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02.01.56 Miscellaneous Bariatric Procedures

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Related Policies:

- 07.01.62 Gastric Electrical Stimulation
- 07.01.60 Vagus Nerve Stimulation (VNS) and Vagal Nerve Blocking Therapy
- 05.04.33 Drugs for Weight Loss Management

Summary

Description

Bariatric surgery is a treatment for class III obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. ***Note:*** *This evidence review will only address surgical and minimally invasive procedures that are considered investigational. For gastric restrictive procedures that require prior approval see Wellmark Authorization Table and the medical necessity clinical coverage criteria using InterQual® criteria.*

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Summary of Evidence

For individuals who have obesity (see Policy Guidelines) who are treated with bariatric surgery or minimally invasive procedures as outlined below in the Policy criteria, the evidence includes systematic reviews, randomized controlled trials (RCTs), observational and case series studies, Relevant outcomes are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life (QOL), and treatment-related mortality and morbidity. Based on the peer reviewed literature the evidence is low-quality, and is limited by the lack of large well-designed clinical trials that provide data on long-term efficacy and safety of these procedures. The evidence insufficient to determine that the technology results in an improvement in the net health outcome**.**

OBJECTIVE

The objective of this evidence review is to evaluate whether various bariatric surgical and minimally invasive procedures improve the net health outcome in individuals with obesity.

PRIOR APPROVAL

Not applicable.

For gastric restrictive procedures that require prior approval see Wellmark Authorization Table and the medical necessity clinical coverage criteria using InterQual® criteria.

POLICY

Surgical or Minimally Invasive Procedures

The following bariatric surgical or minimally invasive procedures are considered **investigational** as a treatment of obesity (see Policy Guidelines) including but not limited to the following because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Adjustable banding as an open procedure
- Aspiration Therapy Device (e.g., the AspireAssist® device)
- Bariatric arterial embolization (BAE)
- Biliopancreatic bypass without duodenal switch
- Endoscopic sleeve gastroplasty (ESD)
- Endoscopically placed duodenal-jejunal sleeve
- Gastrointestinal liners including but not limited to the following:
    - Endobarrier
    - Gastric Vest System
    - ValenTx,
- Intragastric balloon (e.g., ReShape® Integrated Dual Balloon System, Orbera device or Obalon device)
- Laparoscopic gastric plication, also known as laparoscopic greater curvature plication
- Long-limb gastric bypass procedure (i.e., >150 cm) (malabsorptive procedure)
- Mini-gastric bypass, also known as loop gastric by-pass (includes the use of Billroth II type)
- Silastic Ring Vertical Gastric Bypass (Fobi pouch)

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- Single anastomosis duodeno-ileal bypass with sleeve gastrectomy
- Transoral endoscopic surgery (Transpyloric Shuttle (TPS) Device, ROSE, Natural orifice transluminal endoscopic surgery [NOTES])
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Use of any endoscopic closure devices (e.g., StomaphyX™, EndoCinch, OverStitch™)
- Vertical-banded gastroplasty

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Bariatric surgery is performed to treat obesity. The first treatment of obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few individuals with obesity can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, are not subject to regulation by the FDA.

Table 1. shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process:

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 mo treatment period.
AspireAssist System®	Aspire Bariatrics	Jun 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m^2 and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy.
ORBERA® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no

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Device	Manufacturer	PMA Date	Labeled Indications
			contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.

- In March 2007, the FDA granted 510(k) pre-marketing clearance to the StomaphyX (EndoGastric Solutions, Inc.), an endoluminal fastener and delivery system used to tighten esophageal tissue.
- On July 28, 2015, the Food and Drug administration (FDA) approved the ReShape Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, CA) to treat obesity without the need for invasive surgery.
- In April 2019 FDA approved the TransPyloric Shuttle non-surgical device intended for treating obesity, now cleared as a weight loss solution for adults with obesity and a body mass index of 30 to 40 kg/m2.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers "instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications."

- In July 2022, the FDA approved Apollo Endoscopic Sleeve Gastroplasty (ESG) System (formerly Known as OverStitch; Apollo Endosurgery Inc.), Apollo ESG SX System, Apollo REVISE System and Apollo REVISE SX System. An endoscopic suturing device for altering anatomy for weight loss uses suturing to approximate gastric tissue to restrict the volume of the stomach for the intended purpose of weight loss. In September 2023 the FDA approved newer version that uses newer materials Apollo ESG NXT System and Apollo REVISE NXT System.

RATIONALE

This evidence review was created in December 2015 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through June 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of bariatric surgical and minimally invasive procedures is to provide a treatment option that is an alternative to or an improvement on existing therapies, in individuals with obesity.

The following PICO was used to select literature to form this review.

Populations

The relevant population of interest are individuals with a diagnosis of obesity.

Diagnosis is based on body mass index (BMI) plus clinical judgment. Clinicians are advised to consider age, gender, ethnicity, fluid status, and muscularity when evaluating individuals for weight management. Classification of overweight and obesity and associated risk of comorbidities is shown in Table 2. Lower BMI threshold recommended in South Asian, Southeast Asian, and East Asian adult populations.

Table 2. Overweight and Obesity Classification

Classification	**Body Mass Index (kg/m^2)**	**Comorbidity Risk**
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	Moderate
Class 2 obesity	35-39.9	Severe
Class 3 obesity	≥40	Very severe

Interventions

The therapy being considered is surgical and minimally invasive bariatric procedures:

- **Adjustable banding as an open procedure**: Performed as an open procedure rather than laparoscopically. The surgeon puts an adjustable band around the top part of the stomach which creates a very small stomach pouch which causes the individual to feel fuller after eating less food.

- **Aspiration device therapy** (e.g., the AspireAssist® device): To place the device, surgeons insert a tube in the stomach with an endoscope via a small incision in the abdomen. A disk-shaped port valve that lies outside the body, flush against the skin of the abdomen, is connected to the tube

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and remains in place. Approximately 20 to 30 minutes after meal consumption, the patient attaches the device's external connector and tubing to the port valve, opens the valve and drains the contents. Once opened, it takes approximately five to 10 minutes to drain food matter through the tube and into the toilet. The device removes approximately 30 percent of the calories consumed.

- **Bariatric arterial embolization (BAE):** Is a minimally invasive procedure, a small catheter is passed through the radial artery in the wrist or the femoral artery in the groin and utilize live x-ray imaging to guide the catheter to the artery that supplies blood to the left side of the stomach. Here the physician injects tiny particles that are just large enough to block and kill the cells that make the appetite hormone ghrelin to minimize feelings of hunger to initiate weight loss.

- **Biliopancreatic bypass without duodenal switch**: In this procedure portion of the stomach are removed creating a smaller stomach pouch and allowing food to bypass part of the small intestine so the individual absorbs fewer calories.

- **Endoscopic closure devices** StomaphyX™, EndoCinch, OverStitch™,Over-the-Scope-Clip: Utilized to reduce the size of the stomach.

- **Endoscopic sleeve gastroplasty**: Reduction of the size of the stomach completed endoscopically.

- **Endoscopically placed duodeno-jejunal sleeve:** Endoscopically delivered duodeno-jejunal bypass liner (DJBL), is a plastic flexible tube that is placed in the duodenal bulb, directly behind the pylorus. It extends from the duodenum to the proximal jejunum.

- **Gastrointestinal liners:** Gastrointestinal liners including but not limited to the following are endoscopically placed as part of dueodeno-jejunal bypass. Once implanted the device is purported to influence gastrointestinal hormones and satiety. It is suggested to promote weight loss in individuals who are potential candidates for bariatric surgery but are too heavy to safely undergo the procedure.
  - Endobarrier
  - Gastric Vest System
  - ValenTx,

- **Intragastric balloon** (e.g., ReShape® Integrated Dual Balloon System, Orbera® device or Obalon™ device): Also known as the silicone intragastric balloon or SIB which are endoscopically implanted intragastric devices which are filled with liquid or gas after insertion and intended to reduce gastric capacity, delay gastric emptying and stimulate the feeling of satiety. The TransPyloric Shuttle Device is placed in the stomach through the mouth during an endoscopic procedure. Once in place, the TPS is formed, using the TPS Delivery Device, into a smooth large bulb connected to a smaller bulb by a flexible silicone tether. The large bulb remains in the stomach. The smaller bulb can remain in the stomach or cross the stomach into the small intestine to slow the time it takes for food to leave the stomach and enter the small intestine (gastric emptying). The TPS remains in the stomach for up to 12 months to help patients lose weight.

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- **Laparoscopic gastric plication**: Also known as laparoscopic greater curvature plication. This is a bariatric procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. To achieve gastric restriction the procedure requires 2 main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach.

- **Long-limb gastric bypass:** Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways (e.g., resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses.

- **Mini-gastric bypass**: Also known as loop gastric by-pass (includes the use of Billroth II type): This procedure is performed laparoscopically. The surgeon splits the stomach into unequal parts sealing them using surgical stapes. The smaller part of the divided stomach about 25% of its original size will be the main stomach with the rest remaining unused. The surgeon will attach the remainder of the intestines to the new stomach. Food flows into the small tube-like stomach and then bypasses between 2 to 7 feet of intestines where it resumes the normal digestive process in the remaining intestine.

- **Silastic Ring Vertical Gastric Bypass (Fobi pouch)**: With the Fobi pouch, there is no use of staples; rather, the stomach is bisected and hand-sewn them to maintain the separation. A synthetic band is placed around the stomach opening to keep it from stretching.

- **Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S):** Also known as loop duodenal switch or stomach intestinal pylorus-sparing surgery. This procedure is a variant of the duodenal switch (DS) which was developed to address the inherent limitations of the current standard bariatric surgeries including inadequate weight loss, weight regain, variable improvement of weight-related co-morbidities, hypoabsorptive complications, internal hernias, and technical difficulty. The procedure involves first creating a sleeve gastrectomy then replacing the RYGB reconstruction with a single anastomosis duodenoileostomy with a 250 cm or longer absorptive channel. The 1-loop Billroth II-like connection avoids the need for forming a distal ileo-ileal anastomosis and alimentary limb.

- **Transoral Endoscopic Surgery:**
  - Transoral endoscopic surgery is an option being explored for bariatric surgery. Natural orifice transluminal endoscopic surgery (NOTES) is performed via a natural orifice (e.g., mouth, vagina, etc.), and in some cases eliminates the need for abdominal incisions. This form of surgery is being investigated as an alternative to conventional bariatric surgery.
  - Transoral restorative obesity surgery (ROSE) is another endoscopic procedure. The endoscope with four channels is inserted into the esophagus and then the stomach.

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Specialized instruments are placed through the channels to create multiple folds around the existing stoma to reduce the diameter.

- The transpyloric shuttle (TPS) device is a non-balloon, space occupying device with a 12-month treatment duration that is proposed as a new endoscopic bariatric therapy. This device is comprised of a spherical silicone bulb connected to a smaller cylindrical silicone bulb by flexible tether, it is delivered and removed from the stomach using transluminal endoscopic procedures in the outpatient setting. TPS is intended to be used in conjunction with a diet and behavior modification program.

- **Two-stage bariatric surgery procedures:** Sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time.

- **Vertical-banded gastroplasty**: Also known as stomach stapling. In this procedure the upper stomach near the esophagus is stapled vertically to create a small pouch along the inner curve of the stomach. The outlet from the pouch to the rest of the stomach is restricted by a band made of special material. The band delays the emptying of food from the pouch, causing a feeling of fullness. The percentage of reoperations necessary with vertical banded gastroplasty is increased from all other approved procedures. This procedure is no longer the standard of care.

Comparators

Comparators of interest include standard of care which includes dietary and lifestyle changes.

Clinical practice guidelines recommend that comprehensive lifestyle intervention (CLI, i.e., interventions that combine behavioral, dietary, and physical activity components together, should always be provided in conjunction with other weight loss interventions). VA guidelines note that although there is insufficient evidence to recommend a specific number of sessions, most CLIs offer at least 12 intervention sessions in the first 12 months of intervention.

Outcomes

The general outcomes of interest are overall survival (OS), change in disease status, functional outcomes, health status measures, QOL, treatment-related mortality, and treatment-related morbidity.

Percent weight lost (e.g., proportions achieving 5%, 10%, and 15% weight loss or mean difference between groups) is commonly used in studies of interventions. Decrease in BMI can be used, especially if change leads to a change in risk category.

Recommended primary outcome measures are summarized in Table 3.

Table 3. Primary Outcome Measures for Bariatric Procedures

Outcome	Measures	Clinically Important Difference	Duration of Follow Up
Weight loss	% TBWL	•5% •FDA: varies (2% to 5%) depending on indication sought (weight loss, limited weight loss, or weight management)	12 months (6 months if indication is short-term weight loss)

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Outcome	Measures	Clinically Important Difference	Duration of Follow Up
		•Should be appropriate for associated risk •AACE: for tertiary prevention, based on comorbidities	
	Responder rate	Proportion achieving at least 5% TBWL •Devices guidance - at least 50% of treated participants •Drugs guidance - at least 35% and double the control group	12 months
Adverse events	Incidence, severity	•Intervention-specific	12 months or longer

AACE: American Association of Clinical Endocrinology; FDA: Food and Drug Administration; TBWL: total body weight loss.

Indirect evidence of the effectiveness of weight loss interventions on health outcomes is provided by studies of the strength of the association between weight loss and health outcomes. AACE (2016) guidelines include a table of weight loss targets for clinical outcomes.[1,]

Direct evidence would come from studies of the effect of the intervention on health outcomes, preferably from randomized controlled trials.

The following secondary outcomes are of interest:

- Percent excess weight loss;
- Change in weight;
- Change in BMI (especially if decrease results in a change to a different risk group);
- Change in waist circumference;
- Patient-reported outcomes and patient preference information;

The existing literature evaluating gastric bypass as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 3 years. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

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Review of Evidence

This evidence review briefly summarizes the key evidence on the following surgical or minimally invasive bariatric procedures for the treatment of obesity that are considered *investigational*, see Policy.

Adjustable Banding as an Open Procedure

Laparoscopic adjustable banding is the preferred method rather than performing as an open procedure due to wound complications. The majority of the studies are related to laparoscopic approach. Gastric banding surgery is no longer commonly performed because of its high failure rate.

Aspiration Therapy Device (e.g., The AspireAssist® Device)

The evidence consists of an RCT (Thompson et al 2017) with 4 years of follow-up and a small case series (Noren et al 2016) with up to 2 years of follow-up. The RCT found significantly greater weight loss (measured several ways) with AT compared with LT at 1 year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the PATHWAY study noted a potentially high degree of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years post-gastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on AT remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, safety, and nutrition.

Bariatric Arterial Embolization

In 2019 Weiss et. al. in a prospective, open-label, single-arm, two center study evaluated the safety and efficacy of bariatric arterial embolization (BAE) in severely obese adults at up to 12 months after the procedure. Twenty patients were included. At 12 months the mean excess weight loss was 11% and mean total weight loss of 7.6 kg. Eight participants experienced minor adverse events. While this procedure is considered less invasive than bariatric surgeries, weight loss does not appear to be as robust when compared to other therapies i.e., 19% by gastric banding and 36% by Roux-en-Y gastric bypass. BAE is at least as effective as some pharmacotherapies which induce mean weight loss of 2%-9%.

Biliopancreatic Bypass without Duodenal Switch

A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without the DS and gastric bypass. However, BPD without DS leads to complications, especially long-term nutritional and vitamin deficiencies

Endoscopic Closure Devices

The StomaphyX device was determined to be equivalent to the EndoCinch system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. Eid et al (2014) reported on

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results from a single-center RCT that compared the StomaphyX device with a sham procedure for revisions in patients with prior weight loss after RYGB at least 2 years earlier. Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary 12-month efficacy endpoint (reduction in pre-RYGB excess weight by ≥15%, excess BMI loss, and BMI <35 kg/m^2) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group (p<.01).

A meta-analysis by Dhindsa et al (2020) evaluated the efficacy and safety of a particular TORe device (Overstitch™; Apollo Endosurgery, Texas, United States) to treat weight regained following RYGB. The primary outcomes chosen included technical success of the procedure, the absolute weight loss and the percent of total weight loss at 3, 6, and 12 months after the procedure. A total of 13 prospective and retrospective studies with 850 individuals were included in the analysis. The pooled rate of technical success was 99.89%. While the pooled percent absolute weight loss and percent total weight loss at 3 and 6 months showed persistent weight loss, there was some weight gain at 12 months. The adverse event rate was 11.4% (± 10.11), there was no mortality. The meta-analysis was limited by the short-term follow-up and lack of any control or comparison groups. Long-term safety and efficacy outcomes and comparative RCTs are still needed.

Endoscopic Sleeve Gastroplasty

Abu Dayyeh (2022) conducted a prospective, multicenter, randomized controlled trial (MERIT) that explored the efficacy and safety of endoscopic sleeve gastroplasty (ESG) with lifestyle modifications compared with lifestyle modifications alone. This study enrolled adults from December 20, 2017 to October 24, 2019 at 9 U.S. centers (5 gastroenterology centers and 4 bariatric surgery centers). Patients age ranged 21-65 years with a BMI between 30 kg/m^2 and less than 40 kb/m^{2,} with history of failure with nonsurgical weight loss methods, and who agreed to comply with the lifelong dietary restrictions required by the procedure. Primary outcome was the percentage of excess weight loss (EWL), with excess weight being that over the ideal weight for a BMI of 25 kg/m^2 (5% or 10% more). Secondary outcome measures included change in metabolic comorbidities between groups. Reviewers utilized multiple imputed intention-to-treat analyses with mixed-effects models to determine outcome results. Patients were randomly assigned to ESG with lifestyle modifications (n=85) and to lifestyle modifications alone (n=124, control), with potential retightening or crossover to ESG, respectively, at 52 weeks. Lifestyle modifications included a low-calorie diet and physical activity. Participants in the primary ESG group were followed up for 104 weeks. At 52 weeks, the primary endpoint of mean percentage of EWL was 49·2% (SD 32·0) for the ESG group and 3·2% (18·6) for the control group (p<0·0001). Mean percentage of total bodyweight loss was 13·6% (8·0) for the ESG group and 0·8% (5·0) for the control group (p<0·0001), and 59 (77%) of 77 participants in the ESG group reached 25% or more of EWL at 52 weeks compared with 13 (12%) of 110 in the control group (p<0·0001). At 52 weeks, 41 (80%) of 51 participants in the ESG group had an improvement in one or more metabolic comorbidities, whereas six (12%) worsened, compared with the control group in which 28 (45%) of 62 participants had similar improvement, whereas 31 (50%) worsened. At 104 weeks, 41 (68%) of 60 participants in the ESG group maintained 25% or more of EWL. ESG-related serious adverse events occurred in three (2%) of 131 participants, without mortality. Serious adverse events included device or procedure related adverse events requiring surgical, endoscopic or radiological intervention (abdominal abscess, GI bleed, case of malnutrition requiring endoscopic reversal of ESG). Also, results were generalizable as the trial was performed in academic and community setting in which the procedures were performed by gastroenterologists and bariatric surgeons with a range of experience and technical proficiency with the procedure. Limitations related to this study included absence of sham intervention group, the absence of comparative group between 52 and 104 weeks, and

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inadequate sample size to detect important health outcomes such as the incidence of end-organ and cardiovascular outcomes and mortality.

In a Hayes health technology assessment (September 2024) the reviewers searched the PubMed and Embase databases published through October 2023 and performed an evidence review related to the Apollo ESG System (Apollo Endosurgery, Inc.) for endoscopic sleeve gastroplasty for treatment of obesity. This review included six clinical studies: 1 RCT (Abu Dayyeh 2022 referenced above, MERIT trial), 1 retrospective propensity score-matched study (Algahtani 2022), 1 retrospective observational case-matched study (Cheskin (2020), and 3 retrospective comparative cohort studies (Novikov 2018, Lopez-Nava 2021, Spry 2023). The evidence was considered poor or very poor quality. All six studies compared ESG using Apollo ESG or OverStitch with another obesity treatment (lifestyle management [LM], LSG [laparoscopic sleeve gastrectomy], laparoscopic greater curve plication and/or laparoscopic banding), This systematic review consistently found that ESG was associated with statistically and clinically significant weight loss from baseline with a low rate of adverse events through 3-years of follow-up. Data from Sharaiha (2021) showed the majority of patients treated with ESG maintained a clinically meaningful weight loss through 5-years of follow-up. However, the amount of weight loss was generally lower than weight lost after laparoscopic sleeve gastrectomy. The evidence was considered poor or very poor quality, providing a “Minimal” level of support for using the Apollo ESG System for the treatment of obesity. Current clinical practice guidelines and position statements appear to provide weak support on the use of Apollo ESG System for ESG regarding the treatment of obesity as patient populations are inconsistent and several guidelines were conditional, vague or used language that suggests less than strong support for ESG.

Endoscopic Placed Duodenal-Jejunal Sleeve/Gastrointestinal Liners

Chen et al. (2024) performed a systematic review of 30 studies (N=1751) to assess the efficacy and safety of the duodenal-jejunal sleeve for treating obesity and T2DM. At 12 months post-implantation, there was a reduction in BMI of 4.8 kg/m² (95% CI 4.1, 5.5), an EWL of 41.3% (95% CI 33.4%, 49.2%), and TWL of 13.1% (95% CI 10.1%, 16.0%). Significant reductions in HbA1c and fasting glucose were observed, with standardized mean differences of -0.72 (95% CI -0.95, -0.48) and -0.62 (95% CI -0.82, -0.42), respectively. However, these improvements in weight loss and glycemic control were only partially maintained after explantation. The pooled early removal rate was 19%, and the incidence of severe adverse events was 17%, including device migration (6%), gastrointestinal hemorrhage (4%), device obstruction (4%), and hepatic abscess (2%). Further research is needed to better understand the long-term efficacy and safety of this procedure, including its associated risks.

Rhode et al (2016) in a systematic review and meta-analysis evaluated the evidence on a duodenal-jejunal bypass sleeve (DJBS) including the EndoBarrier Gastrointestinal Liner. Five RCTs (235 subjects) and 10 observational studies (211 subjects) were included. The risk of bias was evaluated as high in all studies. While the meta-analyses found that the DJBS was associated in weight loss compared with diet modification, the mean difference in glycated hemoglobin and fasting glucose among the subjects did ot reach statistical significance. Adverse events included abdominal pain, nausea and vomiting. The authoris concluded “future high-quality long -term RCTs are needed to further assess efficacy and safety.”

Intragastric Balloon

Evidence includes RCTs (Genco 2006, Courcoulas 2017), a case series (Kotzampassi et al 2012) with long-term follow-up on 1 of the devices, and systematic reviews on various intragastric balloon (IGB) devices (Kotinda 2015, Zheng 2015, Moura 2016, Saber 2017). RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or LT alone. One RCT followed

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patients for an additional 6 months after IGB removal and found sustained weight loss. A large case series with follow-up up to 5 years has suggested that patients regain weight over time. Additional long-term follow-up data are needed. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, 1 warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016 to 2017 following the IGB procedure. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S. Health care providers are encouraged to monitor patients receiving IGBs.

Laparoscopic Gastric Plication

There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication with other bariatric surgery procedures. A 2021 systematic review (Li et al) demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One RCT (Sullivan et al 2017) compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. Longer-term follow-up and additional comparative studies are needed.

Long-Limb Gastric Bypass

There were no high-quality RCTs with long-term follow-up identified for long-limb gastric bypass.

Mini Gastric Bypass

Parmar et al (2020) published a systematic review of 1075 patients (n=17 studies) who underwent 1 anastomosis/mini gastric bypass (OABG-MGB) as a revisional bariatric procedure after failure of a primary LAGB and SG. No RCTs were available on this topic and no meta-analyses were performed as part of this systematic review. The most commonly reported reason for revisional surgery was poor response (81%) followed by gastric band failure (35.9%), GERD (13.9%), intolerance (12.8%), staple line disruption (16.5%), pouch dilatation (17.9%), and stomal stenosis (10.3%). Results revealed that after the revisional OABG-MGB, the mean percent EWL was 50.8% at 6 months, 65.2% at 1 year, 68.5% at 2 years, and 71.6% at 5 years. Resolution of comorbidities after OAGB-MGB was significant with 80.5% of patients with T2D, 63.7% of patients with hypertension, and 79.4% of patients with reporting resolution. The overall readmission rate following OAGB-MGB was 4.73%, the mortality rate was 0.3%, and the leak rate was 1.54%. Although the authors concluded that OAGB-MGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy

Esparham et al. (2024) conducted a systematic review of 10 studies (N=1707 patients) to examine the mid- and long-term outcomes of SADI-S. The included studies focused on laparoscopic SADI-S procedures with follow-up periods of ≥ 3 years (ranging from 3 to 10 years). The %EWL ranged from 71% to 89%, with an average of 80% at six and ten years, respectively. The most common late complications observed were malabsorption (6.3%) and GERD (3.6%). Remission rates for hypertension, diabetes, GERD, obstructive sleep apnea, and dyslipidemia varied between 43% and 81%.

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In a recent Swedish RCT by Axer et al (2024), the clinical outcomes of SADI-S were compared to those of biliopancreatic diversion with duodenal switch (BPD/DS). Fifty-six patients, with BMI values between 42 and 72 kg/m², were randomly assigned to either the SADI or BPD/DS group. After one year, both procedures demonstrated similar weight loss outcomes (%EWL: 81.8% ± 13.6% vs. 84.2% ± 14.0%; %TWL: 40.1% ± 5.9% vs. 41.6% ± 6.4%). Early complications occurred in five patients in the SADI group and in four patients in the BPD/DS group with no mortality. Median length of stay was 2 days for both SADI and BPD/DS. Within 30 days, one SADI patient and three BPD/DS patients required re-admission. Serious late complications necessitating reoperation were observed in three SADI and two BPD/DS patients. Additional confirmatory RCTs with larger sample sizes and longer-term follow-up are needed.

Silastic Ring Vertical Gastric Bypass (Fobi Pouch)

There is a paucity of comparative studies of direct comparison of silastic ring vertical gastric bypass (Fobi pouch) to traditional gastric bypass surgery, The published literature has been limited to descriptive articles, case series and prospective non-randomized controlled study. Long-term safety and efficacy outcomes and comparative RCTs are still needed.

Transoral Endoscopic Surgery

The evidence for transoral endoscopic surgery for bariatric surgery is limited (Guder et al 2023, Sandler et al 2018, Marinos et al 2014, Eid et al 2014, and Mullady et al 2009), additional studies including RCTs with long-term data to include the safety and efficacy of this procedure is warranted.

Two-stage Bariatric Surgery

The evidence from an RCT (Coffin et al 2017) and several case series (Alexandron 2012, Silecchia 2009, Cottam 2006) does not support a 2-stage bariatric surgery procedure for improving outcomes in patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year so that a second procedure is no longer indicated. Also, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.

Vertical-Banded Gastroplasty

A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG with gastric bypass. The Assessment found that weight loss was significantly greater with open gastric bypass than with VBG. Also, VBG has relatively high rates of complications, revisions, and reoperations.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

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Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Clinical Endocrinologist, ACE, Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists.[131,] Recommendations on the following questions are summarized below.

- "Which patients should be offered bariatric surgery?"
  - "Patients with a BMI [body mass index] ≥40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure."
  - "Patients with a BMI ≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
  - "Patients with the following comorbidities and BMI≥35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
  - "Patients with BMI of 30 to 34.9 kg/m^2 with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
  - "The BMI criterion for bariatric procedures should be adjusted for ethnicity (eg, 18.5 to 22.9 kg/m^2 is normal range, 23 to 24.9 kg/m^2 overweight, and ≥25 kg/m^2 obesity for Asians)."
  - "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related complications cannot be obtained using only structured lifestyle change with medical therapy."
- "Which bariatric surgical procedure should be offered?"
  - "Selecting a bariatric procedure should be based on individualized goals of therapy (e.g., weight loss target and/or improvement in specific obesity-related complications), available local-regional expertise (obesity specialists, bariatric surgeon, and institution), patient preferences, personalized risk stratification, and other nuances as they become apparent. Notwithstanding technical surgical reasons, laparoscopic bariatric procedures should be preferred over open bariatric procedures due to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding, sleeve gastrectomy,

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RYGB [Roux-en-y gastric bypass], and LBPD/DS [laproscopic biliopancreatic diversion/duodenal switch], or related procedures should be considered as primary bariatric and metabolic procedures performed in patients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD [biliopancreatic diversion], BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (ie, about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy."

National Institute of Health (NICE)

A 2016 NICE guidance on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity stated "the current evidence on the safety shows that there are well-recognized complications. Evidence on efficacy is limited in both quality and quantity. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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151. Hayes, a SymplrCompany. Health Technology Assessment Apollo ESG System (Apollo Endosurgery, Inc) for Endoscopic Sleeve Gastroplasty for the Treatment of Obesity

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
	43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
	43659	Unlisted, laparoscopic, stomach
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
	43889	Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed
	43999	Unlisted, stomach
	44799	Unlisted procedure small intestine
HCPCS		
	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
Type of Service	Surgery	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

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Date	Action	Action
June 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Revised
May 2023	Annual Review	Policy Revised
July 2022	Annual Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Interim Review	Policy Revised
December 2015		New Medical Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
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