MEDICAL POLICY

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Medical Policy Title	**Bariatric and Metabolic Surgery**
Policy Number	**7.01.29**
Current Effective Date	**May 21, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The surgical treatment of obesity by Roux-en-Y gastric bypass (open or laparoscopic), biliopancreatic diversion with duodenal switch (BPD-DS), single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), laparoscopic adjustable gastric banding (LAGB), and sleeve gastrectomy is considered **medically appropriate** when **ALL** of the following criteria are met:

A. The individual's body mass index (BMI) meets **one (1)** 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; **or**

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 the individual's participation efforts to achieve weight loss or metabolic improvements including **all** of the following:

1. Pre-operative lifestyle and medical 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-operative nutrition evaluation conducted by a registered dietician is mandatory; **and**
3. Planned participation in a post-operative weight management program through the first year after surgery that supports long-term health outcomes through nutritional management (including assessment for malabsorption), physical activity, and behavioral health support;

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

D. Behavioral health clearance for surgery is documented by **either** 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 **either** of the following:
   a. history of alcohol or substance use disorder with 6 months or less of abstinence; **or**
   b. psychosocial, psychological, or psychiatric concerns identified by any member of the bariatric pre-operative evaluation team.

II. Bariatric and metabolic surgery as a treatment for individuals with a BMI less than or equal to 29.9 kg/m^2 is considered **investigational.**

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

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

B. One anastomosis gastric bypass (OAGB) (also known as mini-gastric bypass);

C. Vertical banded gastroplasty (VBG);

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

E. Endoscopic/endoluminal procedures or devices, including but not limited to:

1. Gastric aspiration therapy;
2. Transoral gastroplasty (TOGA, also known as vertical sutured gastroplasty, endoluminal vertical gastroplasty, System);
3. Restorative obesity surgery endoluminal (ROSE);
4. Closure/plication and suturing (e.g., StomaphyX, EndoCinch, Apollo Overstitch)
5. TransPyloric Shuttle;
6. Gastrointestinal liners (e.g., duodenal-jejunal bypass liners such as EndoBarrier); and
7. Endoscopic sleeve gastroplasty (ESG);

8. Transoral outlet reduction [TORe]).

Revisional and Corrective Surgery

IV. Surgical revision is considered **medically necessary** for documented complications following the primary procedure (e.g., malabsorption or malnutrition, obstruction, or stricture, staple-line disruption, severe gastroesophageal reflux disease that does not respond to medical treatment).

V. LAGB revision or removal is considered **medically appropriate** for 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).

VI. Revision or conversion to another medically appropriate procedure due to inadequate weight loss or metabolic improvement following the primary bariatric procedure is considered **medically appropriate** when **BOTH** of the following are met:

A. Documented compliance to the prescribed post-operative nutrition and physical activity program for at least 6-months;

B. **Either** of the following are met:

1. Non-response to the primary procedure (failure to achieve adequate outcomes); **or**

2. Weight recurrence following initial successful weight reduction from the primary procedure.

VII. Reoperation or revision surgical treatment of obesity is considered **investigational** for **EITHER** of the following:

A. Placement of a second adjustable gastric band (AGB);

B. Endoscopic/endoluminal procedures (e.g., transoral outlet reduction [TORe], endoscopic sleeve gastroplasty [ESG]).

Concomitant Procedures

VIII. 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).

IX. 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

3.01.24 Neuropsychological and Psychological Testing

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.53 Abdominoplasty and Panniculectomy, and Lipedema Reduction Surgery

7.01.64 Gastric Electrical Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Body mass index (BMI) requirements are based on preoperative measurements. BMI is calculated by dividing a person's weight in kilograms (kg) by the square of height in meters (m^2).

II. 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).

III. Individuals considering surgery must participate in a multidisciplinary pre- and post-operative lifestyle modification program that addresses long-term commitment and management of modifiable risk factors (e.g., dietary changes, nutritional monitoring, physical activity, behavioral modification, and psychosocial support). The post-operative plan must include participation in ongoing postoperative follow-up through the first year after surgery.

IV. Revision or conversion surgery may be performed for weight recurrence, non-response, or post-operative symptoms (e.g., gastroesophageal reflux disease) that do not respond to medical management.

   A. Surgery for medical complication(s) or technical failure(s) does not require adherence to post-operative follow-up recommendations.

   B. Surgery for weight recurrence or non-response requires documented adherence to post-operative program recommendations for at least six (6) months.

V. The American Society of Metabolic and Bariatric Surgery (ASMBS) reiterates that a multidisciplinary team should evaluate patients to optimize surgical outcomes including:

   A. Comprehensive preoperative 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. Pre-operative optimization refers to the management of modifiable risk factors prior to elective surgery, with the goal of reducing the risk of perioperative complications and improving outcomes by implementing interventions that can address disordered eating, severe uncontrolled mental illness, or active substance abuse (Carter 2021; Eisenberg 2022).

VI. Adult classification of obesity by BMI (National Heart, Lung, and Blood Institute [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 95th percentile
- 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

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 provides ongoing care for the patient may also provide this evaluation. For psychological testing criteria, refer to the Related Policies section.

IX. Adolescents should be referred to an accredited pediatric/adolescent bariatric surgery program, such as a Surgical Review Corporation (SRC) or a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited pediatric program to ensure care in programs that meet established standards for patient safety and quality.

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.

XIII. The adjustment of a previously placed laparoscopic adjustable gastric band (LAGB), beyond the global, 90-day limit, controls 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).

DESCRIPTION

Obesity is a complex multifactorial condition that substantially increases the risk of weight-related complications and comorbidities associated with excess adiposity. Complications may 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). 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 (m2).

Clinically severe obesity includes class III obesity (formerly referred to as morbid obesity) and class II 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	BMI (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 modification, including intensive lifestyle intervention (ILI). Under medical supervision ILI programs include comprehensive behavioral management strategies that focus on improving dietary habits, increasing physical activity, and enhancing self-care and psychological well-being. 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 individuals, not all individuals can reduce and control weight through diet and activity/exercise/movement. When conservative measures fail, some individuals consider surgical approaches.

Bariatric surgery, also referred to as metabolic or bariatric surgery (MBS), is an evidence-based option for individuals with class II or III obesity who have not achieved sufficient weight loss through non-surgical interventions. 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 works 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 individuals with class I obesity and T2D is increasingly performed based on evidence showing improvement or remission of diabetes following surgery, sometimes occurring before substantial weight loss. Various surgical procedures have different effects on weight loss. Gastrointestinal rearrangement appears to confer antidiabetic benefits independent of weight loss and caloric restriction, although the precise mechanisms remain under investigation. Proposed mechanisms include changes in gastrointestinal peptides such as glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY). GLP-1, secreted by L cells in the distal ileum, enhances glucose-dependent insulin secretion, slows gastric emptying, blunts postprandial glycemia, and promotes satiety. GIP acts on pancreatic beta cells to increase insulin secretion, while PYY contributes to satiety and delayed gastric emptying. These hormonal changes may also improve insulin sensitivity.

Bariatric surgery is generally categorized into two types: gastric restrictive procedures and malabsorptive procedures. Restrictive procedures mechanically limit the volume of food intake before satiety is achieved, while malabsorptive procedures reduce nutrient absorption by altering the normal digestive pathway. Many operations combine both mechanisms.

Procedures/Interventions

Roux-en-Y gastric bypass (RYGB) combines restrictive and malabsorptive components. The stomach is partitioned horizontally or vertically and connected to the jejunum via a Roux-en-Y configuration, bypassing the duodenum and proximal small bowel. This procedure can be performed via open or laparoscopic techniques. Potential complications include dumping syndrome, anastomotic complications, (e.g., leakage or marginal ulceration), and nutritional deficiencies due to altered absorption (e.g., iron, vitamin B-12, and calcium).

Sleeve gastrectomy (SG) involves resection of the greater curvature of the stomach from the angle of His to the distal antrum, creating a tubular gastric remnant. The pylorus is preserved, allowing more physiological gastric emptying and reducing the risk of dumping syndrome. SG may serve as a standalone procedure or as a first stage before a more extensive malabsorptive operation (e.g., BPD).

Adjustable gastric banding (AGB) uses a laparoscopically placed band around the upper stomach, connected to a subcutaneous reservoir for saline injection. Adjustments alter stoma size to regulate food passage. Complications include band slippage, erosion, and port-related issues.

Biliopancreatic diversion (BPD), also known as the Scopinaro procedure, combines subtotal gastrectomy with diversion of biliopancreatic secretions to the distal ileum via a long Roux-en-Y limb. This procedure carries significant risks, including protein malnutrition, iron deficiency anemia, hypocalcemia, and bone demineralization. BPD with duodenal switch (DS) modifies BPD by replacing distal gastrectomy with sleeve gastrectomy, preserving the pylorus and proximal duodenum. This reduces dumping syndrome and ulcer risk while maintaining selective malabsorption.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S), also known as stomach-intestine pylorus-sparing surgery (SIPS), combines SG with a single duodeno-ileal anastomosis, preserving the pylorus and reducing complexity compared to DS. It aims to minimize risks such as short bowel syndrome while maintaining malabsorptive benefits.

Gastric plication is a restrictive laparoscopic procedure that reduces gastric volume by folding and suturing the stomach without tissue resection.

Vertical banded gastroplasty (VBG) creates a small pouch by vertically stapling and horizontally banding the upper stomach. This once common legacy procedure has largely been abandoned due to high revision rates from complications such as staple line disruption and band erosion.

Reversal or Revisional Surgery

Professional society guidance recognizes the role of revisional procedures to address device- or procedure-related complications, technical failures, or inadequate outcomes following prior bariatric interventions. Endoscopic revision, including TORe and repeat gastric remodeling using suturing techniques (e.g., repeat ESG/re-suturing patterns), is described as a stepwise strategy to manage weight regain or anatomic dilation after prior endoscopic or surgical procedures.

Procedures are generally not indicated when failure is attributable to noncompliance with recommended dietary and behavioral protocols, such as gastric pouch dilation resulting from overeating.

Endoscopic and Device-Based Procedures

As revisional metabolic and bariatric surgery (MBS) is associated with a higher complication rate than primary MBS, there is interest in endobariatric revisional procedures to treat weight related issues while potentially minimizing the risk of complications (Docimo 2026). The primary goals vary by intervention type, with gastric endoscopic bariatric and metabolic therapies (EBMTs) primarily targeting weight loss, whereas small-bowel interventions focus on glycemic improvement as the primary efficacy endpoint, with weight loss assessed as a co-primary or secondary outcome (e.g., duodenal–jejunal bypass liner).

Endoscopic suturing is an endoscopic tissue-approximation technique used to place full-thickness sutures or plications within the gastrointestinal tract and is used to perform several EBMTs and revisional procedures, including endoscopic sleeve gastroplasty (ESG) and other gastric remodeling procedures. Specialized devices (e.g., EndoCinch, Apollo OverStitch) place stitches inside the gastrointestinal tract.

Endoscopic gastric remodeling (EGR) refers to a group of endoscopic interventions that use endoscopic tissue-approximation technologies to remodel the stomach, reduce gastric volume, alter motility, and promote early satiety. EGR encompasses ESG and includes multiple devices (e.g., Apollo ESG System/OverStitch, POSE system, and Endomina).

Endoscopic sleeve gastroplasty (ESG) is a minimally invasive endoscopic procedure that reduces gastric volume by creating full-thickness plications along the greater curvature of the stomach using endoscopic suturing to produce a sleeve-like gastric remodeling and clinically meaningful weight loss. ESG mimics the restrictive effect of sleeve gastrectomy without gastric resection. Endoscopic “resleeve” gastroplasty has been described as an endoscopic option for revision following sleeve gastrectomy.

Transoral outlet reduction (TORe) is an endoscopic revisional procedure for weight regain after Roux-en-Y gastric bypass due to dilation of the gastrojejunal anastomosis (GJA). Techniques to reduce anastomotic diameter, to support satiety and weight control, include endoscopic suturing, argon plasma coagulation (APC), or both

Transoral gastroplasty (TG), also known as vertical sutured gastroplasty or endoluminal vertical, is an endoluminal approach intended to create gastric restriction using incisionless or stapling-based (e.g., TOGA) to create a restrictive gastric pouch.

Intragastric balloons (e.g., Orbera, Obalon, Spatz3) are temporary, endoscopically placed balloons that reduce gastric capacity to promote satiety. They are used for short-term weight loss or as a bridge to definitive surgery.

Aspiration therapy (AT) uses a percutaneous gastrostomy tube to aspirate gastric contents post-meal, reducing caloric absorption. Success depends on individual adherence.

TransPyloric shuttle (TPS) is an endoscopically inserted device that intermittently obstructs the pylorus to delay gastric emptying, promoting early and prolonged satiety.

Small-bowel interventions include the duodenal–jejunal bypass liner (DJBL) (e.g., EndoBarrier), which limits nutrient contact with the proximal small intestine and is evaluated primarily for glycemic

improvement. Duodenal mucosal resurfacing (DMR) is an endoscopic treatment to ablate the duodenal mucosa in an attempt to improve diabetes mellitus and fatty liver disease in patients with obesity.

SUPPORTIVE LITERATURE

The 1991 National Institute of Health (NIH) Consensus Statement first supported the safety and effectiveness of bariatric surgery. The Swedish Obese Subjects (SOS) trial, the most influential study comparing bariatric surgery to conservative treatment, demonstrated substantial weight loss, improved comorbid conditions, and enhanced quality of life after surgery (Sjostrom 2007).

Class II and III Obesity

There is sufficient published 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; Wolnerhanssen 2021; Vitiell 2023), adjustable gastric band (Dixon 2008; Himpens 2011), biliopancreatic diversion with duodenal switch (Prachand 2006; Strain 2007; Skogar 2017), and SADI-S (Dijkhorst 2021; Esparham 2023; Axer 2024).

Class III Obesity with BMI ≥45 kg/m^2

Pereira et al (2024) conducted a prospective, interventional, open-label randomized study that assessed weight trajectories and postprandial endocrine/metabolic responses through 12 months in adults with class III obesity (BMI 45–55 kg/m²). Participants were randomized to SADI-S (n=7) or to sleeve gastrectomy (SG) as the first step of a planned two-step SADI-S (n=7). Study visits occurred pre-operatively and at 3, 6, and 12 months. Anthropometric, metabolic, and micronutrient profiles did not differ significantly between groups at baseline or at follow-up. Fasting and postprandial glucose, insulin, C-peptide, ghrelin, insulin secretion rate, and insulin clearance during the mixed-meal tolerance test (MMTT) were not significantly different between SADI-S and SG. No participants were lost to follow-up. At 12 months, the study reports no significant between-group differences in the clinical and metabolic outcomes assessed.

Esparham et al (2025) performed a systematic review and meta-analysis comparing duodenal switch (DS) and Roux-en-Y gastric bypass (RYGB) in patients with BMI ≥ 50 kg/m² (12 studies; n=2,678; 1–15 years follow-up). DS showed significantly greater BMI reduction ($p < .001$) and greater total weight loss ($p < .001$) than RYGB. Complication, reoperation, mortality, and comorbidity remission rates (diabetes, hypertension, dyslipidemia, obstructive sleep apnea) did not differ significantly between groups. However, DS was associated with higher malnutrition rates (8.3% vs. 1.2%; $p = .02$), more revisional surgeries for malnutrition (5.4% vs. 0%; $p = .05$), and increased gallbladder disease requiring cholecystectomy (24.6% vs. 4.5%; $p = .01$). The authors concluded that DS provides superior weight loss for patients with BMI ≥50 kg/m² but carries a higher risk of major malnutrition and revisional surgery compared to RYGB.

Class I Obesity with Type 2 Diabetes

Bariatric surgery as treatment for class 1 obesity and type 2 diabetes is supported meta-analysis and systematic reviews (e.g., De Luca 2023) which have found significantly greater remission rates of

diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. Supporting randomized controlled trials (RCTs) include the STAMPEDE 5-year outcomes, which demonstrated that RYGB and SG were superior to intensive medical therapy for individuals with BMI 27–43 (Schauer 2017). The Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) 3-year follow-up showed durable metabolic benefit with bariatric surgery compared with medical/lifestyle interventions across RYGB, SG, and adjustable gastric banding (Kirwan 2022), and 12-year long-term ARMMS-T2D data demonstrating sustained, clinically significant improvements in glycemic control, higher diabetes remission rates, and reduced need for diabetes medications after surgery (Courcoulas 2024).

Class I Obesity without Type 2 Diabetes

Evidence is limited for individuals with a BMI 35 kg/m^2 who do not have type 2 diabetes. A few small randomized controlled trials and case series have reported weight loss and improvements in comorbidities in this population; however, the available evidence does not allow conclusions regarding the long-term risk-benefit profile of bariatric surgery for these individuals.

One-Anastomosis Gastric Bypass (OAGB),

OABG, formerly known as mini-gastric bypass or loop gastric by-pass lacks sufficient published in the medical literature to draw conclusions about the safety and effectiveness of the procedure.

Robert et al (2024) reported the 5-year extension study of the YOMEGA trial, a prospective, open-label, non-inferiority, randomized controlled trial done across nine high-volume bariatric institutions in France, enrolling adults aged 18–65 years with BMI ≥ 40 kg/m² or BMI ≥ 35 kg/m² with ≥1 comorbidity, and excluding those with severe gastro-esophageal reflux disease (GERD), Barrett's esophagus, or prior bariatric surgery (OAGB used a 200-cm biliopancreatic limb). A total of 127 participants were assigned to OAGB and 121 to RYGB, with scheduled assessments at 1, 3, 6, 12, 18, and 24 months and annually thereafter; at 5 years, OAGB was non-inferior to RYGB for percentage excess BMI loss, and there was no significant between-group difference in the frequency of type 2 diabetes remission, while the mean decrease in HbA1c from 2 to 5 years did not differ between procedures. Diarrhea decreased from 2 to 5 years in the OAGB arm while increasing in the RYGB arm; early dumping syndrome at 5 years was more frequent with RYGB than OAGB; and GERD increased over time in both groups but was significantly higher after OAGB, with greater proton-pump inhibitor use; ten OAGB patients were converted to RYGB during follow-up. The investigators noted that malabsorption-related adverse events improved over time in the OAGB group (no hospitalizations for malnutrition from years 2–5 after nine serious malnutrition events within the first 2 years). Although the authors concluded that OAGB was non-inferior to RYGB for weight and metabolic outcomes at 5 years, the higher frequency of GERD after OAGB supports the need for ongoing surveillance. Study limitations include substantial loss to follow-up at 5 years, reliance on symptom-based GERD assessment rather than standardized reflux testing, and a relatively small diabetes subgroup, all of which may affect the precision and generalizability of adverse-event and metabolic outcome estimates.

Endobariatric Procedures

Mrad et al (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 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.

Docimo et al (2026) with the American Society for Metabolic and Bariatric Surgery (ASMBS) conducted a systematic review of pertinent endoluminal bariatric therapies for both primary and revisional indications. Available evidence has shown intragastric balloons (IGBs) to be associated with percent total weight loss (%TWL) ranging from 4–13% across most studies, with a serious adverse event rate of less than 2%. The majority of studies do not report outcomes beyond one year; therefore, long-term effects on weight remain unknown and require further investigation in the context of treating a chronic disease. Available evidence for endoscopic sleeve gastroplasty (ESG) shows favorable improvement in weight (excess weight loss [EWL] of 45–60%) and metabolic disease. Although laparoscopic sleeve gastrectomy (LSG) consistently demonstrates greater improvement in weight loss and comorbidities, ESG may be a suitable option for patients who are unable or unwilling to undergo LSG. Based upon current results, endoluminal duodenal-jejunal liners in their present form remain investigational. The literature for transoral outlet reduction (TORe) reports modest weight loss (%TWL 7–8%) up to one year after treatment, with weight regain observed between 6 and 12 months, and no longer-term follow-up available. Techniques including full-thickness endoscopic suturing alone, argon plasma coagulation (APC) alone, and suturing combined with APC have all been described without clear evidence of superiority among methods. The ASMBS concluded that obesity is a chronic disease best treated in a multidisciplinary setting. Therefore, endoluminal bariatric procedures should be performed within a multidisciplinary program that provides longitudinal support for patients with obesity over time and facilitates ongoing data collection on patient outcomes.

Endoscopic Sleeve Gastroplasty (ESG)

Abu Dayyeh et al (2022) conducted a prospective, multi-center, randomized trial (MERIT) with individuals (n=209) aged 21-65 with class I or class II 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.

Docimo et al (2023), on behalf of the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee, published a systematic review of the peer-reviewed literature on endoscopic sleeve gastroplasty (ESG) and primary obesity surgery endoluminal procedures (POSE, POSE 2.0), collectively regarded as alternative forms of endoscopic sutured gastroplasty. The panel noted that most published studies used ESG in patients with a BMI of 30–40 kg/m², with limited data available for patients outside this range. Across multiple studies, ESG yielded an average total body weight loss of 13%–20% at 12 months, which was significantly less than the weight loss observed after laparoscopic sleeve gastrectomy in comparative analyses. Among the studies reporting 2- and 3-year outcomes, most demonstrated sustained weight loss. ESG was also associated with improvements in metabolic disease, and postoperative surveys across several studies indicated a <3% incidence of de novo GERD. With similar weight-loss outcomes and complication rates, POSE and POSE 2.0 represent alternative endoluminal plication techniques to ESG. Endoscopy may be performed in advance or as the first step of a single-stage conversion. For practices offering ESG or POSE, these procedures should be integrated within a comprehensive multidisciplinary bariatric program, optimally within a bariatric center of excellence.

Abad et al (2025) conducted a prospective, multicenter, randomized, controlled, and double-blind study to evaluate the effectiveness and safety of ESG (with OverStitch) in patients with metabolic dysfunction-associated steatohepatitis (MASH). A total of 40 patients were randomized 1:1 to ESG plus lifestyle modification vs sham endoscopy plus lifestyle intervention. Inclusion criteria included biopsy-proven MASH with nonalcoholic fatty liver disease activity score (NAS) ≥3 and fibrosis stage F0 to F3. At the 72-week follow-up, 18 participants from the ESG group and 19 in the endoscopic simulated intervention (ESI) group completed the study. From baseline to the end of follow-up, total body weight loss was significantly greater with ESG than ESI ($P < .05$). ESG also resulted in significantly greater reductions in liver stiffness ($P < .05$) and steatosis ($P = .033$). In patients achieving weight loss >10%, there was significant improvement on NAS score ($p < .01$), but not in fibrosis stage. Only two patients in the ESG group had an adverse event, which resolved conservatively. Study limitations may limit generalizability and long-term inference, including a small sample, the single-disease population (MASH), and trial duration. The authors concluded that the results suggest that ESG may be an effective alternative therapy in the treatment of patients with MASH and should be used as part of second-line treatment, with or without other complementary weight loss therapies, especially in patients who do not respond to lifestyle modification. Further studies are needed to confirm these findings and to better characterize its potential role in the management of patients with MASH.

Duodenal-Jejunal Bypass Liner (DJBL)

There is insufficient published evidence to establish DJBL safety and clinical efficacy.

Glaysher et al (2021) published a sub-study of a multicenter, randomized, controlled trial of patients within two treatment groups (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 et al (2022) conducted an open-label RCT of 170 adults with inadequate 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 et al (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 et al (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.

Gastric Plication

Research preliminarily supported that the procedure has acceptable short-term complication rates and weight loss outcomes (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.

Intragastric Space Occupying Devices

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 et al (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.

Sullivan et al (2018) conducted a 24-week, double-blinded, randomized, sham-controlled trial of the Obalon 6-month swallowable gas-filled IGB system (Carlsbad, CA) at 15 academic and private practice centers in the United States. Adults aged 22–60 years with BMI 30-40 kg/m^2 were randomized to receive either treatment (n=198) or control (n=209). Among participants who completed the 24 week treatment mean percent total body weight loss was 7.1% ± 5.0% in the treatment group and 3.6% ± 5.1% in the control group, for a mean difference of 3.5% (p = 0.0085). Although balloons were removed after 24 weeks, 89% of the treatment group maintained weight loss through 48 weeks. Nonserious adverse events occurred in 91.1% of patients, but only 0.4% were severe. Despite several study limitations, the authors concluded Treatment with lifestyle therapy and the 6-month swallowable gas-filled intragastric balloon system was safe and resulted in twice as much weight loss compared with a sham control, with high weight loss maintenance at 48 weeks.

Study limitations include the short duration of randomized treatment (24 weeks) and limited long-term comparative data beyond balloon removal, which restricts conclusions regarding the durability of weight loss and longer-term safety outcomes.

Transoral Gastroplasty (TG)

For the treatment of obesity, TG has limited published literature, and the evidence 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.

Transoral Outlet Reduction (TORe)

Although preliminary results showing promising feasibility, safety, and short-term efficacy being demonstrated in case series (Jirapinyo 2013 [RESTORe trial]; Thompson 2013; Kumar 2014), longer-term durability of the procedure still needs to be proven in larger studies.

Jirapinyo et al (2020) conducted a retrospective review of prospectively collected data on RYGB patients who underwent TORe for weight regain or inadequate weight loss to assess long-term (5 year) efficacy. A total of 331 RYGB patients, with a mean BMI of 40±9 kg/m^2, underwent 342 TORe procedures. On follow-up, patients experienced a %TWL of 8.5 ± 8.5%, 6.9 ± 10.1%, and 8.8 ± 12.5% at 1, 3, and 5 years, respectively. At 5 years after TORe, nearly all patients had cessation of weight gain with the majority experiencing and maintaining clinically significant weight loss. Pre-TORe GJA size was 23.4 ± 6.0 mm, which decreased to 8.4 ± 1.6 mm after TORe. There were no severe or fatal AEs, with moderate AEs occurring in 11 out of 342 cases. The study was limited by a 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.

Valats et al (2024) conducted a prospective, multicenter, simple blind, randomized study evaluating the percentage of excess weight loss (%EWL) at 12 months following TORe in adults with weight recurrence after Roux-en-Y gastric bypass (RYGB). The final analysis included 50 subjects (25 per group), with a mean BMI of 40.6 kg/m^2. At 12 months, the TORe group demonstrated a significantly higher %EWL compared with the Sham group ($p = 0.002$), with a large effect size (Cohen's $d = 0.91$). No significant between-group differences were observed in the improvement of obesity-related comorbidities (diabetes, dyslipidemia) or quality-of-life measures at 12 months. Adverse events occurred more frequently in the TORe group (20% procedural-related events). Three adverse events were classified as serious, including two gastro-jejunal anastomosis perforations in the TORe group, which led to 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.

Barajas-Gamboa et al (2025) performed a retrospective analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database from 2020 to 2022 of patients undergoing primary Roux-en-Y gastric bypass or sleeve gastrectomy with or without

concomitant liver biopsy. Of the 511,981 patients, 30,819 (6.02%) underwent concomitant liver biopsy. The authors concluded that after adjusting for patient factors, the analysis demonstrates that concomitant liver biopsy during bariatric surgery does not independently increase the risk of major complications (Clavien-Dindo grade III and IV), readmission, or mortality. However, it is associated with statistically significant increases in both postoperative bleeding and transfusion requirements, though not with reoperation rates. When balancing the potential benefits of early liver disease diagnosis against risks, concomitant liver biopsy remains a reasonable option for appropriately selected patients undergoing bariatric surgery, provided clinicians are prepared for increased bleeding-related complications and blood product utilization. Careful patient selection, pre-operative optimization, and availability of blood products are essential considerations when planning concomitant liver biopsy.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

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 (Santonicola 2014; Gulkarov 2008).

Chen et al (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.

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 RCTs 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). 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.

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 outcomes 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 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 long-term 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 there is 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.

Adults - Endoscopic Bariatric and Metabolic Therapies (EBMTs)

In 2024, the IFSO Bariatric Endoscopy Committee endorsed ESG as an effective and valuable intervention for managing obesity based on a comprehensive systematic review and meta-analysis of 44 articles (n=15,714 patients) (Abu Dayyeh 2024). The committee concluded that ESG is particularly beneficial for patients with class I and II obesity, as well as for those with class III obesity who are not suitable candidates for traditional MBS. This minimally invasive procedure not only achieves significant weight loss outcomes in the short and mid-terms but also maintains a favorable safety profile, as evidenced by a low incidence of serious adverse events.

In 2024, Jirapinyo and colleagues authored a joint guideline from the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE) on primary endoscopic bariatric and metabolic therapies (EBMTs). Conditional recommendations (very low to moderate certainty) were made for lifestyle modification plus the use of intra-gastric balloons, aspiration therapy, duodenal-jejunal bypass liner, and endoscopic gastric remodeling (EGR) devices (e.g., Overstitch Endoscopic Suturing System) in adults with a BMI ≥30 kg/m², or a BMI of 27.0–29.9 kg/m² with at least one obesity-related comorbidity. Based on limited evidence, transpyloric shuttle and duodenal mucosal resurfacing (DMR) are recommended only in the context of a clinical trial.

In 2024, NICE recommended endoscopic sleeve gastroplasty as an option to treat obesity in adults. Reporting that evidence supports safety in the short and long term, and efficacy when combined with lifestyle changes for people with a body mass index (BMI) over 30 kg/m^2.

In 2013, NICE recommended that duodenal-jejunal bypass sleeve for managing obesity should only

be used in the context of research given the limited quality and quality of evidence on safety and efficacy.

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 long-term durability and physiological consequences are needed.

In 2017, the Endocrine Society's clinical practice guideline on pediatric obesity suggested that bariatric surgery be considered only for adolescents who have reached Tanner stage 4 or 5 and near-final adult height, have severe obesity (BMI ≥40 kg/m² or ≥35 kg/m² with serious comorbidities), and continue to have extreme obesity despite compliant lifestyle treatment, provided they also demonstrate psychological stability, the ability to follow healthy habits, and have access to an experienced pediatric bariatric surgery center capable of long-term metabolic and psychosocial

follow-up (Styne 2017).

Intragastric Space Occupying Mechanisms

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, intragastric balloon (IGB) 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 suggests 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.

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).

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.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates bariatric surgery and endoscopic bariatric devices as medical devices. All bariatric surgery and endoscopic bariatric devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Apr 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Apr 27]

Adjustable Gastric Bands

- LAP-BAND (BioEnterics/Allerga/ReShape): Premarket approval (PMA) 2001, with expanded indication in 2011 allowing use in adults with BMI ≥30 with a comorbidity.
- REALIZE Band (Ethicon Endo-Surgery): PMA approved in 2007 for adults with BMI ≥40 or ≥35 with a comorbidity.

Intragastric Balloons/Space-Occupying Devices

- ORBERA (Apollo): PMA approved in 2015 for adults with BMI 30–40 as a temporary implant requiring removal at 6 months.
- ReShape Integrated Dual Balloon (ReShape Medical): PMA approved in 2015 for adults with BMI 30–40 as a temporary (remove at 6 months).
- Obalon Balloon System (Obalon): PMA approved in 2016 for adults with BMI 30–40 as a temporary implant.
- Allurion/ Elipse Swallowable Balloon (Allurion): FDA-approved in February 2026.
- TransPyloric Shuttle (TPS) (BAROnova): PMA approved in 2019 for BMI 35–40 or 30–34.9 with a comorbidity, indicated for up to 12 months of treatment.

Endoluminal Suturing/Tissue Approximation

- OverStitch (Apollo Endosurgery): 510(k)-cleared endoscopic suturing system for tissue approximation/ligation in the GI tract.
- StomaphyX (EndoGastric Solutions): 510(k)-cleared device in 2008 for trans-oral tissue approximation/ligation in the GI tract.

Not Approved for U.S. Marketing

- EndoBarrier (GI Dynamics): Not FDA-approved for commercial use in the U.S.

- TOGA System (Satiety): Not FDA-approved for U.S. marketing.
- AspireAssist (Aspire Bariatrics): PMA approved in 2016, but withdrawn from the U.S. market effective April 8, 2022, for business, not safety/effectiveness, reasons.

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
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)

Code	Description
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
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 2026 Apr 21]

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.

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- 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	
05/18/00, 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, 05/21/26	
Date	**Summary of Changes**
05/21/26	• Annual review, policy intent unchanged.
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.
05/18/00	• Original effective date