MEDICAL POLICY

Medical Policy Title	**Bariatric and Metabolic Surgery**
Policy Number	**7.01.29**
Current Effective Date	May 22, 2025
Next Review Date	May 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The surgical treatment of obesity by open or laparoscopic Roux-en-Y gastric bypass, duodenal switch procedure (biliopancreatic diversion), single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)/stomach-intestine pylorus-sparing surgery (SIPS), laparoscopic adjustable gastric banding (LAGB), and sleeve gastrectomy is considered **medically appropriate** for patients who meet **ALL** of the following criteria:

A. The patient has a body mass index (BMI) of **ONE** of the following:

Adult

1. Class 3 obesity (BMI 40 kg/m^2 or greater),
2. Class 2 obesity (BMI 35 to 39.9 kg/m^2) and at least one (1) obesity-related comorbidity (e.g., cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, or weight-bearing joint arthropathy), **or**
3. Class 1 obesity (BMI 30 to 34.9 kg/m^2) and type 2 diabetes (T2D) with documentation of inadequate glycemic control despite optimized lifestyle and medical management.

Adolescent

4. Class 3 obesity (BMI greater than or equal to 40 kg/m^2, or BMI greater than or equal to 140% of the 95th percentile, whichever is lower based on age and sex), **or**
5. Class 2 obesity (BMI 35 to 39.9 kg/m^2, or BMI between 120% to 139.9% of the 95th percentile, whichever is lower based on age and sex), and at least one (1) obesity-related comorbidity (e.g., cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, type 2 diabetes, or weight-bearing joint arthropathy);

B. Documentation of efforts to achieve weight loss/metabolic improvements, including **ALL** the following:

1. Pre-surgical lifestyle and medical management optimization efforts including the type of the weight-loss/nutritional program(s), applicable medication(s), length of participation, and results achieved (e.g., weight loss, lowered hemoglobin A1C). Documentation can

be provided by the bariatric surgeon, primary care provider, registered dietician, or nutritionist;

2. Pre-surgical nutritional evaluation conducted by a registered dietician is mandatory and documentation must be included; **and**
3. Documentation that the patient will participate in a one-year post-operative weight management program that promotes long-term success through nutritional management (including assessment for malabsorption), physical activity, and behavioral health support;

C. Medical clearance attestation for bariatric surgery from the primary care provider or bariatric surgeon;

D. Behavioral health clearance for bariatric surgery is documented by **ONE** of the following:

1. The bariatric surgeon or primary care provider documents the absence of any psychiatric or psychosocial comorbidities; **or**
2. A licensed behavioral health provider familiar with the implications of weight loss surgery is required for patients with **ANY** of the following:
   a. history of alcohol or substance use disorder with six (6) months or less of abstinence; **or**
   b. psychosocial, psychological, or psychiatric concerns identified by any member of the bariatric pre-operative evaluation team, including but not limited to the patient's primary care, bariatric surgeon, or Registered Dietician.

II. The following procedures for the primary surgical treatment of obesity are considered **investigational:**

A. Aspiration therapy (e.g., AspireAssist device);

B. Laparoscopic gastric plication (also known as laparoscopic greater curvature plication);

C. Mini-gastric bypass (also known as loop or one anastomosis gastric bypass);

D. Intragastric space occupying mechanisms (e.g., intragastric balloon or expanding material/capsules);

E. Endoscopic/endoluminal procedures or devices (e.g., transoral gastroplasty [also known as vertical sutured gastroplasty, endoluminal vertical gastroplasty, TOGA System]; restorative obesity surgery, endoluminal [ROSE]); StomaphyX device; closure devices [e.g., EndoCinch, Apollo Overstitch, and TransPyloric Shuttle Device]; gastrointestinal liners [duodenal-jejunal bypass liner (e.g., EndoBarrier)]; and Endoscopic sleeve gastroplasty;

F. Transoral outlet reduction [TORe]).

III. Bariatric surgery as a treatment for patients with a BMI less than or equal to 29.9 kg/m^2, with or without type 2 diabetes mellitus, is considered **investigational.**

<u>Reoperation</u>

IV. The adjustment of a previously placed laparoscopic adjustable gastric band (LAGB), beyond the global, 90-day limit, is considered **medically appropriate** to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following the initial medically necessary adjustable gastric banding procedure. Adjustment of LAGB is performed via accessing the subcutaneous port, with or without imaging).

V. Surgical revisions are considered **medically necessary** for complications, such as malabsorption/malnutrition, obstruction, staple disruption, severe gastroesophageal reflux disease refractory to medical treatment, or stricture following the primary procedure. (Refer to Policy Guidelines)

VI. A revision or removal of a LAGB is considered **medically appropriate** for a documented complication(s) or technical failure(s) (e.g., band slippage, band erosion, infection, esophageal dilation, dysphagia, heartburn/reflux, displaced band, port dislocation band intolerance [e.g., pain or vomiting], and port and/or catheter leakage).

VII. A revision or conversion to another medically appropriate procedure due to unsatisfactory/inadequate weight loss or metabolic improvements from the primary bariatric procedure is considered **medically appropriate** when **BOTH** of the following are met:

   A. Patient remained compliant with the prescribed post-operative nutrition and exercise program for at least six (6) months (Refer to Policy Guideline II); **and**

   B. **ONE (1)** of the following are met:

      1. Patient is a non-responder (failed to lose weight); **or**

      2. Primary procedure was initially successful in inducing weight loss.

VIII. Repeat surgery for morbid obesity is considered **not medically necessary** for patients who are either non-responders or who have weight recurrence due to non-adherence with the prescribed post-operative nutrition and exercise program following the primary surgery.

IX. Placement of a second adjustable gastric band (AGB) is considered **investigational**.

X. Revision surgery with an endoscopic/endoluminal procedure (e.g., transoral outlet reduction [TORe]) is considered **investigational**.

<u>Concomitant Procedures</u>

XI. Performing a routine liver biopsy at the time of the bariatric surgery is considered **not medically necessary** in the absence of documented signs or symptoms of liver disease (e.g., abnormal liver function tests of unknown etiology, knowledge of a specific diagnosis that will likely alter the treatment plan, known liver disease where prognostic information about fibrosis may guide subsequent treatment, the presence of a mass or lesions, or focal or diffuse abnormalities seen on imaging studies of unknown etiology).

XII. Prophylactic removal of a normal and asymptomatic gallbladder at the time of bariatric surgery is considered **not medically necessary**, unless cholelithiasis is present, or the patient will undergo biliopancreatic diversion with or without duodenal switch based on a higher incidence of

biliary complications.

RELATED POLICIES

Corporate Medical Policy

3.01.02 Psychological Testing

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.53 Abdominoplasty and Panniculectomy (for criteria related to surgical removal of redundant/excessive skin as a result of bariatric surgery)

7.01.64 Gastric Electrical Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Patients considering surgery must participate in an integrated pre- and post-surgery program consisting of dietary therapy, physical activity, and behavioral and social support programs. These multidisciplinary programs support people through the long-term commitment of weight loss (e.g., lifestyle changes and psychosocial impacts), and the post-operative plan must include that the patient will be involved in a formal program for at least one (1) year.

II. Some post-bariatric surgery patients experience weight recurrence or are non-responders, and other patients may develop unacceptable post-operative symptoms (e.g., gastroesophageal reflux disease) that do not respond to medical therapies. Before a revision or conversion surgery will be considered medically necessary for weight recurrence or non-response, a patient must demonstrate post-operative program compliance for at least six (6) months. A revision or conversion due to medical complications does not require six (6) months of demonstrated compliance.

   A. Non-patient controllable factors which can lead to pouch dilation include but are not limited to variations in technique in the initial pouch creation (e.g., size and the anatomic configuration [lesser curvature-based pouch creation vs a horizontally oriented pouch incorporating the gastric fundus] or distal subacute stricture or narrowing can lead to proximal gastric pouch dilation). These failures may warrant reversal surgery or revision surgery (e.g., conversion to Roux-en-Y).

   B. Failures due to patient noncompliance reflect poor patient selection and do not warrant revision procedures. A clue to this is gastric pouch dilation in a patient not adhering to the recommended eating protocols. These patients are likely to fail again.

III. Body mass index (BMI) is a measure used to screen for excess body adiposity (body fat) and is calculated by dividing a person's weight in kilograms (kg) by the square of height in meters (m^2).

IV. BMI thresholds may be adjusted for ethnicity (e.g., Asian population) on a case-by-case basis. Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m^2 (Eisenberg 2022).

Mechanick and colleagues (2020) report that BMI for identifying excess adiposity and risks of cardiometabolic disease are lower for some ethnicities and should be considered during screening and diagnosis.

V. The American Society of Metabolic and Bariatric Surgery (ASMBS) reiterates the 1991 National Institute of Health (NIH) Consensus statement that a multidisciplinary team should evaluate patients to optimize surgical outcomes including:

   A. Comprehensively evaluating patients seeking metabolic and bariatric surgery through assessment of medical history, physical examination, laboratory testing (e.g., *H.* pylori, kidney function, liver profile, thyroid stimulating hormone), psychosocial history (e.g., functioning, substance use, maladaptive eating patterns), lifestyle/nutritional evaluation (e.g., sleep hygiene, smoking, healthy eating index) (Carter 2021; Mechanick 2019).

   B. Management of modifiable risk factors prior to elective surgery, with the goal of reducing the risk of perioperative complications and improving outcomes, by making proactive referrals to specialists to mitigate identified risks and to coordinate pre- and post-surgical care (Sogg 2016).

   C. Pre-surgical evaluation process to optimize surgical outcomes and implement interventions that can address disordered eating, severe uncontrolled mental illness, or active substance abuse (Eisenberg 2022).

VI. Adult classification of obesity by BMI (NHLBI 1998):

- Class 1 obesity: BMI 30 to 34.9 kg/m^2
- Class 2 obesity: BMI 35 to 39.9 kg/m^2
- Class 3 extreme obesity: BMI 40 kg/m^2 or greater

VII. Child and adolescent BMI interpretation is age- and sex-specific with weight category and classification of (Hampl 2023):

- Class 2 obesity: BMI 35 to 39.9 kg/m^2 or BMI between 120% to 139.9% of the 95^{th} percentile
- Class 3 obesity: BMI greater than or equal to 40 kg/m^2 or BMI greater than or equal to 140% of the 95^{th} percentile

VIII. The behavioral health evaluation should be performed by a licensed behavioral health provider familiar with the implications of weight reduction surgery. A current licensed behavioral health provider familiar with the implications of weight reduction surgery who is providing ongoing care for the patient may also provide this evaluation. The use of routine psychological testing as a screening tool or as part of the psychological evaluation prior to bariatric surgery is considered not medically necessary (Refer to Corporate Medical Policy #3.01.02 Psychological Testing).

IX. Adolescents, due to their special needs, should be referred to a Center of Excellence or other facilities specializing in bariatric surgery procedures for the adolescent population. This will allow for greater consideration to be given to psychosocial and informed consent issues.

X. Coverage is limited to physicians who have been properly trained in performing a bariatric

procedure at facilities with the diagnostic and support services necessary for the care of morbidly obese patients.

XI. Any device used for bariatric surgery must be used in accordance with the approved indications of the United States Food and Drug Administration (FDA).

XII. An expected outcome of successful bariatric surgery is redundant/excessive skin.

DESCRIPTION

Obesity is a complex, multifactorial, chronic condition that substantially raises an individual's risk of weight-related complications and morbidity caused by or exacerbated by excess adiposity. Complications include but are not limited to asthma, nonalcoholic fatty liver disease, hypertension, dyslipidemia, pre-diabetes, type 2 diabetes, metabolic syndrome, coronary artery disease, stroke, gallbladder disease, osteoarthritis, obstructive sleep apnea, respiratory problems, and a variety of certain types of cancers (e.g., colorectal cancer).

Clinically severe obesity includes class 3 obesity (formerly referred to as morbid obesity) and class 2 obesity with associated comorbid conditions (NHLBI 1998). The NHLBI outlines the following relationship between overweight/obesity BMI and disease risk, which is noted to vary among individuals and different populations:

Obesity Classification	Body Mass Index (kg/m^2)	Disease Risk*
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	High
Class 2 obesity	35-39.9	Very High
Class 3 extreme obesity	>40	Extremely High

*Disease risk for type 2 diabetes, hypertension, and cardiovascular disease.

The first line of treatment for obesity is dietary and lifestyle changes, including intensive lifestyle intervention (ILI). Under medical supervision ILI programs include multiple comprehensive behavioral management activities that focus on increasing healthful food consumption, participating in physical activity for enjoyment and self-care reasons, and improving overall self-esteem and self-concept. Strong evidence suggests that multidomain ILI reduces cardiovascular risk factors among persons with type 2 diabetes (Huckfeldt 2023). Although this strategy may be effective in some patients, not all individuals can reduce and control weight through diet and activity/exercise/movement. When conservative measures fail, some patients consider surgical approaches.

Bariatric surgery, also referred to as metabolic or bariatric surgery (MBS), has proven results as a weight loss option for people with class II or III obesity who fail to lose weight with conservative measures. Long-term evidence demonstrates significant and durable clinical improvement, and in some cases remission, of co-morbidities (e.g., type 2 diabetes). Bariatric or metabolic surgery work by changing the anatomy and size of the stomach to reduce/restrict food intake, as well as modifying the digestion process to improve fat metabolism. Some procedures can also affect the production of

intestinal hormones, which can influence appetite and metabolic improvements.

Bariatric and metabolic surgery for people with Class 1 obesity and T2D is increasingly being performed as a treatment option based on published findings of the resolution (cure) or improvement of T2D after bariatric surgery, and observations that glycemic control may improve immediately after surgery before a significant amount of weight is lost. The various surgical procedures have different effects on weight loss, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides (e.g., glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

Procedures/Interventions

Bariatric surgery can be divided into two categories: gastric restrictive procedures and malabsorptive procedures. Gastric restrictive procedures mechanically typically limit volume of food intake prior to achieving satiety; malabsorptive procedures interfere with the absorption of ingested nutrients. Examples of gastric restrictive procedures include legacy procedures such as vertical and horizontal banded gastroplasty and adjustable gastric banding. Laparoscopic sleeve gastrectomy is generally considered a predominately restrictive procedure but has the distinction of also stimulating hindgut derived GI hormones. Predominantly malabsorptive procedures also incorporate a component of restriction and include operations such as biliopancreatic diversion, biliopancreatic diversion with duodenal switch malabsorptive procedures include biliopancreatic bypass, and long-limb gastric bypass. The Roux-en-Y gastric bypass is a combination of a gastric restrictive and malabsorptive procedure.

The original gastric bypass surgeries were based on the observation that post gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., gastrojejunal). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome," in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweets eaters." Dumping syndrome can cause absolute or relative postprandial reactive hypoglycemia. Autonomic dumping syndrome cannot be mitigated with dietary or medical intervention and may require reversal of gastric bypass. Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron

deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Gastric bypass may be performed with either an open or laparoscopic technique.

Sleeve gastrectomy (SG) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] with duodenal switch [DS]). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through the stomach into intestines) seen with distal gastrectomy. Weight loss following SG may improve a patient's overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., BPD).

Endoscopic sleeve gastroplasty (ESG) is a stomach-sparing, per-oral endobariatric procedure that gained popularity as a treatment option for patients with obesity who do not fulfill eligibility criteria for established bariatric procedures (Docimo 2023). ESG was first described in 2013 and has undergone various refinements, evolving first from many interrupted endoluminal stitches to several running stitches along the greater curvature of the stomach to plicate the anterior to the posterior walls in a U pattern with additional reinforcement stitches. ESG is designed to replicate a luminal version of a sleeve gastrectomy. Key to the performance of ESG is the ability to create full-thickness surgical plications using an endoscopic device. An alternative form of endoscopic sutured gastroplasty is the primary obesity surgery endoluminal (POSE and POSE-2.0) procedure.

Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy. Many potential metabolic complications are related to BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition.

Biliopancreatic diversion with duodenal switch was introduced in 2005 as a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a SG is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the BPD, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodeno-ileal by providing a more physiologic transfer of stomach contents to the duodenum. The SG also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment is similar to that of the BPD.

Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The

band is attached to a reservoir implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss or expanded if complications develop. Complications include slippage of the external band or band erosion through the gastric wall.

Gastric plication (GP) is a restrictive bariatric procedure similar to endoscopic gastrectomy (ESG) but performed laparoscopically without resection of stomach tissue. The stomach is folded and sutured reduce the stomach volume.

Aspiration therapy as a treatment for obesity involves the percutaneous endoscopic placement of a gastrostomy tube system to aspirate (drain) a portion of the stomach contents after every meal. This restrictive procedure induces weight loss by removing a portion of the ingested caloric intake and is dependent of the patient's compliance.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) (also known as stomach-intestine pylorus-sparing surgery [SIPS]) has a restrictive component when reducing the greater curvature of the stomach, but especially a malabsorptive component, as the common channel is also reduced. The intention of the SADI-S procedure is to address certain limitation and complexities inherent to other standard bariatric and metabolic procedures (Kallies 2020), with an objective to lessen the intestinal loop where nutrients are absorbed. The procedure is based on biliopancreatic diversion, in which a sleeve gastrectomy is followed by an end-to-side duodeno-ileal diversion. The preservation of the pylorus makes possible the reconstruction in one loop. A proposed benefit of the procedure is that it does not cause abrupt rise and fall of blood glucose, thus preserving the pyloric valve. Also, by not bypassing as much intestine, it may reduce the complications of short bowel syndrome.

Intragastric balloons (e.g., Orbera, Obalon, Spatz3), have been proposed as a temporary, non-surgical obesity treatment for short-term weight loss in patients who have had unsatisfactory results with their diet and exercise programs. The intragastric balloon has also been proposed for weight loss in the super-obese patient prior to a permanent, invasive surgical procedure. The saline-filled intra-gastric balloon, placed endoscopically, is intended to reduce gastric capacity, creating satiety, and reducing food intake.

TransPyloric Shuttle (BAROnova Inc. Goleta, CA) is an endoscopically inserted device that delays gastric emptying by intermittently obstructing the pylorus, which may enable an overall reduction in caloric intake and weight loss by helping the subject feel full sooner (early satiation) and/or feel full longer (prolonged satiety/reduced hunger. The device is a solid coiled cord of silicone and cannot be deflated.

Vertical banded gastroplasty (VBG) was formerly one of the most common gastric restrictive procedures performed in the United States but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. This bariatric procedure creates a small pouch by vertically stapling and horizontally banding the upper stomach. Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site.

Transoral gastroplasty (TG), also known as vertical sutured gastroplasty or endoluminal vertical, is a procedure that consists of a set of endoscopically guided staples used to create a restrictive pouch along the lesser curvature of the stomach. The TOGA system (Satiety, Inc) was developed specifically for this procedure.

EndoCinch endoscopic suturing device was initially developed for endoscopic treatment of gastroesophageal reflux disease (GERD). EndoCinch, is a partial-thickness endoscopic suturing system that deploys a continuous and cross-linked fashion from the proximal fundus to the distal body. Once the suture is fixed, distention of the stomach is significantly limited, thus providing a method of restricting food intake. The RESTORe Suturing System (Bard/Davol, Warwick, RI) is an updated version.

The Apollo OverStitch (Apollo Endosurgery) device allows for full-thickness endoscopic suturing, compared to the superficial-thickness suturing provided by other devices. They are being investigated as the primary bariatric surgery and as a revisional procedure to treat weight gain (e.g., large gastric pouch, large gastric stoma/dilated gastrojejunal anastomosis).

Transoral outlet reduction (TORe) is a procedure that reduces the gastric outlet opening (the opening between the gastric pouch and the small intestine) in people who have weight recurrence after gastric bypass surgery. Overtime, the gastric outlet can enlarge, allowing food to move into the small intestine faster and increasing hunger. Endoscopically, sutures are placed to tighten the gastric outlet opening to slow down the emptying of food from the stomach, leaving the patient to feel full longer.

Duodenal-jejunal bypass liner (e.g., EndoBarrier, GI Dynamics Inc., Boston MA), is a barrier sleeve used to prevent the absorption of luminal contents in the small intestine. The fluoropolymer sleeve is inserted endoscopically and fixated to the duodenal bulb and extends 80 cm into the small bowel, usually terminating in the proximal jejunum.

Reversal or Revisional Surgery

Post-bariatric surgery patients who experience weight recurrence, do not lose sufficient weight, or develop unacceptable post-operative symptoms due to structural complications may warrant reversal or revision surgery. Reversal or revision of bariatric procedures is usually not warranted in patients whose failure is due to noncompliance (e.g., gastric pouch dilation from 20cc to greater than 100cc in a patient who is not adhering to the recommended eating protocols).

Revisional surgery for complications, such as those related to malabsorption resulting in hypoglycemia, malnutrition, or weight loss of 20% below ideal body weight may be warranted. Complications associated with laparoscopic adjustable gastric banding are well-documented in published literature. Examples of complications that may warrant revision, removal or conversion to another procedure include, but are not limited to, band slippage, band erosion, infection, esophageal dilation, dysphagia, and heartburn/reflux. Technical failures of LAGB include, but are not limited to, a displaced band, port dislocation, too tight a band (creating food passage problems), band intolerance (e.g., pain, reflux, vomiting), and port and/or catheter leakage.

SUPPORTIVE LITERATURE

The hallmark piece of literature supporting the safety and effectiveness of bariatric surgery was

published in 1991 by the National Institutes of Health (NIH) Consensus Statement. In 2022 the American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement based on the current available scientific information on metabolic and bariatric surgery and its indications (Eisenberg 2022).

Bariatric surgery as treatment for class 2 and 3 obesity is supported by sufficient data published in medical literature demonstrating the safety and efficacy of specific bariatric procedures including: open or laparoscopic Roux-en-Y gastric bypass procedures (Himpens 2012; Wadden 2019; Cui 2021; Angrisani 2021), sleeve gastrectomy (Leyba 2011; Himpens 2010; D'Hondt 2011; Chouillard 2011; Wölnerhanssen 2021; Vitiell 2023), adjustable gastric band (Dixon 2008; Himpens 2011) or the biliopancreatic diversion with duodenal switch (Prachand 2006; Strain 2007; Skogar 2017).

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. Beginning in 1987 the prospective controlled trial of surgically induced weight loss, reported findings of the 2,010 people who chose surgery, and 2,037 people who chose conservative care for at least 10 (Sjöström 2007). This trial demonstrated that surgery resulted in substantial weight loss, improved co-morbid conditions, and improved quality of life after surgery.

Bariatric surgery as treatment for class 1 obesity and type 2 diabetes is supported by the systematic reviews of RCTs and observational studies that have found certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in adults with obesity, including those with a BMI between 30 and 34.9 kg/m^2. The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Meta-analysis (DeLuca 2023; Wu 2016; Rao 2015) and systematic reviews (Yan 2016; Muller-Stich 2015) have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most randomized clinical trial (RCTs) in this population have 1 to 5 years of follow-up data; however, longer-term (>5 years) data is beginning to be published. The 5-year outcomes of the randomized controlled STAMPEDE trial reported medical therapy with RYGB or sleeve gastrectomy were shown to be superior to medical therapy alone in the long-term treatment of T2D among patients with T2D and a BMI between 27 to 43 (Schauer 2017).

Courcoulas and colleagues (2024) reported long-term follow-up of participants in the Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) project at the primary end point of 7 years, and up to 12 years, after randomization. During follow-up, 25% of participants randomized to undergo medical/lifestyle management underwent bariatric surgery. Based on follow-up the authors concluded that participants originally randomized to undergo bariatric surgery had superior glycemic control with less diabetes medication use and higher rates of diabetes remission, compared with medical/lifestyle intervention. From the 305 eligible participants, 262 participants (86%) enrolled in long-term follow-up were used for this pooled analysis. The median follow-up was 11 years. At 7 years, HbA1c decreased by 0.2% (95% confidence interval [CI], −0.5% to 0.2%) from a baseline of 8.2% in the medical/lifestyle group and by 1.6% (95% CI, −1.8% to −1.3%), from a baseline of 8.7%, in the bariatric surgery group. The between-group difference was −1.4% (95% CI, −1.8% to −1.0%; $p < 0.001$) at 7 years and −1.1% (95% CI, −1.7% to −0.5%; p

= 0.002) at 12 years. Fewer anti-diabetes medications were used in the bariatric surgery group. Diabetes remission was greater after bariatric surgery (6.2% in the medical/lifestyle group vs. 18.2% in the bariatric surgery group; p = 0.02) at 7 years and at 12 years (0.0% in the medical/lifestyle group vs. 12.7% in the bariatric surgery group; p < 0.001).

Kirwan and colleagues (2022) published ARMMS-T2D project data from the 3-year follow-up which is noted as the largest cohort of randomized patients followed to date. Results demonstrated that metabolic/bariatric surgery is more effective and durable than medical/lifestyle intervention in remission of type 2 diabetes, including among individuals with class I obesity, for whom surgery is not widely used.

Bariatric surgery as treatment for a BMI less than 35 kg/m^2 who do not have T2D has limited evidence for. A few small RCTs and case series have reported a loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

Esparham and colleagues (2025) identified that there is no consensus on the best bariatric surgery type for individuals with a BMI ≥50 kg/m^2 and conducted a systematic review and meta-analysis aimed to compare outcomes of duodenal switch (DS) and Roux-en-Y gastric bypass (RYGB) in terms of weight loss, resolution of obesity-related comorbidities, and complications among patients with a BMI ≥50 kg/m^2. Twelve articles were included in this study (n=2678 patients, follow-up ranged from 1-15 years). Patients with DS had 7.31 kg/m^2 higher BMI loss (p < .001) and 9.9% more total weight loss (p < .001) compared with RYGB. The rate of complications, reoperation, mortality, and remission of comorbidities including diabetes, hypertension, dyslipidemia, and obstructive sleep apnea was not significantly different between DS and RYGB. Rate of malnutrition was 8.3% in the DS group compared with 1.2% in RYGB (p= .02). In addition, 5.4% DS patients needed revisional surgery for malnutrition versus none in RYGB (p = .05), and 24.6% of DS patients developed gallbladder disease needed cholecystectomy versus 4.5% after RYGB (p = .01). DS leads to significantly higher BMI and total weight loss in patients with BMI ≥50 kg/m^2 but may be associated with a higher rate of major malnutrition and needed revisional surgery.

Endoscopic sleeve gastroplasty (ESG) is being investigated as an option for the treatment of obesity, with several published observational studies (case series and cohort studies) and one RCT. Abu Dayyeh and colleagues (2022) conducted a prospective, multi-center, randomized trial with individuals (n=209) aged 21-65 with class 1 or class 2 obesity and who agreed to comply with lifelong dietary restrictions. Participants were randomly assigned (1:1) to ESG with lifestyle modifications (ESG group; n=85) or lifestyle modifications alone (control group; n=124), with potential retightening or crossover to ESG, respectively, at 52 weeks. 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% for the ESG group and 3.2% for the control group (p<0.0001). Mean percentage of total bodyweight loss was 13.6% for the ESG group and 0.8% for 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 or need for intensive care or surgery. Study limitations include the absence of a sham intervention group, inadequate cohort size and follow-up to detect differences outcomes.

Mrad and colleagues (2025) conducted a network meta-analysis of randomized trials comparing any of the currently commercially available endoscopic bariatric therapies (EBTs) with controls, either sham procedures or diet plus lifestyle interventions for patients with obesity or overweight. Ten and eight studies were eligible for the qualitative and quantitative analysis, respectively. The authors concluded that, considering percentage of total weight loss (%TWL) at the time of IGB removal, all EBTs were associated with statistically higher % TWL than controls. There were no significant differences among EBTs. All currently available EBTs approved by the U.S. Food and Drug Administration (FDA) are more effective than both diet plus lifestyle intervention and sham procedures with an acceptable safety profile. ESG seems the most effective and may be prioritized for patients fit for both ESG and IGBs; however, direct controlled trials between EBTs are warranted to confirm these findings.

Duodenal-jejunal bypass liner (DJBL) for the treatment of obesity lacks U.S. Food and Drug Administration (FDA) approval or sufficient published literature to draw conclusions about the safety and effectiveness of the device. Glaysher and colleagues (2021) published a sub-study of a multicenter, randomized, controlled trial of patients within two treatment group (n=70 per group) diagnosed with type-2 diabetes mellitus and BMI 30-50 kg/m^2. The authors reported that one year of DJBL therapy is associated with significantly greater weight loss and greater reduction in cholesterol; however, DJBL depleted essential fatty acids (EFAs). Ruban and colleagues (2021) conducted an open-label RCT of 170 adults with inadequately controlled T2DM and obesity. The authors reported there was no significant difference in the percentage of patients achieving a glycated hemoglobin reduction of at least 20%, and 16 patients (24%) achieved at least 15% weight loss in the DJBL group compared to 2 patients (4%) in the control group at 12 months. Hollenbach and colleagues (2024) reported on a RCT of 33 patients (11 DJBL, 15 intragastric balloon, and 7 sham group) which was terminated early after the DJBL device lost its CE mark in Europe. The authors concluded that, despite the lack of power, the data strongly suggest that intragastric balloon and DJBL lead to comparable weight loss while implanted; however, these procedures failed to achieve effective weight loss 12 months after explantation. Chen and colleagues (2024) conducted a systematic review and meta-analysis of 30 studies (1751 patients), concluding that DJBL offers significant improvement in weight loss, glycemic control, and cardiovascular parameters while in situ; however, recommended that further studies are warranted to better understand the long-term efficacy and safety of DJBL and that the benefits of DJBL need to be carefully weighed against the risks in clinical decision-making.

Intragastric balloon devices (IGB) (e.g., ORBERA Intragastric Balloon, Obalon Balloon System, ReShape Integrated Dual Balloon System, Allurion Gastric Balloon/Elipse Balloon) are gastric space occupying devices being investigated for the treatment of obesity. Published finding are insufficient and further studies are needed to demonstrate the long-term effects of utilizing intragastric balloon as a weight loss strategy (Ponce 2015; Bazerbachi 2018; Hollenback 2024; Silva 2024; Mrad 2025). Dang and colleagues (2018) performed a propensity-matched analysis between IGB and laparoscopic bariatric surgery (LBS) to compare safety profiles, concluding that IGB was associated with a higher adverse event rate than LBS, more research is needed, and IGB appears less safe than bariatric

surgery as a standalone weight loss intervention.

Transoral gastroplasty (TG), for the treatment of obesity, has limited published literature and the data is insufficient to provide conclusions on its safety and efficacy. Well-designed studies with long-term follow-up are needed, to measure the durability of the observed weight loss. In particular, the stability of the gastric sutures' procedure remains unproven, given the lack of long-term data.

Mini-gastric bypass (also called loop gastric by-pass) lacks sufficient published in the medical literature to draw conclusions about the safety and effectiveness of the procedure.

Gastric plication research preliminarily supports that the procedure has acceptable complication rates and weigh loss outcomes in the short-term (e.g., Fried 2012; Skrekas 2011; Kourkoulos 2012; Talebpour 2012); however, additional well-designed comparative studies with established bariatric procedures are needed, to determine its overall safety, efficacy, and impact on health outcomes.

Single-anastomosis duodenal switch (also known as the loop duodenal switch, stomach intestinal pylorus-sparing surgery, and most descriptively single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S]) is a modification of the classic Roux-en-Y duodenal switch (DS) and is intended to address certain limitations and complexities inherent to other standard bariatric and metabolic procedures, (Kallies 2020). Citing evidence, this procedure is endorsed by the American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

Dijkhorst and colleagues (2021) retrospectively investigated the effectiveness of the single anastomosis duodenoileal bypass (SADI-S) versus the Roux-en-Y gastric bypass (RYGB) on health outcomes in (morbidly) obese patients who had previously undergone SG, with up to 5 years of follow-up. From 2007 to 2017, 141 patients received revisional laparoscopic surgery after SG in three specialized Dutch bariatric hospitals (SADI-S n=63, RYGB n=78). Percentage total weight loss following revisional surgery at 1, 2, 3, 4, and 5 years was 22%, 24%, 22%, 18%, and 15% for SADI-S and 10%, 9%, 7%, 8%, and 2% for RYGB ($p<0.5$ for 1-4 years). Patients who underwent RYGB surgery for functional complications experienced no persistent symptoms of GERD or dysphagia in 88% of cases. No statistical difference was found in longitudinal analysis of change in quality of life scores or cross-sectional analysis of complication rates and micronutrient deficiencies. A number of potential limitations exist, including the retrospective study design, the small sample size of SADI-S patients who have reached 5 years of follow-up, and data on QOL was not available for all participating centers and was missing for RYGB patients who were operated before 2011.

Esparham and colleagues (2023) conducted a systematic review aimed to investigate the mid- and long-term results single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S). The included 10 studies (n=1707 patients) focused on laparoscopic SADI-S procedures with follow-up periods greater than or equal to 3 years (ranging from 3 to 10 years). The percentage of excess weight loss (%EWL) was 70.9%-88.7%, and 80.4% at 6, and 10 years, respectively. The more common late complications were malabsorption (6.3%) and gastroesophageal reflux disease (GERD) (3.6%). The remission rates of hypertension, diabetes, GERD, obstructive sleep apnea, and dyslipidemia were 62.9%, 81.3%, 53.2%, 60.9%, and 69.7%, respectively. The authors concluded that SADI-S is a safe and effective surgical technique with durable weight loss and a high rate of

comorbidity resolution in mid- and long-term.

Axer and colleagues (2024) conducted a randomized control trial (RCT) to evaluate the clinical outcomes of two surgical interventions for obesity treatment, single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI) and biliopancreatic diversion with duodenal switch (BPD/DS). The study primarily focused on early complications and short-term result of 56 patients with BMI values between 42 - 72 kg/m^2. Patients were randomly assigned to either the SADI or the BPD/DS group. After one year, both procedures demonstrated similar weight loss outcomes. 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. The authors concluded that although additional confirmatory RCTs with larger sample sizes and longer-term follow-up are needed, both SADI and BPD/DS yield comparable weight loss outcomes after one year.

Pereira and colleagues (2024) reported that single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) is a restrictive/hypoabsorptive procedure recommended for patients with obesity class 3. For safety reasons, SADI-S can be split into a two-step procedure by performing a sleeve gastrectomy (SG) first. A prospective, interventional, open-label randomized study was conducted to assess weight trajectories and endocrine/metabolic post-prandial responses of patients with obesity class 3 randomized to SADI-S or SG, up to 12 months post-operatively. This study enrolled subjects with obesity (BMI between 45 and 55 kg/m^2), and randomized subjects to SADI-S (n = 7) or SG as the first step of a two-step SADI-S (n = 7). Participants were scheduled for study visits before and 3-, 6-, and 12- months after surgery. Anthropometric parameters, as well as metabolic and micronutrient profiles, were not significantly different between groups, neither before nor after surgery. There were no significant differences in fasting or postprandial glucose, insulin, C-peptide, ghrelin, insulin secretion rate, and insulin clearance during the mixed meal tolerance test (MMTT) between subjects submitted to SADI-S and SG. There were no participants lost to follow-up. This is the first study to provide evidence on weight loss outcomes of a head-to-head comparison of a single-step or two-step SADI-S. Given that clinical outcomes and molecular profiles of patients submitted to SADI-S or SG are identical 1 year after surgery, these data provide support for surgeons' choice of a two-step SADI-S without jeopardizing the weight loss outcomes.

Transoral outlet reduction (TORe) is being evaluated as an endoscopic revisional surgery in patients with weight recurrence following their primary bariatric procedure (e.g., gastric bypass). Although preliminary results showing promising feasibility, safety, and short-term efficacy being demonstrated in case series (Jirapino 2013; Thompson 2013; Kumar 2014), longer-term durability of the procedure still need to be proven in larger studies.

Jirapino and colleagues (2020) conducted a retrospective review of prospectively collected data on RYGB patients who underwent TORe for weight regain or inadequate weight loss. The primary outcome was efficacy of TORe at 1, 3, and 5 years. Secondary outcomes were procedure details, safety profile, and predictors of long-term weight loss after TORe. The study included RYGB patients who underwent TORe procedures and met inclusion criteria. Of these, 331 (83.8%), 258 (81.8%), and 123 (82.9%) patients were eligible for 1-, 3- and 5-year follow-ups, respectively. At 1 year, TORe

was successful at preventing weight gain in 87.4% of the patient cohort, with the number needed to treat of 1.1. On average, patients lost 9.4±12.3 kilograms (kg), which corresponded to 8.5±8.5% TWL ($p<0.0001$), with 65% of the cohort experiencing at least 5% TWL. At 3 years, TORe was successful at preventing weight gain in 79% of the patient cohort, with the number needed to treat of 1.3. On average, patients lost 8.7±13.8 kg, which corresponded to 6.9±10.1% TWL ($p<0.0001$), with 54% of the cohort experiencing at least 5% TWL. At 5 years, TORe was successful at preventing weight gain in 77% of the patient cohort, with the number needed to treat of 1.3. On average, patients lost 10.3±14.6 kg, which corresponded to 8.8±12.5% TWL ($p<0.0001$), with 62% of the cohort experiencing at least 5% TWL. Some patients (39.3%) had adjunctive therapies for weight regain (e.g., pharmacotherapy or procedure), with 3.6% getting repeat TORe. Amount of weight loss at 1 year and an additional endoscopic weight loss procedure were predictors of percentage of TWL at 5 years. There were no severe adverse events, and moderate AEs occurred in 11 out of 342 cases (3.2%). Study limitations include single site, retrospective design without a control group, one third of the patient received adjunctive therapy after the initial TORe, and technique variations over the years. The authors concluded that TORe appears to be safe, effective, and durable at treating weight regain after RYGB. At 5 years after TORe, nearly all patients have cessation of weight gain with the majority experiencing clinically significant weight loss. TORe appears to be safe, effective, and durable at treating weight regain after RYGB. At 5 years after TORe, nearly all patients have cessation of weight gain with the majority experiencing clinically significant weight loss.

TORe after Roux-en-Y gastric bypass (RYGB) with weight recurrence was studied in a prospective, multicenter, simple blind, randomized study (Valats 2024). Evaluating the percentage of excess weight loss (%EWL) at 12 months after endoscopy, the final analysis involved 50 subjects, 25 in each group, with an average BMI of 40.6 kg/m^2. At 12 months, the average %EWL was significantly higher in the TORe group than in the Sham group ($p = 0.002$), with a large effect size (Cohen's $d = 0.91$). There was no significant difference between groups concerning the improvement of obesity-related comorbidities (diabetes and dyslipidemia) and quality of life at 12 months. Frequent adverse events were reported in the TORe group (20% had adverse events related to the procedure). Three adverse events were serious, including two perforations of the gastro-jejunal anastomosis after TORe group that led to the premature termination of the study.

Routine Liver Biopsy in Conjunction with Bariatric Surgery

The impact on patient health outcomes has not been well-established, and there is insufficient clinical evidence to support routine liver biopsy in patients undergoing bariatric surgery.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

Chen and colleagues (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus sleeve gastrectomy (SG) in obese patients (N=937). Results demonstrated that patients who underwent hiatal hernia repair during SG had significant reductions in BMI, and the risk of GERD symptoms and esophagitis. Hiatal hernia repair during SG was superior to SG alone for GERD remission, but not de novo GERD.

There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for

patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia (Ardestani 2014; Santonicola 2014; Gulkarov 2008).

PROFESSIONAL GUIDELINE(S)

Adults

The 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on the impact of metabolic and bariatric surgery on nonalcoholic steatohepatitis concluded that metabolic and bariatric surgery has a positive impact on nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) either with or without fibrosis (Mazzini 2022). Although randomized controlled trials are needed to determine whether MBS should be considered as a frontline therapy for NAFLD and NASH, metabolic and bariatric surgery should be considered for patients with severe obesity.

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications (Eisenberg 2022). The understanding of obesity and MBS has significantly grown based on a large body of clinical experience and research. Long-term data, published in the decades following the 1991 NIH Consensus Statement, consistently demonstrates the safety, efficacy, and durability of MBS in the treatment of clinically severe obesity. With significant improvement of metabolic disease, decreases in overall mortality, and superior weight loss outcomes compared with nonoperative treatment, the joint statement indicates:

- MBS is recommended for individuals with BMI >35 kg/m^2, regardless of presence, absence, or severity of comorbidities.
- MBS is recommended in patients with T2D and BMI >30 kg/m^2.
- MBS should be considered in individuals with BMI of 30 - 34.9 kg/m^2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25kg/m^2. Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Children and adolescents with BMI >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.
- MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.

Endoscopic sleeve gastrectomy (ESG) and primary obesity surgery endoluminal (POSE) procedures are supported by the ASMBS for the treatment of obesity when performed within a comprehensive multidisciplinary bariatric program, preferably a bariatric center of excellence (Docimo 2023). In

2024, the International Federation for Surgery of Obesity (IFSO) conducted a comprehensive systematic review and meta-analysis of 44 articles, including 15,714 patients receiving ESG. Despite the limitations of the included observational studies, the IFSO reported that the included randomized controlled trial reinforced the efficacy and safety of ESG, thus, the IFSO position statement supports and provides an evidence base for the role of ESG within the broader spectrum of obesity management as an effective and valuable treatment for obesity.

The 2024 American Diabetes Association Standards of Medical Care in Diabetes sets forth recommendations for the treatment diabetes, including Section 8, which discusses metabolic surgery (ADAPPC, 2024). Citing that a substantial body of evidence has demonstrated that metabolic surgery has beneficial effects on type 2 diabetes irrespective of pre-surgical BMI, including achieving superior glycemic management, reduction of cardiovascular risk and obesity, the ADAPPC recommends:

- Consider metabolic surgery as a weight and glycemic management approach in people with diabetes with BMI ≥30.0 kg/m^2 (or ≥27.5 kg/m^2 in Asian American individuals) who are otherwise good surgical candidates (grade A.)
- People being considered for metabolic surgery should be evaluated for comorbid psychological conditions and social and situational circumstances that have the potential to interfere with surgery outcomes (grade B).
- In people who undergo metabolic surgery, routinely screen for psychosocial and behavioral health changes, and refer to a qualified behavioral health professional as needed (grade C).
- Metabolic surgery should be performed in high-volume centers with interprofessional teams knowledgeable about and experienced in managing obesity, diabetes, and gastrointestinal surgery (grade E).

<u>Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)</u>

The ASMBS endorses SADI-S as a modification of the classic Roux-en-Y duodenal switch (DS), an already-endorsed metabolic/bariatric procedure (Kallies 2020). The ASMBS states that it is reasonable to consider the SADI-S could be considered for endorsement with less available published peer-reviewed data than would be required for an entirely novel surgical procedure for which no predicate procedure exists. Based on additional publications the ASMBS concludes that SADI-S provides for similar outcome to those reported after classic DS.

SADI-S was initially endorsed by the IFSO in 2020 (Brown 2021) and re-affirmed in 2023 (Ponce de Leon-Ballesteros 2024). Based on an updated systematic review of current evidence on SADI-S/SADS, the IFSO made the following recommendations:

- SADI-S/SADS is as a safe and reproducible procedure with low rates of early and late complications. Also, it seems that primary procedures provide better outcomes in comparison to revisional procedures.
- SADI-S/SADS yields significant and sustained weight loss over a medium- to long-term period (5 years). However, there is a lack of data beyond the 6-year mark.
- SADI-S/SADS shows significant and sustained improvement in controlling type 2 diabetes mellitus

(T2DM) in the medium term.

- To enhance the quality of evidence, the IFSO encourages participation in national and international registries, publication of longterm follow-up studies, and randomized controlled trials (RCTs).

In 2016, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Based on six case series and zero randomized trials, the committee commented that the there is a potential for serious metabolic complication after the procedure and there may be a need for revision procedures. Evidence on efficacy is limited in both quality and quantity. NICE recommends that this procedure should only be used with special arrangements for clinical governance, consent and audit or research; patient selection should be done by a multidisciplinary team experienced in managing morbid obesity; treatment should be done by surgeons with specific training in the procedure, in centers with expertise in the treatment of morbid obesity.

Routine Liver Biopsy in Conjunction with Bariatric Surgery

American guidelines do not endorse routine liver biopsies with abdominal surgeries.

In 2023, the American Association for the Study of Liver Diseases (AASLD) published a practice guideline on the clinical assessment and management of nonalcoholic fatty liver disease, citing NAFLD is closely linked to and often precedes the development of metabolic abnormalities such as insulin resistance, dyslipidemia, central obesity, and hypertension (Rinella 2023). Statements within the guidance include:

- Liver biopsy should be considered when there is diagnostic uncertainty, competing or concomitant possible diagnoses (e.g., autoimmune hepatitis, iron overload); or when there is persistent elevation (>6 month) in liver chemistries.
- General population-based screening for NAFLD is not advised.
- High-risk individuals (e.g., with T2DM, medically complicated obesity, family history of cirrhosis, or more than mild alcohol consumption) should be screened for advanced fibrosis.
- Patients with NAFLD who are overweight or obese should be prescribed a diet that leads to a caloric deficit. When possible, diets with limited carbohydrates and saturated fat and enriched with high fiber and unsaturated fats (e.g., Mediterranean diet) should be encouraged due to their additional cardiovascular benefits.
- Patients with NAFLD should be strongly encouraged to increase their activity level to the extent possible. Individualized prescriptive exercise recommendations may increase sustainability and have benefits independent of weight loss.
- Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves NAFLD or NASH in the majority of patients without cirrhosis and reduces mortality from CVD and malignancy.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery concluding that combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection (Menzo 2018).

The 2013 Society of American Gastrointestinal and Endoscopic Surgeons evidence-based guidelines on the management of a hiatal hernia, recommended repair of hiatal hernias incidentally detected at the time of bariatric surgery (Kohn 2013).

Children and Adolescents

In 2023, the American Academy of Pediatrics (AAP) published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity. (Hampl 2023). The recommendations are based on evidence from RCTs, comparative effectiveness trials, high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is: "Pediatricians and other pediatric health care providers should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery center)."

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications, stating MBS is safe and produces durable weight loss and improvement in comorbid conditions (Eisenberg 2022).

In 2019, the AAP published a report outlining the current evidence regarding adolescent bariatric surgery for adolescent metabolic and bariatric surgery that reflected the 2018 American Society for Metabolic and Bariatric Surgery (ASMBS) recommendations (Armstrong 2019). The AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2018, the American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee updated its evidence-based guidelines published in 2012 (Pratt 2018). Based on an increased body of evidence the committee stated that metabolic and bariatric surgery (MBS) with vertical sleeve gastrectomy (VSG) and RYGB can be considered both safe and effective treatments for adolescents with a BMI of 35 kg/m^2 or 120% of the 95th percentile with a co-morbidity or BMI ≥40 kg/m^2 or 140% of the 95th percentile without a comorbidity (whichever is lower). With limited data the committee indicated that adjustable gastric banding and biliopancreatic diversion with or without duodenal switch is less desirable and should be reserved for adults in most cases. Endoscopic bariatric therapies (e.g., intragastric balloons, vagal stimulation, gastric aspiration) are not currently FDA for under 18 years of age. Studies on the long-term durability and physiologic consequences are needed.

Intragastric Space Occupying Mechanisms (e.g., intragastric balloon)

The American Society for Metabolic and Bariatric Surgery (ASMBS) published a position statement on intragastric balloon therapy which was endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (Ali 2016). Based on current evidence, balloon therapy is FDA approved as an endoscopic, temporary (maximum 6 months) tool for the management of obesity, and further review will evaluate the impact of diet, lifestyle changes, and pharmacotherapy during and after balloon removal. Overall, the data suggest that the intragastric balloon is an effective tool for weight loss. Most of its effect was observed in the first 3 months after insertion, during which patients usually lost greater than 12 kilograms. At removal, or 6 months after insertion, studies, including randomized controlled trials, have suggested that the expected %EWL is about 24%. Early postoperative tolerance challenges can be significant but can be controlled with pharmacotherapy in the majority of patients, thereby minimizing voluntary balloon removals.

REGULATORY STATUS

The following devices currently do not have FDA approval for use: EndoBarrier Gastrointestinal Liner (GI Dynamics, Lexington, MA), TOGA system (Satiety Inc., Palo Alto, CA),

The LAP-BAND Adjustable Gastric Banding System (BioEnterics Corp, Carpinteria, CA) received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for use in weight reduction for severely obese adults with a BMI of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or for those who weight 100 lbs. or more over their estimated ideal weight in June 2001. The FDA granted expanded approval for use in adult patients with a BMI of 30-35 kg/m^2 in the presence of at least one weight-related comorbidity in February 2011. The adjustable gastric band is not currently FDA-approved for use in patients under 18 years of age.

The REALIZE Adjustable Gastric Band (Ethicon Endo-Surgery, Cincinnati, OH) received FDA premarket approval (PMA) for use in weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m 2, or a BMI of at least 35 kg/m 2 with one or more co-morbid conditions in September 2007.

The AspireAssist device (Aspire Bariatrics, King of Prussia, PA) received FDA premarket approval (PMA) to assist in weight reduction of obese patients in June 2016. It is indicated for use in adults aged 22 or older with a BMI of 35.0-55.0 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring.

The TransPyloric Shuttle (BAROnova, San Carlos, CA) received FDA premarket approval (PMA) for weight reduction in adult patients with obesity with a Body Mass Index (BMI) of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with one or more obesity-related comorbid conditions and is intended to be used in conjunction with a diet and behavior modification program in 2019,

The StomaphyX device (EndoGastric Solutions, Redmond, WA) was cleared by FDA through the 510(k) process in 2007, and the Apollo OverStitch Suture System received FDA approval in 2008. Both are approved for endoluminal trans-oral tissue approximation and ligation in the GI tract.

<u>Intragastric Space Occupying Mechanisms/Devices</u>

The Obalon Intragastric Balloon System (ReShape Lifesciences, San Clemente, CA) received FDA

premarket approval (PMA) for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40 kg/m^2) who have failed to lose weight through diet and exercise in September 2016. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.

The ReShape Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA) received FDA premarket approval (PMA) as a temporary implant designed to facilitate weight loss by occupying space in the stomach in July 2015. The device is also intended to facilitate weight loss in obese adult patients with a BMI of 30-40 kg/m^2 who have been unsuccessful in losing weight through diet and exercise. Patients must have one or more obesity-related conditions, such as diabetes, high blood pressure, or high cholesterol. Both approved devices are considered temporary and should be removed after six months.

The ORBERA Intragastric Balloon (Apollo Endosurgery, Inc.) received FDA approval for patients with a BMI of 30-40, to assist those patients in losing and maintaining weight in August 2015. Obalon Therapeutics received FDA approval for the Obalon Balloon System in September 2016.

The Allurion Gastric Balloon/Elipse Balloon (Allurion Technologies) is a liquid-filled swallowable intragastric balloon that is currently not FDA approved in the United States.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0813T (E/I)	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
43290 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	revision of adjustable gastric restrictive device component only
43772	removal of adjustable gastric restrictive device component only

Code	Description
43773	removal and replacement of adjustable gastric restrictive device component only
43774	removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	removal of subcutaneous port component only
43888	removal and replacement of subcutaneous port component only
47000 (*NMN)	Biopsy of liver, needle; percutaneous (*NMN when billed with an ICD-10 code listed below unless criteria under concomitant procedures is met.)
47001 (*NMN)	Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (List separately in addition to code for primary procedure) (*NMN when billed with an ICD-10 code listed below unless criteria under concomitant procedures is met.)
47100 (*NMN)	Biopsy of liver, wedge (*NMN when billed with an ICD-10 code listed below unless criteria under concomitant procedures is met.)
47379 (*NMN)	Unlisted laparoscopic procedure, liver (*NMN when billed with an ICD-10 code listed below)

HCPCS Codes

Code	Description
C9784 (E/I)	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785 (E/I)	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD10 Codes

Code	Description
E66.0	Obesity due to excess calories
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.3	Overweight
E66.811	Obesity, class 1
E66.812	Obesity, class 2
E66.813	Obesity, class 3
E66.89	Other obesity not elsewhere classified
E66.9	Obesity, unspecified
K91.0 - K91.32	Postprocedural complications and disorders of digestive system (code range)
K95.01- K95.09	Complications of gastric band procedure (code range)
K95.81- K95.89	Complications of other bariatric procedure (code range)
Z68.35- Z68.45	Body mass index (BMI), 35.0-70 or greater, adult (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (NCD 100.1). [accessed 2025 Apr 7]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product)

covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
03/21/02, 02/20/03, 10/15/03, 11/18/04, 08/18/05, 04/20/06, 11/16/06, 11/15/07, 12/18/08, 01/21/10, 12/16/10, 10/20/11, 12/20/12, 11/21/13, 12/18/14, 11/19/15, 10/20/16, 04/20/17, 03/15/18, 08/16/18, 05/16/19, 10/17/19, 09/17/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 05/22/25	
Date	**Summary of Changes**
05/22/25	• Annual review, policy statement revised for single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)/stomach-intestine pylorus-sparing surgery (SIPS) to change from investigational to medically necessary.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date