this refers to. It is presumed to be item 30478 which carries a fee of \$279.80. Without modifications, MBS item 30478 would not be appropriate for a reversal procedure as it requires the removal of a foreign body in addition to one or more endoscopic procedures listed in the item.

Conversion to other bariatric procedures may also be undertaken after ESG. MBS item 31584 is available for the surgical reversal of previous bariatric procedures, including revisions or conversions, although will need amending if it is to be used to convert ESG.

## 7. Population

The ADAR presented 2 PICO set populations (Table 5; Table 6).

<sup>16</sup> The BMI Clinic. Endoscopic Sleeve Gastroplasty (ESG) Common Questions (FAQs) n.d. [Available from: <https://bmiclinic.com.au/endoscopic-sleeve-gastroplasty-faq/>. viewed 7 Jan 2024]

<sup>17</sup> Department of Health 2021, 'MSAC Application 1555.1: Endoscopic sleeve gastroplasty for the treatment of patients with cClass I and II obesity with/without comorbidities who have failed first-line (lifestyle modification) and second-line (VLED/pharmacotherapy) treatments. Ratified PICO Confirmation.', viewed 4 Dec 2024, [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/2256889BB5AB7382CA258737000463E1/\\$File/1555.1%20Ratified%20PICO.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/2256889BB5AB7382CA258737000463E1/$File/1555.1%20Ratified%20PICO.pdf).

**Table 5: PICO set 1**

| Component                                                                                                                                                                                                                     | Description                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Population                                                                                                                                                                                                                    | Patients with class I and II obesity with or without comorbidities who have failed first- and second-line weight loss interventions (diet, lifestyle modifications, pharmacotherapy)                                                                                                 |
| Intervention                                                                                                                                                                                                                  | ESG and lifestyle modifications                                                                                                                                                                                                                                                      |
| Comparator                                                                                                                                                                                                                    | Lifestyle modifications only<br>(Bariatric surgery not currently subsidised for this population and is not considered a relevant comparator.)                                                                                                                                        |
| Outcomes                                                                                                                                                                                                                      | <b>Efficacy:</b><br>Primary: %TBWL<br>Secondary: %EWL, durability of weight loss (3–5 years), weight-related comorbidities, revision, conversion to bariatric surgery<br><b>Safety:</b><br>Primary: ESG-related severe AEs<br>Secondary: Long-term AEs, worsening and new onset GORD |
| <b>Systematic review questions:</b> What is the safety, effectiveness and cost-effectiveness of ESG vs moderate intensity lifestyle interventions in the treatment of class I and II obesity (with or without comorbidities)? |                                                                                                                                                                                                                                                                                      |

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy; MBS: Medicare Benefits Schedule; PICO: population, intervention, comparator, outcomes; %EWL: per cent excess weight loss; %TBWL: per cent total body weight loss.

Source: Table ES 2 pg. 23 from ADAR

**Table 6: PICO set 2**

| Component                                                                                                                                                                                              | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Population                                                                                                                                                                                             | Patients with class II obesity with comorbidities and class III obesity with or without comorbidities who would be eligible to receive a bariatric procedure such as LSG (subsidised on the MBS)<br><br>Note: It should be noted that while a significant proportion of patients with obesity are eligible for bariatric surgery, uptake remains minimal, with nearly 98% opting for non-surgical interventions (as per ADAR). This low uptake may be influenced by multiple factors, including patient preference, clinical recommendations, access to care, and the broader availability of non-surgical options.<br>Note: “who would be eligible and <i>elect</i> to receive a bariatric procedure”. The word “elect” was deleted from the patient population by the AG. Removing “and elect” ensures the PICO remains focused on the eligible population as a whole, rather than a subset. |
| Intervention                                                                                                                                                                                           | ESG and lifestyle modifications                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Comparator                                                                                                                                                                                             | LSG<br>(Bariatric surgery is the current clinical alternative for this population and is subsidised on the MBS for those with severe obesity.)<br><br>Note: adjustable gastric banding, gastric bypass by Roux-en-Y and sleeve gastrectomy are alternatives to LSG that are available on the MBS; however, the ADAR considered LSG as the only nominated comparator given it is the most performed bariatric surgery in Australia, supported by expert recommendations.                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Outcomes                                                                                                                                                                                               | <b>Efficacy:</b><br>Primary: %TBWL<br>Secondary: %EWL, durability of weight loss (3–5 years), weight related comorbidities, revision, conversion to bariatric surgery<br><b>Safety:</b><br>Primary: ESG-related severe AEs<br>Secondary: Long-term AEs, worsening and new onset GORD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Systematic review questions:</b> What is the safety, effectiveness and cost-effectiveness of ESG vs bariatric interventions in the treatment of class II (with comorbidities) or class III obesity? |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy; MBS: Medicare Benefits Schedule; PICO: population, intervention, comparator, outcomes; %EWL: per cent excess weight loss; %TBWL: per cent total body weight loss.

Source: Table ES 2 pg. 23 from ADAR

Patients with clinical obesity—with or without comorbidities—are offered 2 treatment lines based on their prior weight loss history and response:

1. First-line intervention: VLED is recommended for those who have not previously tried it and are open to meal replacements. If successful, the diet transitions to weight maintenance. If unsuccessful, VLED may be reintroduced or escalated to second-line treatment.
2. Second-line intervention: Pharmacotherapy is considered for patients who regain weight after relaxing VLED or those who fail to respond adequately. VLED and pharmacotherapy are prescribed together. Treatment is self-funded and depends on patient willingness to proceed.

If target weight loss is not achieved after both interventions, patients can choose to continue with non-surgical options (diet, lifestyle modification, pharmacotherapy) or consider surgical interventions.

The current clinical management algorithm limits bariatric surgery for patients with a BMI of 35–40 kg/m<sup>2</sup> (class II obesity) to those with comorbidities. Patients with class II obesity without comorbidities must continue first- or second-line treatments. Post-surgery, patients who fail to maintain or achieve target weight loss can revisit VLED with pharmacotherapy or opt for revision surgery.

The proposed algorithm introduces ESG as an additional option for patients who fail first- and second-line interventions, including for patients with class I and class II obesity, who are not currently indicated for bariatric surgery. ESG serves as an alternative to non-surgical options or bariatric surgery (for those who are currently eligible). If ESG fails to achieve or maintain weight loss, patients can pursue VLED with pharmacotherapy, bariatric surgery (if BMI is 35–40 kg/m<sup>2</sup> and they have comorbidities) or revision ESG.

The commentary noted that both PICO sets differ from the PASC advice in terms of population, comparator and outcomes.

**Table 7: Alignment of the ADAR with the PASC-ratified PICO Confirmation**

| Component  | Description                                                                                                                                                                                                                                                                                             | Alignment to Ratified PICO Confirmation for MSAC 1555.1 (December 2021 PASC meeting) | ADAR's justification for change                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Population | PICO Set 1: Patients ≥18 years of age who have class I or II obesity (BMI 30–40 kg/m <sup>2</sup> ) and failed first- and second-line weight loss therapies.                                                                                                                                            | Yes                                                                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|            | PICO Set 2: Patients ≥18 years of age who have class II obesity (with comorbidities) or class III obesity (BMI ≥40 kg/m <sup>2</sup> ) without comorbidities who have failed first- and second-line weight loss therapies or those with comorbidities who have failed first-line weight loss therapies. | No<br>This patient population was not previously included.                           | Based on clinician feedback, restriction of ESG to patients with BMI <40kg/m <sup>2</sup> would be inappropriate as this restriction forces those with a higher BMI to undergo a riskier procedure (e.g. LSG or gastric bypass), which was seen as clinically unjustified and inequitable. Evidence presented in single-arm studies and non-randomised studies also demonstrates the benefit and safety of ESG for patients with class III obesity. Additionally, this population is consistent with the population defined for bariatric |

| Component    | Description                                                                                                                                                                                                                                         | Alignment to Ratified PICO Confirmation for MSAC 1555.1 (December 2021 PASC meeting)                                                                                                                                                                           | ADAR's justification for change                                                                                                                                                                                                                                                                                                                                           |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                | procedures in the Australian guidelines. <sup>18</sup>                                                                                                                                                                                                                                                                                                                    |
| Intervention | Endoscopic sleeve gastroplasty with lifestyle modifications.                                                                                                                                                                                        | Yes                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                                                                                                                                       |
| Comparator   | For patients with BMI 30.00–34.99 kg/m <sup>2</sup> with or without comorbidities and BMI 35.00–39.99 kg/m <sup>2</sup> without comorbidities: moderate intensity lifestyle interventions (VLED, behavioural interventions and/or pharmacotherapy). | Yes                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                                                                                                                                       |
|              | For patients with BMI 35.00–39.99 kg/m <sup>2</sup> with comorbidities and patients with BMI ≥40 kg/m <sup>2</sup> with or without comorbidities: bariatric surgery.                                                                                | Yes<br>Bariatric surgery was previously excluded as a comparator for class II obesity patients with comorbidities due to contraindications and by virtue of patient choice. PASC noted that bariatric surgery could be a relevant comparator in some patients. | Based on PASC advice for MSAC Application 1555.1, the current application includes bariatric surgery as an additional comparator for patients with BMI 35.00–39.99 kg/m <sup>2</sup> with comorbidities, which is aligned with the Australian clinical guidelines for bariatric procedures. <sup>18</sup>                                                                 |
| Outcomes     | <b>Safety:</b> Mortality, perioperative AEs, long-term AEs (e.g. sutures reopening).                                                                                                                                                                | Partial<br>PICO 1555.1 stated revision procedures or conversion to gastric sleeve or gastric bypass as safety endpoints.                                                                                                                                       | Revision procedures and conversions to gastric sleeve or gastric bypass are considered as an efficacy outcome instead of a safety endpoint.                                                                                                                                                                                                                               |
|              | <b>Effectiveness:</b> Total body weight loss, maintenance of weight loss, revision procedures required, conversion to bariatric surgery, changes in comorbidity markers, quality of life.                                                           | Partial<br>PICO 1555.1 stated the effectiveness outcome of excess body weight loss to be a primary outcome.                                                                                                                                                    | Based on Australian clinicians feedback, it was noted that this outcome is no longer commonly used in this disease area, as it is not consistently defined or easily understood. The recommended outcome of total body weight lost was considered a more appropriate primary for this application. Excess weight loss is presented as a secondary effectiveness endpoint. |
|              | <b>Healthcare system outcomes:</b> Cost associated with the intervention and comparator, including those of any AEs.                                                                                                                                | Yes                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                                                                                                                                       |

Abbreviations: AE: adverse event; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy; PASC: PICO Advisory Sub-Committee; VLED: very low energy diet  
Source: Ratified PICO Application 1555.1

In 2021 PASC recommended that the applicant revise the proposed population to align with current Australian guidelines for reimbursement of bariatric procedures (NHMRC 2013). MBS explanatory note TN8.29 details that currently available bariatric surgery items, including sleeve gastrectomy (MBS 31575), gastric band (MBS 31569), gastroplasty (31578), and 'Roux-en-Y

(MBS 31572), provide treatment for clinically severe obesity referring to a patient with a BMI 40kg/m<sup>2</sup>, or those with a BMI of 35-40 kg/m<sup>2</sup> with major comorbidities. Such recommendations are consistent with the 2013 NHMRC clinical practice guidelines (BMI > 40 kg/m<sup>2</sup> or adults with BMI > 35 kg/m<sup>2</sup> and comorbidities).<sup>18</sup>

The population in PICO 1 does not align with the current NHMRC clinical practice guidelines regarding the BMI recommendations for patients referred for bariatric surgery. The population of PICO 1 represents a new group of patients, with lower BMI who have failed some non-surgical interventions, being considered for bariatric procedures.

The population of PICO 2 partially aligns with the 2013 NHMRC clinical practice guidelines. The key difference between PICO 2 and the 2013 guidelines is the inclusion in the proposed MBS item of patients who are unsuitable for or have elected not to undergo bariatric surgery. The lack of an agreed and accepted clinical definition for this cohort means that potentially more patients would have access to ESG than other variations of MBS funded bariatric surgery. The ADAR did not compare ESG to alternative bariatric surgery comparators except for LSG.

## 8. Comparator

### PICO set 1

As previously approved by PASC the proposed comparator for patients with class I and II obesity is moderate-intensity lifestyle modification, including VLED, behavioural interventions and pharmacotherapy.<sup>17</sup> Behavioural interventions involve guidance from general practitioners (GPs) or allied health professionals, while pharmacotherapies include TGA-registered drugs such as orlistat (listed under the RPBS), as well as phentermine, liraglutide, naltrexone/bupropion, metformin, semaglutide and off-label topiramate for patients with a BMI of 30 kg/m<sup>2</sup> or higher (Table 8). The majority of these comparator interventions are not PBS-reimbursed in Australia and are accessed privately.

At the time of writing, only one pharmacotherapy specifically intended for weight loss is listed on the RPBS: orlistat as an initial course in patients with BMI ≥35 kg/m<sup>2</sup> with no known comorbidities, or ≥30 kg/m<sup>2</sup> with either diabetes, ischaemic heart disease, psychiatric conditions or hypertension. Semaglutide is currently listed on the PBS for the treatment of patients with type 2 diabetes. The population presented in this application could include those with type 2 diabetes, some of whom may be eligible for treatment with semaglutide on the PBS.

**Table 8: Weight-loss drug ARTG and reimbursement status for obesity**

| Drug                    | ARTG listed? | PBS listed?                           | RPBS listed? |
|-------------------------|--------------|---------------------------------------|--------------|
| Semaglutide (Ozempic®)  | Yes          | No (type II diabetes only)            | No           |
| Semaglutide (Wegovy®)   | Yes          | No                                    | No           |
| Tirzepatide (Mounjaro®) | Yes          | No                                    | No           |
| Orlistat                | Yes          | No                                    | Yes          |
| Phentermine             | Yes          | No                                    | No           |
| Liraglutide             | Yes          | No                                    | No           |
| Naltrexone/bupropion    | Yes          | No (alcohol/nicotine dependence only) | No           |
| Topiramate              | No           | No (for seizure management only)      | No           |

Abbreviations: ARTG: Australian Register of Therapeutic Goods; PBS: Pharmaceutical Benefits Scheme; RPBS: Repatriations Pharmaceutical Benefits Scheme.

Source: compiled during commentary development

## PICO set 2

The second proposed comparator for patients with class II obesity with comorbidities and class III obesity is bariatric surgery. This aligns with current Australian guidelines and was noted in the ratified PICO for MSAC Application 1555.1. For patients with BMI 35–40 kg/m<sup>2</sup>, LSG—item 31575 sleeve gastrectomy (SG)—is the most performed bariatric surgery in Australia, accounting for 80% of procedures reported in the 2023 Bariatric Surgery Registry annual report.<sup>1819</sup> Further, in 2023, according to the bariatric surgery registry, 95.4% of primary procedures and 93.2% of revision procedures were privately funded. Comparisons between datasets are a guide only, as MBS data form an administrative dataset and do not always match the Registry's data due to differences in reporting. Other surgeries, such as gastric bypass, comprise a smaller share. Considering LSG is the most performed bariatric surgery in Australia, the ADAR considered LSG as the nominated comparator, supported by expert recommendations, for this patient population.

## 9. Summary of public consultation input

Consultation input was received from three medical, health, or other (non-consumer) organisations. Four inputs were received from individuals – three health professionals and one consumer.

The organisations that submitted input were:

- Private Healthcare Australia (PHA)
- Medtronic Australasia Pty Ltd
- Gastroenterological Society of Australia (GESA)

### Level of support for public funding

Support for public funding was mixed. All health professionals and GESA were supportive of public funding, however the consumer and other organisations were not supportive for various reasons including those which had already been raised by MSAC following their first consideration of the application.

### Comments on PICO

- Organisations not supportive of the service considered the proposed population as too broad and noted it may result in bracket creep. It was suggested the population should be narrowed to patients with a BMI of 35+ with comorbidities who have failed first- and second-line treatments.
- Organisations noted the lack of inclusion of new pharmacotherapies to treat obesity (i.e. GLP-1 antagonists) which were not available during the previous consideration of the application.
- It was noted that bariatric surgery as a comparator was not included in the MERIT trial.
- It was considered that the follow up period for the studies was short, noting 12 months as too short as a follow up time to observe the safety and effectiveness of the procedure.
- It was noted there was a lack of inclusion of allied professionals in the service delivery to support patients in maintaining weight loss beyond three months.

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<sup>18</sup>National Health and Medical Research Council. Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia 2013. Available from:

<https://www.nhmrc.gov.au/sites/default/files/documents/reports/clinical%20guidelines/n57-obesity-guidelines-.pdf>.

<sup>19</sup> School of Translational Medicine Monash University 2024, The Bariatric Surgery Registry Annual Report – 2023, viewed 4 Dec 2024, [https://www.monash.edu/\\_data/assets/pdf\\_file/0007/3757876/Bariatric\\_Surgery\\_Registry\\_-Annual\\_Report\\_2023.pdf](https://www.monash.edu/_data/assets/pdf_file/0007/3757876/Bariatric_Surgery_Registry_-Annual_Report_2023.pdf)

## Perceived Advantages

Advantages of the service noted by GESA and the health professionals included:

- The procedure being minimally invasive.
- The procedure may potentially produce better outcomes compared to current non-surgical options available.
- Shorter recovery time following the procedure compared to other surgical options,
- Decrease in overall cost to health budget with reduction in comorbidities as obesity is treated.
- Improve equity of access to treatments for obesity (noting a small number of pharmacotherapy options are currently publicly funded for the proposed population).

## Perceived Disadvantages

Disadvantages of the service were primarily raised by those not supportive of the service and included noting:

- High rate of adverse events noted in the MERIT trial.
- A higher likelihood of mid to longer term decline in weight loss (compared to a sleeve procedure) which can lead to revision and/or subsequent bariatric procedures.
- The effectiveness of ESG in the proposed population (<40 BMI, without comorbidities) is uncertain.

The consumer described their experience with the service and noting having to tolerate a severe adverse event immediately after the procedure. They were required to receive a 'revision' operation and additional therapies to compensate for the adverse event. The consumer paid out-of-pocket for the procedure and regretted that they did so as they did not experience any benefit or positive outcome from receiving the service.

## Support for Implementation /issues

- All respondents supportive of funding agreed the service should be performed by specialist accredited surgeons and delivered holistically by a multidisciplinary team.
- Some respondents supportive of funding considered the item descriptor should be limited to the specific Apollo ESC NXT system (overstitch).
- A comprehensive training program and accreditation would need to be developed if the service is supported for public funding. This includes developing eligibility criteria to identify suitable patients.
- A national registry may be of benefit if the service is supported for public funding.

# 10. Characteristics of the evidence base

## PICO set 1

The clinical evidence presented in the ADAR for PICO set 1 is based on 1 RCT and 14 single-arm studies (Table 9; Table 10).

The MERIT trial featured adult participants with class 1 or 2 obesity, comparing ESG plus lifestyle modifications to exposure to lifestyle modifications only. The primary follow-up period was 52 weeks, with crossover occurring at 52 weeks for the lifestyle modifications-only group to undergo ESG.

**Table 9: Key features of the included evidence, PICO 1**

| Reference                                                   | N     | Design               | Duration  | Risk of bias | Patient population (ESG only) |                                 |                                   | Outcome(s)                                                                                                                                                      | Use in modelled evaluation |
|-------------------------------------------------------------|-------|----------------------|-----------|--------------|-------------------------------|---------------------------------|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
|                                                             |       |                      |           |              | mean age (years)              | female (%)                      | mean BMI (kg/m <sup>2</sup> )     |                                                                                                                                                                 |                            |
| RCT: ESG + lifestyle modification vs lifestyle modification |       |                      |           |              |                               |                                 |                                   |                                                                                                                                                                 |                            |
| MERIT (Abu Dayyeh 2022) <sup>20</sup>                       | 209   | RCT                  | 2 years   | Low          | 47.3                          | 88                              | 35.5                              | %TBWL at 12 and 24 months, %EWL at 12 months, revision and conversion to bariatric surgery, comorbidity markers, patient-reported endpoints, AEs, long-term AEs | Yes                        |
| Single-arm studies: ESG + lifestyle modification            |       |                      |           |              |                               |                                 |                                   |                                                                                                                                                                 |                            |
| Abu Dayyeh 2017 <sup>21</sup>                               | 25    | Prospective cohort   | 1.6 years | Low          | 47.6                          | 84.0                            | 35.5                              | Revision and conversion to bariatric surgery, comorbidity markers, patient-reported endpoints, AEs, long-term AEs                                               | No                         |
| Lopez-Nava 2017 <sup>22</sup>                               | 154   | Prospective cohort   | 2 years   | Low          | 44.9                          | 70.1                            | 38.3                              | %TBWL at 12 months, %EWL at 12 months                                                                                                                           | No                         |
| Saumoy 2018 <sup>23</sup>                                   | 128   | Prospective cohort   | 1 year    | Low          | 43.6                          | 67.2                            | 38.9                              | %TBWL at 12 months, AEs                                                                                                                                         | No                         |
| Kumar 2018 <sup>24</sup>                                    | 99    | Prospective cohort   | 1 year    | High         | 41.3                          | Phase II: NR<br>Phase III: 81.9 | Phase II: 34.3<br>Phase III: 36.1 | %TBWL at 12 months                                                                                                                                              | No                         |
| Sartoretto 2018 <sup>25</sup>                               | 112   | Retrospective cohort | 0.5 years | Low          | 45.1                          | 69.0                            | 37.9                              | AEs                                                                                                                                                             | No                         |
| Morales 2018 <sup>26</sup>                                  | 148   | Retrospective cohort | 1.5 years | Low          | 41.5                          | 81.8                            | 35.1                              | %TBWL at 12 months, %EWL at 12 months, AEs                                                                                                                      | No                         |
| Alqahtani 2019 <sup>27</sup>                                | 1,000 | Prospective cohort   | 1.5 years | Low          | 34.4                          | 89.7                            | 33.3                              | %TBWL at 12 months, %EWL at 12 months, AEs                                                                                                                      | No                         |
| Barrichello 2019 <sup>28</sup>                              | 193   | Prospective cohort   | 1 year    | Low          | 42.3                          | 76.7                            | 34.1                              | %TBWL at 12 months, %EWL at 12 months, AEs                                                                                                                      | No                         |

<sup>20</sup> Abu Dayyeh, BK, Bazerbachi, F, Vargas, EJ, Sharaiha, RZ, Thompson, CC, Thaemert, BC, Teixeira, AF, Chapman, CG, Kumbhari, V, Ujiki, MB, Ahrens, J, Day, C, Acosta, AJ, Badurdeen, D, Buttar, NS, Clark, MM, Eaton, L, Ghanem, O, Grothe, K, Jirapinyo, P, Kellogg, T, Klein, CL, Mundi, M, Storm, AC, Rivera, AR, Wilson, TD, Galvao Neto, M, Zundel, N & Wilson, EB 2022, 'Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial', *The Lancet*, vol. 400, no. 10350, pp. 441-51.

<sup>21</sup> Abu Dayyeh, BK, Acosta, A, Camilleri, M, Mundi, MS, Rajan, E, Topazian, MD & Gostout, CJ 2017, 'Endoscopic Sleeve Gastroplasty Alters Gastric Physiology and Induces Loss of Body Weight in Obese Individuals', *Clin Gastroenterol Hepatol*, vol. 15, no. 1, pp. 37-43.e1.

<sup>22</sup> Lopez-Nava, G, Galvão, MP, Bautista-Castaño, I, Fernandez-Corbelle, JP, Trell, M & Lopez, N 2017, 'ENDOSCOPIC SLEEVE GASTROPLASTY FOR OBESITY TREATMENT: TWO YEARS OF EXPERIENCE', *Arq Bras Cir Dig*, vol. 30, no. 1, pp. 18-20.

<sup>23</sup> Saumoy, M, Schneider, Y, Zhou, XK, Shukla, A, Kahaleh, M, Aronne, L & Sharaiha, RZ 2018, 'A single-operator learning curve analysis for the endoscopic sleeve gastroplasty', *Gastrointest Endosc*, vol. 87, no. 2, pp. 442-7.

<sup>24</sup> Kumar, N, Abu Dayyeh, BK, Lopez-Nava Breviere, G, Galvao Neto, MP, Sahdala, NP, Shaikh, SN, Hawes, RH, Gostout, CJ, Goenka, MK, Orillac, JR, Alvarado, A, Jirapinyo, P, Zundel, N & Thompson, CC 2018, 'Endoscopic sutured gastroplasty: procedure evolution from first-in-man cases through current technique', *Surg Endosc*, vol. 32, no. 4, pp. 2159-64.

<sup>25</sup> Sartoretto, A, Sui, Z, Hill, C, Dunlap, M, Rivera, AR, Khashab, MA, Kalloo, AN, Fayad, L, Cheskin, LJ, Marinos, G, Wilson, E & Kumbhari, V 2018, 'Endoscopic Sleeve Gastroplasty (ESG) Is a Reproducible and Effective Endoscopic Bariatric Therapy Suitable for Widespread Clinical Adoption: a Large, International Multicenter Study', *Obesity Surgery*, vol. 28, no. 7, pp. 1812-21.

<sup>26</sup> Graus Morales, J, Crespo Pérez, L, Marques, A, Marín Arribas, B, Bravo Arribas, R, Ramo, E, Escalada, C, Arribas, C & Himpens, J 2018, 'Modified endoscopic gastroplasty for the treatment of obesity', *Surg Endosc*, vol. 32, no. 9, pp. 3936-42.

<sup>27</sup> Alqahtani, A, Al-Darwish, A, Mahmoud, AE, Alqahtani, YA & Elahmedi, M 2019, 'Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients', *Gastrointest Endosc*, vol. 89, no. 6, pp. 1132-8.

<sup>28</sup> Barrichello, S, Hourneaux de Moura, DT, Hourneaux de Moura, EG, Jirapinyo, P, Hoff, AC, Fittipaldi-Fernandez, RJ, Baretta, G, Felício Lima, JH, Usuy, EN, de Almeida, LS, Ramos, FM, Matz, F, Galvão Neto, MDP & Thompson, CC 2019, 'Endoscopic sleeve gastroplasty in the management of overweight and obesity: an international multicenter study', *Gastrointest Endosc*, vol. 90, no. 5, pp. 770-80.

| Reference                          | N   | Design               | Duration | Risk of bias | Patient population (ESG only) |            |                               | Outcome(s)                                                                                                                  | Use in modelled evaluation |
|------------------------------------|-----|----------------------|----------|--------------|-------------------------------|------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------|----------------------------|
|                                    |     |                      |          |              | mean age (years)              | female (%) | mean BMI (kg/m <sup>2</sup> ) |                                                                                                                             |                            |
| Espinet 2019 <sup>29</sup>         | 15  | Prospective cohort   | 1 year   | Low          | 46.9                          | 50.0       | 38.8                          | %TBWL at 12 months, %EWL at 12 months                                                                                       | No                         |
| Bhandari 2020 <sup>30</sup>        | 53  | Retrospective cohort | 1 year   | Low          | 40.5                          | 81.1       | 34.8                          | %TBWL at 12 months, %EWL at 12 months                                                                                       | No                         |
| De Miranda Neto 2020 <sup>31</sup> | 233 | Prospective cohort   | 1 year   | Low          | 41.1                          | 73.0       | 34.7                          | %TBWL at 12 months, durability of ESG, AEs                                                                                  | No                         |
| Sharaiha 2021 <sup>32</sup>        | 216 | Prospective cohort   | 5 years  | Low          | 46.0                          | 68.0       | 39.0                          | %TBWL at 12 months, %EWL at 12 months, durability of ESG, revision and conversion to bariatric surgery, long-term AEs       | No                         |
| Bhandari 2022 <sup>33</sup>        | 612 | Prospective cohort   | 4 years  | Low          | 40.7                          | 69.3       | 34.3                          | %TBWL at 12 months, %EWL at 12 months, durability of ESG, revision and conversion to bariatric surgery, comorbidity markers | No                         |
| Frey 2024 <sup>34</sup>            | 143 | Retrospective cohort | 3 years  | High         | 43.0                          | 90.2       | 33.6                          | %TBWL at 12 months, %EWL at 12 months, durability of ESG                                                                    | No                         |

Abbreviations: AE: adverse event; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy, NR: not reported; PICO: population, intervention, comparator, outcome; RCT: randomised controlled trial; %EWL: excess weight loss; %TBWL: % total body weight loss  
Source: compiled during commentary

<sup>29</sup> Espinet Coll, E, Vila Lolo, C, Díaz Galán, P, Gómez Valero, JA, Bacchiddu, S, Quintana Tomás, C, Irigoyen, D, Gunnard, K & Juan-Creix Comamala, A 2019, 'Bariatric and metabolic endoscopy in the handling of fatty liver disease. A new emerging approach?', *Revista Española de Enfermedades Digestivas*, vol. 111, no. 4, pp. 283-93.

<sup>30</sup> Bhandari, M, Jain, S, Mathur, W, Kosta, S, Neto, MG, Brunaldi, VO & Fobi, M 2020, 'Endoscopic sleeve gastroplasty is an effective and safe minimally invasive approach for treatment of obesity: First Indian experience', *Digestive Endoscopy*, vol. 32, no. 4, pp. 541-6.

<sup>31</sup> de Miranda Neto, AA, de Moura, DTH, Ribeiro, IB, Khan, A, Singh, S, da Ponte Neto, AM, Madruga Neto, AC, do Monte Junior, ES, Tustumi, F, Bernardo, WM & de Moura, EGH 2020, '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*, vol. 30, no. 5, pp. 1971-87.

<sup>32</sup> Sharaiha, RZ, Hajifathalian, K, Kumar, R, Saunders, K, Mehta, A, Ang, B, Skaf, D, Shah, S, Herr, A, Igel, L, Dawod, Q, Dawod, E, Sampath, K, Carr-Locke, D, Brown, R, Cohen, D, Dannenberg, AJ, Mahadev, S, Shukla, A & Aronne, LJ 2021, 'Five-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity', *Clinical Gastroenterology and Hepatology*, vol. 19, no. 5, pp. 1051-7.e2.

<sup>33</sup> Bhandari, M, Kosta, S, Reddy, M, Mathur, W, Neto, MG & Bhandari, M 2022, 'Four-year outcomes for endoscopic sleeve gastroplasty from a single centre in India', *J Minim Access Surg*, vol. 19, no. 1, pp. 101-6.

<sup>34</sup> Frey, S, Sejour, E, Cougard, PA, Benamran, D & Sebbag, H 2024, 'From Early to Mid-Term Results of Endoscopic Sleeve Gastroplasty: A Retrospective Analysis of a Bariatric Center', *Obes Surg*, vol. 34, no. 7, pp. 2537-45.

**Table 10: Key features of included evaluations, PICO set 1**

| Evaluation type | Included studies                                                                                                                                                                                                 | Outcome            |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Meta-analysis   | MERIT, Sharaiha 2021, Lopez-Nava 2017, Kumar 2018 phase II, Kumar 2018 phase III, Sumoy 2018, Morales 2018, Espinet 2018, Alqahtania, 2019, Barrichello 2019, Bhandari 2022, Neto 2019, Bhamdari 2022, Frey 2024 | %TBWL at 12 months |
| Meta-analysis   | MERIT, Sharaiha 202, Lopez-Nava 2017, Dayyeh 2017, Morales 2018, Espinet 2018, Alqahtania, 2019, Barrichello 2019, Bhandari 2022, Frey 2024                                                                      | %EWL at 12 months  |
| Meta-analysis   | Abu Dayyeh 2017, Alqahtani 2019                                                                                                                                                                                  | Mild AEs           |
| Meta-analysis   | Abu Dayyeh 2017, Saumoy 2018, Sartoretto 2018, Morales 2018, Alqahtani, 2019, Barrichello 2019                                                                                                                   | Moderate AEs       |
| Meta-analysis   | Saumoy 2018, Barrichello 2019, Neto 2019                                                                                                                                                                         | Severe AEs         |
| Meta-analysis   | Abu Dayyeh 2017, Saumoy 2018, Sartoretto 2018, Morales 2018, Alqahtani, 2019, Barrichello 2019, Neto 2019                                                                                                        | Total AEs          |

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty, GORD: gastro-oesophageal reflux disease; PICO: population, intervention, comparator, outcome, LSG: laparoscopic sleeve gastrectomy. %EWL: excess weight loss, %TBWL: % total body weight loss  
Source: compiled during commentary

## PICO set 2

The clinical evidence presented in the submission for PICO set 2 is based on 9 single-arm studies (Table 11; Table 12).

**Table 11: Key features of the included evidence, PICO set 2 (ESG vs LSG)**

| Reference                    | N     | Design                                        | Duration  | Risk of bias | Patient population (ESG/LSG) |            |                  | Outcome(s)                                                                                                                                                 | Use in modelled evaluation |
|------------------------------|-------|-----------------------------------------------|-----------|--------------|------------------------------|------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
|                              |       |                                               |           |              | mean age (years)             | female (%) | mean BMI (kg/m²) |                                                                                                                                                            |                            |
| ESG vs LSG                   |       |                                               |           |              |                              |            |                  |                                                                                                                                                            |                            |
| Alqahtani 2022 <sup>35</sup> | 6,036 | Retrospective propensity score-matched cohort | 36 months | Moderate     | 33.8/33.9                    | 89/89      | 32.5/32.9        | Durability, revision and conversion to bariatric surgery, obesity-related comorbidities (hypertension, type II diabetes), AEs, visits to ambulatory clinic | No                         |
| Carr 2022 <sup>36</sup>      | 61    | Prospective cohort                            | 12 months | Moderate     | 41.4/40.4                    | 81.2/84.4  | 35.5/40.7        | Patient-reported endpoints, AEs, changes in GI symptoms                                                                                                    | No                         |

<sup>35</sup> Alqahtani, AR, Elahmedi, M, Aldarwish, A, Abdurabu, HY & Alqahtani, S 2022, 'Endoscopic gastroplasty versus laparoscopic sleeve gastrectomy: a noninferiority propensity score-matched comparative study', *Gastrointest Endosc*, vol. 96, no. 1, pp. 44-50.

<sup>36</sup> Carr, P, Keighley, T, Petocz, P, Blumfield, M, Rich, GG, Cohen, F, Soni, A, Maimone, IR, Fayet-Moore, F, Isenring, E & Marshall, S 2022, 'Efficacy and safety of endoscopic sleeve gastroplasty and laparoscopic sleeve gastrectomy with 12+ months of adjuvant multidisciplinary support', *BMC Primary Care*, vol. 23, no. 1, p. 26.

| Reference                     | N       | Design                                          | Duration  | Risk of bias | Patient population (ESG/LSG) |            |                               | Outcome(s)                                                                                                         | Use in modelled evaluation |
|-------------------------------|---------|-------------------------------------------------|-----------|--------------|------------------------------|------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------|
|                               |         |                                                 |           |              | mean age (years)             | female (%) | mean BMI (kg/m <sup>2</sup> ) |                                                                                                                    |                            |
| Fayad 2019 <sup>37</sup>      | 18,137  | Retrospective propensity score-matched cohort   | 6 months  | Moderate     | 48/47                        | 57.4/71.1  | 43.1/44.1                     | Adverse events, new onsets of GORD                                                                                 | No                         |
| Fiorillo 2020 <sup>38</sup>   | 46      | Retrospective propensity score-matched cohort   | 6 months  | Moderate     | 41/37                        | 69.6/73.9  | 39.5/41                       | Obesity-related comorbidities (hypertension, type II diabetes), patient-related endpoints, AEs, new onsets of GORD | No                         |
| Lopez-Nava 2020 <sup>39</sup> | 24      | Prospective cohort                              | 6 months  | Low          | 49.3/50.5                    | 75/75      | 38.3/39.2                     | AEs                                                                                                                | No                         |
| Lopez-Nava 2021 <sup>40</sup> | 260     | Retrospective cohort                            | 24 months | Moderate     | 44.6/44.6                    | 71/59      | 39.4/40.1                     | AEs                                                                                                                | No                         |
| Novikov 2018 <sup>41</sup>    | 211     | Retrospective cohort                            | 12 months | Low          | 43.9/40.7                    | 68.1/78.3  | 38.6/47.2                     | AEs                                                                                                                | No                         |
| Gudur 2023 <sup>42</sup>      | 36,323  | Retrospective propensity score-matched analysis | 30 days   | High         | 47.5/44.9                    | 84.5/82.3  | 40.6/42.8                     | AEs                                                                                                                | No                         |
| Gudur 2024 <sup>43</sup>      | 151,448 | Retrospective analysis                          | 30 days   | High         | 44.0/41.7                    | 75/74.1    | 56.9/56.6                     | AEs                                                                                                                | No                         |

Abbreviations: AE: adverse event; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy, NR: not reported; PICO: population, intervention, comparator, outcome; RCT: randomised controlled trial; %EWL: excess weight loss; %TBWL: % total body weight loss  
Source: compiled during commentary

<sup>37</sup> Fayad, L, Adam, A, Schweitzer, M, Cheskin, LJ, Ajayi, T, Dunlap, M, Badurdeen, DS, Hill, C, Paranj, N, Lalezari, S, Kalloo, AN, Khashab, MA & Kumbhari, V 2019, 'Endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy: a case-matched study', *Gastrointest Endosc*, vol. 89, no. 4, pp. 782-8.

<sup>38</sup> Fiorillo, C, Quero, G, Vix, M, Guerriero, L, Pizzicannella, M, Lapergola, A, D'Urso, A, Swannstrom, L, Mutter, D, Dallemagne, B & Perretta, S 2020, '6-Month Gastrointestinal Quality of Life (QoL) Results after Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: A Propensity Score Analysis', *Obes Surg*, vol. 30, no. 5, pp. 1944-51.

<sup>39</sup> Lopez-Nava, G, Negi, A, Bautista-Castaño, I, Rubio, MA & Asokkumar, R 2020, 'Gut and Metabolic Hormones Changes After Endoscopic Sleeve Gastroplasty (ESG) Vs. Laparoscopic Sleeve Gastrectomy (LSG)', *Obes Surg*, vol. 30, no. 7, pp. 2642-51.

<sup>40</sup> Lopez-Nava, G, Asokkumar, R, Bautista-Castaño, I, Laster, J, Negi, A, Fook-Chong, S, Nebreda Duran, J, Espinett Coll, E, Gebelli, JP & Garcia Ruiz de Gordejuela, A 2021, 'Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic greater curve plication: do they differ at 2 years?', *Endoscopy*, vol. 53, no. 3, pp. 235-43.

<sup>41</sup> Novikov, AA, Afaneh, C, Saumoy, M, Parra, V, Shukla, A, Dakin, GF, Pomp, A, Dawod, E, Shah, S, Aronne, LJ & Sharaiha, RZ 2018, 'Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: How Do They Compare?', *J Gastrointest Surg*, vol. 22, no. 2, pp. 267-73.

<sup>42</sup> Gudur, AR, Geng, CX, Kshatri, S, Martin, D, Haug, R, Radlinski, M, Lei, Y, Buerlein, RCD, Strand, DS, Sauer, BG, Shami, VM, Hallowell, P, Schirmer, B, Wang, AY & Podboy, A 2023a, 'Comparison of endoscopic sleeve gastroplasty versus surgical sleeve gastrectomy: a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database analysis', *Gastrointest Endosc*, vol. 97, no. 1, pp. 11-21.e4.

<sup>43</sup> Gudur AR, Geng C, Mannava A, Buerlein RCD, Strand DS, Sauer BG, et al. Early safety of endoscopic sleeve gastroplasty in super obesity (body mass index > 50). *Surgery for Obesity and Related Diseases*. 2024.

**Table 12: Key features of included evaluations, PICO 2 (ESG vs LSG)**

| Evaluation type | Included studies                                                                                                               | Outcome                                      |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Meta-analysis   | Alqahtani 2022, Carr 2022, Fayad 2019, Fiorillo 2020 a, Lopez-Nava 2020, Lopez-Nava 2021, Novikov 2017                         | 6 months %TBWL                               |
| Meta-analysis   | Alqahtani 2022, Carr 2022, Lopez-Nava 2021, Novikov 2018                                                                       | 12 months %TBWL                              |
| Meta-analysis   | Alqahtani 2022, Carr 2022, Fiorillo 2020                                                                                       | 6 months %EWL                                |
| Meta-analysis   | Alqahtani 2022, Carr 2022                                                                                                      | 12 months %EWL                               |
| Meta-analysis   | Alqahtani 2022, Fiorillo 2020                                                                                                  | Remission or improvement in hypertension     |
| Meta-analysis   | Alqahtani 2022, Fiorillo 2020                                                                                                  | Remission or improvement in type II diabetes |
| Meta-analysis   | Alqahtani 2022, Carr 2022, Fayad 2019, Fiorillo 2020 a, Lopez-Nava 2020, Lopez-Nava 2021, Novikov 2018, Gudur 2023, Gudur 2024 | Severe AEs                                   |
| Meta-analysis   | Alqahtani 2022, Carr 2022, Fayad 2019, Fiorillo 2020, Lopez-Nava 2020, Lopez-Nava 2021, Novikov 2018                           | Severe AEs (excluding high-risk studies)     |
| Meta-analysis   | Fayad 2019, Fiorillo 2020                                                                                                      | New onset GORD                               |

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty, GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy, PICO: population, intervention, comparator, outcome; %EWL: excess weight loss, %TBWL: % total body weight loss  
Source: compiled during commentary

The commentary considered that these studies may be subject to bias, due to large losses to follow-up, combined with incomplete reporting of reasons for attrition, and the lack of strategies for handling missing data.

## 11. Comparative safety

The clinical evidence presented in the ADAR was primarily based on 1 RCT, featuring a primary and crossover ESG group and a lifestyle modifications-only group, and 14 single-arm studies for PICO set 1 and 9 non-randomised comparative studies for PICO set 2. Most of these studies also presented efficacy outcomes.

### PICO 1: ESG + lifestyle modifications vs lifestyle modifications alone

Reported outcomes for the ESG group in PICO 1 (ESG vs lifestyle modification) included AEs. In the MERIT trial, 3 participants (2%) who received an ESG procedure had a device-related or procedure-related serious AE that met the criteria of grade 3 (requiring surgical, endoscopic, or radiological intervention) or higher on the Clavien-Dindo classification scale. These events included abdominal abscess managed endoscopically, upper gastrointestinal (GI) bleed managed conservatively without transfusion, and one case of malnutrition requiring endoscopic reversal of the ESG. Endoscopic reversal is only possible in certain cases of ESG, particularly in early stages following surgery. AEs were not reported for participants undergoing lifestyle modifications only, with no comparison available between the intervention groups. In the MERIT trial, 92% of participants in the primary and crossover ESG group reported a procedure-related AE. Two-thirds (66%) of such AEs were identified to be accommodative GI symptoms such as stomach upset, pain, nausea and vomiting.<sup>20</sup> Most were resolved within one week post-procedure; however, 4% required subsequent hospitalisation. Within the included single-arm studies, few serious AEs were reported and no patient mortality due to ESG was identified.

Long-term AEs were reported as a secondary safety outcome for PICO 1. Long-term (up to 5 years) AEs were investigated by one single-arm study, with an overall rate of 1.3% moderate AEs identified, associated with overeating and dietary indiscretion. These included upper left-

quadrant pain leading to ESG reversal and peri-gastric leak, which was treated by antibiotics and percutaneous drainage.<sup>32</sup>

The applicant identifies an inferior safety profile for ESG as compared to lifestyle modification alone, which is attributable to the surgical, more invasive nature of the intervention. The applicant also identified that, in the long term, safety may be non-inferior. However, although the rate of severe AEs for ESG is low, the quality of evidence is also low. Assessment of long-term AEs, in particular, may suffer from attrition bias. Further, the safety of pharmacological interventions was not investigated as initially recommended by PASC. Expert opinion cited by the ADAR stated that pharmacotherapies may have poor side-effect profiles, which was not investigated within the ADAR. The applicant's claim of non-inferior long-term safety of ESG compared to lifestyle modifications only is not well supported, due to low-quality evidence and the lack of randomised long-term studies to investigate patient outcomes.

## PICO 2: ESG vs LSG

For PICO set 2, AES are summarised in Table 13, Table 14 and Table 15.

**Table 13: Summary of AEs and complications reported in the postoperative period for ESG and LSG across the included studies in PICO 2**

| Trial ID                   | Rate of AEs post-ESG n (%) | Rate of AEs post-LSG/SG n (%) | OR (95% CI)        |
|----------------------------|----------------------------|-------------------------------|--------------------|
| Alqahtani 2022             | 14 (0.5)                   | 10 (0.4)                      | 1.36 (0.60, 3.06)  |
| Carr 2022                  | 0                          | 1 (2.2)                       | 0.90 (0.03, 23.19) |
| Fayad 2019                 | 3 (5.2)                    | 14 (16.9)                     | 0.29 (0.08, 1.06)  |
| Fiorillo 2020 <sup>a</sup> | 0                          | 2 (8.7)                       | 0.18 (0.01, 4.03)  |
| Lopez-Nava 2020            | 0                          | 0                             | Not estimable      |
| Lopez-Nava 2021            | 1 (0.5)                    | 3 (4.9)                       | 0.10 (0.01, 0.96)  |
| Novikov 2018               | 2 (2.2)                    | 11 (9.2)                      | 0.22 (0.05, 1.03)  |
| Gudur 2023                 | 86 (1.4)                   | 340 (1.1)                     | 1.27 (1.00, 1.61)  |
| Gudur 2024                 | 15 (1.8)                   | 2356 (1.6)                    | 1.18 (0.71, 1.98)  |
| Total                      | --                         | --                            | 0.80 (0.48, 1.32)  |

Abbreviations: AE: adverse event; CI: confidence interval; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy; n: number of patients; OR: odds ratio

Notes: <sup>a</sup> Severity of AEs not specified; assume reported AEs were severe only

Source: Table 229 pg. 124 from ADAR

**Table 14: New-onset GORD in ESG and LSG groups**

| Study         | ESG Events | ESG Total | LSG Events | LSG Total | Odds Ratio (95% CI) |
|---------------|------------|-----------|------------|-----------|---------------------|
| Fayad 2019    | 1          | 52        | 12         | 83        | 0.12 (0.01, 0.92)   |
| Fiorillo 2020 | 0          | 23        | 7          | 23        | 0.05 (0.00, 0.88)   |
| Overall       | 1          | 75        | 19         | 106       | 0.09 (0.02, 0.47)   |

Abbreviations: CI: confidence interval; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy

Source: Figure 223 pg. 114 from ADAR

**Table 15: Grade analysis of AE outcomes for ESG compared to LSG for people with obesity who are eligible for bariatric surgery**

| Outcomes           | Anticipated absolute effects* (95% CI) |                                  | Relative effect (95% CI)         | No of participants (studies)          | Certainty of the evidence (GRADE) | Comments                                                                                                                                                                                                                                     |
|--------------------|----------------------------------------|----------------------------------|----------------------------------|---------------------------------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | Risk with LSG                          | Risk with ESG                    |                                  |                                       |                                   |                                                                                                                                                                                                                                              |
| Rate of severe AEs | 15 per 1,000                           | <b>12 per 1,000</b><br>(7 to 20) | <b>OR 0.80</b><br>(0.48 to 1.32) | 194,126<br>(9 non-randomised studies) | ⊕⊕○○<br>Low                       | ESG is likely to reduce the rate of severe AEs compared to LSG but the evidence is uncertain. This analysis includes 2 studies that have a high risk of bias. Exclusion of these 2 high-risk studies further reduces the rate of severe AEs. |

Abbreviations: AE: adverse event; CI: confidence interval; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy; OR: odds ratio

Note: \*The risk in the intervention group (plus 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (plus 95% CI).

Source: Table 5.9 appendix pg. 236 of ADAR.

Nine non-randomised studies reported safety data for both ESG and LSG procedures. These studies utilised methods of AE classification including Clavien-Dindo and the National Institute of Health classification scales. Rates of AEs in ESG patients ranged from 0–5.2%, while rates of AEs in those treated with LSG ranged from 0–16.9%. Reported AEs for ESG patients included bleeding, peri-gastric collection and leaks. In LSG patients, these were observed in addition to pancreatitis and jaundice, wound dehiscence, pulmonary embolism and vein thrombosis, respiratory failure, postoperative ileus and wound and urinary tract infection.

Meta-analysis of the 9 studies revealed a lower rate of severe AEs and a lower total mean difference for severe AEs for the ESG group as compared to LSG, favouring ESG with a non-significant odds ratio of 0.80 (95% CI: 0.48, 1.32). The applicant stated that the non-significant results could be attributed to 2 studies with a high risk of bias that identified higher rates of severe AEs within ESG groups.<sup>42, 43</sup> The applicant further stated that such findings could be explained by less experienced proceduralists for the ESG groups and potentially lower thresholds for readmission and reintervention. The short-term nature of the study was also criticised, with patients only followed for 30 days post-operation. Some AEs possibly arising following ESG or LSG procedures could occur after this period. However, the effect estimate indicates that ESG is superior in safety to LSG, with an estimated 60% reduction in risk of AEs for ESG patients when the 2 studies with a high risk of bias were removed from the analysis.

As a secondary safety endpoint, rates of gastroesophageal reflux disorder (GORD), visits to ambulatory clinics and changes to GI symptoms were recorded. One study investigated the rates and reasons for visiting an ambulatory clinic among ESG and LSG patients, with 32% (95% CI 29 to 34) of ESG patients and 18% (95% CI 15 to 20) of LSG patients seeking additional treatment following discharge.<sup>27</sup> No changes in GI symptoms were identified within ESG or LSG groups from baseline to 6 or 12 months post-procedure.<sup>36</sup> Higher rates of post-surgical GORD were identified in LSG patients compared to ESG patients, as identified in 2 studies (OR 0.09; CI 0.02 to 0.46,  $p = 0.004$ ).<sup>37, 38</sup>

Both ESG and LSG had relatively low rates of severe AEs. Small patient populations were identified in 6 of the 9 included studies, which impacted the results of the meta-analyses. Although the applicant suggests a superior safety profile for ESG, the lack of quality randomised studies, small populations, the lack of long-term safety data and the decision to exclude 2 studies favouring LSG should be considered when considering the conclusions made in the report.<sup>42, 43</sup> Based on the applicant's claim that ESG possesses a superior safety profile to LSG, the available evidence suggests that there are several caveats to such findings that have not

been taken into consideration, such as the lack of long-term safety data and poor study quality, indicating that the statement is not well supported.

## 12. Comparative effectiveness

### PICO set 1: ESG vs lifestyle modifications

#### **%TBWL**

The primary outcome of %TBWL was reported within the ADAR on the recommendation of the current literature and consulted physicians. A meta-analysis was conducted by the ADAR featuring 1 RCT and 12 single-arm studies. Meta-analysis results identified a pooled mean %TBWL at 12 months of 18% (95% CI: 18% to 19%) using a common effects model and 17% (95% CI 16% to 18%) using a random effects model (Table 16, Table 17). This commentary report identified that the random effects model may be more relevant, to account for variability in patient characteristics including baseline BMI, gender representation and other factors such as study design. No comparison between lifestyle modification alone and ESG is available within meta-analysed results, due to the inclusion of single-arm studies. This also contributes to the high meta-analysis heterogeneity at 97% I<sup>2</sup>. Meta-analysis findings reveal statistically significant weight loss among ESG patients. The ADAR noted that observational studies identified a higher %TBWL than the MERIT trial. Within the MERIT trial, mean %TBWL for the primary ESG group was 13.6%, compared to 0.8% for the lifestyle intervention-only group. After adjusting for age, sex, type 2 diabetes, hypertension and baseline BMI in a modified intention-to-treat (mITT) analysis with mixed-effects models, participants in the ESG group had a mean difference of 12.6% (10.7 to 14.5 CI) TBWL at 52 weeks (1 year) compared to the lifestyle group ( $p < 0.0001$  using last observation carried forward (LOCF) and  $p < 0.0001$  using mixed-model imputations for missing data).<sup>20</sup> At 104 weeks, participants in the primary ESG group maintained a %TBWL of 11.4% (SD 8.4%) within MERIT.<sup>20</sup> The ADAR stated that consulted clinicians believed that the efficacy of ESG was likely underestimated in the MERIT trial due to trial design. The ADAR also suggests that patients may have been incentivised to gain weight when nearing the 52-week follow-up to qualify for retightening procedures to induce further weight loss (no evidence was presented to substantiate this claim). It further suggests that less experienced proceduralists may have completed the ESG procedures in MERIT, reducing the overall efficacy of the procedure due to surgeon inexperience.

#### **%EWL**

The primary outcome of per cent excess weight loss (%EWL), defined by the ADAR as excess weight over a BMI of 25 kg/m<sup>2</sup>, was presented in the MERIT trial. Within this RCT, %EWL at 52 weeks was 49.2% (SD 32.0) for the ESG group and 3.2% (SD 18.6) for the lifestyle modification-only group.<sup>20</sup> In a modified ITT analysis with mixed effects model, participants in the ESG group had a mean difference of 44.7% (95% CI 37.5 to 51.9), compared to the control group ( $p < 0.0001$  using LOCF and  $p < 0.0001$  using mixed-model imputations for missing data).<sup>20</sup> Of participants in the ESG group, 77% achieved >25% EWL at 52 weeks—reaching The American Society for Gastrointestinal Endoscopy (ASGE) and The American Society for Metabolic and Bariatric Surgery (ASMBS) Task Force on Endoscopic Bariatric Therapy minimum threshold recommendations—compared to 12% of those in the control group.<sup>20</sup> However, the commentary noted that patients were censored from some analyses when they failed to maintain a weight loss of  $\geq 25\%$  EWL. A meta-analysis conducted by the ADAR, including the MERIT trial, 3 single-arm studies and 6 studies from an included systematic review, revealed that the total pooled

mean %EWL was 57% for both common and random effects models (95% CI 56% to 57% and 52% to 61%, respectively) (Table 16; Table 17).

Although ESG appeared to induce a greater weight loss than lifestyle modification alone, a lack of rigorous comparative evidence remains to support the superiority claim of the technique. The greater baseline BMI for ESG patients in single-arm studies might have contributed to the greater observed %TBWL and %EWL in ESG patients. Patients experiencing benefits from ESG might be more likely to remain within observational study cohorts over long periods, which might skew the results in favour of the efficacy for ESG. Loss to follow-up was minimal within several observational ESG studies, while a loss to follow-up of 16% was identified within the MERIT trial.<sup>20, 32, 39</sup> The ADAR claimed that weight loss benefits observed in the MERIT trial might have been underestimated due to the trial methodology and context. However, consistent clinician monitoring and support in a clinical trial setting might have incentivised patients to adhere closely to the weight loss program. Consistent patient-clinician follow-up is likely to be less prevalent in real-world clinical practice than in the single-arm observation studies. GRADE analysis of the MERIT trial for both %TWL and %EWL is presented in Table 17.

The commentary also noted that the mean BMI at baseline within the MERIT trial was lower than for many single-arm studies, which may also account for the greater weight loss observed within observational cohorts. Previous studies identified that a higher baseline BMI may predict greater weight loss. It was also unclear why patients were excluded from %EWL analysis in the MERIT trial when they failed to maintain  $\geq 25\%$  EWL. This may impact data from this outcome.

**Table 16: Meta-analysis results for %TBWL and %EWL in class I and II obesity ESG patients at 12 months**

|                 | Common effects model |            | Random effects model |            |
|-----------------|----------------------|------------|----------------------|------------|
|                 | MRAW <sup>a</sup>    | 95% CI     | MRAW <sup>a</sup>    | 95% CI     |
| %TBWL 12 months | 0.18                 | 0.18; 0.19 | 0.17                 | 0.16; 0.18 |
| %EWL 12 months  | 0.57                 | 0.56; 0.57 | 0.57                 | 0.52; 0.61 |

Abbreviations: CI: confidence interval; MRAW: raw mean; %EWL: percentage excess weight loss; %TBWL: percentage total body weight loss.

Source: compiled during commentary

Note: a. This is an untransformed mean used to calculate the overall mean.

**Table 17: ESG plus lifestyle modifications compared to lifestyle modifications only for people with class I or II obesity with or without comorbidities (MERIT trial)**

| Outcomes                                              | Anticipated absolute effects<br>(95% CI) |                                                     | Relative<br>effect<br>(95%<br>CI) | No of<br>participants<br>(studies) | Certainty<br>of the<br>evidence<br>(GRADE) | Comments                                                                                                                     |
|-------------------------------------------------------|------------------------------------------|-----------------------------------------------------|-----------------------------------|------------------------------------|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
|                                                       | Risk with<br>lifestyle<br>modifications  | Risk with<br>ESG with<br>lifestyle<br>modifications |                                   |                                    |                                            |                                                                                                                              |
| %TBWL at 12 months (scale 0–100) follow-up: 12 months | mean %TBWL at 12 months<br><b>0.8%</b>   | The mean <b>12.6% more</b> (10.7 more to 14.5 more) | -                                 | 157<br>(1 RCT)                     | ⊕⊕⊕⊕<br>High                               | ESG with lifestyle modifications results in a large increase in %TBWL at 12 months compared to lifestyle modification alone. |
| %EWL at 12 months (scale 0–100) follow-up: 12 months  | mean %EWL at 12 months<br><b>0%</b>      | The mean <b>44.7% more</b> (37.5 more to 51.9 more) | -                                 | 157<br>(1 RCT)                     | ⊕⊕⊕⊕<br>High                               | ESG with lifestyle modifications results in a large increase in %EWL at 12 months compared to lifestyle modifications alone. |

Abbreviations: CI: confidence interval; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy; RCT: randomised control trial; %EWL: per cent excess weight loss; %TBWL: per cent total body weight loss

Source: Table 4.1 pg. 221 from ADAR

### **Durability of weight loss**

Three single-arm studies provide evidence for the longer-term treatment effect of ESG procedures. Bhandari et al. (2022) and Sharaiha et al. (2021) observed that mean %TBWL after 4 and 5 years was 18.19% and 15.9%, respectively.<sup>32, 33</sup> However, Frey et al. (2024) observed weight loss was maintained at 2 years (%TBWL = 9.8%), but not 3 years post-procedure (%TBWL = 3.73%).<sup>34</sup> Meta-analysis of results was completed for years 1, 2 and 3 post-surgery using a random effects model, with data presented in Table 18. The ADAR noted limitations including a reduced rate of follow-up, proceduralist learning curves throughout the study, and the retrospective and observational nature of a study identifying that the durability of ESG was not maintained at the 3-year study endpoint.<sup>34</sup> The ADAR also reported a study suggesting long-term durability of ESG up to 10 years post-procedure; however, this study could not be sourced, as the final study results have not yet been published. The ADAR also referenced specific Australian patients who underwent ESG and maintained their weight loss; however, again, the citations for such patients or case reports could not be found.

Although the durability of ESG is substantiated in some short-term, single-arm studies, the longer-term durability of the procedure is unclear due to the lack of high-quality evidence. The ADAR criticised one study that revealed poor durability of ESG at 3 years post-procedure<sup>34</sup>; however, the other studies presented as evidence for this outcome were also affected by limitations cited within the report, including high attrition rates that might have impacted the outcome data. The single-arm study utilised for 5-year follow-up data was found to have a loss to follow-up of >80%, greatly impacting the reliability of the study findings.<sup>32</sup>

**Table 18: Mean %TBWL up to 5 years after ESG in single-arm studies**

| Study               | Baseline BMI (n±SD kg/m <sup>2</sup> ) | Mean %TBWL (95% CI), n      |                             |                                |                                |                            |
|---------------------|----------------------------------------|-----------------------------|-----------------------------|--------------------------------|--------------------------------|----------------------------|
|                     |                                        | Year 1                      | Year 2                      | Year 3                         | Year 4                         | Year 5                     |
| Sharaiha et al 2021 | 39±6                                   | 15.6<br>(14.1–17.1),<br>142 | 15.3<br>(13.4–17.2),<br>NR  | 14.9<br>(12.1–17.7), 68        | 13.5<br>(9.6–17.4), NR         | 15.9<br>(11.7–20.5),<br>56 |
| Bhandari et al 2022 | 34.30±5.05                             | 21.2<br>(20.8–21.6),<br>570 | 20.1<br>(19.6–20.5),<br>552 | 18.74<br>(18.31–19.12),<br>466 | 18.19<br>(17.71–18.57),<br>254 | --                         |
| Frey et al 2024     | 33.6±3.4                               | 14.4 ± 8.9,<br>115          | 9.8 ± 11.4, 68              | 3.73 ± 10.65,<br>34            | --                             | --                         |

Abbreviations: CI: confidence interval; ESG: endoscopic sleeve gastroplasty; NR: not reported; %TBWL: per cent total body weight loss  
Source: Table 211 pg. 89 from ADAR

### **Weight-related comorbidities**

The MERIT trial found improvements in obesity-related comorbidities. At 52 weeks, diabetes improved clinically in 92% of patients in the ESG group compared to 15% of those in the lifestyle intervention group, with 44% of patients in the lifestyle modifications-only group experiencing worsening diabetes symptoms, compared to none within the ESG group (Table 19). Hypertension improved in 67% and 40% of patients in the ESG and lifestyle groups, respectively.<sup>7</sup> Metabolic syndrome was also found to improve in 83% of ESG patients, compared to 35% in the control group. Overall, 12% of patients in the ESG group experienced the worsening of one or more obesity-related comorbidities, compared to 50% in the lifestyle intervention group.<sup>7</sup> Findings were substantiated by one single-arm study, with 51% of type 2 diabetes cases, 66% of hypertension cases, 74% of dyslipidaemia cases and 90% of obstructive sleep apnoea cases resolved or improved within 3 months of the ESG procedure.<sup>30</sup>

Although ESG appears to be beneficial in reducing the severity of obesity-related comorbidities, further research is required to support both comparative and single-arm studies in different trial and observational settings. Further, reported ‘improvements’ in diabetes reported within the MERIT trial are not well described, with the study not reporting if these improvements were based on HbA1c measurements or reported symptoms alone.<sup>20</sup>

**Table 19: Comorbidity 52-week change from baseline for all randomly assigned participants in MERIT trial**

| Condition                              | ESG (primary)<br>(n/N; 95% CI) | Control<br>(n/N; 95% CI) | Rate difference <sup>a</sup><br>(SE; 95% CI) | p value <sup>b</sup> | ESG (primary and crossover) N/<br>(%; n) <sup>c</sup> |
|----------------------------------------|--------------------------------|--------------------------|----------------------------------------------|----------------------|-------------------------------------------------------|
| Diabetes                               |                                |                          |                                              |                      |                                                       |
| Improving <sup>d</sup>                 | 92% (12/13; 65–100)            | 15% (4/27; 5–33)         | –77.5 (10.1; –91.4 –47.4)                    | <0.0001              | 93% (25/27; 76–99)                                    |
| Worsening                              | 0% (0/13; 0–27)                | 44% (12/27; 28–63)       | 44.4 (9.6; 16.1–60.2)                        | 0.0041               | 0% (0/27; 0–15)                                       |
| Hyperlipidaemia                        |                                |                          |                                              |                      |                                                       |
| Improving                              | 40% (6/15; 20–64)              | 32% (8/25; 17–52)        | 8.0 (15.7; –37– –22)                         | 0.61                 | 30% (7/23; 10–15)                                     |
| Worsening                              | 27% (4/15; 11–52)              | 28% (7/25; 14–48)        | 1.3 (14.9; –28–28)                           | 0.93                 | 30% (7/23; 10–15)                                     |
| Hypertension                           |                                |                          |                                              |                      |                                                       |
| Improving                              | 67% (24/36; 50–80)             | 40% (19/48; 27–54)       | –27.1 (10.6; –46.1–5.5)                      | 0.014                | 60% (39/65; 48–71)                                    |
| Worsening                              | 6% (2/36; 1–19)                | 23% (11/48; 13–37)       | 17.4 (7.2; 1.5–30.7)                         | 0.029                | 9% (6/65; 4–19)                                       |
| Metabolic syndrome                     |                                |                          |                                              |                      |                                                       |
| Improving                              | 83% (24/29; 65–93)             | 35% (10/29; 20–53)       | –48.3 (11.3; –67.0– –23.3)                   | 0.0002               | 83% (35/42; 69–92)                                    |
| Worsening                              | 0% (0/29; 0–14)                | 38% (11/29; 23–56)       | 37.9 (9.0; 17.2–53.7)                        | 0.0002               | 5% (2/42; 1–17)                                       |
| Effect on multiple comorbid conditions |                                |                          |                                              |                      |                                                       |
| Improved at least 1 condition          | 41 (80%; n=51)                 | 28 (45%; n=62)           | --                                           | --                   | 70 (78%; n=90)                                        |
| Worsened at least 1 condition          | 6 (12%; n=51)                  | 31 (50%; n=62)           | --                                           | --                   | 15 (17%; n=90)                                        |

Abbreviations: CI: confidence interval; ESG: endoscopic sleeve gastroplasty; n: number of participants with that event; N: total number of participants in that group; SE: standard error

Notes: Data are rate (n/N; 95% CI), rate difference (SE; 95% CI) or n (%; N). A negative rate difference indicates that the ESG rate was greater than the control rate.

<sup>a</sup> Mean difference calculated as the difference between the rate for the control group minus the ESG group

<sup>b</sup> p value determined with an independent samples proportions test to evaluate differences between 2 rates

<sup>c</sup> Uncertainty regarding some results in this column presented within the ADAR

<sup>d</sup> Defined as decrease in medication (either number or dose) or decrease in HgbA1c  $\geq$  0.5%.

Source: Abu Dayyeh, Bazerbachi et al. (2022) Table 2 pg. 448

### ***Revision/conversion to bariatric surgery***

Within the MERIT trial, patients who did not reach the 25% EWL endpoint or those recommended by treating investigators were considered for a retightening procedure at the 52-week timepoint. Within the trial, 11 patients (14.3%) underwent retightening.<sup>20</sup> According to experts cited within the ADAR, it is anticipated that the retightening rate would reduce outside of the study context.

Single-arm evidence suggests that 27% of patients started adjunct pharmacotherapy at a median of 5 months after ESG, with many of these patients showing gradual weight regain.<sup>32</sup> Patients who received pharmacotherapy did not experience further weight gain. At 24 months, 6% of patients had a repeat ESG procedure, with 1% of patients undergoing an LSG procedure due to inadequate weight loss.<sup>32</sup>

In another single-arm study, 3.6% of patients underwent revision, or redo, ESG within the study period.<sup>30</sup> A total of 3.1% of the study population later underwent sleeve gastropasty surgery after 12 months.<sup>30</sup>

The literature presents conflicting evidence for the revision and conversion of ESG. Limited single-arm studies reveal a relatively low number of retightening and revision procedures for ESG, although the MERIT trial suggests significantly greater revision rates amongst participants. These greater revision rates in the MERIT trial could be explained by reduced retightening thresholds for participants. Further research in both controlled and observational study contexts is justified to better elucidate the requirements for revision and conversion to alternative bariatric methods, including LSG.<sup>20</sup>

### ***Patient-reported endpoints***

The MERIT trial reported that quality of life (QoL) improvements were superior among ESG patients after surgery compared to lifestyle intervention-only patients, including statistically significant improvements in SF-36 scores in the following domains at all timepoints: physical function, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, social functioning, pain and general health.<sup>20</sup> No significant improvements were reported in the domain of emotional wellbeing, after adjusting for age, gender, diabetes, hypertension, BMI and baseline sub-scale score.<sup>20</sup> Self-report questionnaires also revealed no worsening in GORD symptoms in ESG patients, with symptoms commencing in patients undergoing alternative forms of bariatric surgery. No difference was observed between the lifestyle modification-only and ESG groups.<sup>20</sup>

RCT evidence suggests improvements in self-reported health-related QoL (HRQoL) measures in ESG patients. However, the lack of further studies to substantiate findings among both HRQoL and GORD measures should be viewed as a limitation of the current research. Due to the non-blinding of trial participants, participant bias may have been present, which would favour the ESG procedure. This should also be considered in the interpretation of these results.

### **PICO set 2: ESG vs LSG**

#### ***%TBWL***

A meta-analysis of 7 non-randomised studies revealed that the mean difference in %TBWL at 6 months between ESG and LSG was -7.48 (-10.47 to -4.50 CI). A meta-analysis of 4 studies reporting %TBWL at 12 months revealed a total mean difference in %TBWL between ESG and LSG of -9.95% (-10.70 to -9.19 CI) (Table 20). A non-inferiority margin of 10% was set by the

authors of the ADAR based on a previously published study, with the %TBWL falling within the defined non-inferiority margin.<sup>27</sup> The non-inferiority claim of ESG to LSG was supported by the opinions of consulted clinicians. Near-superior results for LSG were partially explained within the ADAR, claiming that LSG patients typically having a higher BMI than those undergoing ESG. No citation was provided to substantiate this claim.

The lower 95% CI for %TBWL at both 6 and 12 months exceeds the 10% non-inferiority margin set within the ADAR, indicating that equivalence of ESG and LSG in reducing total body weight cannot be confirmed. The ruling of the 10% non-inferiority margin is questioned within this evaluation. This ADAR derived the 10% non-inferiority margin from Alqahtani (2022), which was included within the evidence base for PICO 2.<sup>27</sup> The authors of Alqahtani (2022) do not justify the use of this value based on prior research or study findings.<sup>27</sup>

### **%EWL**

Meta-analyses conducted at 6 and 12 months for %EWL within ESG and LSG patients is presented in Table 20. At 6 months, the total mean %EWL difference between ESG and LSG was -10.23% (-11.90, -8.56 CI); at 12 months the mean difference in %EWL was -18.01% (-19.32, -16.70), both in favour of LSG.

The findings of the meta-analyses suggest that as per the 10% non-inferiority margin, LSG significantly outperforms ESG in induction of greater %EWL. These findings are not highlighted within the report. The commentary also noted that a study utilised in this analysis was identified to have a population with a significantly lower baseline BMI than the population established in the PICO (defined in ADAR at BMI >40 kg/m<sup>2</sup>).<sup>35</sup> The relevance of such results is thus brought into question.

**Table 20: ESG compared to LSG for people with class II or class III obesity**

| Outcomes                                              | Anticipated absolute effects*<br>(95% CI) |                                                          | Relative effect<br>(95% CI) | No of participants<br>(studies)         | Certainty of the evidence<br>(GRADE) | Comments                                                                                                                                                                                                             |
|-------------------------------------------------------|-------------------------------------------|----------------------------------------------------------|-----------------------------|-----------------------------------------|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                       | Risk with LSG                             | Risk with ESG                                            |                             |                                         |                                      |                                                                                                                                                                                                                      |
| %TBWL at 12 months (scale 0–100) follow-up: 12 months | <sup>a</sup>                              | Mean <b>9.95% lower</b><br>(10.7% lower to 9.19% lower)  | -                           | 51135,113<br>(4 non-randomised studies) | ⊕⊕⊕○<br>Moderate <sup>b</sup>        | ESG likely results in a lower total body weight loss compared to LSG at 12 months but this difference is small and likely not clinically significant <sup>d</sup> , as noted by expert clinical opinion in the ADAR. |
| %EWL at 12 months (scale 0–100) follow-up: 12 months  | Mean %EWL at 12 months <b>0%</b>          | Mean <b>18.0% lower</b><br>(19.32% lower to 16.7% lower) | -                           | 46424,642<br>(2 non-randomised studies) | ⊕⊕⊕○<br>Moderate <sup>c</sup>        | ESG likely results in a lower excess body weight loss compared to LSG at 12 months; however, the excess weight loss achieved by ESG is still clinically significant.                                                 |

Abbreviations: CI: confidence interval; ESG: endoscopic sleeve gastroplasty; GORD: gastro-oesophageal reflux disease; LSG: laparoscopic sleeve gastrectomy; RCT: randomised controlled trial, %EWL: per cent excess weight loss; %TBWL: per cent total body weight loss

Notes: a This cell incomplete within the ADAR document. Reasons unclear.

b Three of the 4 included studies were assessed to have moderate risk of bias due to the potential for confounding and missing data, while the fourth study has a low risk of bias. Certainty of evidence downgraded.

c Two studies were assessed as having a moderate risk of bias mainly due to missing data and confounding. Certainty of evidence downgraded.

d Minimal clinically important difference defined at 10%.

Source: Table 4.5 pg. 236 from ADAR

### **Durability of weight loss**

One non-randomised study investigated %TBWL up to 3 years post-procedure.<sup>27</sup> The mean %TBWL at 36 months for the ESG group was 14.0% (SD 12.1%) and for the LSG group it was 18.8% (SD 7.5%), with a mean difference of -4.8% (-1.5, 8.7 CI). The ADAR states that due to the non-inferiority measure of 10%, ESG is non-inferior to LSG, demonstrating the short- and long-term durability of ESG.<sup>27</sup>

Although such evidence suggests a non-inferiority margin in the durability of ESG compared to LSG, only one non-randomised study provides the evidence base for this claim. This study included a population that does not align with the proposed population of PICO 2.<sup>27</sup> Additionally, a 3-year timeframe to assess longevity of such procedures may be insufficient to assess long-term efficacy. Further, as previously explained, the 10% non-inferiority margin was not substantiated by the study from which it was derived. The clinical significance of such findings is uncertain.

## Weight-related comorbidities

The ADAR suggests that several studies support the finding of improvements in obesity-related comorbidities, as observed within the MERIT study in PICO 1 for ESG.<sup>27, 38</sup> A meta-analysis of 2 non-randomised studies revealed that the total mean difference for remission or improvement in type II diabetes was 0.78 (0.68, 0.91 CI) in favour of LSG, while the mean difference in hypertension was 1.12% (0.86, 1.47 CI) in favour of ESG, as identified by overall reduction in HbA1c and lipid blood measures, respectively (Table 21). In one study assessing comorbidity outcomes up to 6 months, improvements in hypertension (ESG 66.6%, LSG 42.8%), type 2 diabetes (ESG 50.0%, LSG 66.6%), sleep apnoea (ESG 40.0%, LSG 33.3%) and joint pain (ESG 57.0%, LSG 50.0%) were reported.<sup>38</sup> The study also identified no new-onset GORD within the ESG group, while 30.7% of patients in the LSG group reported new-onset GORD following the procedure, aligning with currently available clinical evidence.<sup>38, 44, 45</sup> Other studies report significant decreases in markers for diabetes from 5% (SD 0.3%) at baseline to 4.7% (SD 0.3%) for ESG and 5.3% (SD 0.5%) at baseline to 5.2% (SD 0.7%) for LSG at 12 months.<sup>36</sup> Carr et al. also identified non-significant reductions in total cholesterol (ESG 5.6 mmol/L to 4.5 mmol/L; LSG 5.1 mmol/L to 4.7 mmol/L) and significant improvements in high density lipoprotein (HDL), cholesterol and triglycerides from baseline to 12 months (ESG 1.2 mmol/L to 1.4 mmol/L and LSG 1.4 mmol/L to 1.0 mmol/L).<sup>36</sup>

The ADAR authors claim that the effects of ESG and LSG on obesity-related comorbidities are comparable. However, in considering the current evidence, there is an apparent superior effect on improving diabetes symptoms for LSG, while the effect on hypertension management appears to be similar between the two interventions. The comorbidity results from Fiorello et al. 2020 should be interpreted with caution, as these are short-term, raw datapoints that have not been tested for significance.<sup>38</sup>

**Table 21: Meta-analysis of changes in hypertension and type 2 diabetes**

| Subtotal (95%CI)               | Risk ratio (M-H, random, 95% CI) |
|--------------------------------|----------------------------------|
| Improvement in hypertension    | 1.12 [0.86, 1.47]                |
| Improvement in type 2 diabetes | 0.78 [0.68, 0.91]                |

Abbreviations: CI; confidence interval; M-H: Mantel-Haenszel test/method

Source: Figure 220 pg. 121 from ADAR

## Revision/conversion to bariatric surgery

One non-randomised study directly comparing revision rates between ESG and LSG was identified, following patients 3 years postoperatively (Table 22).<sup>35</sup> A total of 28 patients (0.9% of total patients) had a repeat ESG and 80 patients (2.7% of total patients) underwent conversion to LSG. No weight-related conversion was completed in LSG patients.<sup>35</sup>

The ADAR suggests that the overall rate for revision in ESG is low, as identified in the evidence for PICO 1 and as suggested by clinicians. Clinicians also suggest a higher risk of complications in revision for LSG, which may contribute to the overall risk of revision procedures. The ADAR suggests that the revision rate for LSG may be underestimated, citing the Bariatric Surgery Registry annual report 2023 and indications of a 9% complication rate in revision procedures, as

<sup>44</sup> El-Hadi M, Birch DW, Gill RS, Karmali S. The effect of bariatric surgery on gastroesophageal reflux disease. *Can J Surg*. 2014;57(2):139-44.

<sup>45</sup> Wölnerhanssen BK, Meyer-Gerspach AC, Nussbaumer R, Sauter M, Thumshirn M, Bueter M, et al. Prospective clinical cohort study: low incidence of Barrett esophagus but high rate of reflux disease at 5-year follow-up after sleeve gastrectomy versus Roux-en-Y gastric bypass. *Surgery for Obesity and Related Diseases*. 2023;19(7):707-15.

compared to 2% in primary procedures.<sup>46</sup> Consulting clinicians advise that the risk of revision and retightening in ESG is likely lower than the risks observed in LSG.

Although the risk of revision surgery may be greater in LSG as compared to ESG, there is no current evidence suggesting a higher rate of revision within LSG patients compared to ESG. Evidence presented in the Bariatric Surgery Registry and annual report offers no insight into the rates of revision in LSG patients generally, nor does it compare or evaluate the risks and rate of revision in ESG patients. Further research is required to better investigate revision among ESG and LSG patients, beyond the single non-randomised study utilised within the ADAR that had a high attrition rate.<sup>32</sup> The commentary also noted that the population evaluated in the included study for this outcome is not highly relevant to the population explored in the PICO, with the patient population having a significantly lower BMI than that established within the ADAR, potentially influencing outcomes.

**Table 22: Summary of included studies reporting on the proportion of patients undergoing repeat ESG or revision surgery**

| Trial                      | Proportion of patients after ESG undergoing repeat ESG n (%) | Proportion of patients after ESG undergoing revision n (%) | Proportion of patients after LSG undergoing revision n (%) |
|----------------------------|--------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| Alqahtani 2022 (36 months) | 28 (0.9)                                                     | 80 (2.7)                                                   | 0                                                          |

Abbreviations: ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy.  
Source: Table 277, pg. 119 from ADAR

### **Patient-reported endpoints**

HRQoL was reported in 2 non-randomised observational studies. A non-statistically significant improvement for the ESG group was identified (using the Impact of Weight on Quality of Life–Lite measure), while a statistically significant improvement in HRQoL was identified for the LSG group.<sup>36</sup> In a separate study, QoL measures showed no difference between patients treated with ESG or LSG, with authors noting significantly superior scores for the ESG group in the GI symptoms subdomain of the assessment (ESG 66.5 (61–70.5 CI) vs LSG 59 (55–63 CI);  $p = 0.001$ ).<sup>38</sup> The ADAR states that the non-statistically significant results identified for the first study were due to a very small population size ( $n = 9$ ) assessed at 12 months.

### **Clinical claim**

For PICO 1, the ADAR claimed that ESG—when combined with lifestyle interventions—has superior efficacy and inferior but manageable safety at short-term timepoints. The ADAR indicated that inferior safety was anticipated for ESG, as lifestyle modification is a non-surgical intervention. The ADAR suggested that the clinical evidence presented demonstrates that ESG is safe, with a low rate of AEs identified. It was also suggested that long-term safety post-ESG will be non-inferior to lifestyle modifications.

The commentary suggests that the clinical claim be reworded as follows:

*Current clinical evidence indicates that ESG combined with lifestyle interventions is superior in efficacy and inferior but manageable in regard to short-term safety. Although few severe AEs were identified within the current clinical evidence, further investigation is warranted into the long-term safety and efficacy of ESG due to a lack of long-term safety and efficacy data.*

<sup>46</sup> Bariatric Surgery Registry. Bariatric Surgery Registry 2022 Annual Report. Melbourne, Victoria: Central Clinical School, Monash University; 2023. Report No. 10.

For PICO 2, the ADAR claimed that ESG for patients who are eligible for bariatric surgery is non-inferior efficacy for weight loss, for reduction in comorbidities and HRQoL outcomes. The report also claims superior safety compared to LSG, stating that ESG produces clinically significantly lowered risks of severe AEs, based on comparative, non-randomised studies.

This commentary suggests that the clinical claim be reworded as follows:

*Current evidence suggests that LSG is superior at inducing weight loss and improving type 2 diabetes. ESG is non-inferior to LSG for reduction of other comorbidities such as hypertension. Evidence suggests a non-statistically significant improvement in the rates of severe AEs favouring ESG compared to LSG. Further randomised and comparative studies are needed to more clearly assess the safety of ESG and its comparators.*

## 13. Economic evaluation

Two economic analyses were presented in the ADAR: a CUA comparing ESG to lifestyle modification in people with class I or II obesity with or without comorbidities (Section 10.1), and a cost-minimisation analysis comparing ESG to LSG in patients eligible to receive MBS-funded bariatric procedures (Section 10.2).

### 10.1 PICO set 1: cost-utility analysis

A CUA was presented in the submission that compared ESG to lifestyle intervention for treating patients with class I or II obesity with or without comorbidities from an Australian healthcare system perspective. This approach was appropriate, given the claim of clinical superiority. A Markov model was developed in Microsoft Excel to estimate the incremental cost per QALY gained for patients treated with ESG plus lifestyle modification compared to lifestyle modification alone. The ADAR reported that in the ESG group, patients receive more intensive lifestyle modification,<sup>47</sup> incurring costs associated with more frequent visits with dietetics and specialist appointments in the first year after ESG. From second year onwards, the same lifestyle modifications were applied to both ESG and control group. The model consists of 5 BMI-based health states, comprising healthy weight, overweight, class I obesity, class II obesity and class III obesity, and an absorbing death state. Patients enter the model in either the class I or class II obesity states, from where they receive ESG plus lifestyle modification or lifestyle modification alone. Health state allocations were based on MERIT trial data for the first 2 years, followed by assumption-based projections. The CUA extrapolated for a 40-year time horizon, which was used as the basis for the base case analysis. This was further applied in the sensitivity analyses to compare the model outcomes. The extrapolated analyses were included with horizons of 5, 10, 15, 20, 30 and 40 years and lifetime. Model outcomes, including costs, QALYs and ICERs, were estimated separately for patients in obesity class I and class II. A brief overview of model elements is provided in Table 23.

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<sup>47</sup> The ADAR reported that the more intensive lifestyle modification incorporated liquid diet in the first week following the procedure, a “pureed” diet in the subsequent week, a “mechanically altered soft diet” in the following week, before transitioning to a regular texture diet by the end of the fifth week. Following the immediate phase after the procedure, patients require a high-protein diet, coupled with supervised strength training to overcome the loss in muscle strength after the surgery. The rationale was to accommodate the dietary changes required to ensure optimal effectiveness of ESG.

**Table 23: Summary of cost-utility analysis**

| Component                   | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Perspective                 | Australian healthcare system perspective                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Population                  | Adults with class I or class II obesity (BMI 30–39.9 kg/m <sup>2</sup> ) with or without comorbidities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Intervention                | ESG with lifestyle modification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Comparator                  | Lifestyle modification alone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Type of economic evaluation | Cost-utility analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Start age                   | 47.3 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Time horizon                | Extrapolated 5, 10, 15, 20, 30, 40 years and lifetime horizon; 40-year time horizon used in base case analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Outcomes                    | QALYs and LYs gained                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Computational method        | Markov model                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Generation of the base case | Modelled evaluation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Health states               | 6 health states: 5 BMI-based (healthy weight, overweight, obesity class I, obesity class II, obesity class III) and dead                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Cycle length                | 6 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Transition probabilities    | Health state allocation: individual patient data from the MERIT trial for the first 2 years for ESG and 1 year for lifestyle modification<br>Assumptions: <ul style="list-style-type: none"> <li>• 3–5 years (80% remain in the same health state as at the end of year 2; 20% regress to baseline BMI; 100% remain in the higher obesity class for those who gain weight during first 2 years)</li> <li>• 5 years onwards (remain in the same health state as at the end of year 5)</li> </ul> Mortality (end of each cycle): <ul style="list-style-type: none"> <li>• based on Australian life tables</li> <li>• relative risk of death applied to the higher obesity classes</li> </ul> |
| Discount rate               | 5% for both costs and effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Software used               | Microsoft Excel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

Abbreviations: BMI: body mass index; ESG: endoscopic sleeve gastroplasty; MERIT: Multicentre Endoscopic Sleeve Gastroplasty Randomised Interventional Trial; LY: life years; QALY: quality-adjusted life years  
Source: Submission Table 3–4 (pp. 127); Summary of economic evaluation

### **Transition probabilities and variables**

Transition probabilities for the model were derived from the 2-year MERIT trial's individual patient data and converted to 6-month transition probabilities. It was unclear how the reported clinical trial data were converted to transition probabilities between the BMI classes.

Transitions across obesity classes in the first 2 years were based on individual patient data from the MERIT trial. Beyond year 2, assumptions (detailed in [Table 23](#)) were applied to both obesity class I and class II to inform the health state transitions occurring between the end of the trial period and the end of the model (40-years in the base case). The durability and long-term safety of ESG remain an area of uncertainty; therefore, there is a high degree of uncertainty in the longer-term cost-effectiveness results. The impact of baseline BMI on longer-term weight loss outcomes is unclear, thus the relative applicability of these assumptions across the 2 models may differ, requiring further investigation to assess how baseline BMI influences the effectiveness and sustainability of weight loss intervention over time.

Moreover, weight re-gain or treatment failure is not currently accounted for in the model, even though it can be managed clinically. A study by Alhayo and Devadas in 2019 <sup>48</sup> discussed an ESG failure rate of 50–90%. As such, it is essential to include procedure failure as a parameter in the model, reflecting its associated costs and QALYs.

<sup>48</sup> Alhayo, S & Devadas, M 2019, 'Laparoscopic sleeve gastrectomy following multiple failed endoscopic sleeve gastroplasties', *J Surg Case Rep*, vol. 2019, no. 12, p. rjz315.

## **Health outcomes**

In the base case analysis, health state utilities were derived from the study by Kelly et al. which is based primarily on the MERIT trial.<sup>49</sup> Equivalent utility values were used for both the intervention and control arms, based on the model health states, despite comparative QoL data having been collected in the MERIT trial. In the sensitivity analyses, alternate literature-based sources were applied. The modelled ICERs in these analyses were significantly higher than in the base case analysis.

A limited number of AEs comprising upper GI bleed, nausea/vomiting/pain and perigastric leak were considered in the model; however, bridging fibrosis, pulmonary embolism, stomach tears and infection were excluded, without clear reason. This biases the CUA towards cost-effectiveness, due to under-reporting of serious AEs. The ADAR used a meta-analysis of single-arm studies was used to inform AE incidence given the small sample size in the MERIT trial.

## **Adverse event disutility**

In the ADAR, the utility decrements associated with serious AEs are considered separately from the health state utilities. The serious AEs included upper GI bleeding, nausea/vomiting/pain and perigastric leak. The incidence of each included procedure-related serious AE was informed by a meta-analysis of single-arm studies. This was due to the larger sample size, which captured rarer AEs than those reported in the MERIT trial. The assessment group noted that only a select number of AEs reported in the meta-analyses (Section 8) source documents are included. For example, unreported serious AEs from the study by Hedjoudie, Abu Dayyeh et al. in 2020 comprise pulmonary embolism (0.06%, n = 1) and pneumoperitoneum (0.06%, n = 1).<sup>50</sup> The reasoning for the selective inclusion of serious AEs is unclear, as a decision rule is not provided in the text. In addition, the assessment group noted that the other reviews and meta-analyses on ESG included infection and abscesses (caused by stomach tears from excessive tension around the surgical suture sites) as serious AEs.<sup>31, 50, 51, 52</sup>

In the ADAR, the disutilities allocated with each included serious AE are sourced from the published literature. The duration of each serious AE was informed by the MERIT trial. The assumed duration of the AE was the week of the ESG procedure. The AE was assumed to have resolved within the first week. Therefore, serious AE disutilities are only applied for the first week of the model. However, a sensitivity analysis was extended the serious AE length to 2 weeks. The assessment group did not identify any issues with the assumed duration of serious AEs or the method of sourcing disutility values.

## **Healthcare resource use and costs**

The CUA was based on the healthcare system perspective and included direct medical costs for hospitalisation, device costs, pre-surgery costs and ESG procedure MBS item costs. Lifestyle management treatment costs comprising allied health, GP visits and blood test costs were included across both treatment arms. The frequency of these visits differed across arms over the

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<sup>49</sup> Kelly, J, Menon, V, O'Neill, F, Elliot, L, Combe, E, Drinkwater, W, Abbott, S & Hayee, B 2023, 'UK cost-effectiveness analysis of endoscopic sleeve gastroplasty versus lifestyle modification alone for adults with class II obesity', *International Journal of Obesity*, vol. 47, no. 11, pp. 1161-70.

<sup>50</sup> Hedjoudie, A, Abu Dayyeh, BK, Cheskin, LJ, Adam, A, Neto, MG, Badurdeen, D, Morales, JG, Sartoretto, A, Nava, GL, Vargas, E, Sui, Z, Fayad, L, Farha, J, Khashab, MA, Kalloo, AN, Alqahtani, AR, Thompson, CC & Kumbhari, V 2020, 'Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis', *Clin Gastroenterol Hepatol*, vol. 18, no. 5, pp. 1043-53.e4.

<sup>51</sup> Li, P, Ma, B, Gong, S, Zhang, X & Li, W 2020, 'Efficacy and safety of endoscopic sleeve gastroplasty for obesity patients: a meta-analysis', *Surgical Endoscopy*, vol. 34, no. 3, pp. 1253-60.

<sup>52</sup> Yoon, JY & Arau, RT 2021, 'The efficacy and safety of endoscopic sleeve gastroplasty as an alternative to laparoscopic sleeve gastrectomy', *Clinical Endoscopy*, vol. 54, no. 1, pp. 17-24.

first 12 months (patients undergoing ESG receive higher-intensity lifestyle modifications in the first 12 months). Beyond 12 months, the same frequency of lifestyle modification resources used was assumed across arms.

AE management costs (ESG only), palliative care costs and the cost of managing comorbidities (assigned based on the model health states) were also captured. The use of pharmacotherapy, and the associated side effects, were not captured in the evaluation. The ADAR suggested that, although some pharmacotherapies are being utilised by this population, expert opinion has indicated that pharmacotherapies such as phentermine, orlistat or semaglutide are costly and have poor side effect profiles which lead to short-term or intermittent use. Moreover, there is a lack of available drug options for obesity on the PBS (see Table 8).

The use of a healthcare system perspective in the bases case aligns with MSAC guidelines. The ADAR also included indirect costs and argued that ESG patients with higher obesity classes would accrue productivity benefits as a consequence of fewer hospital readmissions and reinterventions.<sup>43</sup> The ADAR's Inclusion of indirect costs had a large impact on the ICER but there was no consideration by the applicant of the potential double-counting of impacts that occurs when a broader perspective is taken.

Dietary changes, mechanically soft diets and high-protein diets are mentioned in the submission; however, their costs were not accounted for in the model. Due to clinical guideline variation around dietary changes for bariatric surgery (e.g. ESG) and lifestyle modification, a clear conclusion cannot be drawn on what (if any) prescription supplementation (vitamin, protein, etc.) is necessary. Therefore, the commentary concluded it is not possible to perform a sensitivity analysis that includes PBS costs of prescribed supplementation. This exclusion may create uncertainty in the model outcomes.

### ***Results: incremental costs and effectiveness***

For obesity class I patients, the ICER over a 2-year time horizon was estimated to be \$15,407,000 per life year (LY) gained. The extrapolated ICER over a 40-year time horizon was estimated to be \$45,552 per LY gained and \$7,553.62 per QALY gained (Table 24).

For obesity class II patients, the ICER over a 2-year time horizon was estimated to be \$15,988,000 per LY gained. The extrapolated ICER over a 40-year time horizon was estimated to be \$68,363 per LY gained and \$12,591.14 per QALY gained (Table 24).

**Table 24: Results of stepped analysis for obesity class I and II patients**

| Step                                              | ESG      | LM       | Increment | ICER                       |
|---------------------------------------------------|----------|----------|-----------|----------------------------|
| Obesity class I                                   |          |          |           |                            |
| Step 1: (cost per LY over 2-year time horizon)    |          |          |           |                            |
| Cost                                              | \$20,672 | \$5,265  | \$15,407  | \$15,407,000 per LY gained |
| Effectiveness                                     | 2.378    | 2.377    | 0.001     |                            |
| Step 2: (cost per LY over 40-year time horizon)   |          |          |           |                            |
| Cost                                              | \$45,525 | \$38,055 | \$7,471   | \$45,552 per LY gained     |
| Effectiveness                                     | 16.641   | 16.477   | 0.164     |                            |
| Step 3: (cost per QALY over 40-year time horizon) |          |          |           |                            |
| Cost                                              | \$45,526 | \$38,055 | \$7,471   | \$7,553 per QALY gained    |
| Effectiveness                                     | 13.410   | 12.421   | 0.989     |                            |
| Obesity class II                                  |          |          |           |                            |
| Step 1: (cost per LY over 2-year time horizon)    |          |          |           |                            |
| Cost                                              | \$21,889 | \$5,901  | \$15,988  | \$15,988,000 per LY gained |
| Effectiveness                                     | 2.377    | 2.376    | 0.001     |                            |
| Step 2: (cost per LY over 40-year time horizon)   |          |          |           |                            |
| Cost                                              | \$54,582 | \$42,022 | \$12,561  | \$68,363 per LY gained     |
| Effectiveness                                     | 16.449   | 16.265   | 0.1837    |                            |
| Step 3 (cost per QALY over 40-year time horizon)  |          |          |           |                            |
| Cost                                              | \$54,582 | \$42,022 | \$12,561  | \$12,591 per QALY gained   |
| Effectiveness                                     | 12.291   | 11.293   | 0.9976    |                            |

Abbreviations: ESG: endoscopic sleeve gastroplasty; ICER: incremental cost-effectiveness ratio; LM: lifestyle modification; LY: life year; QALY: quality-adjusted life year

Source: Submission Table 3-31 and Table 3-36 (pp. 155 and 157)

Over the 40-year timeframe, ESG plus lifestyle modification generates an additional 0.1639 LY and 0.9890 QALY compared to lifestyle modification alone for patients at obesity class I. Similarly, for patients at obesity class II, ESG plus lifestyle modification provides an additional 0.1837 LY and 0.9976 QALY compared to lifestyle modification alone (Table 25).

**Table 25: Results of the economic evaluation (base case)**

| Parameter                        | Obesity class I |             |            | Obesity class II |             |             |
|----------------------------------|-----------------|-------------|------------|------------------|-------------|-------------|
|                                  | ESG             | LM          | Increment  | ESG              | LM          | Increment   |
| Cost                             | \$45,525.38     | \$38,054.82 | \$7,470.56 | \$54,582.37      | \$42,021.85 | \$12,560.52 |
| LY                               | 16.6413         | 16.4774     | 0.1639     | 16.4485          | 16.2648     | 0.1837      |
| QALY                             | 13.4100         | 12.4210     | 0.9890     | 12.2905          | 11.2930     | 0.9976      |
| Incremental cost per LY gained   | \$45,552.20     |             |            | \$68,363.16      |             |             |
| Incremental cost per QALY gained | \$7,553.62      |             |            | \$12,591.14      |             |             |

Abbreviations: ESG: endoscopic sleeve gastroplasty; LM: lifestyle modification; LY: life year; QALY: quality-adjusted life year

Source: Submission Table 3-31 and Table 3-36 (pp. 155 and 157); Attachment 3.1-ESG cost-effectiveness model

The key drivers of the model are summarised in Table 26.

**Table 26: Key drivers of the model**

| Description             | Method/value                                                                                                                                                                                                                                                                                                                                                                                        | Impact: Base case ICER (40 yrs): ICER \$7,552.89/QALY gained                                                                                                                                                                                                                                       |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Obesity class I</b>  |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                    |
| Extrapolation           | A 40-year time horizon was used in the base case model. There is a long period of extrapolation beyond the 2-year follow-up period of the MERIT trial up to the 40 years over which benefits accumulate. Extrapolations over the 40-year and lifetime horizons reported favourable outcomes. Extrapolation on short-term (i.e. 5- and 10-year) time horizons remain uncertain.                      | High, favours the ESG procedure.<br>The base case and lifetime extrapolation may favour ESG, where the lifetime ICER was 6% lower compared to base case. At 5 and 10 years, the ICERs are \$55,605 and \$27,559 per QALY gained, respectively.                                                     |
| Health state utilities  | Utility values were derived from the MERIT trial and other literature, indicating the current analysis is likely to create uncertainty in the cost-effectiveness of ESG due to the absence of real Australian trial-based data.                                                                                                                                                                     | Moderate, potentially favours the ESG procedure.<br>Use of values from Australia based literature such as Carrello et al. (2023) <sup>53</sup> and Ngo et al. (2022) <sup>54</sup> generates higher ICERs of 67% and 55%, respectively.                                                            |
| Perspective             | The base case analysis applied a healthcare system perspective. Inclusion of indirect costs, assigned based on the model health states, based on data from Lee et al. (2018) <sup>55</sup> , resulted in ESG being less costly and more effective.                                                                                                                                                  | High, favours the comparator.<br>A healthcare system perspective was applied in the base case, which may favour the comparator. Inclusion of indirect costs in each health states results in a dominant outcome. The incremental cost is -\$5,208 and the QALY is 0.989.                           |
| Reintervention          | A 6% reintervention rate was applied in the base case (based on data from Sharaiha (2021)). An alternate reintervention rate of 18.18% (informed by the MERIT trial) was explored in sensitivity analysis. A scenario assuming a higher probability of redo i.e. 30%, due to its minimal invasive nature with less harm (Shah-Khan et al., 2023) <sup>56</sup> was also explored in the commentary. | Moderate, favours the ESG procedure.<br>The base case reintervention rate may favour ESG. The reintervention rate and modelled outcomes are directly associated (e.g. assuming 18.18% and 30% reintervention rates resulted in ICERs, 24% and 67.58% higher, respectively, compared to base case). |
| <b>Obesity class II</b> |                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                    |
| Extrapolation           | A 40-year time horizon was used in the base case model. There is a long period of extrapolation beyond the 2-year follow-up period of the MERIT trial up to the 40 years over which benefits accumulate. Extrapolations over the 40-year and lifetime horizons reported favourable outcomes. Extrapolation on short term i.e., 5-, 10- and 15-year time horizons remain uncertain.                  | High, favours the ESG procedure.<br>The base case and lifetime extrapolation may favour ESG where the lifetime ICER was 4% lower compared to base case. At 5, 10 and 15 years, the ICERs are \$56,496.97, \$31,868.70 and \$23,030.12 per QALY gained, respectively.                               |

<sup>53</sup> Carrello, J, Hayes, A, Baur, LA & Lung, T 2023, 'Potential cost-effectiveness of e-health interventions for treating overweight and obesity in Australian adolescents', *Pediatric Obesity*, vol. 18, no. 4, p. e13003.

<sup>54</sup> Ngo, PJ, Wade, S, Banks, E, Karikios, DJ, Canfell, K & Weber, MF 2022, 'Large-Scale Population-Based Surveys Linked to Administrative Health Databases as a Source of Data on Health Utilities in Australia', *Value in Health*, vol. 25, no. 9, pp. 1634-43.

<sup>55</sup> Lee, CMY, Goode, B, Nørtøft, E, Shaw, JE, Magliano, DJ & Colagiuri, S 2018, 'The cost of diabetes and obesity in Australia', *Journal of Medical Economics*, vol. 21, no. 10, pp. 1001-5.

<sup>56</sup> Shah-Khan, S, Hadi, Y, Zitun, M, Krishnan, A, Thakkar, S & Singh, S 2023, 'Redo endoscopic sleeve gastroplasty', *Endoscopy*, vol. 55, no. S 01, pp. E349-e50.

| Description            | Method/value                                                                                                                                                                                                                                                                                                                                                                             | Impact: Base case ICER (40 yrs): ICER \$7,552.89/QALY gained                                                                                                                                                                                                                                           |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health state utilities | Utility values were derived from the MERIT trial and other literature, indicating the current analysis is likely to create uncertainty in the cost-effectiveness of ESG due to the absence of real Australian trial-based data.                                                                                                                                                          | Moderate, potentially favours the ESG procedure.<br>Use of values from the literature, such as Carrello et al. (2023), Saumoy et al. (2023) <sup>57</sup> , Ngo et al. (2022) and Haseeb et al. (2024) <sup>58</sup> , generates higher ICERs by almost 132%, 83%, 80% and 79%, respectively.          |
| Reintervention rate    | A 6% reintervention rate was applied in the base case (based on data from Sharaiha (2021)). An alternate reintervention rate of 18.18% (informed by the MERIT trial) was explored in sensitivity analysis. A scenario assuming a higher probability of redo i.e. 30%, due to its minimally invasive nature with less harm (Shah-Khan et al., 2023). was also explored in the commentary. | Moderate, favours the ESG procedure.<br>The base case reintervention rate may favour ESG. The reintervention rate and modelled outcomes are directly associated (e.g. assuming 18.18% and 30% reintervention rates resulted in ICERs, 4.5% and 77.80% higher, respectively, compared to the base case. |

Abbreviations: ESG: endoscopic sleeve gastroplasty; LM: lifestyle modification; QALY: quality-adjusted life year; ICERs: incremental cost-effectiveness ratio; MERIT: multi-centre ESG randomised interventional trial  
Source: Submission Table 3-40 and Table 3-41 (pp. 160 and 162); Attachment 3.1-ESG cost-effectiveness model

There are uncertainties and missing evidence within the model-based economic analysis. The intervention is not cost-effective within a shorter timeframe (e.g. 2- and 5-year extrapolations). However, at time horizons of 10 years or more the ICER falls within the range typically considered to represent acceptable cost-effectiveness. QALYs at 10 years (0.4349) are almost double those at the 5-year time horizon (0.2499). In other words, the lower ICERs achieved with longer time horizons rely entirely on assumptions made to extrapolate the trial-based outcomes.

For the base case analysis, health states utilities were derived from a UK-based study.<sup>49</sup> Some sensitivity analyses were performed using Australia-based literature, which shows larger effects in the ICER. This indicates that the current analyses for both classes of obesity are likely to create uncertainties in the cost-effectiveness of ESG, due to the absence of Australian trial-based data. The literature shows a higher possibility of reintervention, due to the less invasive and less harmful nature of the ESG procedure.<sup>56</sup> As such, sensitivity analyses demonstrate that the higher the reintervention rate, the higher the ICER will be, indicating uncertainty in the ESG procedure. Similar assumptions were made for both obesity class I and class II. For example, between 3 and 5 years, 80% of patients remain in the same health state and the remaining 20% return to their baseline weight. This transition may not apply equally to both obesity classes, which may be affected differently by patient severity, response to ESG and age.

<sup>57</sup> Saumoy, M, Gandhi, D, Buller, S, Patel, S, Schneider, Y, Cote, G, Kochman, ML, Thiruvengadam, NR & Sharaiha, RZ 2023, 'Cost-effectiveness of endoscopic, surgical and pharmacological obesity therapies: a microsimulation and threshold analyses', *Gut*, vol. 72, no. 12, pp. 2250-9.

<sup>58</sup> Haseeb, M, Chhatwal, J, Xiao, J, Jirapinyo, P & Thompson, CC 2024, 'Semaglutide vs Endoscopic Sleeve Gastroplasty for Weight Loss', *JAMA Network Open*, vol. 7, no. 4, pp. e246221-e.

**Table 27: One-way sensitivity analyses (PICO set 1)**

| Analysis                                                                                                     | Incremental cost   | Incremental QALY | ICER (\$/QALY gained) | % change in ICER from BC |
|--------------------------------------------------------------------------------------------------------------|--------------------|------------------|-----------------------|--------------------------|
| <b>Obesity class I (base case (BC))</b>                                                                      | <b>\$7,470.56</b>  | <b>0.9890</b>    | <b>\$7,552.89</b>     | <b>—</b>                 |
| Time horizon (BC: 40 years)                                                                                  |                    |                  |                       |                          |
| 5-year                                                                                                       | \$13,896.29        | 0.2499           | \$55,604.84           | 636.1%                   |
| 10-year                                                                                                      | \$11,985.19        | 0.4349           | \$27,559.43           | 264.9%                   |
| Lifetime                                                                                                     | \$7,437.17         | 1.0434           | \$7,127.90            | -5.6%                    |
| Health state utilities (BC: using Kelly et al.)                                                              |                    |                  |                       |                          |
| using Carrello et al. 2023                                                                                   | \$7,470.56         | 0.5922           | \$12,614.35           | 67.0%                    |
| using Ngo et al. 2022                                                                                        | \$7,470.56         | 0.6387           | \$11,696.47           | 54.8%                    |
| Health state costs (BC: no indirect costs)                                                                   |                    |                  |                       |                          |
| with indirect costs (Lee et al. 2018)                                                                        | -\$5,208.00        | 0.9890           | Dominant              | —                        |
| Reintervention rate (BC: 6% at 2 years)                                                                      |                    |                  |                       |                          |
| 18.2% at 2 years (from MERIT trial)                                                                          | \$9,289.60         | 0.9890           | \$9,392.88            | 24.3%                    |
| <i>Assuming 30% at 2 years*</i>                                                                              | <i>\$11,054.33</i> | <i>0.9890</i>    | <i>\$11,177.24</i>    | <i>67.6%</i>             |
| <b>POST ESC ANALYSES</b>                                                                                     |                    |                  |                       |                          |
| <i>Per cycle probability of 0.015**</i>                                                                      |                    |                  |                       |                          |
| <i>Applied for 5 years</i>                                                                                   | <i>\$13,224.33</i> | <i>0.2499</i>    | <i>\$52,926.58</i>    | <i>600.64%</i>           |
| <i>Applied for 10 years</i>                                                                                  | <i>\$11,313.23</i> | <i>0.4349</i>    | <i>\$26,017.26</i>    | <i>244.42%</i>           |
| <i>Applied for 15 years</i>                                                                                  | <i>\$9,854.35</i>  | <i>0.5823</i>    | <i>\$16,922.75</i>    | <i>124.02%</i>           |
| <b>Applicant's pre-MSAC multivariate sensitivity analyses***</b>                                             |                    |                  |                       |                          |
| Scenario 1 (Criteria I, II a, III)                                                                           | \$10,089.00        | 0.91             | \$11,123.65           | 47.3%                    |
| Scenario 2 (Criteria I, II a)                                                                                | \$8,735.03         | 0.99             | \$8,832.15            | 16.9%                    |
| Scenario 3 (Criteria I, II b)                                                                                | \$12,245.06        | 0.99             | \$12,381.21           | 63.9%                    |
| Scenario 4 (Criteria I, II b, III)                                                                           | \$13,599.03        | 0.91             | \$14,993.64           | 98.5%                    |
| <i>MSAC extra analysis [Criteria I, IIa and duration of probability of reintervention=15 yrs (BC=5 yrs)]</i> | <i>\$13,319.22</i> | <i>0.9890</i>    | <i>\$13,467.31</i>    | <i>78%</i>               |
| <b>Obesity class II (base case)</b>                                                                          | <b>\$12,560.52</b> | <b>0.9976</b>    | <b>\$12,591.14</b>    | <b>—</b>                 |
| Time horizon (BC: 40 years)                                                                                  |                    |                  |                       |                          |
| 5-year                                                                                                       | \$15,288.23        | 0.2706           | \$56,496.97           | 348.7%                   |
| 10-year                                                                                                      | \$14,412.50        | 0.4522           | \$31,868.70           | 153.1%                   |
| Lifetime                                                                                                     | \$12,643.17        | 0.8854           | \$14,358.52           | -4.0%                    |
| Health state utilities (BC: using Kelly et al.)                                                              |                    |                  |                       |                          |
| using Carrello et al. 2023                                                                                   | \$12,560.33        | 0.4302           | \$29,194.23           | 131.9%                   |
| using Ngo et al. 2022                                                                                        | \$12,560.53        | 0.5556           | \$22,605.96           | 79.5%                    |
| Reintervention rate (BC: 6%)                                                                                 |                    |                  |                       |                          |
| 18.2% at 2 years (from MERIT trial)                                                                          | \$14,379.56        | 0.9976           | \$14,414.60           | 14.5%                    |
| <i>Assuming 30% at 2 years*</i>                                                                              | <i>\$16,144.30</i> | <i>0.9976</i>    | <i>\$16,183.64</i>    | <i>77.8%</i>             |
| <b>POST ESC ANALYSES</b>                                                                                     |                    |                  |                       |                          |
| <i>Per cycle probability of 0.015**</i>                                                                      |                    |                  |                       |                          |
| <i>Applied for 5 years</i>                                                                                   | <i>\$14,616.27</i> | <i>0.2706</i>    | <i>\$54,023.70</i>    | <i>329.04%</i>           |
| <i>Applied for 10 years</i>                                                                                  | <i>\$13,740.55</i> | <i>0.4522</i>    | <i>\$30,386.22</i>    | <i>141.32%</i>           |
| <i>Applied for 15 years</i>                                                                                  | <i>\$13,083.86</i> | <i>0.5972</i>    | <i>\$21,906.94</i>    | <i>73.98%</i>            |
| <b>Applicant's pre-MSAC multivariate sensitivity analyses***</b>                                             |                    |                  |                       |                          |
| Scenario 1 (Criteria I, II a, III)                                                                           | \$14,402.25        | 0.87             | \$16,610.50           | 31.9%                    |
| Scenario 2 (Criteria I, II a)                                                                                | \$13,824.99        | 1.00             | \$13,858.68           | 10.1%                    |
| Scenario 3 (Criteria I, II b)                                                                                | \$17,335.03        | 1.00             | \$17,377.27           | 38.0                     |
| Scenario 4 (Criteria I, II b, III)                                                                           | \$17,912.28        | 0.87             | \$20,658.72           | 64.1%                    |
| <i>MSAC extra analysis [Criteria I, IIa and duration of probability of reintervention=15 yrs (BC=5 yrs)]</i> | <i>\$18,409.18</i> | <i>0.9976</i>    | <i>\$18,454.05</i>    | <i>47%</i>               |

Abbreviations: BC: base case; ICER: Incremental cost-effectiveness ratio; QALY: quality-adjusted life year

Source: Submission Table 3-40 and Table 3-41 (pp. 160 and 162); Attachment 3.1-ESG cost-effectiveness model; Table 4 of applicant's pre-MSAC response.

\* Additional sensitivity analyses conducted during the evaluation are presented in *italics*.

\*\* Additional sensitivity analyses conducted by the assessment group, at ESC's request, are also presented in *italics*. The assessment group manually adjusted the model to accumulate costs for revision/reintervention procedures based on an annual reintervention rate and used arbitrary assumptions. Specifically, the 2-year probability used in the model was converted to a per cycle (6-monthly) probability and

applied over varying time intervals (5, 10 and 15 years) in a series of sensitivity analyses. No changes were made to the cost of reintervention procedures (i.e. they remain to be costed at the same cost as the initial ESG procedure).

\*\*\* Applicant's pre-MSAC multivariate sensitivity analyses. Criterion I: Including a 2.7% proportion of patients converting to LSG at 3 years; Criterion IIa: Re-intervention 1.5% per 6-month cycle Yr 2-5 (Sharaiha 6%); Criterion IIb: Re-intervention 4.9% per 6-month cycle Yr 2-5 (MERIT trial 18.2%); Criterion III: An assumption for weight loss that in both arms after 5 years, 1% of patients in weight classes below baseline weight transition to a higher weight class every cycle until the end of the time horizon. This scenario ensures that patients have a small but continuous probability of gaining weight over time.

**Table 28: Post-ESC Sensitivity Analyses for impact of anaesthesia times**

|                        | ICER, Obesity class I | ICER, Obesity class II | CMA      |
|------------------------|-----------------------|------------------------|----------|
| Submission base case   | \$7,544               | \$12,592               | -\$5,658 |
| Use item 23045 for ESG | \$7,578               | \$12,616               | -\$5,636 |
| Use item 23055 for ESG | \$7,602               | \$12,640               | -\$5,613 |
| Use item 23065 for ESG | \$7,627               | \$12,664               | -\$5,591 |

Abbreviations: CMA: cost-minimisation analysis; ESG: endoscopic sleeve gastroplasty; ICER: incremental cost-effectiveness ratio.

Source: Post-ESC additional analysis conducted by the evaluation

## 10.2 PICO set 2: cost-minimisation analysis

In the ADAR, a cost-minimisation analysis was presented that compared ESG to LSG for the treatment of patients with class II obesity (BMI 35–40 kg/m<sup>2</sup>) with comorbidities and patients with class III obesity (BMI >40 kg/m<sup>2</sup>) with or without comorbidities. A summary of the economic evaluation is presented in Table 29.

**Table 29: Summary of cost-minimisation analysis in the ADAR (PICO set 2: ESG vs LSG)**

| Component                        | Description                                                                                                  |
|----------------------------------|--------------------------------------------------------------------------------------------------------------|
| Perspective                      | Healthcare system perspective                                                                                |
| Population                       | Adults with class II obesity with comorbidities; adults with class III obesity with or without comorbidities |
| Comparator                       | LSG                                                                                                          |
| Type of analysis                 | Cost-minimisation analysis                                                                                   |
| Time horizon                     | Procedural (30 days after the procedure)                                                                     |
| Therapeutic claim: effectiveness | Based on evidence presented in Section 9 (PICO 2), the effectiveness of ESG is non-inferior to LSG           |
| Therapeutic claim: safety        | Based on evidence presented in Section 8 (PICO 2), the safety of ESG is non-inferior to LSG                  |
| Evidence base                    | Systematic review of non-randomised studies                                                                  |
| Direct health technology costs   | Cost of index procedure                                                                                      |

Abbreviations: ESG: endoscopic sleeve gastroplasty; LSG laparoscopic sleeve gastrectomy

Source: Table 3-42 of ADAR

MSAC Guidelines (TG 26.1, page 205) state that a cost-minimisation approach can only be used when the proposed medical service has been demonstrated to be non-inferior to its comparator in terms of both effectiveness and safety.

ESC agreed with the commentary that a cost-minimisation analysis is inappropriate in this instance. As indicated in Section 9 (PICO 2), the assumption of clinical equivalence is inappropriate, as both summary measures from the meta-analyses of observational studies of %TWL at 6 months (MD -7.48; 95% CI -10.47 to -4.50) and 12 months (MD -9.95; 95% CI -10.70 to -9.19) exceed the 10% margin for %TWL non-inferiority. Additional reasons to question the clinical non-inferiority claim between ESG and LSG include that LSG (compared to ESG) provides both a statistical and clinical benefit (based on the PASC minimum clinically important difference [MCID] of 5%) at 6 and 12 months, and that uncertainty around the appropriateness of the 10% non-inferiority margin for %TWL that does not meet the PICO 2 criteria due to the study population including overweight patients and not detailing obesity classes. <sup>35</sup>

ESC noted that whilst the commentary provided additional comments on the CMA, these comments should not over-ride the advice from ESC that a CMA is inappropriate for PICO Set 2.

### Model costs

The applicant modelled pre-surgery costs, hospital costs (based on private hospital AR-DRGs), procedure MBS fee, anaesthesia costs, and device costs (with the proposed ESG cost provided by the applicant).

The applicant did not model AE costs, as the ADAR stated that there was inconsistent reporting of rates between the identified studies. The ADAR used the cost of AEs in the ESG arm of the CUA (Section 10.1) to narratively estimate the potential impact of AEs (\$172.62) on the cost-minimisation analysis (although these costs were not included in the CMA).

The assessment group considers the use of MBS, PBS and PL costs with AR-DRG codes to be appropriate and representative of the costs of care. However, use of the MBS item for LSG alone does not represent the full suite of bariatric surgery items currently available to this patient group. There are multiple MBS items for bariatric surgery.

- The individual MBS item for 'gastric band' (MBS 31569), 'sleeve gastrectomy' (MBS 31575) and 'gastroplasty' (MBS 31578) are all costed at \$967.90.
- The MBS items for 'Roux-en-Y' (MBS 31572) and 'biliopancreatic diversion' (MBS 31581) are costed at \$1,190.95 each.
- An MBS item for 'surgical reversal' (including revision or conversion) of a previous bariatric procedure (MBS 31584) exists. This item is costed at \$1,753.45.

The proposed cost for ESG is equivalent to the cost of sleeve gastronomy, LSG (MBS 31575).

ESC agreed with the commentary that excluding AE costs related to ESG and LSG from the cost-minimisation analysis was inappropriate. ESC agreed with the commentary that the comparative safety outcomes (i.e. ESG vs LSG) reported in the clinical evaluation provide sufficient information to inform the impact of AEs in the cost-minimisation analysis. ESC noted that the commentary had conducted a sensitivity analysis where AE costs were included in the CMA.

The assessment group found that the meta-analysis of AEs for PICO 2 is impacted by only moderate heterogeneity ( $I^2$  55%), substantially less heterogeneity ( $I^2$  94%) than the 6-month meta-analysis of observational studies, which compared %TWL in ESG and LSG, used to claim the non-inferiority of ESG. If the heterogeneity was a concern for the ADAR authors, the assessment group suggests that statistical techniques such as sensitivity analysis (for bleeding, revision surgery etc.), subgroup analysis or meta-regression could have been conducted to explore potential causes. For example, conducting a safety analysis purely on types of bleeds and BMI class subgroup (e.g. class II vs class III) or age group (e.g. >50 years vs <50 years). The selective inclusion of AEs (exclusion of bridging fibrosis, pulmonary embolism, stomach tears, infection etc.) biases the non-comparative data between ESG and LSG, thus biasing the results in favour of ESG. ESG-related AEs are more frequent and severe than for LSG, therefore ESG is associated with higher treatment costs.

The cost-minimisation analyses captured LSG and ESG procedure costs and related costs up to 30 days post-procedure. The assessment group found that the time horizon of 30 days after the procedure is likely inappropriate. The cost-minimisation analysis should have used a time horizon that captures the costs associated with treatment failure (e.g. weight loss  $\geq 5\%$  of %TBW, retightening [ESG only], conversion to other forms of bariatric surgery).

Exclusion of treatment failure biases the cost-minimisation analysis towards favouring ESG over LSG, due to the high rate of treatment failure (reoperation with ESG, conversion to other forms of bariatric surgery, treatment for bleeding) not being captured.

## Model results

The applicant presented a cost saving of \$5,658.15 per patient over the 30-day time horizon for ESG (\$14,932.39) over LSG (\$20,590.54) (Table 30).

As previously mentioned, the commentary highlights several concerns with the cost-minimisation analysis that creates uncertainty around the model results. These concerns include the inappropriate assumption of non-inferiority between ESG and LSG, the exclusion of comparative AE data and costs, and the short-term 30-day time horizon that does not capture the treatment failure data and costs associated with both ESG and LSG.

The key drivers of the model are presented in Table 31. In addition to these causes of uncertainty, the complexity of the ESG- and LSG-related AR-DRG cost items are considered key model drivers.

**Table 30: Results of the economic evaluation in the ADAR (PICO set 2)**

| Description                                              | Item number |        | ESG                | LSG                | Cost difference     |
|----------------------------------------------------------|-------------|--------|--------------------|--------------------|---------------------|
|                                                          | MBS/PL      | AR-DRG |                    |                    |                     |
| <b>Subtotal pre-surgery cost</b>                         |             |        | <b>\$981.90</b>    | <b>\$981.90</b>    | <b>\$0.00</b>       |
|                                                          | 65070       | NA     | \$16.95            | \$16.95            | \$0.00              |
|                                                          | 12527       | NA     | \$96.75            | \$96.75            | \$0.00              |
|                                                          | 110         | NA     | \$174.50           | \$174.50           | \$0.00              |
|                                                          | 116         | NA     | \$87.30            | \$87.30            | \$0.00              |
|                                                          | 721         | NA     | \$164.35           | \$164.35           | \$0.00              |
|                                                          | 723         | NA     | \$130.25           | \$130.25           | \$0.00              |
|                                                          | 10954       | NA     | \$70.95            | \$70.95            | \$0.00              |
|                                                          | 10968       | NA     | \$70.95            | \$70.95            | \$0.00              |
|                                                          | 10953       | NA     | \$70.95            | \$70.95            | \$0.00              |
|                                                          | 17615       | NA     | \$98.95            | \$98.95            | \$0.00              |
| <b>Subtotal hospital cost based on AR-DRG*</b>           |             |        | <b>\$2,551.93</b>  | <b>\$14,037.59</b> | <b>-\$11,485.68</b> |
|                                                          | NA          | K40A   | \$14,399.49        | \$0.00             | \$14,399.49         |
|                                                          | NA          | K40B   | \$2,098.54         | \$0.00             | \$2,098.54          |
|                                                          | NA          | G46A   | \$10,934.25        | \$0.00             | \$10,934.25         |
|                                                          | NA          | G46B   | \$2,328.69         | \$0.00             | \$2,328.69          |
|                                                          | NA          | K11A   | \$0.00             | \$18,204.15        | -\$18,204.15        |
|                                                          | NA          | K11B   | \$0.00             | \$13,496.98        | -\$13,496.98        |
| <b>Subtotal procedure cost</b>                           |             |        | <b>\$967.90</b>    | <b>\$967.90</b>    | <b>\$0.00</b>       |
|                                                          | 31575       | NA     | \$967.90           | \$967.90           | \$0.00              |
| <b>Subtotal anaesthesia cost</b>                         |             |        | <b>\$293.15</b>    | <b>\$293.15</b>    | <b>\$0.00</b>       |
|                                                          | 20791       | NA     | \$225.50           | \$225.50           | \$0.00              |
|                                                          | 23035       | NA     | \$67.65            | \$67.65            | \$0.00              |
| <b>Subtotal device cost</b>                              |             |        | <b>\$10,137.51</b> | <b>\$4,310.00</b>  | <b>\$5,827.51</b>   |
| Apollo ESG NXT system                                    | NA          | NA     | \$redacted         | \$0.00             | \$redacted          |
| Endotherapy overtube                                     | NA          | NA     | \$redacted         | \$0.00             | \$redacted          |
| Echelon Disposable powered stapling device               | MN215       | NA     | \$0.00             | \$445.00           | -\$445.00           |
| Echelon staple reload                                    | MN219       | NA     | \$0.00             | \$1,908.00         | -\$1,908.00         |
| GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement | GT224       | NA     | \$0.00             | \$1,188.00         | -\$1,188.00         |
| TISSEEL DUPLOCATH 35cm MIC/MIS                           | BX268       | NA     | \$0.00             | \$588.00           | -\$588.00           |
| TISSEEL Two Component Fibrin Sealant Syringe             | BX215       | NA     | \$0.00             | \$53.00            | -\$53.00            |
| Dermabond Prineo                                         | MN230       | NA     | \$0.00             | \$128.00           | -\$128.00           |
| <b>Total cost (base case)</b>                            |             |        | <b>\$14,932.39</b> | <b>\$20,590.54</b> | <b>-\$5,658.15</b>  |

Abbreviations: AR-DRG: Australian Refined-Diagnostic Related Group; ESG: endoscopic sleeve gastropasty; LSG: laparoscopic sleeve gastrectomy; MBS: Medical Benefits Schedule; NA: not applicable; PL: Prescribed List

Notes: \* AR-DRG costs were weighted.

Source: Table 3-46 of ADAR; Table 3-17 to 3-10 of ADAR; Table 3-43 to 3-45 of ADAR.

**Table 31: Key model drivers (PICO set 2)**

| Description           | Method/value                                                                                                                                                                                                                                                                | Impact<br>Base case: cost saving of <b>-\$5,658.15</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hospitalisation costs | Differences in hospital costs (-\$11,486 in the base case) explain the cost savings observed. However, there is a high degree of uncertainty in the unit costs applied, which are weighted average private hospital AR-DRG costs for LSG (K11A/B) and ESG (K40A/B, G46A/B). | <ul style="list-style-type: none"> <li>– Major complexity costs of laparoscopic [LSG] intervention (K11A) results in incremental cost of ESG of -\$6,026.27 (-6.51%)</li> <li>– Minor complexity costs of laparoscopic [LSG] intervention (K11B) results in incremental cost of ESG of -\$5,117.55 (9.6%)</li> <li>– Costs of endoscopic [ESG] intervention (K40) results in incremental cost of ESG of -\$5,822.32 (-2.9%)</li> <li>– Costs of endoscopic [ESG] intervention (G46) results in incremental cost of ESG of -\$5,624.91 (0.6%)</li> <li>– Major complexity costs of endoscopic [ESG] intervention (K40A, G46A) results in incremental cost of ESG of \$3,201.49 (156.6%)</li> <li>– Minor complexity costs of endoscopic [ESG] intervention (K40B, G46B) results in incremental cost of ESG of -\$5,920.35 (-4.6%)</li> <li>– Major complexity costs for both [ESG &amp; LSG] interventions (K11A, K40A, G46A) results in incremental cost of ESG of \$965.07 (82.9%)</li> <li>– Minor complexity costs of endoscopic [ESG &amp; LSG] interventions (K11B, K40B, G46B) results in incremental cost of ESG of -\$5,379.74 (4.9%)</li> </ul> |
| Costs related to AEs  | Using PICO 1 data and costs to narratively estimate the impact of AEs instead of PICO 2 AE comparative data detailed in Section 8.                                                                                                                                          | <p>AEs from PICO 1 were selectively reported and not all the serious AEs reported in the trials were allocated disutility values in the cost-utility analysis, biasing the results in favour of ESG.</p> <p>The comparative data shows that AEs for ESG are more frequent and severe than for LSG and are therefore associated with higher treatment costs.</p> <p>A sensitivity analysis including AE costs, as well as costs for reoperation and readmission costs (undertaken during the commentary) resulted in an incremental cost of -\$5,024.28 (11% change from base case)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Time horizon          | Using 30-day post-procedure time horizon.                                                                                                                                                                                                                                   | <p>The 30-day, short time horizon biases the results in favour of ESG, as treatment failure costs are not captured.</p> <p>Treatment failure includes:</p> <ul style="list-style-type: none"> <li>• weight regain &gt;5%</li> <li>• conversion to other forms of bariatric surgery</li> <li>• revision surgery (ESG only)</li> <li>• retightening surgery (ESG only)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy.

Source: compiled by the assessment group; treatment failure definition supported by assessment group's clinical expert.

**Table 32: PICO set 2: Results of sensitivity analyses**

|                                                                     | ESG                     | LSG                   | Difference         |
|---------------------------------------------------------------------|-------------------------|-----------------------|--------------------|
| <b>Base case</b>                                                    | <b>\$14,932.39</b>      | <b>\$20,590.54</b>    | <b>-\$5,658.15</b> |
| <b>Additional SA presented in the pre-ESC and pre-MSAC response</b> |                         |                       |                    |
| Adding additional AE costs of reoperation and readmission           |                         |                       |                    |
| AE costs                                                            | \$1,259.73 <sup>a</sup> | \$489.83 <sup>a</sup> | \$769.91           |
| Total cost at 12 months                                             | \$16,192.12             | \$21,080.36           | -\$4,888.24        |

Source: Excel workbook titled '1555.1 – Applicants Pre-ESC response model' (tab 'Settings & Results') the applicant supplied at the request of ESC; Table 5 of applicant's pre-MSAC response.

Abbreviations: AE: adverse event; ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy.

<sup>a</sup> Weighted average cost of AEs. The pre-ESC response added costs associated with reoperation using same or different procedure and readmission to the cost of AEs included in the economic model (c.f. Table 33 for details of estimation).

**Table 33: Estimation of AE costs for CMA in pre-ESC response**

|                                         | Cost per event    | Source                        | Incidence | Source                                                                                                          |
|-----------------------------------------|-------------------|-------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------|
| <b>ESG</b>                              |                   |                               |           |                                                                                                                 |
| Upper Gastrointestinal Bleed            | \$4,209.13        | IHACPA 2023 G61 weighted      | 0.56%     | Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis - PubMed (nih.gov) |
| Nausea/Vomiting/Pain                    | \$4,481.89        | IHACPA 2023 G70, Z61 weighted | 1.08%     | Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis - PubMed (nih.gov) |
| Perigastric leak                        | \$20,966.74       | IHACPA 2023 G12 weighted      | 0.48%     | Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis - PubMed (nih.gov) |
| Reoperation - Same procedure (ESG)      | \$14,932.39       | ESG Procedure Cost            | 0.90%     | Alqahtani, Elahmedi et al. (2022)                                                                               |
| Reoperation - Different procedure (LSG) | \$20,590.54       | LSG Procedure Cost            | 2.70%     | Alqahtani, Elahmedi et al. (2022)                                                                               |
| Readmission                             | \$10,441.62       | IHACPA 2023 K12Z              | 3.80%     | Gudur, Geng et al., 2023b                                                                                       |
| <b>Weighted Total Cost</b>              | <b>\$1,259.73</b> |                               |           |                                                                                                                 |
| <b>LSG</b>                              |                   |                               |           |                                                                                                                 |
| Bleeding                                | \$4,209.13        | IHACPA 2023 G61 weighted      | 0.18%     | Alqahtani, Elahmedi et al. (2022)                                                                               |
| Nausea/Vomiting/Pain                    | \$4,481.89        | IHACPA 2023 G70, Z61 weighted | 0.00%     | None reported, assumed statistically insignificant                                                              |
| Staple Line Leak                        | \$20,966.74       | IHACPA 2023 G12 weighted      | 0.12%     | Alqahtani, Elahmedi et al. (2022)                                                                               |
| Reoperation - Different procedure (ESG) | \$14,932.39       | ESG Procedure Cost            | 0.00%     | Gudur, Geng et al., 2023b                                                                                       |
| Reoperation - Same procedure (LSG)      | \$20,590.54       | LSG Procedure Cost            | 0.80%     | Gudur, Geng et al., 2023b                                                                                       |
| Readmission                             | \$10,441.62       | IHACPA 2023 K12Z              | 2.80%     | Gudur, Geng et al., 2023b                                                                                       |
| <b>Weighted Total Cost</b>              | <b>\$489.83</b>   |                               |           |                                                                                                                 |

Source: Excel workbook titled '1555.1 – Applicants Pre-ESC response model' (tab 'Adverse events') the applicant supplied at the request of ESC.

## 14. Financial/budgetary impacts

The financial impact analysis in the ADAR adopted a market-share approach. The ESG procedure was assumed to substitute for the LSG procedure. The estimated market size was calculated using statistics for MBS item 31575, specifically, the average number of claims over the period 2019–2023. The proportions of the private bariatric procedures undertaken on patients in each obesity class, as reported in the 2023 Bariatric Surgery Registry annual report, were used to inform the number of patients within the defined market within each obesity class. Uptake of ESG, as a substitute for LSG, was assumed to be **redacted**% across all 5 years for class I obesity, **redacted**% in year 1 increasing to **redacted**% by years 4 and 5 for class II obesity, and **redacted**% across all 5 years for class III obesity.

In addition to the substitution of LSG, the ADAR, based on expert opinion, also expected the market size to expand due to patients who previously do not elect to undergo bariatric surgery now accepting ESG if the proposed MBS listing is supported. The ADAR assumed that for class I and II obesity, the market size would grow by 5% in year 1, increasing to a 20% in year 5 of listing. For class III obesity, the ADAR assumed the market size to grow 2.5% every year.

At 75% benefits, the total MBS cost applied for the ESG procedure was \$1,682.21 per patient, which is equivalent to the cost of the LSG procedure. This total MBS cost includes costs of the proposed MBS item for ESG (or existing MBS item 31575 for LSG), pre-surgery costs (haematology, renal function test, professional attendance items with consultant physician and anaesthetist, GP and allied health services) and anaesthesia costs.

The financial analysis assumed ESG as a new bariatric procedure in 52% and 63% of patients predicted to uptake the service in years 1 and 6, respectively. In these patients, ESG incurs a net cost to the MBS. For the remaining patients, ESG is assumed to substitute for LSG. In these patients, the ADAR projects no net cost to the MBS, given the proposed equivalent MBS costs for ESG and LSG.

The ADAR estimated total cost of the ESG procedure to the MBS at 75% benefits was estimated to be \$2.06 million in year 1, increasing to \$4.5 million in year 5. Similarly, the estimated net cost of the ESG procedure to the MBS at 75% benefits was estimated to be \$1.07 million in year 1, increasing to \$2.9 million in year 5. The total cost to the health budget at 75% benefit was projected to be \$1.07 million in year 1, rising to \$2.90 million in year 5 (Table 34).

**Table 34: Net financial implications of ESG to the MBS in the ADAR**

| Parameter                                                         | Year 1                | Year 2       | Year 3       | Year 4       | Year 5       |
|-------------------------------------------------------------------|-----------------------|--------------|--------------|--------------|--------------|
| <b>Estimated use and cost of ESG</b>                              |                       |              |              |              |              |
| Projected number of ESG procedures attributable to market growth* | redacted              | redacted     | redacted     | redacted     | redacted     |
| Projected number of ESG procedures substituting LSG**             | redacted              | redacted     | redacted     | redacted     | redacted     |
| Total number of ESG procedures conducted                          | redacted <sup>c</sup> | redacted     | redacted     | redacted     | redacted     |
| <b>Total ESG cost to MBS, 75% benefit***</b>                      | \$2,068,959           | \$2,602,513  | \$3,136,066  | \$3,975,166  | \$4,586,257  |
| <b>Total ESG cost to MBS, 100% benefit****</b>                    | \$2,758,612           | \$3,470,017  | \$4,181,422  | \$5,300,221  | \$6,115,010  |
| <b>Change in use and cost of LSG</b>                              |                       |              |              |              |              |
| Change in use of LSG procedure**                                  | -593                  | -729         | -864         | -1,000       | -1,000       |
| Total reduction of MBS cost of LSG, 75% benefit <sup>a</sup>      | -\$998,014            | -\$1,226,022 | -\$1,454,029 | -\$1,682,037 | -\$1,682,037 |
| Total reduction of MBS cost of LSG, 100% benefit <sup>b</sup>     | -\$1,330,685          | -\$1,634,695 | -\$1,938,706 | -\$2,242,716 | -\$2,242,716 |
| <b>Net cost to MBS, 75% benefit</b>                               | \$1,070,946           | \$1,376,491  | \$1,682,037  | \$2,293,129  | \$2,904,220  |
| <b>Net cost to MBS, 100% benefit</b>                              | \$1,427,927           | \$1,835,322  | \$2,242,716  | \$3,057,505  | \$3,872,293  |

Abbreviations: ESG: endoscopic sleeve gastropasty; LSG: laparoscopic sleeve gastrectomy; MBS: Medicare Benefits Schedule.

Notes:

\*estimated based on average LSG service utilisation by obesity class from 2019 to 2023, multiplied by the increase in market size estimates

\*\*estimated based on the average number of LSG services by obesity class between 2019 to 2023 multiplied by assumed uptake rate

\*\*\*number of ESG procedures multiplied by the estimated MBS costs of ESG at 75% benefit (\$1,682.21 per procedure)

\*\*\*\*number of ESG procedures multiplied by the estimated MBS costs of ESG at 100% benefit (\$2,242.95 per procedure)

<sup>a</sup> number of changes in use of LSG procedure multiplied by the MBS costs of LSG at 75% benefits (\$1682.21 per procedure)

<sup>b</sup> number of changes in use of LSG procedure multiplied by the MBS costs of LSG at 100% benefits (\$2,242.95 per procedure)

<sup>c</sup> Includes: 277 (class I), 407 (class II) and 547 (class III obesity).

Source: Submission Tables 4-1, 4-12, 4-18, 4-19, 4-21, 4-22, 4-25, 4-27 and 4-28; Attachment 3.4-ESG Budget Impact Model

The financial estimates provided by the applicant are based on the assumption that the device will be listed on the PL, although this is yet to occur (the applicant has signalled they intend to apply for the device to be included on the PL should the current application be supported by MSAC). Under this assumption, the ADAR estimates that ESG will be cost saving for hospital budgets due to shorter lengths of hospital stay compared to the LSG procedure. Hospital stays are costed at \$2,551.93 per-ESG procedure based on AR-DRGs K40 and G46, and at \$14,037.59 per LSG procedure based on AR-DRG K11 (this cost was included as a cost offset

for the proportion of patients in whom ESG was modelled to substitute LSG). The total PL cost of ESG is estimated at \$12.4 million in year 1, increasing to \$27.6 million in year 5, based on the applicant-proposed ESG device costs (\$10,137.51 per procedure, includes Apollo ESG NXT System and Endotherapy Overtube costs). In comparison, per-procedure PL costs for LSG were \$4,310.00 (again, this cost was included as a cost offset in the proportion of patients for whom ESG was modelled to substitute LSG).

The total budget impact of listing ESG (Table 35) is the sum of the net MBS, hospital and PL costs.

**Table 35: Net financial impact to health budget due to listing of ESG**

| Parameter                                              | Year 1      | Year 2      | Year 3       | Year 4       | Year 5       |
|--------------------------------------------------------|-------------|-------------|--------------|--------------|--------------|
| Total budget impact due to listing ESG, 75% benefit*   | \$5,792,574 | \$7,636,035 | \$9,479,496  | \$13,933,327 | \$19,154,066 |
| Total budget impact due to listing ESG, 100% benefit** | \$6,149,556 | \$8,094,866 | \$10,040,175 | \$14,697,703 | \$20,122,139 |
| <b>Pre-MSAC response</b>                               |             |             |              |              |              |
| Incorporating revisions                                | \$6,149,556 | \$8,094,866 | \$11,142,099 | \$16,767,555 | \$22,652,491 |

Abbreviations: ESG: Endoscopic sleeve gastroplasty; MBS: Medicare Benefits Schedule; LSG: Laparoscopic sleeve gastrectomy  
Notes:

\*sum of total MBS costs at 75% benefits, hospital costs and prescribed list costs

\*\*sum of total MBS costs at 100% benefits, hospital costs and prescribed list costs.

Source: Attachment 3.4-ESG Budget Impact Model

ESC noted there are uncertainties and missing evidence within the budget impact analysis. Market growth rates and uptake rates were assumed. The ADAR suggested these assumptions were based on the recommendations of key opinion leaders. However, detailed information on these opinion leaders, including their expertise and the robustness of the process used to elicit their estimates are lacking. Further, the uptake and market growth rates used in the sensitivity analyses are arbitrary, which may exert higher uncertainties on the budget impact.

The ADAR notes that ESG is expected to be used only once per patient per episode of care. Nevertheless, the literature shows that patients may need re-tightening or revision procedures, which have not been accounted for in the financial analysis. The ESG device cost is more than double that of LSG devices. The cost of ESG will increase by 38% per reintervention or per repetition of procedure, which is not considered in the estimates.

Using the expected number of claims for existing MBS item 31575 risks underestimating the market size, given ESG may also substitute other bariatric procedures. MBS item 20791 pertains to the initiation of the anaesthesia management for bariatric surgery in patients with clinically severe obesity and it is relevant to all bariatric surgery procedures. Estimated utilisation using statistics for MBS item 20791 may therefore provide a more accurate reflection of the true market demand. An additional sensitivity analysis was performed during the evaluation using claims for MBS item 20791 to estimate the market size. This analysis showed a total budget impact that was 36% higher compared to the ADAR's base case estimates.

A post-ESC sensitivity analysis based on utilisation on item 20791 is shown below in Table 36.

**Table 36: Results under the scenario estimating market size based on MBS item 20791**

| Parameter                                                        | Year 1       | Year 2       | Year 3       | Year 4       | Year 5           |
|------------------------------------------------------------------|--------------|--------------|--------------|--------------|------------------|
| <b>Estimated use and cost of ESG</b>                             |              |              |              |              |                  |
| Projected number of ESG procedures attributable to market growth | redacted     | redacted     | redacted     | redacted     | redacted         |
| Projected number of ESG procedures substituting LSG              | redacted     | redacted     | redacted     | redacted     | redacted         |
| Total number of ESG procedures conducted                         | redacted     | redacted     | redacted     | redacted     | redacted         |
| <b>Total ESG cost to MBS, 75% benefit</b>                        | \$2,823,095  | \$3,551,129  | \$4,279,162  | \$5,424,113  | \$6,257,947      |
| <b>Change in use and cost of LSG</b>                             |              |              |              |              |                  |
| Change in use of LSG procedure**                                 | -810         | -994         | -1,179       | -1,364       | -1,364           |
| Total reduction of MBS cost of LSG, 75% benefit                  | -\$1,361,790 | -\$1,672,906 | -\$1,984,023 | -\$2,295,139 | -<br>\$2,295,139 |
| <b>Net cost to MBS, 75% benefit</b>                              | \$1,461,305  | \$1,878,222  | \$2,295,139  | \$3,128,974  | \$3,962,808      |

Abbreviations: ESG: endoscopic sleeve gastroplasty; LSG: laparoscopic sleeve gastrectomy; MBS: Medicare Benefits Schedule.

Source: Post-ESC additional analysis conducted by the assessment group.

Estimating market growth as a percentage of the existing bariatric surgery market further risks underestimating ESG utilisation. There may be growth in the market size due to both (1) the expanded BMI eligibility for ESG (as opposed to the tighter restrictions which exist for current bariatric surgery items) and (2) the increased acceptance of ESG relative to existing bariatric surgeries. Expert advice provided in the PICO for Application 1555.1 was that 10–20% of eligible patients may be willing to undergo ESG, as opposed to **redacted**% who would consider bariatric surgery. This indicates the potential for considerable growth in the market size. The PICO suggested approximately 3,040 procedures in year 4 after listing, with PASC noting that the expected utilisation may be higher than this. The number of patients estimated to receive ESG in year 4 in the ADAR was lower than this estimate, at **redacted** patients.

Due to ESC raising concerns about varying ESG procedure lengths, a post-ESC sensitivity analysis has been conducted of the financial impact of differing anaesthesia time for ESG. Results are shown below in Table 37.

**Table 37: Post-ESC sensitivity analysis on MBS anaesthesia items**

| Condition/Year                             | Year 1      | Year 2      | Year 3      | Year 4      | Year 5      |
|--------------------------------------------|-------------|-------------|-------------|-------------|-------------|
| <b>Base case</b>                           |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,068,959 | \$2,602,513 | \$3,136,066 | \$3,975,166 | \$4,586,257 |
| Net cost to MBS, 75% benefit               | \$1,070,946 | \$1,376,491 | \$1,682,037 | \$2,293,129 | \$2,904,220 |
| <b>Use item 23045 for ESG</b>              |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,089,760 | \$2,628,678 | \$3,167,596 | \$4,015,131 | \$4,632,366 |
| Net cost to MBS, 75% benefit               | \$1,091,746 | \$1,402,656 | \$1,713,566 | \$2,333,094 | \$2,950,329 |
| <b>Use item 23055 for ESG</b>              |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,110,558 | \$2,654,839 | \$3,199,120 | \$4,055,090 | \$4,678,468 |
| Net cost to MBS, 75% benefit               | \$1,112,544 | \$1,428,817 | \$1,745,091 | \$2,373,053 | \$2,996,431 |
| <b>Use item 23065 for ESG</b>              |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,131,368 | \$2,681,015 | \$3,230,663 | \$4,095,073 | \$4,724,598 |
| Net cost to MBS, 75% benefit               | \$1,133,354 | \$1,454,994 | \$1,776,634 | \$2,413,036 | \$3,042,561 |
| <b>Include 6% revision rate for ESG</b>    |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,193,886 | \$2,759,288 | \$3,324,689 | \$4,213,803 | \$4,861,229 |
| Net cost to MBS, 75% benefit               | \$1,195,873 | \$1,533,266 | \$1,870,659 | \$2,531,766 | \$3,179,192 |
| <b>Include 18.2% revision rate for ESG</b> |             |             |             |             |             |
| Total ESG cost to MBS, 75% benefit         | \$2,446,390 | \$3,076,866 | \$3,707,342 | \$4,698,788 | \$5,420,729 |
| Net cost to MBS, 75% benefit               | \$1,448,377 | \$1,850,844 | \$2,253,312 | \$3,016,751 | \$3,738,691 |

Abbreviations: ESG: endoscopic sleeve gastroplasty; ICER: incremental cost-effectiveness ratio; MBS: Medicare Benefits Schedule.

Source: Post-ESC additional analysis conducted by the assessment group.

Overall, the ESG procedure is expected to result in a net cost to the healthcare system; however, the total estimated net cost remains uncertain due to a lack of information on AE costs, costs of readmissions, and unknown lengths of hospitalisation.

The overall impact of uncertainties associated with the budget impact of listing ESG still exists. Factors influencing ESG uptake among patients hesitant about LSG remain unclear. The analyses did not account for potential health benefits and cost reductions due to the impact of ESG uptake, particularly decreasing healthcare resource utilisation.

## 15. Other relevant information

The eligible populations as defined are likely to create equity of access issues should ESG be recommended for public funding. At the protocol phase, PASC recommended that the population eligible for ESG be limited to patients who had failed first-line (lifestyle modification) and second-line (VLED plus pharmacotherapy) therapies.

As of writing, only one pharmacotherapy specifically intended for weight loss is listed on the RPBS, that being orlistat (brand name Xenical) as an initial course in patients with BMI  $\geq 35$  kg/m<sup>2</sup> with no known comorbidities, or  $\geq 30$  kg/m<sup>2</sup> with either diabetes, ischaemic heart disease, psychiatric conditions or hypertension.

- Semaglutide (Wegovy) is TGA-registered: (a) as an adjunct to a reduced-energy diet and increased physical activity for chronic weight management (including weight loss and weight maintenance) in adults with an initial BMI of  $\geq 30$  kg/m<sup>2</sup> (obesity), or  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (overweight) in the presence of at least one weight-related comorbidity; and (b) as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents aged  $\geq 12$  years with initial obesity and body weight  $> 60$  kg. PBAC considered semaglutide (Wegovy) for the treatment of severe obesity in March 2022 and November 2023 and did not recommend the proposed PBS listing. Semaglutide (Ozempic) is PBS-listed for the treatment of type 2 diabetes mellitus and is purportedly widely used off-label as a weight-loss treatment, like other anti-diabetic medications.
- The TGA recently extended the indication of tirzepatide (Mounjaro KwikPen) as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management, including weight loss and weight maintenance, in adults with an initial BMI of:  $\geq 30$  kg/m<sup>2</sup> (obesity) or,  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes or type 2 diabetes mellitus). PBAC considered tirzepatide (Mounjaro) for the treatment of adult patients with inadequately controlled type 2 diabetes mellitus who either have comorbid severe obesity or identify as Aboriginal and Torres Strait Islander in July 2023 and November 2024 and did not recommend the proposed PBS listing.
- Other pharmacotherapies available in Australia (phentermine, topiramate, liraglutide, naltrexone/bupropion) are not PBS-listed for treating obesity.

ESC noted that the ADAR has not included PASC's suggested requirement for failure of pharmacotherapy in the proposed MBS item descriptors.

The Commentary noted that the Bariatric Surgery Registry annual report<sup>59</sup> indicated that in 2023 most primary, and revision bariatric procedures were privately funded. In most cases treatment is

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<sup>59</sup>School of Translational Medicine Monash University 2024, The Bariatric Surgery Registry Annual Report – 2023, viewed 4 Dec 2024, [https://www.monash.edu/\\_data/assets/pdf\\_file/0007/3757876/Bariatric\\_Surgery\\_Registry\\_-Annual\\_Report\\_2023.pdf](https://www.monash.edu/_data/assets/pdf_file/0007/3757876/Bariatric_Surgery_Registry_-Annual_Report_2023.pdf)

likely to continue to be via private routes with out-of-pocket costs, which may present a barrier to some patients, however there will be a cohort of patients who can and will continue to privately fund care.

The impact of the proposed listing on the use of pharmacotherapies is unclear. Expert opinion included in the ADAR noted the dose-sparing effect of the procedures with pharmacotherapies when used in combination, suggesting some patients would benefit from both surgery and pharmacotherapy.

## 16. Key issues from ESC to MSAC

### Main issues for MSAC consideration

#### Clinical issues:

PICO set 1: class I (BMI 30-34.99 kg/m<sup>2</sup>) or class II obesity (BMI 35–39.99 kg/m<sup>2</sup>) after failing lifestyle modifications and/or pharmacotherapy

- ESC noted that the proposed use of endoscopic sleeve gastroplasty (ESG) in patients with (a) class I obesity, or (b) class II obesity without comorbidities, does not align with the NHMRC (2013) Clinical Practice Guidelines for the management of overweight and obesity<sup>60</sup> but may align partially with new department-commissioned draft guidelines (November 2024)<sup>61</sup> currently undergoing public consultation (Table 38).
- Comparative safety and effectiveness data was limited to 1 year based on the MERIT trial. ESC considered there is significant uncertainty in the long-term evidence for comparative effectiveness. Follow-up data beyond 12 months are limited, and the loss to follow-up is significant. The pre-ESC response presented a conference abstract which reported on a study with 10-year follow-up. ESC noted that conference abstracts are not usually accepted as evidence by MSAC.
- Applicability of results from the MERIT trial to Australian clinical practice uncertain: ESC noted that the MERIT trial did not require study participants to have failed 12 months of both lifestyle modifications and pharmacotherapy. However, previous PASC advice was for patients to have failed 12 months of lifestyle modification and pharmacotherapy before bariatric surgery is considered.
- ESC noted the potential for equity issues to arise from the requirement to trial and fail treatment with pharmacotherapy as an eligibility criterion for ESG, given that there are no PBS listed medications for weight management. However, ESC also noted that several drugs, including Glucagon-like peptide-1 (GLP-1) agonists, are TGA registered for chronic weight management and are used in clinical practice in Australia, but they are not PBS listed for the indication of weight management.

PICO set 2: class II obesity (BMI 35-39.99 kg/m<sup>2</sup>) with comorbidities or class III obesity (BMI >40 kg/m<sup>2</sup>) eligible for bariatric surgery

- ESC considered the inclusion of patients with class III obesity was outside the PASC-ratified PICO Confirmation and the inclusion of this PICO set in the current ADAR was not adequately

<sup>60</sup> For adults with BMI ≥ 30 kg/m<sup>2</sup> or adults with BMI ≥ 27 kg/m<sup>2</sup> and comorbidities, orlistat may be considered as an adjunct to lifestyle interventions, taking into account the individual situation (Recommendation 12, NMHRC 2013 Guidelines). For adults with BMI > 40 kg/m<sup>2</sup> or adults with BMI > 35 kg/m<sup>2</sup> and comorbidities that may improve with weight loss, bariatric surgery may be considered, taking into account the individual situation (Recommendation 13, NHMRC 2013 Guidelines).

<sup>61</sup> Clinical practice guidelines for the management of Overweight and Obesity in Adults, Adolescents and Children in Australia, Draft Recommendations, October 2024, Australian Government, Department of Health and Aged Care (available: [https://www.deakin.edu.au/\\_data/assets/pdf\\_file/0005/2856299/Draft-Guidelines-Guideines-Recommendation-Summary.pdf](https://www.deakin.edu.au/_data/assets/pdf_file/0005/2856299/Draft-Guidelines-Guideines-Recommendation-Summary.pdf)).

justified. ESC noted that the MERIT trial excluded patients with class III obesity. The ADAR presented only single-arm studies, which included large losses to follow-up, to inform the comparative safety and effectiveness of ESG versus laparoscopic sleeve gastrectomy (LSG). ESC agreed with PASC that patients with class III obesity should be considered in a separate MSAC application.

- The nominated comparator for PICO set 2 is laparoscopic sleeve gastrectomy (LSG) only. ESC noted that LSG does not represent the full spectrum of bariatric surgery procedures available on the MBS. According to registry data, LSG covers 80% of bariatric procedures performed in Australia and New Zealand. However, the registry includes procedures performed in public or private hospitals but excludes procedures that are paid for entirely out-of-pocket by patients. Consequently, the profile of patients and procedures in the registry may not reflect the proposed eligible population for MBS funding.
- ESC did not consider the ADAR's claim of non-inferiority of ESG to LSG to be supported based on the clinical evidence presented. ESC considered that the ADAR's use of 10% as the non-inferiority margin for the minimal clinically important difference (MCID) in % total body weight loss (%TBWL) was uncertain and not adequately substantiated, and noted that the lower 95% confidence interval (CI) for %TBWL at both 6 and 12 months exceeded the proposed 10% non-inferiority margin. ESC agreed with the commentary that the claimed non-inferiority of ESG and LSG in reducing total body weight was not supported by the evidence presented.

#### **Economic issues:**

- PICO set 1: Although ESG combined with lifestyle modification appears cost-effective compared to lifestyle modification alone over the long term in the CUA, significant uncertainty in model assumptions (based on the limited clinical evidence) – particularly concerning key adverse events and patient adherence – raises concerns about the reliability of these results.
- PICO set 2: ESC agreed with the commentary that the cost minimisation analysis (CMA) presented in the ADAR was inappropriate due to the claim of non-inferiority not being supported. ESC also noted other flaws in the CMA including the omission of key cost differences, and an inadequate time horizon (30 days) that fails to capture treatment failures and adverse events.

#### **Financial issues:**

- ESC considered that the market share approach used in the ADAR, based on MBS item 31575 (LSG), was inappropriate, as ESG has wider BMI eligibility criteria and higher patient acceptance than other bariatric surgeries. Estimating the market size based on the utilisation of MBS item 20791 (anaesthesia item for bariatric surgery) results in an increase (36%) in budget impact, suggesting that the approach in the ADAR underestimated the budget impact of ESG. ESC also noted that increases in the size of the population over time were also underestimated by the ADAR. Overall, ESC considered the estimated net cost to the health budget of \$56 million (at MBS 75% benefit) in Years 1- 5 highly uncertain.

### **ESC discussion**

ESC noted that the current application is a reapplication from Boston Scientific Pty Ltd requesting Medicare Benefits Schedule (MBS) listing of endoscopic sleeve gastroplasty (ESG) as a treatment for obesity. Specifically, the reapplication presented 2 PICO sets and requested an MBS item for each of the PICO sets:

- PICO set 1: Patients aged 18 years and over with class I (BMI 30-34.99 kg/m<sup>2</sup>) or class II (BMI 35-39.99 kg/m<sup>2</sup>) obesity, with or without comorbidities, and who have failed first-line (1L) and second-line (2L) weight loss therapies.<sup>62</sup>
- PICO set 2: Patients aged 18 years and over with class II obesity (BMI 35-39.99 kg/m<sup>2</sup>) with comorbidities or class III obesity (BMI >40 kg/m<sup>2</sup>) with or without comorbidities, and who are eligible and elect to have bariatric surgery.

## Background

ESC noted that MSAC first considered the application in November 2019. At the time, the application requested MBS listing for ESG in patients with class I and II obesity with comorbidities who had failed first-line (1L) treatments such as lifestyle changes and second-line (2L) treatments such as pharmacotherapy. MSAC did not support public funding for ESG, as it considered the evidence base presented to be weak, with limited applicability to the proposed population and highly uncertain comparative safety and clinical effectiveness particularly in the long term. MSAC considered that the impact of ESG on comorbidities was largely unknown and that all these uncertainties flowed onto the economic evaluation resulting in uncertain comparative cost-effectiveness. MSAC noted at the time that new evidence, including 2 randomised controlled trials evaluating the safety and effectiveness of ESG, was anticipated to be published within the following 3 years and that this evidence might address the uncertainties in the original application. Following the completion of a pivotal randomised trial (MERIT), a reapplication was submitted and considered by PASC in December 2021.

## Proposed population

ESC noted that the ADAR's proposed population differed from the proposed population considered by PASC in December 2021 and the original application considered by MSAC in November 2019 (Table 38).

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<sup>62</sup> 1L: lifestyle modification; 2L: very low energy diet (VLED) ± pharmacotherapy (p3, Ratified PICO Confirmation, November 2021 PASC meeting).

**Table 38: Proposed eligibility criteria for ESG – ADAR vs. previous application**

|                                         | Current ADAR (MSAC 1555.1, April 2025 MSAC)                                 |                                                                                                                                               | Reapplication (MSAC 1555.1) considered by PASC in December 2021                                                                                                                                                                                                                                                                | Previous application (MSAC 1555, November 2019 MSAC)                                                                      |
|-----------------------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Prior line(s) of treatment failure      | Failed ≥2L weight loss therapies (lifestyle intervention ± pharmacotherapy) |                                                                                                                                               | Failed 1L and 2L weight-loss therapies:<br>1L: lifestyle modification<br>2L: VLED alone, pharmacotherapy alone or VLED and pharmacotherapy                                                                                                                                                                                     | Failed 1L weight-loss therapies, defined as an inability to achieve a minimum 5% weight loss within 3 months <sup>b</sup> |
| Duration of treatment failure           | None proposed                                                               |                                                                                                                                               | PASC advised that a 12-month time frame to define treatment-failure is more appropriate than 3 months                                                                                                                                                                                                                          | 3 months                                                                                                                  |
| Failed pharmacotherapy                  | Not an essential criterion                                                  |                                                                                                                                               | PASC advised that individuals need to have failed both VLED and pharmacotherapy to be eligible.                                                                                                                                                                                                                                | Not an essential criterion                                                                                                |
| Bariatric surgery as a treatment option | PICO set 1                                                                  | Class I obesity with or without comorbidities: bariatric surgery is not a treatment option                                                    | Not suitable for bariatric surgery <sup>a</sup><br><br>PASC considered the contraindications appear the same for ESG vs. bariatric surgery and thus considered it was unclear whether there is a patient population with a medical condition that would render patients ineligible for bariatric surgery but eligible for ESG. | Not suitable for bariatric surgery                                                                                        |
|                                         |                                                                             | Class II obesity without comorbidities: bariatric surgery is not a treatment option                                                           |                                                                                                                                                                                                                                                                                                                                |                                                                                                                           |
|                                         |                                                                             | Class II obesity with comorbidities: eligible but elect not to receive bariatric surgery (due to fears of risks of surgery and recovery time) |                                                                                                                                                                                                                                                                                                                                |                                                                                                                           |
|                                         | PICO set 2                                                                  | Class II obesity with comorbidities: eligible and elect to receive bariatric surgery                                                          |                                                                                                                                                                                                                                                                                                                                |                                                                                                                           |
|                                         |                                                                             | Class III obesity: eligible and elect to receive bariatric surgery                                                                            | PASC considered this patient group out of scope                                                                                                                                                                                                                                                                                | Not applicable                                                                                                            |

Source: table compiled by the department post-ESC to facilitate reading based on the ADAR, PSD for MSAC application 1555 (November 2019 MSAC meeting) and the Ratified PICO Confirmation for MSAC application 1555.1 (December 2021 PASC meeting).

1L = first-line; 2L = second-line; ESC = endoscopic sleeve gastroplasty; PASC = PICO Advisory Subcommittee; VLED = very-low energy diet.

<sup>a</sup> Patients who are 'not suitable for bariatric surgery' are those who are not eligible or are contraindicated for bariatric surgical procedures. The definition also includes patients who are eligible for bariatric surgery but who would not consider or have refused to undergo the procedure(s).

<sup>b</sup> The definition was derived from the National Health and Medical Research Council (NHMRC) guidelines on obesity, which suggest a weight loss of 5% reduces health risks by lowering blood pressure and reducing the risk of, or delaying the progression of, type 2 diabetes.

**PICO set 1:** Patients aged 18 years and over with class I (BMI 30-34.99 kg/m<sup>2</sup>) or class II (BMI 35-39.99 kg/m<sup>2</sup>) obesity, with or without comorbidities, and who have failed 1L and 2L weight loss therapies.

ESC noted PASC advice that the population for patients receiving ESG should align with the 2013 Clinical practice guidelines for the management of overweight and obesity from the National

Health and Medical Research Council (NHMRC).<sup>63</sup> ESC noted that the NHMRC (2013) guidelines (Recommendation 13) recommend that only patients with BMI >40 kg/m<sup>2</sup> or BMI >35 kg/m<sup>2</sup> with comorbidities that may improve with weight loss should be considered for bariatric surgery, taking into account the individual situation. ESC noted that the NHMRC guidelines were from 2013 and that the NHMRC publication policy is that all documents be reviewed after 5 years and approval re-issued. If this does not occur, NHMRC approval for the guidelines is withdrawn, noting that NHMRC publications more than 10 years old are advised to be rescinded.<sup>64</sup> ESC noted that new draft guidelines (November 2024) commissioned by the Department of Health and Aged Care are currently undergoing public consultation.<sup>65</sup> ESC considered that whilst the 2013 NHMRC guidelines are the most recently published Australian guidelines, the draft recommendations in the yet-to-be published DOHAC guidelines are relevant for MSAC consideration.

ESC noted that PASC had advised that to access ESG, patients should have previously failed 12 months of both lifestyle modifications and pharmacotherapy. ESC noted that the pre-ESC response reported that expert input did not see a need to propose a timeline for failed therapy, as most patients would have tried and failed many weight loss options before seeking ESG. The pre-ESC response further stated that no pharmacotherapy for weight-loss is currently PBS funded so requiring failure on pharmacotherapy as an eligibility criterion to access ESG treatment would introduce equity issues. ESC noted that currently one pharmacotherapy (orlistat) specifically intended for weight loss is listed on the Repatriation Pharmaceutical Benefits Scheme (RPBS) only. ESC noted that in addition to several other drugs, two GLP-1 receptor agonists (tirzepatide and liraglutide<sup>66</sup>) are TGA-registered (but not PBS-listed) for chronic weight management in patients with BMI ≥30 kg/m<sup>2</sup> or in patients with BMI 27 kg/m<sup>2</sup> to <30kg/m<sup>2</sup> who have comorbidities. ESC noted that another GLP-1 receptor agonist, semaglutide, is TGA-registered and listed as a second line agent as an authority prescription on the PBS for the indication of type 2 diabetes (T2DM) only, which may be of benefit to patients with obesity who have T2DM as a comorbid condition but it is not indicated for patients with obesity without T2DM. Semaglutide is also TGA-registered for patients with obesity (BMI >30, or 27 to < 30) with at least one comorbidity, however it is not PBS listed for this indication.

**PICO set 2:** Patients aged 18 years and over with class II obesity (BMI 35-39.99 kg/m<sup>2</sup>) with comorbidities or class III obesity (BMI >40 kg/m<sup>2</sup>) with or without comorbidities, and who are eligible and elect to have bariatric surgery.

ESC noted that PICO set 2 included two subgroups of patients (Table 38):

Subgroup 1: Patients with class II obesity, with comorbidities. ESC noted that the target population are those who are eligible for but do not elect to have bariatric surgery.

Subgroup 2: Patients with class III obesity (BMI ≥40 kg/m<sup>2</sup>) with or without comorbidities. ESC noted that PASC had advised that this patient group was out of scope for assessment and that a separate application would be required, as the pivotal MERIT trial excluded patients with BMI

<sup>63</sup>Clinical Practice Guidelines for the management of overweight and obesity 2013, Australian Government, National Health and Medical Research Council, <https://www.nhmrc.gov.au/about-us/publications/clinical-practice-guidelines-management-overweight-and-obesity#block-views-block-file-attachments-content-block-1>

<sup>64</sup> Guidelines for Guidelines, Australian Government, National Health and Medical Research Council, [https://www.nhmrc.gov.au/guidelinesforguidelines/updates#toc\\_261](https://www.nhmrc.gov.au/guidelinesforguidelines/updates#toc_261)

<sup>65</sup> Clinical practice guidelines for the management of Overweight and Obesity in Adults, Adolescents and Children in Australia, Full Guidelines October 2024, Australian Government, Department of Health and Aged Care, [https://www.deakin.edu.au/\\_data/assets/pdf\\_file/0004/2856298/Draft-Guidelines-Full-Guidelines.pdf](https://www.deakin.edu.au/_data/assets/pdf_file/0004/2856298/Draft-Guidelines-Full-Guidelines.pdf)

<sup>66</sup> Note that tirzepatide and liraglutide are TGA-registered for patients with BMI greater than or equal to 30kg/m<sup>2</sup> or greater than or equal to 27kg/m<sup>2</sup> to <30kg/m<sup>2</sup> in the presence of at least one comorbidity such as dysglycaemia (pre-diabetes and T2DM), hypertension, dyslipidaemia or obstructive sleep apnoea.

>40 kg/m<sup>2</sup>. ESC noted that the original application considered by MSAC in November 2019 did not include this patient group.

ESC noted that the ADAR included patients with class III obesity, as part of PICO set 2. The submission cited expert opinion advising that there should not be an upper BMI limit to the patient population but rather the MBS listing should align with the TGA indication<sup>67</sup> for the device to avoid treatment restriction. ESC noted that the ADAR considered PICO set 2 as an 'extension of the PICO previously considered by PASC with the same outcomes and comparator and does not require specific consideration by PASC'. Additionally, the pre-ESC response stated that clinicians support including this patient group due to the increased risk of morbidity with LSG and suggested that restricting ESG to patients with lower BMI would be inequitable.

ESC considered that there was not reasonable justification to include the BMI >40 kg/m<sup>2</sup> population given their exclusion in the MERIT trial and the weak level of evidence the ADAR presented for this population. ESC agreed with PASC that this population should be the subject of a separate application to MSAC.

ESC also noted that the population specified for ESG was described as patients "who would be eligible to receive a bariatric procedure." However, the proposed MBS item descriptor for class III obesity included patients "unsuitable for or unable to undergo bariatric surgery" (Table 3). ESC noted that current MBS items for bariatric surgery include guidance on eligibility criteria in explanatory note TN.8.29.<sup>68</sup> ESC considered that the population who would be unable to receive bariatric surgery, as outlined in the explanatory note, but able to receive ESG was unclear.

ESC further noted that the Lancet Commission on Obesity<sup>69</sup> have recently proposed changing how obesity is defined, proposing that diagnosis incorporates other measures of obesity, such as waist circumference, and signs and symptoms of reduced organ function due to obesity, rather than relying on BMI alone.

### Proposed comparator and clinical algorithm

ESC noted that lifestyle modifications alone was the comparator for PICO set 1. ESC considered that this was an appropriate comparator. ESC noted PASC advice that if pharmaceutical treatments were to be considered as comparators for ESG, then the cost-effectiveness for these therapies would need to be established first as this has not been determined by the PBAC.

ESC discussed the comparator for PICO set 2, which the ADAR proposed as LSG. ESC noted that only 80% of bariatric procedures in Australia are LSG, based on the Bariatric Surgery Registry data, which collates data across public and private hospitals in Australia and New Zealand.<sup>70</sup> However, ESC questioned if the registry is reflective of the patients who will likely access this procedure in Australia, as 95% of procedures in Australia are privately funded. ESC considered whether a mixed comparator (including sleeve gastrectomy and laparoscopic adjustable gastric banding) may address the remaining 20% of bariatric surgeries which are not accounted for

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<sup>67</sup> The TGA indication for the device is limited to adult patients with BMI between 30-50 kg/m<sup>2</sup>, <https://www.tga.gov.au/resources/artg/461292>

<sup>68</sup> Medicare Benefits Schedule - Note TN.8.29, MBS Online, Australian Government, Department of Health and Aged care, <https://www9.health.gov.au/mbs/fullDisplay.cfm?type=note&q=NoteID&q=TN.8.29>

<sup>69</sup> Rubino, F., Cummings, D. E., Eckel, R. H., Cohen, R. V., Wilding, J. P. H., Brown, W. A., Stanford, F. C., Batterham, R. L., Farooqi, I. S., Farpour-Lambert, N. J., le Roux, C. W., Sattar, N., Baur, L. A., Morrison, K. M., Misra, A., Kadowaki, T., Tham, K. W., Sumithran, P., Garvey, W. T., ... Mingrone, G. (2025). Definition and diagnostic criteria of clinical obesity. *The Lancet. Diabetes & Endocrinology*. [https://doi.org/10.1016/S2213-8587\(24\)00316-4](https://doi.org/10.1016/S2213-8587(24)00316-4)

<sup>70</sup> Bariatric Surgery Registry; Medicine, Nursing, and Health Sciences; Monash University (available: <https://www.monash.edu/medicine/translational/research/registries/bariatric#:~:text=The%20primary%20aim%20of%20the%20Bariatric%20Surgery%20Registry,it%20is%20predominantly%20a%20quality%20and%20safety%20registry>).

when using LSG as a sole comparator. ESC considered that uptake for ESG will likely be higher than expected due to the potential for patients to preference ESG over other bariatric surgeries.

ESC noted that the proposed clinical management algorithm does not include patients with BMI >40 kg/m<sup>2</sup>, even though these patients are included in PICO set 2. ESC considered that this discrepancy requires clarification from the applicant. ESC also noted that the clinical management algorithm did not consider patients with BMI >50 kg/m<sup>2</sup>, noting that the TGA indication for the device restricts its use to patients with a BMI between 30 and 50 kg/m<sup>2</sup>. The clinical management algorithm also includes revision ESG, however a separate MBS item for revisions has not been proposed by the applicant.

ESC noted the pre-ESC response which stated that while rare, reversal of ESG is a quick and easy procedure. However, ESC disagreed with this position and supported previous MSAC advice that the procedure is only reversible for a short period of time following the initial procedure.

## Consultation feedback

ESC considered that there are several issues that could affect consumers, including uncertain safety and efficacy for both class I and II obesity groups, especially people with comorbidities. ESC also considered that it would be valuable for consumers to know the likelihood of the treatment failing, especially as they would have likely already failed other treatments. Patients may also have additional costs, such as for pharmaceuticals and special diets. ESC considered that to gauge quality of life outcomes around ESG it may be useful to search the literature for a decision regret scale, noting similar data were collected for gastric banding: a recent systematic review concluded that up to 19.5% of patients experienced regret following bariatric surgery.<sup>71</sup> A post-ESC analysis did not find any studies which discussed patient regret associated with ESG.

ESC noted the feedback from Private Healthcare Australia was unsupportive of the application. The feedback notes that there are new weight loss medications available to patients in the lower obesity classes as an early line treatment that may lower the risks associated with a high BMI (increased risk of hernias, joint replacements and cardiac conditions) and remove the need for bariatric procedures. The feedback states that private health insurance funds approximately 22,000 surgical bariatric procedures each year. The feedback also claims that surgeons performing the procedure may not provide appropriate psychological and allied healthcare support to patients.

## Clinical claim

ESC noted that the clinical claims are as follows:

- PICO Set 1: Compared with lifestyle modifications only, ESG has superior efficacy for the primary endpoint of percentage total body weight loss (%TBWL), inferior short-term safety (as the comparator is no intervention) and non-inferior long-term safety.
- PICO Set 2: Compared with bariatric surgery, ESG has non-inferior effectiveness and superior safety.

For PICO set 1, ESC noted that the resubmission ADAR presents new direct evidence from the MERIT trial with 1- and 2-year follow-up data, along with 14 additional single arm studies as supportive evidence. ESC noted that the MERIT trial is largely applicable to the proposed population for PICO set 1. However, it is unclear if patients had completed 12 months of

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<sup>71</sup> Thornton, SM, Edalatpour, A & Gast, KM 2024, 'A systematic review of patient regret after surgery- A common phenomenon in many specialties but rare within gender-affirmation surgery', *American Journal of Surgery*, vol. 234, pp. 68-73.

treatment failure in the MERIT study, as previous therapy failure was not required as a part of the selection process. Additionally, ESC noted the issues in the MERIT trial include underestimation of patient age and sex (by 5.5 years) and an under-representation of males (by 8.9%).

## Comparative Safety

### PICO set 1

Regarding safety, ESC noted that short-term safety of the intervention is inherently inferior to current standard of care, which involves no active surgical intervention, and considered that the inferior safety claim was appropriate. ESC noted that in the MERIT trial no serious adverse events (AEs) were reported for the lifestyle modification group, while 2% of ESG patients had a device- or procedure-related serious AE and 92% of ESG patients reported some type of procedure-related AE (66% were 'accommodative' GI symptoms such as nausea, vomiting or stomach upset). Long-term (5-year) safety evidence from one single-arm, uncontrolled cohort study, which had a high rate of loss to follow-up, showed that 1.3% of ESG patients reported moderate AEs, with one leading to surgery reversal. ESC considered that there may be a risk of bias due to the high rates of loss to follow-up within the studies presented. ESC also noted the lack of evidence provided over the long-term, with most studies showing only 1 year of outcome data and only 1 study providing up to 5 years of data. ESC considered that further long-term studies are required to provide more certainty around ESG safety and considered the claim of non-inferior long-term safety to be uncertain. ESC noted that in the pre-ESC response the applicant provided an additional longer-term 10-year follow-up study.<sup>72</sup> Post-ESC, the commentary noted that the study is a conference abstract which are not usually accepted as evidence by MSAC and under the MSAC Guidelines "would only be accepted as evidence under exceptional circumstances".<sup>73</sup> The commentary noted that the BMI of the study population ranged across both PICO sets and allowed ESG in patients with a lower BMI of  $>27$  kg/m<sup>2</sup> if the patient had comorbidities and BMI  $>30$  kg/m<sup>2</sup> in patients without comorbidities. The commentary found the study had limitations in the generalisability to the population in this application, and had a large loss to follow up (38.2%), which also raised concerns about the maturity of the 10 year data.

### PICO set 2

For PICO set 2, ESC noted that 9 non-randomised controlled studies (non-RCTs) were included to demonstrate the safety of ESG vs LSG, with one study providing data for up to 3 years. ESC noted this evidence showed a non-statistically significant lower rate of severe AEs for the ESG group compared with LSG. ESC noted that excluding studies with a high risk of bias, the results demonstrated a more favourable safety profile for ESG compared to LSG, however results were still statistically non-significant. ESC did however note that in 2 studies, higher rates of gastro-oesophageal reflux disease (GORD) were identified in LSG patients than in ESG patients. ESC considered that although there may be some safety benefits to ESG, there was not sufficient evidence presented in the submission to support the clinical claim of ESG having superior safety to LSG. ESC also had concerns about the appropriateness of using LSG-only as a comparator in terms of safety, as no data was presented to compare safety between ESG and non LSG bariatric surgery. ESC noted that the submission did not separate the two subgroups within PICO set 2 (patients with class II obesity with comorbidities and patients with a BMI  $\geq 40$  kg/m<sup>2</sup>) when

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<sup>72</sup> Lahooti, A., Rizvi, A., Baig, M. U., Akagbosu, C., Mahadev, S., Sampath, K., Carr-Locke, D. L., Aronne, L., Shukla, A., Johnson, K. E., Herr, A., Newberry, C., Kumar, S., & Sharaiha, R. (2024). S2063 Ten-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity. *The American Journal of Gastroenterology*, 119(10S), S1473–S1474. <https://doi.org/10.14309/01.ajg.0001037620.30740.d4>

<sup>73</sup> *Guidelines for preparing assessments for the Medical Services Advisory Committee*, Version 1.0, May 2021, Page 241, Medical Services Advisory Committee (available: <https://www.msac.gov.au/sites/default/files/2024-10/guidelines-for-preparing-assessments-for-msac.pdf>).

evaluating comparative safety to LSG. ESC considered that these subgroups, particularly those with a BMI  $\geq 40$  kg/m<sup>2</sup>, may have differing safety outcomes following ESG. ESC considered that further analysis should be done to split the population based on the evidence provided in the submission, to show if there were differing safety outcomes. Post-ESC analysis completed by the commentary determined that due to the studies provided including groups of participants with overlapping BMI classes, and a lack of stratification of obesity classes within those studies, this analysis was not able to be conducted.

## Comparative effectiveness

### PICO set 1

For PICO set 1, ESC noted that comparative evidence from the MERIT trial appears to support effectiveness of ESG at 12 months compared with lifestyle modifications. ESC noted that the single arm studies also supported the clinical claim in the short term, however, ESC considered that there is a potential for bias within the studies as higher BMI patients may lose more weight than patients with lower BMI, which could lead to an overestimation of %TBWL. ESC noted that evidence for long-term clinical effectiveness (>12 months) was from single-arm, uncontrolled cohort studies with high rates of loss to follow-up. ESC considered that this long-term outcome data is uncertain, as patients who have more benefit from treatment and follow the lifestyle changes are also more likely to stay in the study, thus creating potential for bias within the evidence. For weight-related comorbidities, ESC noted that the evidence suggested significant improvements in type 2 diabetes, but the specific outcomes measures used to support this claim are not reported in the MERIT study.

### PICO set 2

For PICO set 2, ESC noted that the results from meta-analyses comparing ESG to LSG for the primary outcome, %TBWL, did not support non-inferior effectiveness at 12 months. ESC noted that the evidence for weight loss for PICO set 2 relied on the dataset for PICO set 1 and thus also carried the potential risk of bias as already discussed. The confidence interval (CI) for pooled effectiveness overlaps the 10% minimal clinically important difference for non-inferiority (–9.95; 95% CI –10.70, –9.19). ESC noted that a non-inferiority margin of 10% was set by the applicant, who stated that the margin was supported by clinicians and included in one publication.<sup>74</sup> However, ESC considered the basis on which this margin was set to be unclear and noted that the commentary suggests that LSG is superior to ESG for weight loss. ESC also considered that the durability of weight loss is uncertain, with the only long-term evidence coming from one non-RCT with a moderate risk of bias reporting non-inferior efficacy based on %TBWL (–4.8; 95% CI –8.7, +1.5) at 36 months. Overall, ESC considered the claim of ESG non-inferiority to LSG was uncertain. Additionally, ESC again had concerns about the appropriateness of LSG-only as a comparator.

ESC noted that health-related quality of life (HRQoL) is reported for both PICO sets. For PICO set 1, ESC noted that the MERIT trial reported that HRQoL was significantly higher for ESG compared with lifestyle modifications, including improvements in various domains in the 36-item Short Form Health Survey (SF36) (including physical function, role limitations due to physical health or emotional problems, energy/fatigue, social functioning, pain and general health). For PICO set 2, HRQoL was reported in 2 non-randomised observational studies using the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) measure. ESC noted that there was a non-statistically significant improvement for the ESG group and statistically significant improvement for the LSG

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<sup>74</sup> Alqahtani, A. R., M. Elahmedi, A. Aldarwish, H. Y. Abdurabu and S. Alqahtani (2022). "Endoscopic gastroplasty versus laparoscopic sleeve gastrectomy: a noninferiority propensity score-matched comparative study." *Gastrointest Endosc* 96(1): 44-50.

group. ESC considered that patients who had undergone ESG had significant improvement in HRQOL compared to lifestyle modification (PICO set 1) but did not experience improvement when compared to LSG (PICO set 2).

## **Comparative cost-effectiveness**

### **PICO set 1**

ESC noted that the ADAR presented a cost-utility analysis (CUA) for PICO set 1, based on a clinical claim of superiority of ESG and lifestyle modification over lifestyle modification only. ESC considered the use of CUA to be appropriate. ESC noted that the economic evaluation purported to compare ESG with lifestyle modification versus lifestyle modification alone. ESC noted that in the ESG group, patients receive more intensive lifestyle modification,<sup>75</sup> incurring costs associated with more frequent visits with dietetics and specialist appointments in the first year after ESG. From second year onwards, the same lifestyle modifications were applied to both ESG and control group.

ESC noted that the ADAR presented a 5-state Markov model with a 40-year time horizon. ESC agreed with the commentary that it was appropriate, noting the time horizon of 40 years was preferable to the 2-year MERIT trial duration as it better captured the long-term costs and benefits. ESC considered that there were no major structural issues with the economic model.

ESC shared the commentary's concern that uncertainties from the MERIT trial data and the appropriateness of the use of non-Australian data (e.g., literature-based utilities) to inform the model would affect the validity of model inputs and the applicability of results to the Australian setting. ESC again noted the issues in the MERIT trial including underestimation of patient age and sex. In addition, ESC agreed with the commentary that some AEs were under-reported.

ESC noted that health state allocation was based on individual patient data from the MERIT trial for first 2 years for ESG and 1 year for lifestyle modification. From years 3-5, the ADAR assumed that 80% remain in same health state as at end of year 2; 20% regress to baseline BMI; 100% remain in the higher obesity class for those who gain weight during first 2 years. From 5 years onward, the ADAR assumed that patients would remain in the same health state as at end of year 5. ESC considered using MERIT trial data reasonable due to lack of published evidence on transition probabilities but agreed with the commentary that the ADAR's conversion of patient-level MERIT trial data to transition probabilities was not transparent.

ESC considered that while the assumptions on extrapolations were appropriate for the short term, the assumptions on the long-term effectiveness and durability of treatment effect for ESG was uncertain, as treatment effectiveness beyond 5 years had not been presented. ESC considered the assumptions of treatment effect beyond 5 years over-simplified. In addition, data from Sharaiha et al. 2021 had not been appropriately applied in the model, as it relies on data from the United States which may not be applicable to an Australian population.

ESC considered that the ADAR had not addressed the issue of treatment failure which remained a key issue for the reapplication. ESC noted that the ADAR applied a one-off revision cost at 2 years and agreed with the commentary that revision costs had not been captured accurately in

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<sup>75</sup> The ADAR reported that the more intensive lifestyle modification incorporated liquid diet in the first week following the procedure, a "pureed" diet in the subsequent week, a "mechanically altered soft diet" in the following week, before transitioning to a regular texture diet by the end of the fifth week. Following the immediate phase after the procedure, patients require a high-protein diet, coupled with supervised strength training to overcome the loss in muscle strength after the surgery. The rationale was to accommodate the dietary changes required to ensure optimal effectiveness of ESG.

the economic model. ESC also noted that the rate of progression to more invasive surgery is uncertain.

ESC noted that, over a 40-year time horizon, the base case incremental cost-effectiveness ratio (ICER) for the class I obesity cohort was \$7,554 per quality-adjusted life year (QALY) gained. This increased to \$12,591/QALY gained for the class II obesity cohort.

ESC discussed the model validation. ESC noted that the model traces show expected trends, with patients undergoing ESG generally transitioning to lower weight states while those undergoing lifestyle modification remain at risk of increasing their weight. ESC considered that while these trends align with clinical expectations, the transition probabilities' accuracy and potential biases, such as overly optimistic ESG outcomes or a pessimistic lifestyle modification assumption, remain unclear.

ESC noted that results from sensitivity analyses showed that the key factors influencing the ICER were the time horizon and costing perspective for obesity class I, and the time horizon for obesity class II. ESC noted that assuming a reintervention rate of 30% at 2 years resulted in a 67.6% and 77.8% change from the base case for class I and II obesity, respectively. ESC requested additional sensitivity analysis on revision/reintervention rates beyond 2 years. Results are presented in Table 27. The assessment group cautioned the interpretation of the results from the additional one-way sensitivity analyses (SAs) which explored alternative revision/reintervention rates, using arbitrary assumptions, on the accumulation of treatment costs only. The additional SAs did not consider any impact of revision/reintervention rates on weight loss or gain over the longer term, which remains a key uncertainty, nor account for patients who may convert to other forms of bariatric surgery downstream.

## **PICO set 2**

ESC noted that the ADAR presented a cost-minimisation analysis (CMA) for PICO set 2 based on a clinical claim of non-inferiority of ESG as versus LSG. ESC agreed with the commentary that this was inappropriate, as the clinical claim was not supported by the evidence presented. In addition, ESC advised that the cost-effectiveness of LSG in patients with BMI >40 kg/m<sup>2</sup> needs to be established before establishing any incremental benefits with ESG.

ESC noted that, when comparing the raw costs of ESG and LSG in the base case, the ADAR estimated that ESG would result in a cost-saving of \$5,658.15 despite much greater device costs than LSG. The estimated cost-savings were mainly from much lower hospital cost.

ESC noted that hospital costs and the time horizon (30 days) were the main drivers of the model. ESC noted the short time horizon excluded costs of treatment failures, revisions, and severe adverse events, which ESC considered would undermine the robustness of the CMA.

ESC noted that inclusion of AE costs in the CMA had a moderate impact (11% change from the base case). ESC noted the pre-ESC response provided a sensitivity analysis which extended the time horizon from 30 days to 12 months, included costs for conversions, revisions, and retightening's as well as adding in readmissions from AEs. ESC noted that in this sensitivity analysis ESG was still associated with cost-savings (\$4,888.24). ESC reviewed the calculations the details of which the applicant provided post-ESC at ESC's request (Table 33) and considered the sensitivity analysis acceptable.

## **Financial implications**

ESC noted that the financial impact for both PICO sets was estimated using a market share approach based on usage of MBS item 31575 for sleeve gastrectomy in a patient with clinically

severe obesity. ESC noted that this differed from the epidemiological approach used in the original application.

ESC noted that the ADAR estimated the number of procedures for ESG to be **redacted** in year 1, rising to **redacted** in year 5 of listing. ESC also noted that the ADAR assumed that ESG would substitute for a number of LSG procedures: **redacted** in year 1, rising to **redacted** in year 5.

ESC considered using MBS item 31575 as a proxy in estimating the market size to be inappropriate as it may not reflect the entire population who will be eligible to receive ESG. ESG has proposed wider BMI eligibility and higher patient acceptance than other surgeries (10–20% for ESG vs **redacted**% for bariatric surgery). As such, ESC considered the use of item 31575 results in a potential underestimation of the market size and, therefore, the net cost.

ESC also considered that market growth is likely underestimated for the same reasons and that there is potential leakage of BMI >40 kg/m<sup>2</sup> patients who are unwilling to undergo full bariatric surgery. ESC noted that the TGA indication for the device includes patients with BMI 30-50 kg/m<sup>2</sup> and therefore considered leakage in the >50kg/m<sup>2</sup> patient group is unlikely.

ESC noted the total cost of ESG procedures to the MBS to be \$2.1 million in year 1 rising to \$4.5 million in year 5 at 75% benefit. ESC noted that the total health budget impact (sum of the net MBS, hospital and Prescribed List costs) was an estimated \$5.8 million in year 1, rising to \$19.1 million in year 5 at 75% benefit, with a total impact of \$56 million over the 5 years. ESC considered that supply of providers should also be factored in when estimating uptake.

ESC considered the utilisation data of ESG proposed in the submission to be uncertain. ESC noted the commentary's sensitivity analysis which used MBS item 20791, which is an anaesthesia item used for all bariatric surgeries, to estimate the market size for the proposed intervention. ESC noted that this showed in a potential 36% underestimation in the base case financial impact. ESC considered that MBS item 20791 was the more appropriate item for determining market share. Post-ESC analysis using utilisation of item 20791 is shown in Table 36.

ESC noted that the MBS item used to cost anaesthesia for ESG was item 23035, which only provides for 31 to 45 minutes of anaesthesia time. ESC noted that the ESG procedure can take between 60-90 minutes, ESC therefore requested additional sensitivity analyses using different MBS anaesthesia items to gauge the financial and economic impact. Post-ESC the commentary has completed analysis using items 23045, 23055, and 23065. The results are shown in Table 28 and Table 37 below.

Additionally, ESC noted the cost of ESG repairs and revisions are not included in the financial model. ESC also noted that private health costs were not presented in the model. ESC considered that the applicant should provide a full analysis including revision and private health costs to inform MSAC decision-making.

### **Proposed MBS listing**

ESC noted that the applicant proposed 2 MBS item descriptors based on obesity level, one for class I or II obesity and the other for class III obesity as noted in Table 2 and Table 3.

ESC noted that each proposed item is applicable once per 24-month period to cover revisions. ESC noted that PASC considered that a separate MBS item would be needed to cover post-ESG revision.

The ADAR implies that revision or removal of ESG could be covered by MBS item 30478 (gastroscopic removal of foreign body), but the pre-ESC response acknowledges that the creation of a separate revision item could help with monitoring usage. ESC noted the Department's advice

that item 30478, as it currently stands, would not be appropriate given it would need to cover reversal and / or converting to a different procedure and the population of item 30478 is not consistent with the population proposed in this application. Due to this, ESC considered that MBS item 30478 was not appropriate to cover post-ESG revision and agreed with PASC's suggestion that should public funding for ESG be supported, a post-ESG revision should be funded under a separate, newly created MBS item. ESC questioned the 24-month restriction between procedures and noted that there may be a need for future surgery and revision if treatment is ineffective.

ESC considered that the descriptor should align with current clinical management guidelines and with already existing MBS requirements as set out in explanatory note TN.8.29. As such, ESC considered that the proposed descriptors should specify the need for prior failure of non-surgical treatment (including pharmacotherapy) for 12 months and a requirement for comorbidities for the PICO set 1 population.

ESC noted that the proposed MBS fee was the same as the current MBS fee for the LSG bariatric surgery item (31575). ESC noted that the procedures take a differing surgical route and may have different durations. ESC considered that there was little justification for why the fee provided was identical to item 31575 and that the applicant should provide more justification to support the proposed fee. ESC noted this service would likely be classified as a Type A procedure for private health insurance purposes.

ESC noted that the clinical evidence provided is limited to ESG using OverStitch™, an endoscopic suturing device that is the applicant's proprietary system. However, the proposed MBS item descriptors are generic.

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

The applicant would like to thank the MSAC, the Secretariat, and the Contracted HTA group for all their work and the consideration of our application. We are naturally disappointed with the outcome and believe that ESG is an attractive minimally invasive endoscopic alternative to surgery that expands the therapeutic benefits of effective obesity interventions targeting the GI tract to patients who do not qualify for or wish to pursue bariatric surgery. The evidence in this field is maturing, and we will take MSAC's advice under consideration and will plan a resubmission at a later date.

## **18. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)