# Bariatric Surgery

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➲ Instructions for Use

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**Related Community Plan Policies**

- Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases
- Obstructive and Central Sleep Apnea Treatment
- Robotic Assisted Surgery Policy, Professional

**Commercial Policy**

- Bariatric Surgery

## Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

| State | Policy/Guideline |
|---|---|
| Idaho | Bariatric Surgery (for Idaho Only) |
| Indiana | None |
| Kansas | Bariatric Surgery (for Kansas Only) |
| Kentucky | Bariatric Surgery (for Kentucky Only) |
| Nebraska | Bariatric Surgery (for Nebraska Only) |
| New Jersey | Bariatric Surgery (for New Jersey Only) |
| New Mexico | Bariatric Surgery (for New Mexico Only) |
| North Carolina | Bariatric Surgery (for North Carolina Only) |
| Ohio | Bariatric Surgery (for Ohio Only) |
| Pennsylvania | Bariatric Surgery (for Pennsylvania Only) |
| Tennessee | Bariatric Surgery (for Tennessee Only) |

## Coverage Rationale

**The following bariatric surgical procedures are proven and medically necessary for treating obesity:**

- Biliopancreatic diversion/biliopancreatic diversion with duodenal switch
- Gastric bypass (includes robotic-assisted gastric bypass)
- Adjustable gastric banding (using open or laparoscopic approaches) for individuals ≥ 18 years of age; refer to the U.S. Food and Drug Administration (FDA) section for additional information
- Sleeve gastrectomy (vertical sleeve gastrectomy)

**In adults aged 18 years or older, bariatric surgery using one of the procedures identified above for treating obesity is proven and medically necessary when all the following criteria are met:**

- **One** of the following:
  - Body Mass Index (BMI) of ≥ 40 kg/m$^2$ (or BMI ≥ 37.5 kg/m$^2$ in individuals of Asian descent); or


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- BMI of ≥ 35 to 39.9 kg/m$^2$ (or BMI ≥ 32.5-37.4 kg/m$^2$ in individuals of Asian descent) in the presence of one or more of the following comorbidities:
  - Insulin resistance or type 2 diabetes; or
  - Cardiovascular disease [e.g., history of stroke and/or myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy), coronary artery disease, hyperlipidemia]; or
  - History of cardiomyopathy; or
  - Obstructive Sleep Apnea confirmed on polysomnography with an Apnea-Hypopnea Index or Respiratory Disturbance Index of ≥ 30; or
  - Evidence of Metabolic Dysfunction–Associated Steatotic Liver Disease; or
  - Idiopathic intracranial hypertension (pseudotumor cerebri)

  and
- The individual must also meet the following criteria:
  - **Both** of the following:
    - Completion of a preoperative evaluation that includes a detailed weight history, along with dietary and physical activity patterns; and
    - Psychosocial-behavioral evaluation by an individual, who is professionally recognized as part of a behavioral health discipline, to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome

    or
  - Participation in a Multidisciplinary surgical preparatory regimen

**In adolescents aged 12 to 17 years, the bariatric surgical procedures identified above are proven and medically necessary for treating obesity when all the following criteria are met:**
- One of the following:
  - Class III obesity; or
  - Class II obesity in the presence of one or more of the following comorbidities:
    - Insulin resistance or type 2 diabetes; or
    - Poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy); or
    - Hyperlipidemia; or
    - Obstructive Sleep Apnea confirmed on polysomnography, with an Apnea-Hypopnea Index or Respiratory Disturbance Index of ≥ 30; or
    - Evidence of Metabolic Dysfunction–Associated Steatotic Liver Disease; or
    - Idiopathic intracranial hypertension (pseudotumor cerebri)

  and
- The individual must also receive an evaluation at or in consultation with a Multidisciplinary center focused on the surgical treatment of severe childhood obesity; this may include adolescent centers that have received accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program or can demonstrate similar programmatic components

**A planned two-stage procedure is proven and medically necessary when all the following criteria are met:**
- Initial BMI of ≥ 50 kg/m$^2$ prior to first-stage bariatric procedure; and
- Second stage occurs within 2 years following the primary bariatric surgery procedure; and
- Individual has been adherent to nutrition and exercise; and
- Individual meets medical necessity criteria listed above at the time of the second-stage procedure

**Revisional Bariatric Surgery using one of the procedures identified above is proven and medically necessary when due to a technical failure or major complication from the initial procedure; potential failure/complications include but are not limited to the following:**
- Bowel perforation (including adjustable gastric band erosion)
- Adjustable gastric band migration (slippage) that cannot be corrected with manipulation or adjustment (records must demonstrate that manipulation or adjustment to correct band slippage has been attempted)
- Leak
- Obstruction (confirmed by imaging studies)
- Staple-line failure
- Mechanical adjustable gastric band failure


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- Uncontrollable reflux related to sleeve gastrectomy when all the following criteria are met:
  - Maximum nonpharmacological medical management failure (e.g., positional, dietary modification, behavioral changes); and
  - Maximum pharmacological medical management failure (e.g., at least 1 month of double-dose proton pump inhibitor, H2 blocker, and/or sucralfate); and
  - Severe esophagitis (grade C or D) confirmed by endoscopy despite maximum medical management

**Removal of an adjustable gastric band and all related components, which does not result in a revisional surgery, is proven and medically necessary.**

**The following procedures are unproven and not medically necessary for treating obesity due to insufficient evidence of efficacy:**
- Revisional Bariatric Surgery for any other indication than those listed above
- Bariatric surgery as the primary treatment for any condition other than obesity
- Bariatric interventions for the treatment of obesity, including but not limited to:
  - Bariatric artery embolization
  - Gastric electrical stimulation with an implantable gastric stimulator
  - Laparoscopic greater curvature plication, also known as total gastric vertical plication
  - Mini-gastric bypass/laparoscopic mini-gastric bypass/one-anastomosis gastric bypass
  - Silastic ring vertical gastric bypass
  - Single-anastomosis duodenal switch (also known as duodenal switch with single anastomosis or stomach intestinal pylorus-sparing surgery)
  - Transoral endoscopic surgery, including:
    - Endoscopic sleeve gastroplasty (includes OverStitch™)
    - Gastrointestinal liners
    - Intragastric balloon
    - Transoral outlet reduction (TORe)
    - TransPyloric Shuttle device
  - Vagus nerve blocking (VBLOC®)

# Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

# Definitions

**Asian**: Refers to origins from the Far East, Southeast Asia, or the Indian subcontinent (e.g., Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, Vietnam) (United States Census Bureau, 2012).

**Body Mass Index**: A person's weight in kilograms divided by the square of height in meters. Body Mass Index (BMI) can be used as a screening tool but is not diagnostic of the body fatness or health of an individual (Centers for Disease Control and Prevention, 2017).

The National Heart, Lung, and Blood Institute's Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults classifies the ranges of BMI in adults as follows:
- < 18.5 kg/m$^2$ – Underweight
- 18.5 to 24.9 kg/m$^2$ – Normal Weight
- 25 to 29.9 kg/m$^2$ – Overweight
- 30 to 34.9 kg/m$^2$ – Obesity Class I
- 35 to 39.9 kg/m$^2$ – Obesity Class II
- ≥ 40 kg/m$^2$ – Obesity Class III

The American Society for Metabolic and Bariatric Surgery (Pratt et al., 2018) classifies severe obesity in adolescents as follows:
- Class II obesity – 120% of the 95th percentile height or an absolute BMI of 35 to 39.9 kg/m$^2$, whichever is lower*
- Class III obesity – 140% of the 95th percentile height or an absolute BMI of ≥ 40 kg/m$^2$, whichever is lower


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*Also as defined by the American Heart Association (Kelly et al., 2013).

**Los Angeles Classification of Oesophagitis**:
- Grade A: One (or more) mucosal break no longer than 5 mm that does not extend between the tops of two mucosal folds
- Grade B: One (or more) mucosal break more than 5 mm long that does not extend between the tops of two mucosal folds
- Grade C: One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but which involves less than 75% of the circumference
- Grade D: One (or more) mucosal break that involves at least 75% of the esophageal circumference

(Lundell et al., 1999)

**Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD)**: Condition that is evidenced by hepatic steatosis, diagnosed either by imaging or histology, without any other cause of steatosis, and in combination with one of the following:
- BMI of ≥ 25 kg/m$^2$ (23 kg/m$^2$ Asia), waist circumference of > 94 cm (M) or > 80 cm (F), or ethnicity-adjusted equivalent
- Fasting serum glucose of ≥ 5.6 mmol/L (100 mg/dL), 2-hour postload glucose level of ≥ 7.8 mmol/L (≥ 140 mg/dL), hemoglobin $A_{1c}$ of ≥ 5.7% (39 mmol/L), type 2 diabetes, or treatment for type 2 diabetes
- Blood pressure of ≥ 130/85 mm Hg or specific antihypertensive drug treatment
- Plasma triglycerides of ≥ 1.70 mmol/L (150 mg/dL) or lipid-lowering treatment
- Plasma high-density lipoprotein cholesterol of ≤ 1.0 mmol/L (40 mg/dL) (M) and ≤ 1.3 mmol/L (50 mg/dL) (F) or lipid-lowering treatment

(Rinella et al., 2023)

**Multidisciplinary**: Bariatric center or regimen combining or involving several academic disciplines or professional specializations in an approach to create a well-trained, safe, and effective environment for the complex bariatric individual. Building the Multidisciplinary team includes staff such as the bariatric surgeon, obesity medicine specialist, registered dietician, specialized nursing professionals, behavioral health specialist, exercise specialist, and support groups (American Society for Metabolic and Bariatric Surgery Textbook of Bariatric Surgery).

**Obstructive Sleep Apnea**: The American Academy of Sleep Medicine defines Obstructive Sleep Apnea as a sleep-related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. Obstructive Sleep Apnea severity is defined as:
- Mild for Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of ≥ 5 and < 15
- Moderate for AHI or RDI of ≥ 15 and ≤ 30
- Severe for AHI or RDI of > 30/hour

For additional information, refer to the Medical Policy titled Obstructive and Central Sleep Apnea Treatment.

**Revisional Bariatric Surgery**:
- Conversion – A second bariatric procedure that changes the bariatric approach from one procedure to a different type of procedure (e.g., sleeve gastrectomy, adjustable gastric band converted to Roux-en-Y gastric bypass). Note: This is not the same as an intraoperative conversion (i.e., converting from laparoscopic approach to an open procedure)
- Corrective – A procedure that corrects or modifies the anatomy of a previous bariatric procedure to achieve the original desired outcome or correct a complication. These procedures also address device manipulation (e.g., gastric pouch resizing, resleeve gastrectomy, limb length adjustments in Roux-en-Y gastric bypass, gastric band replacement)
- Reversal – A procedure that restores original anatomy

(Mirkin et al., 2021)

# Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.


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**Coding Clarification**: Utilize CPT code 43775 to report laparoscopic sleeve gastrectomy rather than the unlisted CPT code 43659.

| CPT Code | Description |
|---|---|
| 0813T | Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon |
| 43290 | Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon |
| 43291 | 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 | Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption |
| 43647 | Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum |
| 43648 | Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum |
| 43659 | Unlisted laparoscopy procedure, stomach |
| 43770 | Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components) |
| 43771 | Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only |
| 43772 | Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only |
| 43773 | Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only |
| 43774 | Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components |
| 43775 | Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy) |
| 43843 | Gastric restrictive procedure, without gastric bypass, for morbid obesity; 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 | Gastric restrictive procedure, with gastric bypass for morbid obesity; 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 |
| 43881 | Implantation or replacement of gastric neurostimulator electrodes, antrum, open |
| 43882 | Revision or removal of gastric neurostimulator electrodes, antrum, open |
| 43886 | Gastric restrictive procedure, open; revision of subcutaneous port component only |
| 43887 | Gastric restrictive procedure, open; removal of subcutaneous port component only |
| 43888 | Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only |
| 43889 | Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed |
| 43999 | Unlisted procedure, stomach |


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| CPT Code | Description |
|---|---|
| 64590 | Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver |
| 64595 | Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array |
| 64999 | Unlisted procedure, nervous system |

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# Description of Services

## Obesity

Obesity is defined clinically using the Body Mass Index (BMI). Obesity is a significant health concern due to its high prevalence and associated health risks.

Health consequences associated with obesity include hypertension, type 2 diabetes, hyperlipidemia, atherosclerosis, heart disease, stroke, diseases of the gallbladder, liver disease, osteoarthritis, Obstructive Sleep Apnea, and other respiratory problems. In addition, certain cancers are more prevalent in obese individuals, including endometrial, ovarian, breast, prostate, colon, renal cell carcinoma, and non-Hodgkin lymphoma.

The U.S. Preventive Services Task Force recommends screening all adults for obesity. Clinicians should offer or refer individuals with a BMI of 30 kg/$m^2$ or higher to intensive, multicomponent behavioral interventions (U.S. Preventive Services Task Force, 2012).

## Bariatric Surgery in the Adolescent Population

For adolescents, physical development and maturation may be determined using the gender-specific growth chart and BMI chart developed by the Centers for Disease Control and Prevention, National Center for Health Statistics.

## First-Line Treatments for Obesity

First-line treatments for obesity include dietary therapy, physical activity, behavior modification, and medication management, all of which have often been unsuccessful in long-term weight management for obese individuals (Lannoo and Dillemans, 2014).

## Bariatric Surgical Procedures

The goal of surgical treatment for obesity is to induce significant weight loss and thereby reduce the incidence or progression of obesity-related comorbidities and improve quality of life. The purpose of performing bariatric surgery in adolescent individuals is to reduce the lifelong impact of severe obesity.

Surgical treatment of obesity offers two main weight loss approaches: restrictive and malabsorptive. Restrictive methods are intended to cause weight loss by restricting the amount of food that can be consumed by reducing the size of the stomach. Malabsorptive methods are intended to cause weight loss by limiting the amount of food that is absorbed from the intestines into the body. A procedure can have restrictive features, malabsorptive features, or both. The surgical approach can be open or laparoscopic. The clinical decision on which surgical procedure to use is made based on a medical assessment of the individual's unique situation.

### *Roux-en-Y Bypass/Gastric Bypass*

The Roux-en-Y bypass (RYGB) procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum.

### *Laparoscopic Adjustable Gastric Banding*

The laparoscopic adjustable gastric banding procedure involves placing an inflatable silicone band around the upper portion of the stomach. The silicone band contains a saline reservoir that can be filled or emptied under fluoroscopic guidance to change the caliber of the gastric opening.

### *Vertical Sleeve Gastrectomy*

Vertical sleeve gastrectomy (VSG) can be performed as part of a two-staged approach to surgical weight loss or as a stand-alone procedure. A VSG involves the removal of 60% to 75% of the stomach, leaving a narrow gastric "tube" or


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“sleeve.” This small remaining “tube” cannot hold as much food and produces less of the appetite-regulating hormone ghrelin, lessening an individual’s desire to eat. VSG is not a purely malabsorptive procedure, so lifetime nutritional supplementation is not required (California Technology Assessment Forum, 2015).

## *Biliopancreatic Diversion With Duodenal Switch (Also Known as the Scopinaro Procedure)*

Biliopancreatic diversion is primarily malabsorptive but has a temporary restrictive component. As seen with RYGB, three "limbs" of intestine are created: one through which food passes, one that permits emptying of fluids (e.g., bile) from digestive organs, and a common limb through which both food and digestive fluids pass. This procedure involves removal of the greater curvature of the stomach instead of the distal portion. The two limbs meet in a common channel that measures only 50 to 100 cm, thereby permitting relatively little absorption.

## *Robotic-Assisted Surgery*

Robotic surgery provides surgeons with three-dimensional vision and increased dexterity and precision by downscaling the surgeon's movements, enabling a fine tissue dissection and filtering out physiological tremor. It overcomes the restraint of torque on ports from a thick abdominal wall and minimizes port site trauma by remote center technology (Bindal et al., 2015).

## *Transoral Endoscopic Surgery*

Transoral endoscopic surgery is an option being explored for bariatric surgery. Natural orifice transluminal endoscopic surgery is performed via a natural orifice (e.g., mouth, vagina) and, in some cases, eliminates the need for abdominal incisions. This form of surgery is being investigated as an alternative to conventional surgery.

Transoral restorative obesity surgery is another endoscopic procedure. The endoscope, with four channels, is inserted into the esophagus and then the stomach. Specialized instruments are placed through the channels to create multiple folds around the existing stoma to reduce the diameter.

The TransPyloric Shuttle device is a nonballoon, space-occupying device with a 12-month treatment duration that is proposed as a new endoscopic bariatric therapy. The TransPyloric Shuttle device comprises a spherical silicone bulb connected to a smaller cylindrical silicone bulb by a flexible tether; it is delivered to and removed from the stomach using transluminal endoscopic procedures in the outpatient setting (Marinos et al., 2014). The device was granted U.S. Food and Drug Administration premarket approval on April 16, 2019, and was approved for up to 12 months of weight loss therapy in individuals with a BMI of 35.0 to 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. The device is intended to be used in conjunction with a diet and behavior modification program (ECRI, 2019).

Endoscopic sleeve gastroplasty is a minimally invasive technique through the mouth that uses an endoscopic suturing device (e.g., OverStitch) to reduce gastric capacity by sealing off most of the stomach, forcing ingested food through an open tube of stomach tissue that connects the esophagus to the small intestine. Endoscopic sleeve gastroplasty is similar to a laparoscopic sleeve gastrectomy, in which the stomach is manipulated to create a tube shape; however, no stomach tissue is removed.

## *Laparoscopic Mini-Gastric Bypass/One-Anastomosis Gastric Bypass*

Laparoscopic mini-gastric bypass/one-anastomosis gastric bypass involves the construction of a gastric tube by dividing the stomach vertically, down to the antrum. As in RYGB, food does not enter the distal stomach. However, unlike gastric bypass surgery, digestive enzymes and bile are not diverted from the stomach after laparoscopic mini-gastric bypass/one-anastomosis gastric bypass. This can lead to bile reflux gastritis, which can cause pain that is difficult to treat.

## *Implantable Gastric Stimulator*

An implantable gastric stimulator is a small, battery-powered device, which is similar to a cardiac pacemaker, that is in a small pocket and created beneath the skin of the abdomen using laparoscopy. The implantable gastric stimulator is programmed externally using a controller that sends radiofrequency signals to the device. Although the exact mechanism of action is not yet understood, gastric stimulation is thought to target ghrelin, an appetite-related peptide hormone (Gallas and Fetissov, 2011).

## *Vagus Nerve Blocking Neurostimulation Therapy*

Vagus nerve blocking neurostimulation therapy uses an implanted subcutaneous neurostimulator to deliver electrical pulses to the vagus nerve, which may suppress appetite (ECRI, 2016).


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Vagus nerve blocking neurostimulation therapy is designed to target the multiple digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

### *Intragastric Balloon*

Intragastric balloons are acid-resistant balloons that are inserted into the stomach and expanded with saline or air. These space-occupying devices promote weight loss by creating a feeling of fullness, which can lead to reduced consumption of food. The devices are intended as an adjunct to diet, exercise, and behavioral counseling for the treatment of obesity (Hayes, 2021). Available clinical data and manufacturer recommendations indicate that 6 months is the current standard duration of therapy from insertion to removal (American Society for Metabolic and Bariatric Surgery, 2016).

### *Laparoscopic Greater Curvature Plication (Also Known as Total Gastric Vertical Plication)*

Laparoscopic greater curvature plication is a restrictive procedure that involves folding and suturing the stomach onto itself to decrease the size of the stomach; it requires no resection, bypass, or implantable device. This procedure is a modification of the gastric sleeve, which requires surgical resection of stomach.

### *Bariatric Artery Embolization*

Bariatric artery embolization is a minimally invasive procedure, which is the percutaneous, catheter-directed, transarterial embolization of the left gastric artery. The procedure is performed by an interventional radiologist and targets the fundus that produces the majority of the hunger-controlling hormone ghrelin. Beads placed inside the vessels purportedly help decrease blood flow and limit the secretion of ghrelin to minimize feelings of hunger to initiate weight loss.

### *Gastrointestinal Liners*

Gastrointestinal liners, such as the EndoBarrier™ system, use a sleeve that is endoscopically implanted into the stomach to reduce the stomach size. The sleeve is then removed after weight loss has been achieved. The EndoBarrier is not approved by the U.S. Food and Drug Administration for use in the United States; it is limited by federal law to investigational use only.

### *Single-Anastomosis Duodenal Switch*

Single-anastomosis duodenal switch (SADS), also called single-anastomosis loop duodenal switch, single-anastomosis duodeno-ileal bypass with sleeve gastrectomy, and stomach intestinal pylorus-sparing surgery, is a modification of biliopancreatic diversion with duodenal switch. SADS consists of a sleeve gastrectomy to remove most of the stomach and an intestinal bypass to shorten the length of the small intestine and to allow bile and pancreatic digestive juices to mix with the food. SADS is typically performed laparoscopically as an inpatient procedure.

### *Revisional Surgery*

The indications for Revisional Bariatric Surgery vary greatly depending on the index procedure performed and nature of the complication. Some complications may be encountered during the acute postoperative recovery period (leaks, abscesses, fistulae, etc.). Prior to revisional surgery, individuals should undergo a thorough Multidisciplinary assessment and consideration of their individual risks and benefits with revisional surgery (Brethauer et al., 2014). It is important to determine if the poor response to primary bariatric surgery is due to anatomical causes that led to inadequate weight loss or weight regain or to the individual's postoperative behavior, such as not following the prescribed diet and lifestyle changes (e.g., consuming large portions, high-calorie foods, and/or snacks between meals, not exercising). Uncontrollable reflux may be a complication experienced by some individuals; first-line therapy for individuals who experience gastroesophageal reflux disease after bariatric surgery includes dietary and lifestyle modification and alcohol and smoking cessation, followed by acid-reducing medications (King et al., 2021).

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) is a national accreditation standard for bariatric surgery centers. In 2012, the American College of Surgeons and American Society for Metabolic and Bariatric Surgery combined their individual accreditation programs into a single unified program. The MBSAQIP works to advance safe, high-quality care for bariatric surgical individuals through the accreditation of bariatric surgical centers. A bariatric surgical center achieves accreditation following a rigorous review process, during which it proves that it can maintain certain physical resources, human resources, and standards of practice. All accredited centers report their outcomes to the MBSAQIP database (MBSAQIP, 2019).


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In 2025, the By-Band-Sleeve Collaborative Group conducted a multicenter, open-label, three-group randomized controlled trial (RCT) evaluating the efficacy of adjustable gastric banding, Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy for severe obesity. The primary outcomes were excess weight loss (EWL) of ≥ 50% and quality of life (QOL) at 3 years. There were 1,346 participants, of whom 462 were in the RYGB group, 464 were in the adjustable gastric banding group, and 420 were in the sleeve gastrectomy group. There were 1,159 participants remaining at the 3-year follow-up. There were 163 who did not undergo surgery, mainly due to participant choice. Of those participants randomized to RYGB, 276 (68%) achieved at least 50% EWL at 3 years compared with 97 of 383 (25%) in the adjustable gastric banding group and 141 of 342 (41%) in the sleeve gastrectomy group. When comparing the risk between groups in relation to the predefined 12% noninferiority margin, both RYGB and sleeve gastrectomy were noninferior (and superior) to adjustable gastric banding, and sleeve gastrectomy was inferior to RYGB for weight loss. At 3 years, the mean utility score for the EQ-5D-5L was significantly higher with RYGB and sleeve gastrectomy than with adjustable gastric banding. The difference in QOL between sleeve gastrectomy and RYGB at 3 years was not significant. The mean percentage of total weight loss (TWL) at 3 years was -26.8% for RYGB, -14.0% for adjustable gastric banding, and -19.4% for sleeve gastrectomy. There were 1,905 adverse events (AEs) reported during the trial, of which 242 occurred between randomization and surgery. AE rates from 30 days post surgery to 3 years were significantly lower following sleeve gastrectomy compared with RYGB and adjustable gastric banding. The proportion of serious AEs (SAEs) was similar between RYGB and sleeve gastrectomy. Complications related to the technical aspects of surgery included internal hernia repairs after RYGB [in 15 of 389 (4%)], leaks from the staple line following sleeve gastrectomy [in three of 429 (1%)], and revision operations comprising correction, removal, or conversion to another procedure following adjustable gastric banding [in 52 of 363 (14%)]. Six of the 429 participants (1%) receiving sleeve gastrectomy developed esophagitis, one (< 1%) had a hiatal hernia repair, and four (< 1%) were subsequently converted to RYGB. The authors concluded that RYGB led to loss of more excess weight, improved QOL, and resulted in a greater reduction in comorbidities than adjustable gastric banding or sleeve gastrectomy over 3 years. Limitations of the study include the fact that baseline measurements were taken at 5 months before surgery; some participants did not have surgery; blinding was not feasible, as the surgeries required a different postoperative care schedule; data completeness for secondary outcomes was low; and the time (6 years) to complete trial recruitment was prolonged.

In a 2025 systematic review and meta-analysis of RCTs, Monteiro Delgado et al. compared the long-term efficacy and safety of RYGB and sleeve gastrectomy. The primary outcomes measured were EWL, TWL, and excess body mass index (BMI) loss. The secondary outcomes included diabetes remission, hemoglobin $A_{1c}$ ($HbA_{1c}$) levels, obesity-related comorbidities, complications (early minor, late minor, early major, and late major), and procedure-related mortality. There were nine RCTs, with ≥ 5 years of follow-up included and 1,489 individuals, of whom 747 received sleeve gastrectomy and 742 received RYGB. RYGB resulted in significantly greater EWL [mean difference (MD), -14.00%; 95% CI, -20.65% to -7.35%; $p < 0.0001$; $I^2 = 53\%$], TWL (MD, -5.73%; 95% CI, -8.62% to -2.84%; $p = 0.0001$; $I^2 = 70\%$), and excess BMI loss (MD, -7.44%; 95% CI, -10.54% to -4.34%; $p < 0.0001$; $I^2 = 0\%$) than sleeve gastrectomy. Type 2 diabetes (T2D) remission was higher in the RYGB group [risk ratio (RR), 0.74; 95% CI, 0.57-0.96; $p = 0.0229$; $I^2 = 0\%$], although $HbA_{1c}$ levels were similar between groups. Gastroesophageal reflux disease (GERD) improvement was significantly higher in the RYGB group (RR, 0.48; 95% CI, 0.31-0.74; $p = 0.0009$; $I^2 = 0\%$); however, there were no significant differences between sleeve gastrectomy and RYGB in dyslipidemia, hypertension, obstructive sleep apnea (OSA) syndrome, or joint pain improvement. Sleeve gastrectomy was associated with significantly lower late major complications (RR, 0.41; 95% CI, 0.20-0.85; $p = 0.0170$; $I^2 = 59\%$), while early minor, early major, and late minor complications did not differ significantly between procedures. The authors concluded that RYGB is associated with greater long-term weight loss, improved T2D remission, and superior GERD control compared with sleeve gastrectomy; however, sleeve gastrectomy showed a lower incidence of late major complications. Both sleeve gastrectomy and RYGB were comparable for the remaining outcomes. The authors noted that the findings highlight the importance of considering both safety and efficacy in the context of individual patient characteristics, rather than focusing solely on weight loss. Limitations of the study include significant heterogeneity in several outcomes and insufficient data, which limited the ability to perform a subgroup analysis and assess publication bias; additionally, due to the long-term nature of the study, there was substantial loss to follow-up, which is expected of long-term studies.

Khalaj et al. (2020) conducted a cohort study comparing gastric bypass with sleeve gastrectomy and the effectiveness and safety of these two procedures. The authors evaluated 2,202 participants who underwent laparoscopic sleeve gastrectomy (LSG) and 1,085 participants who underwent laparoscopic gastric bypass. The sleeve gastrectomy procedure was performed over a 36-F bougie and reinforced with an omental pouch; the gastric bypass procedure was performed as either RYGB or one-anastomosis gastric bypass (OAGB). Evaluation of weight loss included BMI change, percentage of TWL, and percentage of EWL. T2D, hypertension, and dyslipidemia, as obesity-associated comorbidities, were assessed in all participants. No major complications were identified, which were defined as a return to the operating room, prolonged hospital stays beyond 7 days, or the need for readmission. QOL was assessed using the Iranian version


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of the Short Form Health Survey, which measures physical, social, and mental aspects of health. Participant follow-up for both types of procedures occurred at 6, 12, and 24 months after surgery. The authors found no significant differences between the two surgical groups; participants who underwent sleeve gastrectomy had a lower fasting plasma glucose level and $HbA_{1C}$ level than the gastric bypass group. BMI was not significantly different between the two groups. The percentage of EWL was 61.9% ±15.7%, 74.8% ±19.1%, and 75.0% ±21.9% in the sleeve gastrectomy group and 62.7% ±15.3%, 77.5% ±18.4%, and 80.1% ±20.8% in the gastric bypass group at the 6-, 12-, and 24-month follow-ups, respectively. All comorbidities and QOL improved. The authors concluded that bariatric surgery is effective and safe for the treatment of obesity; while both procedures are effective for weight loss, remission of obesity-associated comorbidities, and QOL, sleeve gastrectomy is associated with fewer complications and nutritional deficiencies.

O'Brien et al. (2019) performed a systematic review and meta-analysis on 33 reports containing 10 or more years of follow-up in individuals who underwent bariatric surgery. The authors evaluated the long-term effectiveness of RYGB, laparoscopic adjustable gastric banding (LAGB), or biliopancreatic diversion with duodenal switch (BPD/DS). Results for gastric bypass surgery showed a weighted mean percentage of EWL of 56.7% at 10 or more years, with a mean of 55.4% EWL. Eleven reports addressing BPD/DS showed a mean of 74.1% EWL, and two reports for sleeve gastrectomy showed a mean of 57.0% EWL. A longitudinal cohort study in the individuals receiving LAGB showed that weight loss reached a peak at the 2-year follow-up and remained relatively stable through the next 18 years, with a mean weight loss of 24.8 kg, representing 47.2% EWL. The authors concluded that RYGB, LAGB, and BPD/DS led to substantial weight loss that continued for at least 10 years. Due to the education of individuals and lap band design changes, revisional surgery has decreased significantly in the past 11 years. The findings are limited by the lack of direct comparison between techniques and lack of comparison groups that were not undergoing surgical treatments. (The following publications, previously cited in this policy, are included in this systematic review: Maciejewski et al., 2016, Salminen et al., 2018, Schauer et al., 2017, Sethi et al., 2016, Sheikh et al., 2017, Topart et al., 2017, and Vinzens et al., 2017.)

Zhao and Jiao (2019) conducted a systematic review to determine whether laparoscopic RYGB (LRYGB) and LSG are equivalent for mid- and long-term weight loss and resolution of comorbidities and AEs. Eleven RCTs were included in the meta-analysis, and the authors found no significant difference in EWL between LRYGB and LSG or any significant difference in T2D improvement. This analysis identified more postoperative early complications with LRYGB but no difference between the two procedures in the later postoperative period. Future studies should focus on the comparison of complications and comorbidities. Limitations include the variation in sample size among the included studies, which may have created bias; variation in the age of the individuals; preoperative BMI, which may have led to heterogeneity; and failure of the subgroup analysis for reoperation rate. Additional studies are needed to determine the relative long-term efficacy of different bariatric surgeries. (The publication by Salminen et al., 2018, previously cited in this policy, is included in this systematic review.)

Polega et al. (2017) conducted a matched cohort study of laparoscopic BPD/DS and sleeve gastrectomy to compare 30-day outcomes. Of the 741 individuals who underwent BPD/DS or sleeve gastrectomy, two cohorts of 167 individuals each were matched for age, sex, and BMI. Length of stay was longer in the BPD/DS cohort (2.5 ±.9 days vs 2.1 ±.7 days; $p < 0.001$). No significant differences were observed between the groups in relation to 30-day postoperative rates of leak (0.3% vs 0.6%; $p > 0.99$), bleed (0% vs 0.3%; $p > 0.99$), reoperation (1.2% vs .6%; $p > 0.99$), and readmission (3% vs 1.2%; $p = 0.45$). No mortalities occurred. After matching for age, sex, and BMI, the authors found no significant differences between BPD/DS and sleeve gastrectomy with regard to 30-day postoperative rates of leak, bleed, reoperation, readmission, and mortality.

Xie et al. (2016) prospectively evaluated Apnea-Hypopnea Index and Functional Outcomes of Sleep Questionnaire (FOSQ) scores prior to and post operation in participants undergoing bariatric surgery. A total of 167 participants were studied. The median age was 46 (14-75) years, and the median BMI was 49 (36-69) $kg/m^2$. Overall, 92 participants (55.0%) were diagnosed with OSA prior to the operation. In total, 50 (54.0%) required positive airway pressure (PAP) therapy. The mean reduction in BMI post bariatric surgery was 12.2 ±4.52 $kg/m^2$ at 6.56 ±2.70 months. Overall, 80 (87.9%) reported improved sleep quality, which was reflected in improved scores in all domains of the FOSQ ($p < 0.001$; paired t test). Improvement in FOSQ scores remained significant ($p < 0.05$) in those with or without OSA. In total, 39 participants (90.7%) discontinued PAP due to resolution of daytime sleepiness. In conclusion, the authors identified that weight loss following bariatric surgery has a positive impact on sleep in individuals with or without OSA. However, the findings are limited by a lack of a comparison group without bariatric surgery.

Magallares et al. (2015) conducted a meta-analysis of 21 studies evaluating the mental and physical health-related QOL measures with the 36-Item Short Form Health Survey (SF-36) before and after bariatric surgery. The study authors reported that obese individuals scored less in the mental health component of the SF-36 prior to bariatric surgery (n = 2,680) compared with after surgery (n = 2,251). Similar results were observed in the physical health component of the SF-


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36. The study authors concluded that obese individuals experienced strong improvement in mental and physical QOL measures following surgery. The findings are limited by the lack of a comparison group.

## Biliopancreatic Diversion/Biliopancreatic Diversion With Duodenal Switch

Kapeluto et al. (2020) assessed long-term glycemic outcomes in 132 individuals with T2D who received BPD/DS surgery vs other bariatric surgeries. The inclusion criteria consisted of individuals with a diagnosis of T2D and those who had undergone a BPD/DS surgical procedure. Follow-up of individuals consisted of postsurgical assessments at week 3, then at 4, 8, 12, 18, and 24 months, and annually thereafter. Overall, 15 individuals died during the 10 years of follow-up, and two more died beyond 10 years. In total, 90% of the individuals had clinical remission of their diabetes; three individuals had partial remission, 21 had improvement, and three were unchanged in their status. The authors found that BPD/DS maintained a remission rate of 10 years post operation in the vast majority of individuals with advanced diabetes. The authors concluded that individuals who underwent BPD/DS had positive results for long-term benefits for remission of T2D and that earlier referral for this type of surgery should be made. Limitations include late arrival of the standard use of the $HbA_{1C}$ test, incomplete weight parameters due to the lack of self-reported weights, and the retrospective analysis.

Strain et al. (2017) reported 9-year outcomes with BPD/DS. Initially, 284 individuals received BPD/DS; 275 individuals (69.8% women) aged 42.7 years, with a BMI of 53.4 $kg/m^2$, qualified for the baseline analysis. Overall, 275 individuals were available in year 1; 275 in year 3; 273 in year 5; 259 in year 7; and 228 in year 9. Gender distribution was not different. The BMI was 30.1 $kg/m^2$ at 1 year and 32.0 $kg/m^2$ at 9 years. Body fat was reduced to 26% after 2 years. Nutritional problems developed in 29.8% of individuals during observation. Significant positive changes in QOL were observed between baseline and year 1 in most individuals. Data showed that after surgery, the resolution of comorbidities continued in the 9-year follow-up period. Weight loss during the first year was well maintained; comorbidities resolved, and QOL improved. According to the authors, rates of surgical complications resemble those with other bariatric procedures; however, long-term nutritional deficiencies are of concern. The findings are limited by the lack of a comparison group.

## Gastric Bypass (Roux-en-Y; Gastrojejunal Anastomosis)

Ikramuddin et al. (2018) conducted an observational follow-up of a multicenter, randomized clinical trial involving 120 participants with T2D who had an $HbA_{1C}$ of 8.0% or greater and a BMI between 30.0 and 39.9 $kg/m^2$. Lifestyle-intensive medical management intervention was based on the Diabetes Prevention Program and Look AHEAD trials for 2 years, with and without (60 participants each) RYGB, followed by observation to year 5. Overall, 98 participants (82%) completed 5 years of follow-up. At 5 years, 13 participants (23%) in the gastric bypass group and two (4%) in the lifestyle-intensive medical management group had achieved the composite triple end point (difference, 19%; 95% CI, 4%-34%; p = 0.01). In the fifth year, 31 participants (55%) in the gastric bypass group vs eight (14%) in the lifestyle-medical management group achieved an $HbA_{1c}$ of less than 7.0% (difference, 41%; 95% CI, 19%-63%; p = 0.002). Participants undergoing RYGB had more SAEs than the group receiving lifestyle medical management intervention; 66 events vs 38 events, respectively, occurred and were most frequently gastrointestinal events and surgical complications such as strictures, small bowel obstructions, and leaks. The authors concluded that in this participant population, a significantly better composite triple end point in the surgical group remained at 5 years. However, because the effect size diminished over 5 years, further follow-up is needed to understand the durability of the improvement. One limitation included a poorly controlled glycemic group of participants; therefore, it is unclear if the study results would be the same in a group of better-controlled glycemic participants. Additional limitations include the incomplete follow-up, creating opportunity for bias, and testing of a single type of bariatric surgery; therefore, it is not possible to apply conclusions to other bariatric surgical approaches.

In a matched observational cohort study, Liakopoulos et al. (2017) evaluated 6,132 individuals, with a baseline BMI of 42 $kg/m^2$ and T2D who underwent RYGB, compared with individuals who had not undergone RYGB. Over a 6-year follow-up period, beneficial changes in BMI, $HbA_{1c}$, blood lipid levels, and blood pressure were seen compared with controls. The authors concluded that improvements in risk factors might contribute to the reduction of mortality risk after RYGB in obese individuals with T2D, but the main effect seems to be mediated through a decrease in BMI, which could serve as a proxy for several mechanisms.

In a retrospective analysis, Jirapinyo et al. (2017) evaluated the Bariatric Quality of Life scores in 56 patients who underwent RYGB. The enrolled patients were divided into two groups, stable weight and weight regain, with a review of the Bariatric Quality of Life scores for each. The authors found that in addition to a return to comorbid illness, weight regain was associated with worsening QOL; this shows the importance of close follow-up, early recognition, and intervention. Limitations include the lack of an established definition of weight regain in the current literature, imbalance of weight regain and weight-stable patients, and retrospective nature of the study.


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In a systematic review and meta-analysis, Yan et al. (2016) compared RYGB surgery vs medical treatment for T2D in obese individuals. Six RCTs, with a total of 410 individuals with obesity and T2D, were included, and follow-up ranged from 12 to 60 months. The pooled analysis of T2D remission rates revealed a significantly higher remission rate after RYGB surgery than after medical treatment alone. The meta-analysis showed a significantly lower BMI in individuals who underwent RYGB than those who received medical therapy alone. Based on the results, the authors concluded that RYGB surgery is superior to medical treatment for short- to medium-term remission of T2D, improvement of metabolic condition, and cardiovascular risk factors. The authors recommended well-designed studies, with a consistent definition of AEs as well as a larger number of RCTs with long-term follow-up (> 60 months), to evaluate the safety of and long-term benefits with RYGB surgery in obese individuals with T2D.

Cooper et al. (2015) assessed weight loss and occurrence of weight regain among participants (n = 300) at 1 year of follow-up who underwent RYGB at a single institution. The mean weight regain in all participants was 23.4% of maximum weight loss. Using categorical analysis, the mean weight regain in the < 25%, 25% to 30%, 30% to 35%, and > 35% weight loss cohorts was 29.1%, 21.9%, 20.9%, and 23.8%, respectively. Excessive weight regain, defined as ≥ 25% of total lost weight, occurred in 37% of participants. Despite the percentage of weight loss in the first year, all cohort participant groups regained, on average, between 21% and 29% of lost weight. Excessive weight gain was experienced by over one-third of participants. Greater initial absolute weight loss leads to more successful long-term weight outcomes.

## Robotic-Assisted Gastric Bypass Surgery

Leang et al. (2024) conducted a systematic review and meta-analysis to evaluate the perioperative outcomes in individuals with obesity undergoing robotic gastric bypass vs laparoscopic gastric bypass surgery. Overall, 28 studies (one RCT, one prospective study, and 26 retrospective studies), comprising 82,155 individuals, were included. Robotic bypass surgery (RBS) was performed in 9,051 individuals; 73,104 underwent laparoscopic bypass surgery. The outcomes assessed included overall and intraoperative complication rates, anastomotic leak and stricture, surgical site infection, reoperation rates within 30 days, mortality, and hospital length of stay. The secondary outcomes included operative time, estimated blood loss, conversion, and readmission rates. The results showed that of the 26 articles reporting overall complications, no differences occurred. In the 10 that reported intraoperative complications, no differences occurred between the procedures. No significant differences were seen in anastomotic leak or stricture, surgical site infection, and hospital length of stay. Mortality was not statistically different in the 26 articles reporting on this outcome. The reoperation rate within 30 days was reported by 16 articles and showed RBS with a higher rate of 4.4% compared with 3.4% for laparoscopic bypass surgery. The secondary outcomes also showed no significant differences, but heterogeneity among reporting this outcome was present. The authors concluded that no significant differences in outcomes exist between the two procedures, with RBS findings at a risk of bias. Prospective trials to validate the advantages and limitations of robotic bariatric surgery are needed. (The publication by Ayloo et al., 2016, previously cited in this policy, is included in this systematic review.)

Beckmann et al. (2020) conducted a retrospective analysis of 108 LRYGB surgeries and 114 robotic RYGB surgeries, which were performed between 2016 and 2019. The analysis found that operation time for the robotic RYGB was significantly shorter; robotic RYGB had less complications, and fewer revisions were required when robotic surgery was used. The authors concluded that robotic RYGB surgery is safe and effective. The findings are limited by the lack of randomization.

## Laparoscopic Adjustable Gastric Banding

LAGB is a proven bariatric surgical intervention with demonstrated short-term efficacy and an established safety profile. However, long-term outcomes have shown that weight loss durability with LAGB is inferior compared with that with other proven bariatric procedures, such as sleeve gastrectomy and RYGB. Multiple long-term studies and registry data indicate higher rates of weight regain, band-related complications, and the need for intervention or revision surgery in individuals who undergo LAGB. Given these considerations, individuals should be fully informed of the comparative long-term effectiveness and reintervention risks of LAGB during preoperative counseling. Shared decision-making should emphasize realistic expectations regarding weight loss and resolution of comorbidity durability and the potential need for future procedures. Appropriate selection of individuals remains critical, with careful consideration of individual clinical characteristics, adherence capacity, and long-term follow-up requirements when LAGB is contemplated as a treatment option.

In a longitudinal case series, Mistry et al. (2018) reported changes in glycemic control, blood pressure, and lipids 5 years following LAGB combined with medical care in individuals with T2D. A total of 200 individuals [age, 47 ±9.7 years; BMI, 52.8 ±9.2 kg/m$^2$; $HbA_{1c}$, 7.9% ±1.9% (62.8 mmol/mol); women, n = 123 (61.5%); insulin treatment, n = 71 (35.5%)] were included. The mean follow-up was 62.0 ±13.0 months (range, 18-84 months). Significant reductions in body weight [-24.4% ±12.3% (38 ±22.7 kg)], $HbA_{1c}$ (-1.4% ±2.0%), systolic blood pressure (-11.7 ±23.5 mm Hg), and total cholesterol


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and triglyceride levels were observed. The proportion of individuals who required insulin reduced from 36.2% to 12.3%. The overall band complication rate was 21% (21 individuals). The authors concluded that LAGB, when combined with multidisciplinary medical care, significantly improved metabolic outcomes in individuals with T2D, independent of diabetes duration, and baseline BMI over 5 years. Diabetes duration and baseline BMI did not predict changes in glycemic control, blood pressure, or lipids following LAGB. The findings are limited by the lack of a comparison group.

Froylich et al. (2018) conducted a retrospective case series of LAGB in 74 patients. The mean age at LAGB placement was 50.5 ±9.6 years, and the mean BMI was 45.5 ±4.8 kg/m$^2$. Preoperative comorbidities were diabetes (13.5%), hypertension (32%), hyperlipidemia (12.1%), OSA (5.4%), joints disease (10.8%), mood disorders (5.4%), and GERD symptoms (8.1%). The mean follow-up was 162.96 ±13.9 months; 44 patients (59.4%) had their band removed, and 22 (30%) had another bariatric surgery. The follow-up BMI was 35.7 ±6.9 kg/m$^2$ ($p < 0.001$), and the percentage of TWL was 21.0% ±0.13%. No improvement in any of the comorbidities was observed. GERD symptoms worsened at the long-term follow-up ($p < 0.001$). Undergoing another bariatric procedure was associated with greater weight loss (odds ratio, 12.8; 95% CI, 1.62-23.9; $p = 0.02$). LAGB required removal in the majority of patients and showed poor resolution of comorbidities, with worsening of GERD-related symptoms. In the authors' opinion, individuals who go on to have another bariatric procedure have more durable weight loss outcomes.

In a retrospective case series, Khoraki et al. (2018) reported long-term outcomes in a cohort of 208 patients who underwent LAGB. Complete follow-up was available for 90% at 1 year (186 of 207), 80% at 5 years (136 of 171), and 71% at 10 years (10 of 14). The percentage of EWL at 1, 5, and 10 years was 29.9%, 30%, and 16.9%, respectively. LAGB failure occurred in 118 patients (57%), and 48 (23.1%) required reoperation. A higher baseline BMI was the only independently associated factor (odds ratio, 1.1; 95% CI, 1.0-1.1; $p = 0.016$).

Giet et al. (2018) conducted a retrospective study in 2,246 patients who underwent LAGB. Patients were followed up for a minimum of 2 years and up to 9 years post procedure. Operative mortality was zero, and no in-hospital reoperations occurred. The mean preoperative weight and BMI were 111.2 ±22.1 kg and 39.9 ±6.7 kg/m$^2$, respectively. The mean percentage of excess BMI loss at 1, 2, 5, and 8 years of follow-up was 43.1% ±25.4%, 47.9% ±31.9%, 52.4% ±41.7%, and 57.1% ±28.6%, respectively. No significant difference in the mean percentage of excess BMI loss was observed between those < 50 or ≥ 50 years old ($p = 0.23$) or between patients with an initial BMI of < or ≥ 50 kg/m$^2$ ($p = 0.65$). Complications over 9 years occurred in 130 patients (5.8%) and included 39 (1.7%) slippage or pouch dilatations, two (0.04%) erosions, and 76 (3.4%) complications related to the access port or LAGB tubing. The overall reoperation rate with LAGB complications was 4.2% over 9 years, with an LAGB explantation rate of 1.5%. Overall, 39 LAGBs were converted to a sleeve or gastric bypass procedure, with 11 of these due to complications.

Vinzens et al. (2017) evaluated long-term results in 405 individuals (age, 41 ±10 years) with a BMI of 44.3 ±6 kg/m$^2$ who were treated with LAGB. The mean follow-up was 13 ±3 years, with a follow-up rate of 85% (range, 8-18 years), corresponding to 343 individuals. Overall, 100 individuals exceeded the 15-year follow-up. In 216 individuals (63%), sleeve gastrectomy, gastric bypass, or BPD/DS was performed as revisional surgery. In total, 27 individuals (8%) refused revisional surgery after band removal. Finally, 100 individuals (29%) still had the band in place at the final follow-up, with a mean BMI of 35 ±7 kg/m$^2$, corresponding to an excess BMI loss of 48% ±27%. According to the Bariatric Analysis and Reporting Outcome System, the failure rate was 25%, and 50% had a good to excellent outcome. The authors concluded that more than 10 years after LAGB, 71% of individuals lost their bands, and only 15% of the 343 individuals who were followed up with the band in place had a good to excellent result. The findings are limited by the lack of a comparison group.

## Sleeve Gastrectomy (Vertical Gastrectomy)

Clapp et al. (2018) conducted a meta-analysis to evaluate long-term (7 or more years) outcomes with LSG. Nine studies met the inclusion criteria, with a total of 2,280 individuals included initially. Only 652 individuals had completed ≥ 7 years of follow-up. At ≥ 7 years, the long-term weight recidivism rate was estimated to be 27.8% ($I^2 = .60\%$; 95% CI, 22.8%-32.7%), with a range of 14% to 37%. The overall revision rate was estimated to be 19.9% ($I^2 = 93.8\%$; 95% CI, 11.3%-28.5%). This was broken down into 13.1% ($I^2 = 93.8\%$; 95% CI, 5.6%-20.6%) due to weight regain (five studies) and 2.9% ($I^2 = 60.8\%$; 95% CI, 1%-4.9%) due to GERD (five studies). Based on available data up to the beginning of 2017, in the authors' opinion, bariatric surgeons should be aware of the long-term outcomes with sleeve gastrectomy, especially regarding revisions and weight regain. (The publication by Noel et al., 2017, previously cited in this policy, is included in this systematic review.)

Felsenreich et al. (2017) evaluated long-term outcomes and complications following sleeve gastrectomy. Overall, 53 individuals did not have symptomatic reflux or hiatal hernia prior to the operation, and of the 43 individuals available for follow-up, six (14.0%) were converted to RYGB due to intractable reflux over a period of 130 months. Ten of the remaining nonconverted individuals (n = 26) also experienced symptomatic reflux. Gastroscopies revealed de novo hiatal


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hernias in 45% of the individuals and Barrett metaplasia in 15%. Sleeve gastrectomy individuals with symptomatic reflux scored significantly higher on the Reflux Symptom Index (p = 0.04) and significantly lower on the Gastrointestinal Quality of Life Index (p = 0.02) questionnaire. This study shows a high incidence of Barrett esophagus and hiatal hernias at more than 10 years after sleeve gastrectomy. Therefore, these results suggest maintaining preexisting large hiatal hernia, GERD, and Barrett esophagus as relative contraindications to sleeve gastrectomy. The limitations of this study, including its small sample size as well as the fact that it was based on early experience with sleeve gastrectomy, make drawing any general conclusions about this procedure inconclusive.

Fløl o et al. (2017) presented 5-year outcomes after vertical sleeve gastrectomy (VSG), including complications and revisions, weight change, obesity-related diseases, and health-related QOL. Of 168 operated individuals (mean age, 40.3 ±10.5 years; 71% female), 92% completed the 2-year follow-up, and 82% completed the 5-year follow-up. Reintervention for complications occurred in four individuals, whereas revisional surgery was performed in six individuals for weight regain and in one individual for GERD. BMI decreased from 46.2 ±6.4 kg/m$^2$ at baseline to 30.5 ±5.8 kg/m$^2$ at 2 years and 32.9 ±6.1 kg/m$^2$ at 5 years. Remission of T2D and hypertension occurred in 79% and 62% at 2 years and 63% and 60% at 5 years, respectively. The percentage of individuals treated for GERD increased from 12% prior to the operation to 29% at 2 years and 35% at 5 years. Preventing weight regain and GERD is an important consideration with this procedure. The findings are limited by the lack of a comparison group.

Nocca et al. (2017) reported 5-year outcomes in a cohort of 1,050 individuals who underwent sleeve gastrectomy (mean preoperative BMI was 44.58 kg/m$^2$), either as a primary or revisional surgical procedure. The overall preoperative rate was 6.8%, and the most common late complication was GERD (39.1%). After 3, 4, and 5 years of LSG, the average percentage of excess BMI loss was 75.95% (±29.16%; 382 individuals), 73.23% (±31.08%; 222 individuals), and 69.26% (±30.86%; 144 individuals), respectively. The success rate at 5 years was 65.97% (95 individuals). The improvement and remission of comorbidities was found in 88.4% and 57.2% of individuals with diabetes, respectively; 76.9% and 19.2% of individuals with hypertension; and 98% and 85% of individuals with sleep apnea syndrome. The authors concluded that the 5-year results are very convincing for sleeve gastrectomy, although GERD is the main long-term complication. The findings are limited by the lack of a comparison group.

El Chaar et al. (2017) evaluated the incidence, indications, and outcomes with revisional surgery following LSG in adult patients. Overall, 630 LSGs were performed, and 481 patients were included in the analysis (mean age, 46.2 years; mean BMI, 44.3 kg/m$^2$; 79.5% female; 82.3% White). Twelve of 481 patients underwent conversion to a different bariatric procedure due to inadequate weight loss, GERD, or both. Six of the 12 patients with GERD-related symptoms and failed medical management underwent conversion to RYGB following preoperative wireless Bravo pH monitoring (Given Imaging) to confirm the diagnosis objectively. The other six of 12 patients with inadequate weight loss underwent either RYGB or BPD/DS based on personal choice. Overall, nine of 12 patients underwent conversion to RYGB, and three of 12 underwent conversion to BPD/DS. The median time from the initial surgery to conversion was 27 months (range, 17-41 months). The median operating room time was 168 minutes (range, 130-268 minutes). The median length of stay was 48 hours (range, 24-72 hours). The follow-up rate at 3 months was 100% (12 of 12 patients). The authors concluded that conversion to RYGB or BPD/DS may be done safely and effectively in individuals following LSG who have refractory GERD or inadequate weight loss. Longer-term outcomes are needed. The findings are limited by the lack of a comparison group.

Brethauer et al. (2009) performed a systematic review (36 studies) of the evidence on sleeve gastrectomy as a primary or staged procedure. Studies included a single nonrandomized, matched cohort analysis; RCTs (two studies); and uncontrolled case series (33 studies). Of these studies, 13 differentiated that the sleeve gastrectomy was used as a staged procedure or as a management strategy in a high-risk population of individuals. Those individuals who underwent sleeve gastrectomy as a planned staged procedure went on to undergo RYGB or BPD/DS within 2 years of sleeve gastrectomy after improvement of their comorbidities and surgical risk status. The mean BMI in all 36 studies was 51.2 kg/m$^2$. The mean baseline BMI was 46.9 kg/m$^2$ among the high-risk individuals (range, 49.1-69.0 kg/m$^2$) and 60.4 kg/m$^2$ among the primary sleeve gastrectomy individuals (range, 37.2-54.5 kg/m$^2$). The follow-up period ranged from 3 to 60 months. The mean percentage of EWL after sleeve gastrectomy reported in 24 studies was 33% to 85%, with an overall mean percentage of EWL of 55.4%. The mean postoperative BMI was reported in 26 studies and decreased from a baseline mean of 51.2 to 37.1 kg/m$^2$ post operation. Improvement or remission of T2D was found in more than 70% of individuals. Significant improvements were also seen in hypertension and hyperlipidemia as well as in sleep apnea and joint pain. The mean complication rate for a primary procedure was 6.2%, while the mean complication rate for a high-risk/staged procedure was 9.4%. The overall mortality rate in all studies was 0.19%, which included 0.24% for a high-risk/staged procedure. Despite the high surgical risk in this population of individuals, reported complication rates were acceptably low. The authors concluded that sleeve gastrectomy is an effective weight loss procedure that can be performed safely as a first-stage or primary procedure. Limitations include the lack of long-term follow-up in the high-risk


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group, mainly due to individuals who refused a second-stage operation or had sufficient weight loss and comorbidity reduction with sleeve gastrectomy alone.

## Revisional Surgery

In a 2025 Hayes Health Technology Assessment evaluating revisional bariatric surgery with RYGB following a failed primary sleeve gastrectomy for weight loss, it was noted that there is an overall low-quality body of evidence that revisional RYGB may provide clinically significant weight loss after failed sleeve gastrectomy. There is insufficient evidence to evaluate RYGB relative to other available revisional bariatric procedures.

In a Hayes (2025) Health Technology Assessment, open or laparoscopic revisional bariatric surgery (LRBS) for weight loss following failed primary RYGB was evaluated for safety and efficacy. They noted that there is an overall very low-quality body of evidence that is insufficient to draw conclusions regarding the effectiveness of any specific type of revisional bariatric surgery in individuals with inadequate weight loss or who regained weight after primary RYGB. For safety, low-quality evidence suggests that revisional bariatric surgeries are moderately safe but with numerous and sometimes serious complications, including a high rate of revision or reversal surgeries.

Axer et al. (2023) conducted a systematic review to compare revisional procedures for weight nonresponse after sleeve gastrectomy. The primary outcomes included weight change after revisional surgery, measured as BMI, percentage of total body weight loss (TBWL), percentage of EWL, or percental excess BMI loss. Twelve studies were included in the review, which included 1,046 individuals. No RCTs were included; two studies were at serious risk of bias, and 10 studies were at critical risk of bias. Due to the significant variations in inclusion criteria, benchmarks, follow-up, and outcomes measurements, a meaningful comparison of results was not possible, and evidence-based treatment strategies for weight nonresponse after sleeve gastrectomy cannot be established. The authors noted that prospective studies, with well-defined indications, techniques, and adherence to outcomes measurements, are needed.

In a 2023 systematic review and meta-analysis, Ataya et al. assessed the outcomes with revisional procedures (RYGB and OAGB) following a failed LSG. The primary outcome was the total percentage of weight loss following the revisional surgery. The secondary outcomes included overall weight loss, diabetes remission, and postoperative complications. Seven articles, comprising 404 individuals who underwent OAGB and 413 who underwent RYGB, were included: five retrospective studies, one randomized trial, and one case-cohort study. The results showed a significantly greater rate of diabetes remission in the OAGB group in four separate studies that reported this in 130 individuals. However, both procedures have a significant ability to achieve this. TWL after revisional surgery was measured in four studies, which showed a more pronounced body weight reduction. Similarly, the global TWL was reported in five studies, which showed significantly greater weight loss in the OAGB group. The rate of complications was reported in five articles and showed seven in the RYGB group compared with four in the OAGB group, which was not considered statistically significant. Postoperative GERD was significantly higher in the OAGB group, and no significant differences in the development of Barrett esophagus were observed. The authors concluded that for individuals who achieve insufficient weight loss or weight regain following sleeve gastrectomy, OAGB and RYGB are safe and effective. The systematic review and meta-analysis is limited by a relatively small sample size and limited relevant publications. Furthermore, reports of long-term outcomes differed among the included studies, which limits the conclusions of long-term outcomes. Further research is needed to validate these findings.

Chierici et al. (2022) conducted a systematic review and meta-analysis to identify which revisional bariatric surgery performs best after a failed primary restrictive surgery. A literature search was conducted using the Embase, PubMed, Cochrane Library, and Scopus databases, which returned 39 retrospective and prospective comparative studies. The inclusion criteria included individuals undergoing revisional bariatric surgery after a failed primary restrictive surgery of LAGB, vertical banded gastroplasty (VBG), or sleeve gastrectomy. The authors confirmed that sleeve gastrectomy continues to have a low rate of immediate postoperative complications. The authors found that duodenal switch and biliopancreatic diversion were superior when it came to percentage of EWL and percentage of TWL but not free from the risk of weight regain. Secondary sleeve gastrectomy ensures the lowest rate of early and late complications compared with single-anastomosis duodeno-ileal bypass (SADI) and OAGB, but it also provides the worst benefits for either 1- and 3-year percentage of EWL and percentage of TWL; therefore, it should not be considered when planning revisional surgery unless there are exceptional circumstances that warrant its use. RYGB is the most frequently performed revisional surgery following a primary bariatric procedure; however, this approach has not always been justified in terms of weight loss compared with sleeve gastrectomy. In addition, RYGB is more frequently associated with early and late complications than sleeve gastrectomy, OAGB, and SADI. Finally, the authors found that the most balanced procedures were OAGB and SADI; these two procedures were determined to have 21.16% and 14.66% more EWL, respectively, after 3 years. Limitations include the retrospective design, surgical intervention allocation bias, heterogeneity, and lack of evaluation of important outcomes like GERD or malabsorption, which could affect the individual's QOL. (The publication by Qiu et al., 2018, previously cited in this policy, is included in this systematic review.)


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Koh et al. (2020) performed a systematic review and meta-analysis to examine the impact that revisional bariatric surgery has on obesity-related metabolic outcomes. The analysis included a review of 33 articles, which included 1,593 individuals. The outcomes examined included improvement of diabetes, hypertension, hyperlipidemia, and OSA. The surgeries used for revision included sleeve gastrectomy, RYGB, pouch revision, duodenal switch, and mini-gastric bypass (MGB). The authors found that 92% of the individuals had improvement in their diabetes, 81% had improvement in hypertension, and 86% had improvement in OSA. The authors concluded that revisional bariatric surgery improved outcomes in individuals and should be considered in individuals with persistent metabolic disease after primary bariatric surgery. Limitations include the lack of RCTs, lack of long-term outcomes, and significant heterogeneity.

Janik et al. (2019) assessed the safety of revisional surgery to LSG compared with LRYGB after failed LAGB. Converted LSG cases were matched (1:1) with converted LRYGB individuals by age (±year), BMI (±kg/$m^2$), sex, and comorbidities, including diabetes, hypertension, hyperlipidemia, venous stasis, and sleep apnea. A total of 2,708 individuals (1,354 matched pairs) were included in the study. The mean operative time in conv-LRYGB individuals was significantly longer than that in conv-LSG individuals (151 ±58 vs 113 ±45 minutes; $p < 0.001$). No mortality was observed in either group. Individuals after conv-LRYGB had a clinically increased anastomotic leakage rate (2.07% vs 1.18%; $p = 0.070$) and significantly increased bleed rate (2.66% vs 0.44%; $p < 0.001$). The 30-day readmission rate was significantly higher in conv-LRYGB individuals (7.46% vs 3.69%; $p < 0.001$), as was the 30-day reoperation rate (3.25% vs 1.26%; $p < 0.001$). The length of hospital stay was longer with conv-LRYGB. The authors concluded that a single-stage conversion of failed LAGB leads to greater morbidity and higher complication rates when converted to LRYGB vs LSG in the first 30 days post operation. These differences are particularly notable with regard to bleed events, 30-day reoperation, 30-day readmission, operative time, and hospital stay.

Dardamanis et al. (2018) conducted a retrospective comparative study of primary vs revisional LRYGB (rLRYGB) for insufficient weight loss after VBG or adjustable gastric banding. Overall, 342 LRYGB operations were performed; 245 were primary, and 97 were revisional. The median follow-up was 30 months (range, 0-108 months). The mean BMI (kg/$m^2$) before bypass was 45.2 with primary LRYGB (pLRYGB) and 41.1 with rLRYGB. The median operative time and length of stay were longer with rLRYGB: 157.5 vs 235 minutes ($p < 0.001$) and 6 vs 6.5 days ($p = 0.05$). Conversion to laparotomy was performed in eight patients: 0.4% of primary and 7.2% of revisional. The morbidity rate was 6.5% with pLRYGB vs 10% with rLRYGB (NS). One death occurred in the primary group. The percentage of excess BMI loss was significantly lower in the revisional group at 12, 18, and 24 months of follow-up. The authors concluded that revisional and primary gastric bypass have no statistical differences in terms of morbidity. The percentage of excess BMI loss is lower after revisional gastric bypass during the first 2 years of follow-up. The trend of weight loss or weight regain was similar in both groups.

Altieri et al. (2018) reported the rate of revisions/conversions (RCs) in individuals who originally underwent RYGB, LSG, or LAGB. Individuals were followed up for at least 4 years. Overall, 40,994 bariatric procedures occurred, with 16,444 LAGBs, 22,769 RYGBs, and 1,781 LSGs. The rate of RCs was 26.0% for LAGB, 9.8% for sleeve gastrectomy, and 4.9% for RYGB. Multiple RCs were more common with LAGB (5.7% with LAGB, 0.5% with RYGB, and 0.2% with LSG). Those with band revision/replacements required further procedures compared with individuals who underwent conversion to RYGB/sleeve gastrectomy (939 compared with 48 procedures). The majority of RCs were not performed at the initial institution (68.2% of LAGB individuals, 75.9% with RYGB, and 63.7% with sleeve gastrectomy). Risk factors for multiple procedures included surgery type, as LAGB was more likely to have multiple RCs. The authors concluded that reoperation was common with LAGB but less common with RYGB (4.9%) and sleeve gastrectomy (9.8%). The RC rate was almost twice after sleeve gastrectomy than after RYGB. LAGB had the highest rate (5.7%) of multiple reoperations. Conversion was the procedure of choice after failed LAGB.

Gray et al. (2018 conducted a retrospective review in adult patients undergoing LRBS or robotic revisional bariatric surgery (RRBS). A total of 84 patients who underwent LRBS (n = 66) or RRBS (n = 18) were included. The index operation was adjustable gastric banding in 39 of 84 (46%), sleeve gastrectomy (VSG) in 23 of 84 (27%), RYGB in 13 of 84 (16%), and VBG in nine of 84 (11%). Among patients undergoing conversion from adjustable gastric banding (n = 39), no difference in operative time, length of stay, or complications by surgical approach was observed. Among patients undergoing conversion from a stapled procedure (n = 45), the robotic approach was associated with a shorter length of stay (5.8 ±3.3 vs 3.7 ±1.7 days; $p = 0.04$), with equivalent operative time and postoperative complications. Three leaks occurred in the LRBS group, and none occurred in the RRBS group ($p = 0.36$). Major complications occurred in three of 39 patients (8%) undergoing conversion from adjustable gastric banding and two of 45 patients (4%) undergoing conversion from a stapled procedure ($p = 0.53$), with no difference by surgical approach. RRBS is associated with a shorter length of stay than LRBS in complex procedures and has at least an equivalent safety profile. Long-term follow-up data are anticipated.


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In a retrospective review of pLRYGB vs rLRYGB after failed LSG, Malinka et al. (2017) evaluated 3-year outcomes. No significant differences in patient demographics or median BMI (kg/m$^2$) were observed with pLRYGB or rLRYGB (42.8 ±12.1 vs 42.3 ±11.5, respectively; p = 0.748). Coexisting comorbidities were rated similarly in both groups. At 3 years, the percentage of EWL (74.4% ±23.3% vs 52.0% ±26%, respectively; p = 0.007) was higher with pLRYGB than rLRYGB, while similar improvements in coexisting comorbidities could be observed. The authors concluded that rLRYGB is a feasible and practical surgical approach that allows effective weight loss at 3 years of follow-up and alleviates refractory reflux symptoms. Although weight loss is lower compared with that with pLRYGB, resolution of and improvement in coexisting comorbidities appear similar. According to the authors, rLRYGB appears to be a reliable procedure to address failure after LSG.

Pinto-Bastos et al. (2017) conducted a systematic review of preoperative surgery following the failure of primary bariatric surgery. The etiology of reasons for undergoing a second surgery includes medical (e.g., fistula, ulcer disease) and behavioral aspects. Eating and lifestyle behaviors, difficulty embracing the required lifestyle changes, and reappearance of depressive and anxious symptoms have been associated with failure of weight loss or weight regain after primary surgeries. The authors recommended that particular attention be paid to surgical candidates with a history of difficulties with engaging in healthy eating patterns.

In a retrospective review, Fulton et al. (2017) evaluated outcomes of revisional bariatric surgery in 2,769 patients. The mean preoperative BMI was 44.7 ±9.5 kg/m$^2$ in revision patients compared with 45.7 ±7.6 kg/m$^2$ in primary bariatric surgery patients. Most revision patients had prior VBG (48%) or LAGB (24%). Bands were removed in 36% of all LAGB patients presenting to the clinic. Of the 134 procedures performed in the revision clinic, 83 were bariatric weight loss surgeries, and 51 were band removals. Revision clinic patients experienced a significant decrease in BMI (from 44.7 ±9.5 kg/m$^2$ to 33.8 ±7.5 kg/m$^2$; p < 0.001); their BMI at the 12-month follow-up was similar to that of primary clinic patients (34.5 ±7.0 kg/m$^2$; p = 0.7). The authors identified that complications were significantly more frequent in revision patients than primary patients (41% vs 15%; p < 0.001).

Sharples et al. (2017) conducted a systematic review and meta-analysis of outcomes after revisional bariatric surgery. Overall, 2,617 individuals in 36 studies underwent either adjustable gastric banding to RYGB (B-RYGB) or band to sleeve gastrectomy (B-SG). No difference between the B-RYGB and B-SG groups in morbidity, leak rate, or return to surgery was observed. The percentage of EWL following the revisional procedure in all individuals combined at 6, 12, and 24 months was 44.5%, 55.7%, and 59.7%, respectively. No statistical difference in the percentage of EWL between B-RYGB and B-SG was observed at any time point. The rates of remission of diabetes, hypertension, and OSA were 46.5%, 35.9%, and 80.8%, respectively. Available observational evidence suggests that revisional bariatric surgery is associated with outcomes similar to those experienced after primary surgery. Further high-quality research, particularly RCTs, is required to assess long-term weight loss, comorbidity, and QOL outcomes.

Tran et al. (2016) conducted a systematic review of 24 studies, including 866 individuals, to evaluate outcomes with and complications of different surgical methods of revision that were done after failed primary RYGB. All individuals in the studies reported significant early initial weight loss after revisional surgery. However, of the five surgical revision options considered, BPD/DS, distal RYGB, and gastric banding resulted in sustained weight loss, with what is considered by the authors as an acceptable complication rate.

## Pediatric and Adolescent Bariatric Surgery

Hoeltzel et al. (2021) evaluated adolescent bariatric surgeries from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database from 2015 to 2018. Patients included those 19 years old or younger, with a BMI of ≥ 30 kg/m$^2$, who underwent LRYGB or sleeve gastrectomy. The primary outcomes included mortality and overall complications; the secondary outcomes included rates of readmission and reoperation. A total of 5,068 patients met the inclusion criteria for the study, with 78.5% being female and 70.4% being White. Patients between the ages of 10 and 14 years comprised 1.5% of those included; 18.5% were aged 15 to 17 years, and 79.9% were aged 18 to 19 years. The mean BMI was 47.3 kg/m$^2$, and the most prevalent comorbidities were hypertension, OSA, GERD, and diabetes. The 30-day analysis following surgery demonstrated intraoperative or postoperative complications in only 1.2% of patients and the deaths of two patients, which were likely due to internal hernia. The authors concluded that bariatric surgery for adolescents is a safe and effective procedure, with a low complication rate. They recommended future robust studies to evaluate the long-term outcomes in this age group.

Alqahtani et al. (2021) analyzed the long-term results and AEs associated with LSG in children and adolescents with severe obesity. Overall, 2,504 children and adolescents who underwent LSG between 2008 and 2021 were enrolled in the program. Weight loss was reported in terms of mean weight change, percentage of weight lost, percentage of EWL, change in BMI, and BMI-for-age percentile, along with assessment of comorbid conditions. The mean SD percentage of EWL for 1 to 3 years was 82.3%, for 4 to 6 years was 76.3%, and for 7 to 10 years was 71.1%; 10-year results


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demonstrated that 30% of total weight was lost permanently. Prior to surgery, 263 participants were diagnosed with T2D and 227 with dyslipidemia; 377 had hypertension. After more than 7 years of follow-up, complete remission was observed in 188 participants with T2D, 130 participants with dyslipidemia, and 219 participants with hypertension. Only 1% of the participants were readmitted in the first 90 days after the operation; two participants had a staple-line leak, and 22 were readmitted with nausea and vomiting. The data showed no significant change in growth velocity, including among participants aged younger than 14 years. The authors concluded that long-term follow-up after LSG in children and adolescents demonstrates positive weight loss and comorbidity resolution. However, the findings are limited by the lack of a comparison group.

Lainas et al. (2020) conducted a study to assess whether bariatric surgery is successful in adolescents under the age of 18 years. The authors evaluated 84 adolescent patients (57 female, 27 male) who underwent LSG. Surgical postoperative care included blood work and diet restrictions, with discharge when an oral diet was well tolerated. Patient follow-up included four outpatient visits in the first year and then annually; complete metabolic screening was performed at 3 months, again at 1 year, and annually thereafter. QOL was evaluated prior to surgery using the French version of the SF-36 questionnaire, which assessed general health, physical function, social function, emotional and mental status, and bodily pain. The scoring ranged from 0 to 100, with higher scores indicating better well-being. All patients were contacted 1 year post surgery to answer the same questions. The comorbidities assessed included hypertension, T2D, OSA, dyslipidemia, arthralgia, and GERD. According to the authors, the study showed that LSG is a safe and effective procedure for individuals under the age of 18 years and results in significant weight loss, comorbidity remission, and improvement in QOL. In addition, adherence to the medical team's direction was considered an essential component for successful treatment in this group of patients. Limitations include a small sample size; retrospective design; substantial loss to follow-up, which affected long-term outcomes; and lack of a comparison group.

A Hayes (2019; updated 2022) Comparativeness Effective Review for bariatric surgeries for the treatment of obesity in adolescents analyzed 19 studies that compared adjustable gastric banding, VSG, and RYGB. The authors concluded that while the body of evidence is moderate in size with a low quality overall, these surgical procedures are superior to medical management for promoting weight loss and improving obesity-related comorbidities in adolescents. Adjustable gastric banding was inferior to the others, but all three types are associated with a low to moderate risk of postoperative complications and show similar efficacy.

Inge et al. (2018) compared glycemic control in cohorts of severely obese adolescents with T2D undergoing medical and surgical interventions. Participants in the Teen-Longitudinal Assessment of Bariatric Surgery (LABS) group (n = 242) underwent a primary bariatric procedure, while those in the Youth TODAY consortia (n = 699) were randomized to receive medication alone or an intensive lifestyle intervention. After selection of 30 participants from Teen-LABS with diabetes [mean (SD) age at baseline, 16.9 (1.3) years; 21 (70%) female; 18 (66%) White], 63 matched controls from TODAY were selected [mean (SD) age at baseline, 15.3 (1.3) years; 28 (44%) female; 45 (71%) White], and the two groups were compared. During the 2 years, the mean $HbA_{1c}$ concentration decreased from 6.8% (95% CI, 6.4%-7.3%) to 5.5% (95% CI, 4.7%-6.3%) in Teen-LABS and increased from 6.4% (95% CI, 6.1%-6.7%) to 7.8% (95% CI, 7.2%-8.3%) in TODAY. Compared with baseline, the BMI decreased by 29% (95% CI, 24%-34%) in Teen-LABS and increased by 3.7% (95% CI, 0.8%-6.7%) in TODAY. Overall, 23% of Teen-LABS participants required a subsequent operation during the 2-year follow-up. Compared with medical therapy, surgical treatment of severely obese adolescents with T2D was associated with better glycemic control, reduced weight, and improvement of other comorbidities. According to the authors, these data support the need for a well-designed, prospective, controlled study to define the role of surgery for adolescents with T2D, including health and surgical outcomes.

Ryder et al. (2018) evaluated the factors associated with long-term weight loss maintenance following bariatric surgery in adolescents (n = 50) with severe obesity who underwent RYGB. Follow-up visits occurred at 1 year and at a visit between 5 and 12 years following surgery [Follow-Up of Adolescent Bariatric Surgery at 5 Plus Years (FABS-5+)]. A nonsurgical comparison group (n = 30; mean ±SD age, 15.3 ±1.7 years; mean ±SD BMI, 52 ±8 kg/$m^2$) was recruited to compare weight trajectories over time. The BMI in the surgical group declined from baseline to 1 year (-38.5 ±6.9%), which, despite some regain, was largely maintained until FABS-5+ (-29.6 ±13.9% change). The BMI in the comparison group increased from baseline to the FABS-5+ visit (+10.3 ±20.6%). When the surgical group was split into maintainers and regainers, no differences in weight-related and eating behaviors, health responsibility, physical activity/inactivity, and dietary habits were observed between groups. However, at the FABS-5+ visit, maintainers had greater overall QOL scores than regainers (87.5 ±10.5 vs 65.4 ±20.2; $p < 0.001$) and in each QOL subdomain ($p < 0.01$ for all).

In a retrospective review of 79 adolescents who underwent LSG, Elhag et al. (2018) assessed preoperative levels and postoperative changes in four anthropometric, 15 nutritional, and 10 cardiometabolic parameters. At a mean of 24.2 months post LSG, significantly reduced mean weight and BMI by 51.82 ±28.1 kg and 17 ±6.24 kg/$m^2$, respectively, were observed. The highest prevalence of post-LSG deficiencies pertained to vitamin D, albumin, and ferritin (89.3%, 38%, and


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33.3%, respectively). Low hemoglobin levels (29.3%) were reported only in female patients. Trace elements were not deficient. Significant reductions in the percentage of adolescents with elevated low-density lipoprotein (LDL; from 66.1% to 38.9%), alanine aminotransferase (from 45.3% to 10.9%), and aspartate aminotransferase (from 24.1% to 8.6%) levels were reported. Finally, 100% remission of prediabetes cases and 80% remission of T2D cases were observed. The slight worsening of preexisting nutritional deficiencies warrants careful preoperative surveillance and appropriate postoperative nutritional supplementation.

Beamish et al. (2017) studied bone health and body composition in 72 adolescents who underwent RYGB. The inclusion criteria included age 13 to 18 years and a BMI of > 35 kg/m$^2$. Participants underwent dual-energy x-ray absorptiometry and serum bone marker analyses prior to the operation and annually for 2 years. Differences in body fat and lean mass proportions were observed according to sex following RYGB. The mean BMI reduction at 2 years was 15.1 kg/m$^2$. Body composition changes included a reduction in fat mass (51.8% to 39.6%; $p < 0.001$) and relative increase in lean mass (47.0% to 58.1%; $p < 0.001$). In contrast to previous studies in adults, this study showed that adolescent boys lost a greater percentage of their body fat than girls (-17.3% vs -9.5%; $p < 0.001$). Individual bone mineral density z scores at baseline were within or above the normal range. The mean (SD) bone mineral density z score was 2.02 (1.2) at baseline, decreasing to 0.52 (1.19) at 2 years. Higher concentrations of serum C-telopeptide ($p < 0.001$) and osteocalcin ($p < 0.001$) were observed in boys throughout the study period. Levels rose in the first year before decreasing modestly in the second. Levels of serum markers of bone synthesis and resorption were higher in boys, whose skeletal maturity occurs later than that in girls. Bone turnover increased, and bone mineral density decreased to levels approaching a normal value for age. Long-term outcomes will determine the clinical relevance.

In a systematic review and meta-analysis, Qi et al. (2017) evaluated the effects of bariatric surgery on glycemic and lipid metabolism, surgical complications, and QOL in adolescents with obesity. A total of 49 studies, with 3,007 individuals, were included. RYGB (n = 1,216), LAGB (n = 1,028), and LSG (n = 665) were the most common bariatric surgeries performed. At the longest follow-up (range, 12-120 months), bariatric surgery led to an overall 16.43-kg/m$^2$ (95% CI, 14.84-18.01 kg/m$^2$) and 31% (95% CI, 28%-34%) reduction in BMI. Significant improvements in the following were observed: glycemic and lipid profiles, including $HbA_{1C}$, and levels of fasting blood insulin, fasting blood glucose, total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and LDL cholesterol post operation at 12 months. The remission rate of dyslipidemia was 55% (95% CI, 34%-76%), 70% (95% CI, 55%-82%), and 95% (95% CI, 80%-100%) at 1, 3, and > 5 years after surgery. RYGB produced better improvements than other surgical procedures. The authors concluded that bariatric surgery in adolescents may achieve significant weight loss and glycemic and lipid control. (The publications by Manco et al., 2017, Serrano et al., 2016, Inge et al., 2016, Olbers et al., 2017, Shah et al., 2017, Hervieux et al., 2017, and O'Brien et al., 2010, previously cited in this policy, are included in this systematic review.)

The Teen-LABS study was a prospective, multicenter, observational study that enrolled 242 adolescents (≤ 19 years of age) who were undergoing bariatric surgery from March 2007 through February 2012 at five U.S. adolescent bariatric surgery centers. The participants underwent RYGB (n = 161), sleeve gastrectomy (n = 67), or LAGB (n = 14). Ryder et al. (2016) evaluated 2-year outcomes to determine the impact of bariatric surgery on functional mobility and musculoskeletal pain. Participants completed a 400-m walk test prior to bariatric surgery (n = 206) and at 6 months (n = 195), 12 months (n = 176), and 24 months (n = 149) after surgery. Time to completion, resting heart rate, immediate posttest heart rate, and heart rate difference (resting heart rate minus posttest heart rate) were measured, and musculoskeletal pain concerns, during and after the test, were documented. Data were adjusted for age, sex, race/ethnicity, baseline BMI, and surgical center (posttest heart rate and heart rate difference were further adjusted for changes in time to completion). Compared with baseline, the postsurgery data showed an improvement in all measurements at all times measured. The authors concluded that bariatric surgery in adolescents with extreme obesity is associated with significant improvement in functional mobility and reduction of walking-related musculoskeletal pain up to 2 years after surgery. However, findings are limited by the lack of a comparison group.

## Bariatric Artery Embolization

Bariatric artery embolization for weight loss remains unproven, as the evidence base is small and methodologically limited. Published human studies largely have small samples, variable technique in terms of target vessels, and limited long-term follow-up. The safety profile is not fully characterized for an elective obesity indication with rare but serious complications. Larger, controlled datasets are needed to define the true incidence and risk modifiers.

Reddy et al. (2020) conducted a single-center, sham-controlled, masked RCT to evaluate the efficacy of transcatheter bariatric embolization (TBE) for weight reduction in obesity. Participants were randomized to either the sham procedure (n = 20) or TBE targeting the left gastric artery (LGA) using embolic beads (n = 20). The primary efficacy end point was the difference in TBWL between the two groups at 6 months. All participants entered a lifestyle counseling program, and follow-up was completed by physicians who were masked to allocated therapy. At 6 months, the TBWL with TBE in the intention-to-treat (ITT) population was 7.4 kg compared with 3.0 kg with the sham procedure. The change in BMI at 6


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months in the ITT population was -2.6 with TBE vs -1.1 with sham. The TBE ITT population maintained the weight loss at 12 months. Participants in the sham group were unblinded at 6 months and permitted to cross over to TBE, and then only the initial group was followed up for 12 months. Limitations include the small sample size, single-center design, absence of a control group after 6 months, and possibility that the efficacy of TBE was related to participant participation in weight management counseling; it is unknown if TBE alone would have an impact on obesity without lifestyle counseling. Additionally, four participants withdrew consent after randomization, and another three withdrew consent prior to the 6-month visit. Furthermore, the clinical significance of the effect and its long-term sustainability and safety are unclear.

Hafezi-Nejad et al. (2019) conducted a systematic review and meta-analysis of a case series that investigated the safety and efficacy of LGA embolization as a bariatric procedure. Meta-regression was performed to assess the associations of age, sex, BMI, and ghrelin and leptin levels with weight change after LGA embolization was selected. Six case series were included in the meta-analysis; these case series were published between January 2014 and April 2019, comprised 47 individuals, and investigated the safety and/or efficacy of LGA embolization for weight loss. The results showed a mean weight loss of 8.68 kg (19.14 lb.) after 12 months of follow-up, approximately 8% of baseline total body weight, which is superior to weight loss from diet and exercise and comparable to that with other more invasive interventions. Transient superficial mucosal ulcers were common after LGA embolization, and one case of major complications (severe pancreatitis, splenic infarct, and gastric perforation) was identified. Considerable variations in the age of individuals, sex distribution, and baseline characteristics were present among the studies. Significant variation was observed in the duration of follow-up, which ranged from 3 months to 20 to 24 months. Limitations of this study include the variations in the indications for LGA embolization, study designs, embolization techniques, follow-up plans, dietary assessments, comorbidities in the individuals, and availability of control individuals. The authors concluded that LGA embolization is an investigative method and not yet proven to be effective management for obesity. Larger studies are needed to expand these findings and determine other correlates of weight loss after LGA embolization. (The publications by Bai et al., 2018, Syed et al., 2016, and Weiss et al., 2017, previously cited in this policy, are included in this systematic review.)

Weiss et al. (2019) evaluated the safety and efficacy of bariatric artery embolization up to 12 months following surgery in 20 severely obese participants [five of whom are identified below in the Weiss et al. (2017) case series]. The primary end point was weight loss, with additional end points assessed. Bariatric embolization was performed successfully in all participants. Participants experienced a mean EWL of 8.2% at 1 month, 11.5% at 3 months, 12.8% at 6 months, and 11.5% at 12 months. The mean TWL was 7.6 kg at 12 months. As a result of loss to follow-up, 18 participants remained at 3 months, 16 at 6 months, and 15 at 12 months. No major AEs were identified, and only 11 minor AEs occurred in eight participants. The authors found that bariatric embolization is well tolerated and promotes clinically relevant weight loss in adults with severe obesity. Limitations include the lack of a comparison group; the small sample size; insufficient data due to the lack of continuous follow-up in several participants; required weight management adherence before the embolization procedure for the first five participants only; and inclusion of a large portion of African American participants, resulting in overrepresentation of that population.

## Gastric Electrical Stimulator

While gastric electrical stimulation may provide benefit in obesity, its use remains in clinical question, as there is insufficient high-quality evidence on magnitude, durability, comparative effectiveness, and acceptable risk profile. Additional well-designed RCTs, with long-term follow-up, are warranted to demonstrate safety and efficacy.

In this 2020 first-in-human (early feasibility), multicenter, phase 1, open, prospective cohort study (Paulus et al., 2020), the authors assessed the safety of Exilis™ gastric electrical stimulation. They also sought to investigate whether the settings can be adjusted for comfortable chronic use in class II or III obese individuals. Meal intake and gastric emptying and motility were also evaluated. In this study, 20 obese participants received an implanted Exilis system, and the amplitude was individually set during four amplitude titration visits. Participants underwent two blinded baseline test days [gastric electrical stimulator (GES) ON vs OFF], after which long-term, monthly follow-up continued for up to 52 weeks. The results suggest that this device is safe and caused no participant discomfort. At baseline, food intake and satiety were not significantly different when the device was on or off, and significant weight loss occurred at week 26, with an EWL of 14% at 52 weeks. The authors concluded that the data were comparable to those from studies of participants on diet and/or exercise alone but disappointing when compared with minimally invasive procedures, such as gastric banding or endoscopic gastroplication. Furthermore, the authors did not observe changes in plasma glucose and insulin levels, which other bariatric procedures are known to improve. The authors concluded that considerably more basic research is required before clinical use. Limitations include the small sample size, lack of a control group, and lack of long-term outcomes.

In a 12-month, prospective, multicenter study, Morales-Conde et al. (2018) monitored all participants (n = 47) up to 24 months after laparoscopic implantation of a closed-loop GES (CLGES) system. Weight loss, safety, QOL, and cardiac risk factors were analyzed. Weight regain was limited in the 35 participants (74%) who remained enrolled at 24 months. The


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mean percentage of TBWL changed by only 1.5% between 12 and 24 months, reported at 14.8% (95% CI, 12.3%-17.3%) and 13.3% (95% CI, 10.7%-15.8%), respectively. The only serious device-/procedure-related AEs were two elective system replacements due to lead failure in the first 12 months, while improvements in QOL and cardiovascular risk factors were stable through 24 months. The authors concluded that during the 24-month follow-up, CLGES was shown to limit weight regain, with strong safety outcomes, including no SAEs in the second year. They hypothesized that CLGES and objective sensor-based behavior data combined to produce behavior change, and in their opinion, support GES as a safe obesity treatment, with potential for long-term health benefits. Larger, well-designed RCTs are needed to further evaluate the safety and efficacy of GES therapy in the treatment of obesity.

In a postimplant analysis, Alarcón Del Agua et al. (2017) evaluated possible preoperative predictors for obtaining clinically meaningful weight loss with GES. Overall, 97 obese participants in a prospective, multicenter study conducted in nine European centers received laparoscopic implantation of the abiliti® CLGES system. The mean 12-month percentage of EWL with CLGES was 35.1% ±19.7%, with a success rate of 52% and a failure rate of 19%. Significant predictors of success were a BMI of < 40 kg/m$^2$ and age of ≥ 50 years, increasing the probability of success by 22% and 29%, respectively. A low F1-cognitive-restraint score was a significant predictor of failure ($p = 0.004$). The best predictive model for success included F1-cognitive-restraint, F2-disinhibition, a BMI of < 40 kg/m$^2$, and age of ≥ 50 years ($p = 0.002$). The authors concluded that age, preoperative BMI, and F1-cognitive-restraint and F2-disinhibition scores from a preoperative questionnaire are predictive of weight loss outcomes with CLGES and may be used for participant selection.

In a systematic review, Cha et al. (2014) evaluated the current state regarding implantable gastric stimulators. Overall, 31 studies, consisting of a total of 33 different trials, were included in the systematic review for data analysis. Weight loss was achieved in most studies, especially during the first 12 months, but only very few studies had a follow-up period longer than 1 year. Among those who had a longer follow-up period, many were from the Transcend® (Implantable Gastric Stimulation) device group and maintained significant weight loss. Other significant results included changes in appetite/satiety, gastric emptying rate, blood pressure, and neurohormone levels or biochemical markers such as ghrelin or $HbA_{1c}$, respectively. The authors concluded that although gastric electrical stimulation holds great promise, stronger evidence is required through more studies, with a standardized way of carrying out trials and reporting outcomes, to determine the long-term effect of gastric electrical stimulation on obesity. (The publications by Shikora et al., 2009, Sarr et al., 2012, and Camilleri et al., 2008, previously cited in this policy, are included in this systematic review.)

## Laparoscopic Greater Curvature Plication

Compared with standard proven bariatric surgeries, laparoscopic greater curvature plication (LGCP) has inferior and less durable weight loss, with nontrivial revision and complication concerns. Additional robust RCTs, with comparison groups and long-term data, are needed.

In a 2023 single-center retrospective analysis, Park and Kim presented the weight loss and revision surgery rate outcomes in 75 patients following laparoscopic gastric greater curvature plication (LGGCP) surgery. The results showed that 13 of 75 patients underwent revision surgery. The main reason for revision was weight regain; however, chronic intermittent GERD, dyspepsia, and chronic relapsing melena were also reasons. The mean body weight and BMI at initial LGGCP surgery were 207 lb. (±24 lb.) and 35.6 kg/m$^2$ (±3.9 kg/m$^2$), respectively. The mean nadir body weight after LGGCP was 149 lb. (±13 lb.), and the BMI was 25.8 kg/m$^2$ (±2.8 kg/m$^2$). At revision, the mean body weight was 196 lb. (±25 lb.), and the BMI was 33.9 kg/m$^2$ (±4.2 kg/m$^2$). The results showed that after 5 years, weight gain that was close to presurgery levels had occurred. The authors concluded that LGGCP, as a primary surgery, results in a high rate of weight gain and the need for revisional surgery.

Doležalova-Kormanova et al. (2017) reported outcomes in a cohort of LGCP individuals at the 5-year follow-up. The percentage of individuals with complete weight data through the 5-year follow-up was 86.9% (212 of 244). The analysis of variance database indicated a significant BMI reduction out to 2 years ($p < 0.001$), plateau at 3 and 4 years, and moderate but significant BMI increase at 5 years ($p < 0.01$). Excess BMI loss at 1, 2, 3, 4, and 5 years was as follows: 50.7% ±9.1%, 61.5% ±8.1%, 60.2% ±7.0%, 58.5% ±7.0%, and 56.8% ±6.3%. At 5 years, 79.2% of individuals (168 of 212) were successful, and 20.8% (44 of 212) experienced a suboptimal weight outcome; the mean weight regain was 9.2%. A cluster analysis identified four distinct LGCP profiles in individuals. The diabetes improvement rate was 65.5%. Twelve reoperations (4.9%) occurred: four emergency (1.6%) and eight (3.3%) elective. No mortality was observed. The authors concluded that based on their original cohort, a 56.8% excess BMI loss, and a low rate of complications, LGCP proved to be safe and effective. The findings are limited by the lack of a comparison group. Additional long-term outcomes are needed to evaluate LGCP compared with other bariatric procedures.

In an 18-month, prospective, observational, open-label study, Bužga et al. (2017) reported outcomes in 127 participants; 84 underwent LSG, and 43 underwent LGCP. LSG and LGCP were then compared during long-term follow-ups in terms of glycemic control, hormone and lipid secretion, and changes in body composition. Significant weight loss and improved


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body composition resulted from either procedure vs baseline (i.e., prior to surgery), with levels of fasting glucose and glycated hemoglobin also showing statistically significant reductions (at 3 and 18 months for either surgery). Intergroup comparisons for glycemic parameters yielded no statistically significant differences. However, a dramatic reduction in ghrelin was detected following LSG, with levels falling from presurgery levels of 140.7 to 69.6 ng/L by 6 months ($p < 0.001$). Subsequently, ghrelin levels increased, with levels reaching 107.8 ng/L by month 12. Conversely, after LGCP, a statistically significant increase in ghrelin was seen, with levels rising from 130.0 ng/L before surgery to 169.0 ng/L by month 12, followed by a slow decline. The authors concluded that although the data showed good metabolic outcomes following LGCP, this method was less effective than LSG, possibly due to its preservation of the entire stomach, including secretory regions.

Grubnik et al. (2016) compared 2-year outcomes in a European prospective RCT comparing LGCP vs LSG. A total of 54 participants with morbid obesity were allocated either to the LGCP group (n = 25) or LSG group (n = 27). The main exclusion criteria were an American Society of Anesthesiologists classification of > III, age of > 75 years, and a BMI of > 65 kg/m$^2$. Overall, 40 women and 12 men were included, and the mean age was 42.6 ±6.8 years (range, 35-62 years). Data on the operation time, complications, hospital stay, BMI loss, percentage of EWL, loss of appetite, and improvement in comorbidities were collected during the follow-up examinations. One year after surgery, the mean percentage of EWL was 59.5% ±15.4% in the LSG group and 45.8% ±17% in the LGCP group ($p > 0.05$). After 2 years, the mean percentage of EWL was 78.9% ±20% in the LSG group and 42.4% ±18% in the LGCP group ($p < 0.01$). After 3 years, the mean percentage of EWL was 72.8% ±22% in the LSG group and only 20.5% ±23.9% in the LGCP group ($p < 0.01$). Loss of feeling of hunger after 2 years was 25% in the LGCP group and 76.9% in the LSG group ($p < 0.05$). Comorbidities, including diabetes, sleep apnea, and hypertension, were markedly improved in both groups after surgery. The authors concluded that the short-term outcomes demonstrated equal effectiveness of both procedures, but the 2-year follow-up showed that LGCP is not as effective as LSG as a restrictive procedure for weight loss.

Tang et al. (2015) conducted a meta-analysis to compare LGCP with LSG in terms of efficacy and safety. Eligible studies included one RCT and three nonrandomized controlled trials, involving 299 individuals. The meta-analysis demonstrated a significantly greater percentage of EWL after LSG than LGCP at the follow-up time points of 3 months ($z = 2.26$; $p = 0.02$), 6 months ($z = 4.49$; $p < 0.00001$), and 12 months ($z = 6.99$; $p < 0.00001$). The difference in the resolution of diabetes between these two approaches did not reach statistical significance ($p = 0.66$). According to the pooled data, LGCP was associated with more AEs than LSG ($p = 0.01$). The operation time ($p = 0.54$) and postoperative hospital stay ($p = 0.44$) were comparable between the two groups. LGCP is inferior to LSG, not only in terms of providing effective weight loss but also in terms of safety.

## Mini-Gastric Bypass/Laparoscopic Mini-Gastric Bypass/One-Anastomosis Gastric Bypass

Currently, evidence regarding the long-term effectiveness and safety of OAGB for obesity and weight loss is insufficient. Many studies on OAGB focus on short- to medium-term outcomes of 1 to 5 years. Evidence regarding the long-term efficacy, weight maintenance, and complication rates beyond 5 years is limited. Additional well-designed RCTs are needed to assess its sustained effectiveness and safety.

In a 2025 systematic review with meta-analysis of RCTs, Ahmed et al. compared OAGB with RYGB as primary operations for the treatment of obesity. There were 12 studies included in the review, with a total of 904 individuals. Of the individuals, 445 were assigned to the OAGB group, while 459 were assigned to the RYGB group. While there was a statistically higher percentage of TWL at 6 months for OAGB (95% CI, 0.80-2.94; $p = 0.006$) compared with RYGB, there was no difference in percentage of TWL at 12, 24, and 36 months between OAGB and RYGB. For percentage of EWL, no difference was noted between OAGB and RYGB at 6 and 60 months of follow-up; however, OAGB had a higher percentage of EWL than RYGB at 12 and 24 months of follow-up. For postoperative complications, six studies illustrated a higher incidence of de novo GERD in those who underwent OAGB compared with RYGB (RR, 2.58; 95% CI, 1.55-4.3; $p = 0.0003$; $I^2 = 0\%$). Additionally, marginal ulcers were significantly higher with OAGB than RYGB in the pooled analysis of four studies (RR, 2.7; 95% CI, 1.07-6.84; $p = 0.04$; $I^2 = 0\%$). For comorbidity resolution, studies showed that there was no significant difference between OAGB and RYGB in T2D remission, hypertension remission, OSA, dyslipidemia, or remission of musculoskeletal pain. The authors noted that all but one RCT included in the review had some concerns in the overall risk-of-bias assessment domain according to the assessment tool. They concluded that OAGB is comparable to RYGB with weight loss and comorbidity resolution; however, OAGB can lead to a higher risk of development of marginal ulcers and de novo GERD. Limitations of the study include the concerns of risk of bias of RCTs, high heterogeneity, malalignment of the percentage of EWL and TWL in all the time points of follow-up, and lack of longer-term outcomes. (The publications by Robert et al., 2024, and Eskandaros et al., 2021, previously cited in this policy, are included in this systematic review.)


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Kapellas et al. (2024) conducted a systematic review and meta-analysis of RCTs to evaluate the efficacy of OAGB in the clinical and pathological resolution of GERD compared with that of RYGB in individuals with obesity. There were nine RCTs included in the review, with 643 individuals, of whom 314 received OAGB and 329 received RYGB. The diagnosis of GERD in three studies was based on clinical symptoms; endoscopic findings in two studies; and both clinical symptoms and endoscopic findings in three studies. One study did not provide enough information. In all but one study, the operations were primary procedures. The incidence of GERD with OAGB was 18.5% (n = 58) compared with 7.6% (n = 25) with RYGB. In the pooled analysis, OAGB had a statistically significant higher risk of GERD than RYGB (odds ratio, 3.14; 95% CI, 1.23-8.03; $p < 0.05$). There were five studies that reported de novo postoperative GERD, with 15 (8.5%) incidences in the OAGB group vs one (0.5%) in the RYGB group. The odds for de novo GERD after OAGB were almost six times higher than after RYGB (odds ratio, 5.65; 95% CI, 1.53-20.82; $p < 0.05$). The authors concluded that RYGB has a lower incidence of de novo GERD cases and is more effective than OAGB in reducing GERD. Limitations include the risk of bias due to blinding; an incidence of GERD that differed throughout studies due to changes in follow-up intervals; the differences in surgical protocol (the length of biliopancreatic limb and volume of gastric pouch varied); the lack of consistency in terminology (OAGB and MGB); the exclusion of severe GERD or high-degree esophagitis in some studies; and the inclusion of mostly women. Well-designed RCTs, with more individuals, that primarily focus on objectively diagnosed GERD are warranted.

Parmar et al. (2020) evaluated the role of OAGB-MGB as a revisional/secondary procedure in individuals who needed revisional bariatric surgery. A total of 17 studies were included in this systematic review, with a total of 1,075 individuals. The mean age was 43 years, and 75% were female. The follow-up ranged from 6 to 60 months, with a mean of 29 months. The breakout of the primary procedures performed was as follows: LAGB, 569 individuals; sleeve gastrectomy, 397 individuals; VBG, 105 individuals; and lap gastric plication, five individuals. The most common reason for revisional bariatric surgery was poor response in 81%, followed by gastric band failure in almost 36% of individuals. The mean BMI prior to revisional bariatric surgery was 41.6 $kg/m^2$. Following the OAGB-MGB procedure, the mean percentage of EWL was 50.8% at 6 months, 65.2% at 1 year, 68.5% at 24 months, and 71.6% at 5 years. The authors' conclusion suggests that OAGB-MGB is a safe and effective choice for revisional surgery; however, randomized studies and large, prospective studies, with long-term follow-up, are needed to validate these findings. Limitations include a lack of a comparison group and RCTs in the analysis, along with race and ethnicity differences, which may have impacted the individuals' eating habits, education, adherence, and expectations.

In a Comparative Effectiveness Review from Hayes (2019; updated 2023) for primary bariatric surgery, MGB-OAGB was compared with RYGB and LSG separately. Data from two systematic reviews and four RCTs suggested an overall increase in the percentage of weight loss with the MGB-OAGB procedure compared with RYGB and LSG. The evidence also suggested that MGB-OAGB may have a positive impact on the resolution of T2D and hypertension. However, additional long-term follow-up is warranted for further research on long-term follow-up, complications, adverse effects, and impact on nutrition.

In a prospective case series in 150 morbidly obese participants who underwent laparoscopic OAGB, lipid profiles were evaluated prior to the operation and at different intervals during a 2-year follow-up. The study (Carbajo et al., 2017) reported a mean weight loss of 48.85 kg ±15.64 kg and mean percentage of EWL of 71.87% ±13.41%. Total cholesterol and LDL levels significantly decreased, and HDL levels significantly increased, which the authors believe translate to theoretical relevant cardiovascular risk benefits. The findings are limited by the lack of a comparison group. Long-term, randomized studies are needed to fully evaluate the impact of this procedure.

Wang et al. (2017) conducted a systematic review and meta-analysis to compare the safety and efficacy between laparoscopic MGB and LSG. Thirteen studies met the inclusion criteria of comparative studies between MGB and sleeve gastrectomy; individuals were adults, with ages ranging from 20 to 70 years. At least one of the following end points was included: operation time, mortality, overall early complications, specific early complications, overall late complications, specific late complications, hospital stay, revision rate, remission rate of comorbidities, 1-year percentage of EWL, and 5-year percentage of EWL. The authors observed that individuals receiving MGB had more advantageous indexes than individuals receiving sleeve gastrectomy, such as a higher 1-year percentage of EWL, higher 5-year percentage of EWL, higher T2D remission rate, higher hypertension remission rate, higher OSA remission rate, lower osteoarthritis remission rate, lower leakage rate, lower overall late complications rate, higher ulcer rate, lower GERD rate, shorter hospital stay, and lower revision rate. No significant statistical difference was observed in overall early complications rate, bleed rate, vomiting rate, anemia rate, and operation time between MGB and sleeve gastrectomy. In their opinion, due to the biased data, small sample size, and short follow-up time, the results of this review may be unreliable. RCTs, with larger sample sizes, are needed to compare the effectiveness and safety between MGB and sleeve gastrectomy. (The publications by Kansou et al., 2016, and Plamper et al., 2017, previously cited in this policy, are included in this systematic review.)


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## Silastic Ring Vertical Gastric Bypass

While the overall evidence for silastic ring vertical gastric bypass (SRVGB) suggests slightly better weight loss and maintenance in the medium term compared with RYGB, there are device-specific complications. Randomized evidence exists but is limited in number and scope; generalizability is uncertain; and there are distinct late risks that do not exist with standard RYGB. Evidence regarding the effectiveness and safety of SRVGB for obesity and weight loss is insufficient. More highly powered RCTs are needed, technique and device reporting needs to be standardized to improve reproducibility, and complications require consistent reporting as well as reinterventions.

Hayes (2025) conducted a Health Technology Assessment to evaluate the safety and efficacy of SRVGB compared with those of other bariatric surgical procedures for weight loss. It was noted that there is an overall low-quality body of evidence that suggests that SRVGB is reasonably safe for treatment and provides clinically significant (> 20%) reductions in total weight relative to baseline at 12 months of follow-up. The evidence also suggests that SRVGB provides statistically significant improvements in weight loss relative to RYGB and sleeve gastrectomy, without consistent increases in complications. While one study found that SRVGB provides statistically significant improvements in diabetes resolution vs sleeve gastrectomy, there was no other consistent evidence of improvements in comorbidity resolution or QOL with SRVGB vs RYGB or sleeve gastrectomy. It was also noted that there is a lack of surgical standardization for SRVGB, which varied between studies (ring size and implantation site) and may have impacted outcomes.

## Single-Anastomosis Duodenal-Ileal Switch (SADI-S/SADI/SADS)

The peer-reviewed literature on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) demonstrates promise regarding short- to mid-term weight loss and metabolic improvement, particularly for T2D, but the overall evidence remains limited in quality and maturity for complications. Most published studies are single-center observational cohorts or retrospective case series, often from high-volume centers, which limits generalizability and introduces selection and performance bias. Additional robust RCTs, with comparison groups and long-term results, are needed. Several clinical trials are in progress for single-anastomosis duodenal switch (SADS); information can be found at https://www.ClinicalTrials.gov.

In a 2025 multicenter, open-label, randomized superiority trial, Robert et al. evaluated the efficacy and safety of SADI-S vs those of RYGB for the treatment of obesity. Participants were recruited from 22 bariatric centers across France. The inclusion criteria were participants with a BMI of ≥ 40 or ≥ 35 kg/m$^2$ and at least one obesity-related comorbidity and who were candidates for SADI-S or RYGB as a primary surgery or after sleeve gastrectomy. Participants were randomized using computer-generated block randomization, stratified by study center, previous sleeve gastrectomy failure, and presence of T2D. Procedures were standardized and performed laparoscopically by experienced bariatric surgeons who were trained in SADI-S before the start of the trial. For revisional procedures, resleeving or antral trimming was not permitted in order to minimize procedural variability and avoid additional surgical risk. The primary end point was percentage of EWL at 2 years. The secondary end points were assessments of weight loss trajectories, metabolic efficiency, nutritional status, surgical and medical complications, and participant-reported QOL. There was a total of 381 participants (SADI-S: 190; RYGB: 191). The mean age was 44.4 years; the mean BMI was 46.2 kg/m$^2$; 265 were female; and 79 had a primary sleeve gastrectomy. Overall, 43 participants were lost to follow-up. At 2 years, the mean percentage of EWL was statistically significantly higher in the SADI-S group than the RYGB group (-76.0%, SD, 26.7 vs -68.1%, 28.7), confirming the superiority of SADI-S (MD, -6.72%; 95% CI, -12.64 to 0.80; p = 0.026). The primary outcome was missing for 78 of the 381 participants (20%), with 46 in the SADI-S group and 32 in the RYGB group (p = 0.09). The number of SAEs in the SADI-S group was 40, including three anastomotic leaks and eight severe diarrhea, compared with 35 in the RYGB group, including five internal hernia and five severe abdominal cases, of which two required diagnostic laparoscopy. Regarding secondary outcomes, the incidence of malnutrition remained low in both groups (SADI-S: 11.7%; RYGB: 10.6%); vitamin deficiencies were common in both groups; and iron deficiency and anemia rates were comparable between groups. Signs of gastrointestinal malabsorption were more common in the SADI-S group, with a significantly higher rate of steatorrhea observed in 103 of 113 participants compared with 82 of 110 with RYGB, and a higher rate of diarrhea (15 of 134 SADI-S vs five of 139 RYGB; p = 0.016). Early surgical complications were significantly higher in the SADI-S group (6%) than the RYGB group (2%) (p = 0.042). Late surgical complications were significantly higher in the RYGB group (10%) vs the SADI-S group (2%). Clinical GERD was more frequent in the SADI-S group (19%) vs the RYGB group (8%) (p = 0.004). The authors concluded that SADI-S showed superior weight loss compared with RYGB at 2 years, with a similar safety profile. Limitations of the study include the fact that 20% of the cohort was missing data for the primary end point at 24 months, which could affect the external validity of the findings, and the lack of long-term follow-up to determine if the weight loss advantage of SADI-S is maintained over time and to evaluate late complications, including progressive malnutrition, gastrointestinal symptoms, and metabolic adaptation.

In a 2024 systematic review, Kozonis et al. evaluated the safety and efficacy of robotic SADI-S compared with those of laparoscopic SADI-S for morbid obesity, focusing on perioperative and postoperative outcomes, including intraoperative


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complications, operative time, conversion rates, mortality, length of stay, weight loss, and postoperative complications. The review included seven studies and involved 204 individuals. Of the 204 cases, 173 were primary SADI-S, while 31 cases were revisional. The authors noted only one intraoperative complication (0.49%) regarding minor bleeding, no conversions to laparoscopic/open SADI-S, and no mortality. The authors noted that the low mortality is important, as mortality rates reported by studies assessing the outcomes of laparoscopic SADI-S can be as high as 0.5% to 0.6%. The mean operative time varied from 138 to 205.7 minutes, which is longer in duration than laparoscopic SADI-S, which does not usually exceed 140 minutes. The median hospital stay ranged from 2 to 6.7 days, which, according to the authors, is a shorter time compared with that for laparoscopic SADI-S. There was only one readmission for an unspecified postoperative complication. Of the 204 cases, 13 (6.37%) developed early postoperative complications, including seven (3.43%) classified as Clavien-Dindo grade II, three (1.47%) classified as Clavien-Dindo grade III, and two (0.98%) classified as Clavien-Dindo grade IV; one (0.49%) was not disclosed. There were no late complications (> 30 days) reported. According to the authors, postoperative complication rates for laparoscopic SADI-S can reach 15%, with a range reported in other systematic reviews from 4.8% to 6.1%. Postsurgical weight loss was mentioned in four of the included studies and ranged from 67.1% EWL to 113.7% EWL at 24 months of follow-up, which was comparable to that with laparoscopic SADI-S. The authors noted that robotic-assisted SADI-S demonstrated a favorable safety profile, with promising weight loss outcomes; however, it was also noted that adverse effects such as nutritional deficiencies, anastomotic strictures, and bowel obstruction may manifest years after SADI-S. Therefore, analysis of late long-term follow-up data is necessary. Limitations of this study include a limited number of identified studies, which were predominantly small and may not represent the broader population; possibility of publication bias, as the majority of studies were observational; lack of generalizability of the findings, as the studies were limited to just a few countries; retrospective design; single-institution series; and results that were limited to 2 years of follow-up at best, which is insufficient to assess long-term outcomes and complications.

In a 2024 Hayes Health Technology Assessment, it was determined that there is an overall low-quality body of evidence that suggests that SADS provided clinically significant weight loss and that efficacy and safety are generally similar with SADS vs other common bariatric surgical procedures. SADS was associated with some statistically significant improvements in weight loss compared with RYGB, Roux-en-Y/duodenal switch, and LSG, with no significant differences relative to BPD/DS. However, only one to three studies evaluated each comparison between SADS and a competing bariatric technique, and every study was poor quality.

Esparham et al. (2023) conducted a systematic review that evaluated the efficacy and safety of SADI-S in mid- and long-term follow-up. The review included 10 studies, with a total of 1,707 individuals, reporting outcomes with ≥ 3 years of follow-up. The majority of the articles were retrospective, and due to the heterogeneity of the included studies regarding surgical technique and reported variables, the authors were unable to perform a meta-analysis. The percentage of EWL was 70.9% to 88.7% at 6 years and 80.4% at 10 years. The more common late complications were malabsorption (6.3%) and GERD (3.6%). The remission rates of hypertension, diabetes, GERD, OSA, and dyslipidemia were 62.9%, 81.3%, 53.2%, 60.9%, and 69.7%, respectively. While the authors concluded that SADI-S/SADS is a safe and effective surgical technique, with durable weight loss and a high rate of comorbidity resolution, they also noted that it is important to consider the potential risk and complications associated with this hypoabsorptive procedure and the need for long-term follow-up.

In a 2021 retrospective cohort study, Iranmanesh et al. compared short- and medium-term outcomes between the standard double-anastomosis duodenal switch and SADS. Data from 107 patients were collected in the Ontario Bariatric Registry from a Canadian bariatric center of excellence between 2010 and 2019, with the primary outcome measurement of weight loss at 1 and 2 years post surgery. The short-term secondary outcomes included operative times, intraoperative and early postoperative complications, hospital length of stay, and 30-day readmissions. The medium-term secondary outcomes included late postoperative complications as well as nutritional deficiencies and persistent diarrhea at 1 and 2 years post surgery. Of the 107 patients, 25 received SADS surgery, and 82 received double-anastomosis duodenal switch. Follow-up data were available for 59 patients at 1 year and 47 after 2 years. The results showed a similar percentage of TWL at 1 year (23.6% vs 26.2%) and 2 years (24.8% vs 30.2%) after surgery. Short- and medium-term outcomes were similar between groups. This study is limited by a small number of patients receiving the SADS procedure and high rate of loss to follow-up. Additional high-quality studies, with longer follow-up, are necessary to validate these retrospective findings.

Pereira et al. (2021) conducted a prospective observational cohort study in 112 participants receiving SADS or BPD/DS. The primary end points were BMI and TWL, and the secondary end points included remission of obesity-related disorders (T2D, hypertension, and dyslipidemia), nutritional deficiencies, and postoperative complications. Overall, 83 participants received SADS, and 29 received BPD/DS. No statistically significant differences were observed between the groups' demographic characteristics and clinical features, except for baseline weight and BMI, which were significantly higher in the BPD/DS group. Follow-up times for SADS and BPD/DS ranged from an average of 40 months to 23 months,


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respectively. The results showed no significant differences in BMI and the percentage of excess BMI loss between the groups, although the percentages of TWL observed from 12, 24, and 36 months were significantly higher after BPD/DS. Resolution of obesity-related comorbidities was numerically better in the BPD/DS group than the SADS group, but it was not statistically significant. Nutritional status was not consistently significant between the two procedures, and no differences were observed in surgical complications. Operative time and hospital stay were shorter in the SADS group. The authors concluded that SADS is a simpler technique and shows similar results to BPD/DS. They acknowledged several limitations, including a considerable numerical imbalance between the two groups; additionally, the number of participants with follow-up was small. Large-scale RCTs, with long-term data, are needed to confirm these results.

In a Medtronic-funded study, Cottam et al. (2020) evaluated weight loss and 1-year nutritional outcomes with the SADS procedure. Overall, 120 participants at six different sites were enrolled; participant inclusion criteria included (1) a BMI of 35 to 40 kg/m$^2$, with one obesity-related comorbidity, or (2) a BMI of 40 to 60 kg/m$^2$, with no related comorbidity. Weight loss, comorbidities, QOL, and AEs were followed up post procedure for 12 months. The authors found SADS to be an effective weight loss operation, with the ability to reduce comorbid conditions, particularly diabetes. Limitations include a lack of a comparative cohort, participant loss to follow-up, and a lack of long-term results for efficacy.

In a retrospective cohort study, Surve et al. (2017) compared BPD/DS with SADS [SIPS (stomach intestinal pylorus-sparing surgery)] at a single institution, with a 2-year follow-up. Overall, 182 patients received either a BPD/DS (n = 62) or SIPS (n = 120) procedure. BPD/DS and SIPS resulted in weight loss at 3 months, which was not statistically significantly different; however, the percentage of EWL was more with BPD/DS than SIPS at 6, 9, 12, 18, and 24 months. Patients' mean BMI loss was 23.3 kg/m$^2$ (follow-up, 69%) and 20.3 kg/m$^2$ (follow-up, 71%) at 2 years from the BPD/DS and SIPS surgeries, respectively. However, patients who had undergone the SIPS procedure had significantly shorter operative time, shorter length of stay, and fewer perioperative and postoperative complications than those who had undergone BPD/DS ($p < 0.001$). No statistical difference was observed between the two groups for postoperative nutritional data such as vitamins D, $B_1$, and $B_{12}$; serum calcium; fasting blood glucose; $HbA_{1C}$; insulin; serum albumin; serum total protein; and lipid panel. The authors noted that because the BPD/DS procedures were done prior to SIPS, a learning curve and experience may account for the postoperative complications. RCTs, with larger participant populations and longer follow-up periods, are needed to evaluate the SIPS procedure.

Cottam et al. (2016) conducted a retrospective matched cohort analysis to compare RYGB with SADS, with 18-month follow-up. Overall, 108 patients received either RYGB (n = 54) or SADS (n = 54). A regression analysis was used to compare weight loss outcomes, as measured by BMI and weight loss percentages. The results failed to show statistically significant differences between the two procedures on weight loss at 18 months (39.6% vs 41% weight loss, respectively). However, there were significantly more nausea complaints (26 vs five), diagnostic esophagogastroduodenoscopies (21 vs three), and ulcers (six vs zero) with RYGB than SADS. The 2-year outcomes for this same patient cohort had similar results (Cottam et al., 2017). RCTs, with larger participant populations and longer follow-up periods, are needed to validate these findings.

## Transoral Endoscopic Surgery

The evidence for transoral endoscopic surgery for bariatric surgery is limited; additional studies, including RCTs, and long-term data, including the safety and efficacy of the procedure, are warranted.

In 2025, Zhu et al. conducted a systematic review and network meta-analysis evaluating endoscopic bariatric surgery, comparing the safety and efficacy with those of LSG. There were 18 studies included in the review, with 766,135 individuals for procedures, including LSG, endoscopic sleeve gastroplasty (ESG), nonadjustable intragastric balloon (NIB), BioEnterics Intragastric Balloon (BIB), and adjustable intragastric balloon (AIB). There were 12 retrospective studies, five prospective studies, and one cross-sectional study. The authors noted that for a 6- and 12-month intervention, LSG is the most effective for weight reduction compared with NIB, AIB, and ESG. For percentage of TBWL < 6 months, the LSG group showed the most significant weight loss compared with the other endoscopic bariatric surgery groups. For safety outcomes, the order of the observed incidence of AEs from small to large was ESG, NIB, AIB, LSG, and BIB. The authors concluded that ESG is an effective and safe, minimally invasive surgical method, and its 12-month effect is better than that of NIB. These findings are limited by the indirect nature of network meta-analyses, inclusion of observational studies, and lack of long-term outcomes. (The publication by Gudur et al., 2023, previously cited in this policy, is included in this systematic review.)

Jung et al. (2020) conducted a systematic review and meta-analysis of 22 studies, with 2,141 individuals, to comprehensively evaluate the efficacy of different endoscopic bariatric procedures compared with that of lifestyle modification in the treatment of morbid obesity. Intragastric balloon (IGB), duodenal-jejunal bypass liner (DJBL), aspiration therapy, the Primary Obesity Surgery Endoluminal procedure, and botulinum toxin injection to the stomach were included, and the meta-analysis determined the percentage of weight loss and percentage of EWL. The results revealed that the


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Obalon® Balloon system showed efficacy for both percentage of weight loss and percentage of EWL; its efficacy was not proven due to the small number of studies and comparatively low effect size. Aspiration therapy demonstrated effectiveness for weight reduction compared with lifestyle modification. Gas-filled balloon and botulinum toxin injection did not show a significant difference in percentage of weight loss or percentage of EWL compared with the control. The authors concluded that all bariatric endoscopic procedures, with the exception of a gas-filled balloon and botulinum toxin injection, showed superior short-term efficacy compared with lifestyle modification. These findings are limited by the lack of long-term efficacy and safety quality data. (The following publications, previously cited in this policy, are included in this systematic review: Abu Dayyeh et al., 2015b, Chang et al., 2014, Courcoulas et al., 2017, Gersin et al., 2010, Schouten et al., 2010, Sullivan et al., 2013, and Thompson et al., 2017.)

## *Endoscopic Sleeve Gastroplasty (OverStitch)*

Quality evidence regarding the safety and efficacy of ESG for obesity is insufficient. Future studies, including RCTs, are needed to assess the safety and efficacy of this procedure, along with long-term results.

In a Clinical Evidence Assessment from ECRI (2025), the Apollo ESG System/Overstitch Endoscopic Suturing System was evaluated for safety and efficacy for ESG. There were five studies included in this evidence assessment. The Apollo ESG System/OverStitch was found to be safe and effective for treating obesity, resulting in more weight loss than diet and lifestyle interventions. At the 1-year follow-up, ESG improved T2D, hypertension, and hyperlipidemia in individuals with those conditions. It was noted that there are no studies that compare ESG using OverStitch with other bariatric procedures or with contemporary antiobesity medications.

In a 2024 Evolving Evidence Review (updated 2025), Hayes evaluated ESG using the Apollo ESG System (Apollo Endosurgery Inc.) for obesity. A review of the literature found minimal/weak support for using the Apollo ESG System for ESG to treat obesity, based on six clinical studies, systematic reviews that included between seven and 35 studies, and five practice guidelines. It was noted that clinical trials are ongoing; however, it is unclear if these trials will provide useful information on the place of the Apollo ESG System in the bariatric surgery landscape.

Weitzner et al. (2023) performed a systematic review to evaluate various endoscopic bariatric procedures using only RCTs and observational studies. The authors evaluated weight loss with conservative management, lifestyle modification, and bariatric surgery. A total of 37 studies, which included a total of 15,639 individuals, were included in the review. The primary outcomes included the percentage of TBWL, percentage of excess body weight loss (EBWL), and AEs. The secondary outcomes included data related to QOL and differences in $HbA_{1C}$ levels. ESG had less percentage of TBWL: 4.7% to 14.4% compared with 18.8% to 26.5% after LSG at 6 months and 4.5% to 18.6% compared with 28.4% to 29.3%, respectively, at the 1-year follow-up. Additionally, the study did not demonstrate that endoscopic therapies resulted in significant differences in $HbA_{1C}$ reduction compared with lifestyle modification. Despite endoscopic therapies resulting in greater weight loss than lifestyle modification, they did not result in greater weight loss than bariatric surgery. The clinical utility of endoscopic bariatric procedures has not been convincingly addressed over regulator-approved bariatric surgeries such as LSG. Ultimately, more robust data from RCTs or case-controlled studies are necessary.

In a 2023 retrospective study, Gudur et al. analyzed over 600,000 patients in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database and compared short-term (30 days) AEs, readmissions, reoperations, and reinterventions in patients who underwent ESG compared with sleeve gastrectomy. A total of 6,054 patients underwent ESG, and 597,463 underwent sleeve gastrectomy. The results showed that there was no significant difference in major AEs, but patients undergoing ESG had more readmissions, reoperations, and reinterventions. An additional analysis showed that chronic steroid use, renal insufficiency, and anticoagulation therapy contributed the most to the AEs in both groups. Race did not impact AEs after ESG, with an increased risk of AEs identified in Black patients after sleeve gastrectomy. This retrospective study is limited by a very short follow-up period. The authors concluded that further prospective, long-term evaluations of ESG vs sleeve gastrectomy, with regard to safety and efficacy, are needed.

Abu Dayyeh et al. (2022) conducted a randomized clinical trial to explore the safety and efficacy of ESG with lifestyle modifications compared with those of lifestyle modification alone for the treatment of class I and II obesity. The inclusion criteria were age 21 to 65 years; a BMI of 30 to < 40 $kg/m^2$; a history of experiencing failure of nonsurgical weight loss methods; and adherence to the lifelong dietary restrictions that are required with this procedure. The primary outcome on efficacy was the percentage of EWL at 52 weeks. The secondary efficacy outcomes included the proportion of participants with 25% or more EWL, percentage of TWL, and proportion of participants with 5% or more and 10% or more of TWL. The effect of ESG on obesity-related comorbidities and safety were also assessed. Overall, 77 participants were randomized to ESG plus moderate-intensity lifestyle modifications (ESG group), and 110 were randomized to moderate-intensity lifestyle modifications alone (control group). During the first year, 12 follow-up visits were completed at weeks 1 and 4 and then every 4 weeks until the 52-week visit. The results showed that ESG with lifestyle modifications compared with lifestyle modifications alone resulted in significant improvements in terms of weight loss and metabolic comorbidities,


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with no GERD incidence, as seen with other bariatric surgeries. AEs included gastrointestinal symptoms such as pain, heartburn, nausea, and vomiting, which are not unexpected when acclimating post procedure. Three participants had a Clavien-Dindo grade III device- or procedure-related AE that required intervention; these included abscess, gastrointestinal bleeding, and one case of malnutrition that required reversal of the ESG. The authors concluded that as a minimally invasive alternative to surgical sleeve gastrectomy, ESG is a safe and effective option for individuals who prefer a nonsurgical option. This study is limited by the impact of the COVID-19 pandemic on study follow-up and participant retention as well as a small number of participants.

Marincola et al. (2021) conducted a systematic review with meta-analysis to evaluate LSG vs ESG. The authors selected a total of 16 studies, with a total of 2,188 individuals. One randomized study and seven observational studies on LSG were selected, and eight observational studies on ESG were included. The authors reviewed the studies, which included obese individuals with a baseline BMI between 30 and 40 kg/m² and a minimum of 1 year of follow-up. The mean BMI was 34.34 kg/m² and 34.72 kg/m² for LSG and ESG, respectively. The mean percentage end weight loss was 80.32% in the LSG group and 62.20% in the ESG group. The mean AE rate was 0.19%. The study results indicated a moderate superiority of LSG vs ESG. Although recently emerged bariatric endoscopic techniques are a less invasive approach for the treatment of obesity, scientific evidence is still limited related to their outcomes. ESG was created as a more cost-effective endoscopic alternative to LSG, but very few comparative studies are available. Therefore, a proper meta-analysis that combines data from the two different techniques is needed. The studies revealed notable biases, including the type of design and failure to report loss to follow-up rate in some studies; additionally, one study did not follow its own selection criteria and reported an average BMI lower than the minimum value set. The quality of the available studies is poor, and valid studies to base guidelines on are necessary.

Singh et al. (2020) conducted a systematic review and found eight studies addressing the OverStitch device, which included a total of 1,859 individuals. The studies were all observational and included single-center and multicenter experiences. The primary outcomes measured were the percentage of TWL, the percentage of EWL, and SAEs. The authors found that the pooled mean percentage of TWL at 6, 12, and 24 months was 14.86%, 16.43%, and 20.01%, respectively. Similarly, the percentage of EWL at 6, 12, and 24 months was 55.75%, 61.84%, and 60.40%. The incidence of SAEs was 2.26%, and no mortality was reported. Gastrointestinal bleeding was the most common documented SAE and was usually managed conservatively with packed red blood cell transfusion. Based on the analysis, the authors concluded that ESG is a promising technique, with effective weight loss outcomes. Limitations include a lack of controlled studies, lack of standardization for the definition for SAE, and lack of long-term follow-up data. (The publication by Lopez-Hava et al., 2017, previously cited in this policy, was included in this systematic review.)

Hedjoudje et al. (2020) conducted a systematic review and meta-analysis of eight studies, which included 1,772 individuals who underwent ESG. The primary outcome measurements included relative weight loss, decrease in BMI, and relative estimated weight loss. SAEs were reported in all studies, with an occurrence of 2.2%; the studies included 18 individuals with pain or nausea that required hospitalization, nine individuals with upper gastrointestinal bleeding, eight individuals with perigastric leak or collection, one individual with pneumoperitoneum, and one individual with pulmonary embolism. The authors found that the data suggested that ESG gave way to significant sustained weight loss and safety. Individuals had a BMI decrease of 5.6 kg/m$^2$, the mean TBWL was 15.1%, and the relative EWL was 57.7%. These results appear to be sustained through 18 to 24 months of follow-up. Limitations include a lack of a control group, large loss to follow-up, lack of reporting for mild AEs, and lack of long-term outcomes; future studies are warranted.

## *Gastrointestinal Liner (EndoBarrier)*

Currently, evidence regarding the efficacy and safety of gastrointestinal liners for obesity and weight loss is insufficient; additional well-designed RCTs are needed, along with the long-term effects and safety and efficacy results. Several clinical trials are in progress for the EndoBarrier device; information can be found at https://www.ClinicalTrials.gov.

In a 2024 systematic review and meta-analysis, Chen et al. evaluated the safety and efficacy of DJBL for obesity and T2D. There were 30 studies included, with 1,751 individuals. There were 18 studies that reported BMI reduction at 12 months post implantation; the reduction was 4.8 kg/m$^2$. Post explantation, BMI decreased by only 2.36 kg/m$^2$ from the baseline, based on data from 10 studies. The pooled EWL at 12 months was reported by six studies and was 41.3%. The pooled TWL at 12 months was reported by 10 studies and was 13.1%. The pooled $HbA_{1c}$ reduction after DJBL showed a standardized MD of -0.72% at 12 months (18 studies), and after explantation, the $HbA_{1c}$ reduction showed a standardized MD of -0.36 (10 studies). There were seven studies that reported changes in fasting glucose levels at 12 months, with pooled results indicating a reduction by -0.62; seven studies reported changes after explantation at 12 months, indicating a reduction of -0.40. While there was a systolic and diastolic blood pressure reduction with implantation, post explantation, there was no significant difference. There were also no significant changes in total cholesterol, LDL cholesterol, or triglycerides compared with baseline, except for HDL, which increased. The pooled early removal rate was 19%, mainly due to abdominal pain, and the incidence of SAEs was 17%, including device migration (6%), gastrointestinal hemorrhage


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(4%), device obstruction (4%), and hepatic abscess (2%). The authors concluded that while in situ, DJBL offers improvement in weight loss and glycemic control as well as cardiovascular parameters, and further studies are warranted to determine long-term efficacy. Limitations include significant heterogeneity among the studies in most pooled outcomes and lack of long-term effects, as the longest available follow-up period post explantation was 12 months. (The publications by Ruban et al., 2022, Quezada et al., 2018, Forner et al., 2017, Betzel et al., 2017, and Vilarrasa et al., 2017, previously cited in this policy, are included in this systematic review.)

## *Intragastric Balloon*

There is mixed evidence regarding the long-term efficacy and safety of IGBs and their use in obesity; additional well-designed RCTs and long-term data are warranted.

Based on a Clinical Evidence Assessment by ECRI (2022), the evidence for the Spatz3® IGB is inconclusive. Assessment of two RCTs, three nonrandomized, comparison studies, two case series, and two chart reviews that assessed weight loss and AEs with Spatz3 in adults with obesity revealed short-term, clinically significant weight loss; however, whether these results were long term remains to be seen. Limitations include small sample sizes; the retrospective design of the studies; and the lack of randomization, masking, and controls, along with the single-center focus. Large, robust studies, with long-term results, are warranted, and several ongoing clinical trials may address this in the future.

Zou et al. (2021) performed a systematic review and meta-analysis to evaluate the efficacy of the IGB as an obesity management tool for metabolic dysfunction–associated fatty liver disease (MAFLD). Thirteen observational studies and one RCT met the inclusion criteria (624 individuals in total). The results showed that over time, IGB therapy significantly improved the serum markers Homeostasis Model Assessment of insulin resistance, alanine aminotransferase, aspartate aminotransferase, and γ-glutamyl transpeptidase levels from baseline to follow-up. The authors concluded that IGBs have the potential to become a multidisciplinary management tool in MAFLD; however, the IGB is a temporary measure, and if the individual cannot maintain an active lifestyle after the first balloon is removed, relapse of MAFLD is expected. Limitations include the lack of a comparison group; further RCTs are needed.

Hayes (2018; updated 2022) reported that low-quality evidence suggests that IGBs have mixed results with regard to weight loss over the short term when used as an adjunct to diet and exercise. These devices are consistently associated with increased AEs, and all studies analyzed lacked long-term follow-up on maintaining weight loss and safety concerns.

A 2025 ECRI Clinical Evidence Assessment on the Orbera® Intragastric Balloon System concluded that the evidence is inconclusive, with mixed results, and shows that the use of Orbera results in short-term, clinically significant weight loss in most individuals; however, most individuals regain most of the lost weight within 6 months to 1 year of balloon removal. They concluded that Orbera is unlikely to benefit most individuals, unless it is followed by treatments with long-term effectiveness. Orbera may be beneficial for very heavy individuals to become eligible for bariatric surgery; however, available studies provide too few data to confirm whether Orbera use improves bariatric surgery outcomes. Additional randomized studies are needed to compare Orbera with other treatments, and studies to assess Orbera as an adjunct or alternative to weight loss medications would also be helpful. In a multicenter, open-label, industry-sponsored RCT, Abu Dayyeh et al. (2021; included in the ECRI 2022 report above) investigated the safety and efficacy of the Spatz IGB in adults with obesity. Overall, 288 participants were randomly assigned to receive either the IGB plus dietary and exercise counseling or dietary and exercise counseling alone for 32 weeks. The inclusion criteria were participants aged 22 to 65 years, a BMI of 30 kg/m$^2$ or greater for the past 2 years, a history of unsuccessful nonsurgical weight loss methods, and a willingness to participate in the required dietary restrictions. The IGB was implanted via esophagogastroduodenoscopy under conscious or monitored anesthesia sedation; depending on the participant's height, an initial volume of 400 ml, 450 ml, 500 ml, or 550 ml was used. During the 32 weeks, all participants followed a 1,000- to 1,200-kcal/day diet and exercise plan. After 32 weeks, the IGB was removed, and participants were followed up for another 24 weeks. The primary outcomes consisted of the percentage of TBWL and clinical responder rate, which was achieved by a decrease of at least 5% TBWL at 32 weeks. The mean percentage of TBWL at 32 weeks was 15.0% (95% CI, 13.9%-16.1%) in the IGB group vs 3.3% (95% CI, 2.0%-4.6%) in the control group ($p < 0.0001$). The authors found that the adjustable IGB, combined with lifestyle modification, enabled significant weight loss over a period of 6 months, with an observed acceptable safety profile. Limitations include no masking or sham intervention and an approximately 20% loss to follow-up at 32 weeks. Future studies should assess the long-term safety of the device.

An ECRI (2020) Health Technology Assessment focused on the safety and efficacy of the Elipse™ and Obalon, which are two ingestible IGBs. The evidence was inconclusive, citing that RCTs would be beneficial to determine whether any differences exist in weight loss and SAE risks. Available clinical guideline recommendations on IGBs are mixed, and none pertain to ingestible IGBs. Thus, evidence gaps remain, and additional comparative studies of ingestible and conventional IGBs are needed.


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Moore et al. (2019; included in the ECRI report above) performed a retrospective analysis in patients who received the Obalon Balloon System, which is a swallowable, gas-filled IGB system for weight loss. A web-based registry was accessed for the data on 1,343 patients with a starting BMI of ≥ 25 kg/m$^2$. Nonserious AEs and SAEs were reported in 14.2% and 0.15% of patients, respectively. Weight loss in the indicated use (BMI, 30-40 kg/m$^2$) was 9.7 ±6.1 kg and 10.0% ±6.1% TBWL. Weight loss in the other BMI categories was 8.2 ±5.6 kg or 10.3% ±7.0% TBWL for a BMI of 25 to 29.9 kg/m$^2$ and 11.6 ±7.8 kg or a TBWL of 9.3% ±6.0% for a BMI of > 40 kg/m$^2$. The authors concluded that the Obalon Balloon System is safe and effective at stimulating weight loss and provides practitioners with another tool to treat obese individuals who have experienced failure with other weight loss programs. Limitations include the lack of a comparison group, possible bias of a manufacturer-sponsored study, variation with loss and behavior modification data collection, and lack of data collection for comorbidities and metabolic data, resulting in an inability to perform a data analysis for these areas.

Coffin et al. (2017; included in the Hayes 2021 report above) published findings from their multicenter RCT, in which they compared 6 months of IGB or standard medical care (low-calorie diet, with bimonthly dietician evaluations) as bridge therapies to laparoscopic gastric bypass in super-obese participants (> 45 kg/m$^2$). The surgery was performed at 6 months, shortly after removal of the IGB, and assessments were undertaken through 12 months. While the BMIs between groups were comparable at baseline, IGBs significantly reduced BMI by 6 months compared with standard care, with a median BMI of 47.9 kg/m$^2$ in IGB participants and 50.7 kg/m$^2$ in control participants ($p < 0.001$). However, while the implanted IGB was effective in the short term, having the IGB before surgery did not impact postsurgical outcomes after 12 months (approximately 6 months post surgery); the groups' BMIs were not significantly different at this time point (median BMI: IGB, 38.1 kg/m$^2$ vs standard care, 37.6 kg/m$^2$; $p = 0.56$). The authors concluded that IGB insertion before laparoscopic gastric bypass induced weight loss but did not improve the perioperative outcomes or affect postoperative weight loss. Limitations of the study include a short duration of the IGB intervention, poor recruitment rate, higher-than-expected use of intensive care unit facilities, and poor weight loss in the IGB group.

Nunes et al. (2017) conducted a retrospective review in 2,002 patients who underwent an IGB procedure to determine its effectiveness with different degrees of obesity. A total of 946 patients were lost to follow-up. Overall, 40 (3.78%) had device removal due to intolerance, and 1,016 patients completed the 6-month treatment. The mean weight loss was 18.9%, and EWL was 60.1%; a BMI reduction of 6.76 points was observed. Six months after the removal of the balloon, 842 patients had continued follow-up (82.8%). At this time, weight loss was 19.84%, and EWL was 59.49%; a BMI reduction of 7.06 points was observed. In all groups, a statistical difference between the times T0 and T1 and between T1 and T2 ($p < 0.001$) was seen. No statistical difference between T2 and T3 in any group was observed. The authors concluded that the IGB provided sustained weight loss in patients who remained in dietary follow-up for 1 year. The study is limited by the lack of a comparison group and high rate of loss to follow-up. Longer-term outcomes, with well-designed RCTs, are needed to further evaluate the IGB.

Saber et al. (2017) conducted a systematic review and meta-analysis to evaluate the efficacy and safety of IGB treatment. A total of 20 RCTs, involving 1,195 individuals, were identified. Weight loss results before and after 3 months were analyzed separately. The weight loss results in individuals with or without IGB treatment were compared. A significant effect size was calculated that favored fluid-filled IGBs over air-filled IGBs. Flatulence, abdominal fullness, abdominal pain, abdominal discomfort, and gastric ulcer were significantly more prevalent among IGB individuals than among non-IGB control individuals. No mortality was reported with IGB treatment. In the authors' opinion, IGB treatment, in addition to lifestyle modification, is an effective short-term modality for weight loss. However, evidence confirming its safety or long-term efficacy is insufficient.

The REDUCE pivotal trial (Ponce et al., 2015, included in the Hayes 2021 report above, and Jung et al., 2020, systematic review) was a prospective, randomized controlled, pivotal trial of a dual IGB to evaluate the safety and effectiveness of a dual balloon system (DBS) plus diet and exercise in the treatment of obesity compared with those of diet and exercise alone. Participants (n = 326) with a BMI of 30 to 40 kg/m$^2$ were randomized to endoscopic DBS treatment plus diet and exercise (DUO; n = 187) or sham endoscopy plus diet and exercise alone (DIET; n = 139). The coprimary end points were a between-group comparison of percentage of EWL and DUO participant responder rate, both at 24 weeks. Thereafter, DUO participants had the DBS retrieved, followed by 24 additional weeks of counseling; DIET participants were offered DBS treatment. The mean BMI was 35.4 kg/m$^2$. Both primary end points were met. DUO weight loss was over twice that in DIET. DUO participants had a significantly greater percentage of EWL at 24 weeks [ITT, 25.1%; completed cases (CCs), 27.9% (n = 167)] than DIET participants [ITT: 11.3%, $p = 0.004$; CCs, 12.3% (n = 126)]. DUO participants significantly exceeded a 35% response rate (ITT, 49.1%, $p < 0.001$; CCs, 54.5%) for weight loss, dichotomized at 25% EWL. Accommodative symptoms abated rapidly with support and medication. Balloon deflation occurred in 6% without migrations. Early retrieval for nonulcer intolerance occurred in 9%. Gastric ulcers were observed; a minor device change led to significantly reduced ulcer size and frequency (10%). The authors concluded that the DBS was significantly more


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effective than diet and exercise in causing weight loss, with a low AE profile. Additional RCTs, with longer follow-up, are needed.

### *TransPyloric Shuttle Device*

In a brief from ECRI (2019), the evidence for the TransPyloric Shuttle device is inconclusive. The evidence is limited, indicating that longer-term follow-up data are warranted. The RCT that was reviewed appeared to have a low risk of bias, but results from a single trial were not conclusive and need independent confirmation in another controlled trial. The case series had a very high risk of bias due to a small sample size, lack of a control group and randomization, and blinding. Both the RCT and case series reported relatively short follow-up.

In a prospective, multicenter, single-arm feasibility trial, Sandler et al. (2018) evaluated 32 obese participants with a transoral endoscopic gastrointestinal bypass device. The device is a cuff attached to the distal esophagus by transmural anchors and connected to a 120-cm sleeve, diverting undigested nutrients to the jejunum. The baseline data collected included body weight, vital signs, AEs, medications, $HbA_{1c}$, fasting glucose level, and lipid levels, in addition to follow-up visits. The device status was endoscopically assessed every 6 months. At 12 months, the 32 participants had lost an average of 44.8% of excess body weight, 17.6% of total body weight, 20.8 kg, and 7.5 BMI points. The authors concluded that this study demonstrates the feasibility, safety, and efficacy of a fully transoral gastrointestinal bypass implant and that this endoscopic device may be a valuable addition to the available treatment for the management of morbid obesity. However, this study is limited by the lack of a comparison group, small sample size, and short-term follow-up.

Marinos et al. (2014) conducted a prospective, open-label, nonrandomized, single-center, investigational clinical trial to evaluate the safety and efficacy of the TransPyloric Shuttle device. The study enrolled 20 participants, meeting the criteria in two cohorts, with treatment periods of 3 and 6 months. Participants were required to be ≥ 18 and ≤ 55 years of age, with a BMI between 30 and 50 $kg/m^2$. Before device placement, participants were provided with nutritional guidelines for a low-calorie diet, and no additional dietary counseling was given after the initial consultation. Participants were placed under general anesthesia, and the devices were deployed and retrieved with no complications. All 20 participants enrolled in the study had lost weight at the time of the device removal. Both the 3- and 6-month participants had statistically significant improvements in overall Impact of Weight on Quality of Life-Lite score that exceeded the 7.7- to 12-point threshold to define a clinical change. All but two participants completed the planned treatment period; both participants had the device removed due to complaints of epigastric pain. Limitations of the study include a small number of participants and short treatment duration. The authors concluded that the TransPyloric Shuttle device is a promising technology that has the potential to benefit obese individuals seeking to lose weight.

Eid et al. (2014) conducted a prospective, single-center, randomized, single-blinded study from July 2009 through February 2011 to investigate the safety and effectiveness of endoscopic gastric plication with the StomaphyX device vs those of a sham procedure for revisional surgery in RYGB participants to reduce regained weight. Enrollment was closed prematurely because preliminary results indicated failure to achieve the primary efficacy end point in at least 50% of StomaphyX-treated participants. The 1-year follow-up was completed by 45 participants treated with StomaphyX and 29 participants in the sham treatment group. The primary efficacy outcome was achieved by 22.2% (10) with StomaphyX vs 3.4% (one) with the sham procedure ($p < 0.01$). Participants undergoing StomaphyX treatment experienced a significantly greater reduction in weight and BMI at 3, 6, and 12 months ($p \leq 0.05$). One causally related AE was seen with StomaphyX, which required laparoscopic exploration and repair.

## Vagus Nerve Blocking

Currently, quality evidence supporting the long-term efficacy of vagus nerve blocking for obesity treatment is insufficient; additional robust studies that include randomization are warranted.

Apovian et al. (2017) reported the 2-year outcomes from the ReCharge study in participants initially randomized to an active intervention. At 24 months, 123 VBLOC participants (76%) remained in the trial. Participants who presented at 24 months (n = 103) had a mean EWL of 21% (8% TWL); 58% of participants had ≥ 5% TWL, and 34% had ≥ 10% TWL. Among the subset of participants with abnormal preoperative values, significant improvements were observed in mean LDL (-16 mg/dL) and HDL cholesterol (+4 mg/dL), triglycerides (-46 mg/dL), $HbA_{1c}$ (-0.3%), and systolic (-11 mm Hg) and diastolic blood pressures (-10 mm Hg). QOL measures were significantly improved. Heartburn/dyspepsia and implant site pain were the most frequently reported AEs. The primary related SAE rate was 4.3%. The findings are limited by the lack of a comparison group.

Morton et al. (2016) reported 12-month outcomes from the ReCharge study. Overall, 53 participants were randomized to VBLOC and 31 to sham. Qualifying obesity-related comorbidities included dyslipidemia (73%), hypertension (58%), sleep apnea (33%), and T2D (8%). The VBLOC group achieved a percentage of EWL of 33% (11% TWL) compared with 19%


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of EWL (6% TWL) with sham at 12 months (treatment difference, 14 percentage points; 95% CI, 7-22; p < 0.0001). Common AEs with VBLOC through 12 months were heartburn/dyspepsia and implant site pain; the majority of events were reported as mild or moderate. The authors concluded that VBLOC therapy resulted in significantly greater weight loss than the sham control in participants with moderate obesity and comorbidities; additionally, it had a well-tolerated safety profile. Longer-term outcomes are needed to demonstrate the continued durability of this procedure.

Shikora et al. (2016) reported 2-year outcomes from the VBLOC DM2 study, a prospective case series in 28 participants with T2D, a BMI between 30 and 40 kg/m$^2$, and a previous VBLOC procedure. At 24 months, the mean percentage of EWL was 22% (95% CI, 15%-28%; p < 0.0001) or 7.0% of TWL (95% CI, 5.0%-9.0%; p < 0.0001). $HbA_{1c}$ decreased by 0.6 percentage points (95% CI, 0.2-1.0; p = 0.0026), on average, from 7.8% at baseline. Fasting plasma glucose levels declined by 15 mg/dL (95% CI, 0-29 mg/dL; p = 0.0564), on average, from 151 mg/dL at baseline. Among participants who were hypertensive at baseline, systolic blood pressure declined by 10 mm Hg (95% CI, 2-19 mm Hg; p = 0.02), diastolic blood pressure declined by 6 mm Hg (95% CI, 0-12 mm Hg; p = 0.0423), and mean arterial pressure declined by 7 mm Hg (95% CI, 2-13 mm Hg; p = 0.014). Waist circumference was significantly reduced by 7 cm (95% CI, 4-10 cm; p < 0.0001) from a baseline of 120 cm. The most common AEs were mild or moderate heartburn, implant site pain, and constipation. The authors concluded that improvements in obesity and glycemic control were largely sustained after 2 years of treatment with VBLOC therapy, with a well-tolerated risk profile. The findings are limited by the lack of a comparison group. Randomized controlled studies, with larger participant populations, are needed to validate these findings.

The ReCharge pivotal study, sponsored by the manufacturer (Ikramuddin et al., 2014), was a prospective, randomized, double-blinded, sham-controlled, multicenter trial to evaluate the safety and effectiveness of the Maestro system in treating obesity. The trial enrolled participants who had a BMI of 40 to 45 kg/m$^2$ or a BMI of 35 to 39.9 kg/m$^2$, with at least one obesity-related comorbid condition, and who had experienced failure of a more conservative weight reduction alternative. A total of 239 participants were enrolled at 10 investigational sites; 162 participants were randomized to the device group, and 77 were randomized to the sham control group. Participants randomized to the sham control group underwent a surgical procedure consisting of anesthesia, implantation of a nonfunctional neuroregulator, and the same number of incisions an investigator would use during the laparoscopic placement of the leads. The study authors noted that the trial met its primary safety end point and helped more than half of participants lose at least 20% of their excess weight. The use of vagal nerve block therapy compared with a sham control device did not meet either of the prespecified coprimary efficacy objectives, which were to determine whether the vagal nerve block was superior in mean percentage of EWL to sham by a 10-point margin, with at least 55% of participants in the vagal block group achieving a 20% loss and 45% achieving a 25% loss.

## *Clinical Practice Guidelines*

### American Diabetes Association (ADA)

The ADA Standards of Medical Care in Diabetes – 2024 states that metabolic surgery should be considered as a weight and glycemic management approach for patients with diabetes and a BMI of ≥ 30.0 kg/m$^2$ (or ≥ 27.5 kg/m$^2$ in Asian American patients), who are otherwise good candidates for surgery. They recommend that long-term lifestyle support and routine monitoring of micronutrient and nutritional status be provided to patients after surgery.

The joint statement by international diabetes organizations on metabolic surgery in the treatment algorithm for T2D (ADA, International Diabetes Foundation, Diabetes UK, Chinese Diabetes Society, and Diabetes India) makes the following recommendations:

- Metabolic surgery is recommended as an option to treat T2D in patients with the following conditions:
  - Class III obesity (BMI, ≥ 40 kg/m$^2$), regardless of the level of glycemic control or complexity of glucose-lowering regimens
  - Class II obesity (BMI, 35.0-39.9 kg/m$^2$) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy
- Metabolic surgery should also be considered as an option to treat T2D in patients with class I obesity and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications
- All BMI thresholds used in these recommendations should be reconsidered depending on the ancestry of the patient. For example, for patients of Asian descent, the BMI values above should be reduced by 2.5 kg/m$^2$

The organizations note that additional studies are needed to further demonstrate long-term benefits (Rubino et al., 2016).

### American College of Gastroenterology (ACG)

In the ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease (Katz et al., 2022), the following recommendations are made:


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- For refractory GERD, recommend optimization of proton pump inhibitor (PPI) therapy as the first step in the management of refractory GERD (moderate quality of evidence/strong strength of evidence)
- For GERD management, recommend maintenance PPI therapy indefinitely or antireflux surgery for patients with LA grade C or D esophagitis (moderate quality of evidence/strong strength of evidence)

## American Gastroenterological Association (AGA)

In 2021, the AGA conducted a technical review on IGBs for the management of morbid obesity (Muniraj et al., 2021). The review suggests that IGB therapy, with lifestyle modification, is an effective weight loss intervention and seems to result in improvements in metabolic parameters and medical comorbidities. Several evidence gaps were addressed in this review and included the long-term efficacy of IGB therapy compared with that of standard of care beyond 1 year; variables such as the filling medium (fluid vs gas); the potential efficacy of an ongoing dietary intervention or pharmacotherapy; the need for sequential balloon placement for sustained weight loss; and the role of exercise in weight loss sustainability. Although the risk of SAEs appears to be relatively low, early removal due to device intolerance seems to be relatively common. The AGA makes the following recommendations:

- In patients with obesity who are seeking a weight loss intervention and have experienced failure of a trial of conventional weight loss strategies, suggest the use of IGB therapy, with lifestyle modification, over lifestyle modification alone (conditional recommendation, moderate certainty).
- In patients with obesity undergoing IGB therapy, recommend moderate- to high-intensity concomitant lifestyle modification interventions to maintain and augment weight loss (strong recommendation, moderate certainty).
- In patients undergoing IGB therapy, recommend prophylaxis with PPIs (strong recommendation, moderate certainty).
- In patients undergoing IGB therapy, suggest using the intraoperative anesthetic regimens associated with the lowest incidence of nausea, along with perioperative antiemetics; suggest a scheduled antiemetic regimen for 2 weeks after IGB placement (conditional recommendation, low certainty).
- In patients undergoing IGB therapy, suggest against perioperative laboratory screening for nutritional deficiencies (conditional recommendation, low certainty).
- Suggest daily supplementation with one to two adult-dose multivitamins after IGB placement (conditional recommendation, very low certainty).
- After IGB removal, suggest subsequent weight loss or maintenance interventions that include dietary interventions, pharmacotherapy, repeat IGB, or bariatric surgery; the choice of weight loss or maintenance method after IGB is determined based on the patient's context and comorbidities following a shared decision-making approach (conditional recommendation, low certainty).

## American Society for Gastrointestinal Endoscopy (ASGE)

The Association for Bariatric Endoscopy, along with the ASGE Technology Committee, conducted a systematic review and meta-analysis to assess if transoral outlet reduction meets the performance thresholds outlined in the ASGE Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) document for the clinical adoption of endoscopic bariatric therapies (EBTs) (Jirapinyo et al., 2025). The outcomes measured were the amount of weight loss at 6 and 12 months as well as the pooled SAE rate. Subgroup analyses were conducted based on device and suture pattern. There were 18 studies included in the review, with 1,749 individuals. Of those, 14 studies consisted of 134 nonoverlapping individuals; however, the remaining four studies had some individuals from the previous 14 studies. The pooled TWL across 12 studies (1,154 individuals) was 8.9%, meeting the prespecified PIVI threshold of 5% TWL. A subgroup analysis by suture pattern demonstrated significantly greater weight loss with the pursestring suture pattern (five studies; 687 individuals), achieving 12.8% TWL, whereas non-pursestring patterns (six studies; 306 individuals) yielded 6.5% TWL, which did not meet the PIVI threshold. The pooled SAE rate across 15 studies (1,373 individuals) was 1.5%, meeting the PIVI threshold of 5% for SAEs. The authors concluded that the transoral outlet reduction procedure meets the ASGE PIVI thresholds for both effectiveness and safety, supporting its clinical adoption regardless of the device used, and should be offered to individuals experiencing recurrent weight gain after RYGB. For suturing transoral outlet reduction, the pursestring suture pattern appears to be associated with superior outcomes compared with other suturing techniques. Limitations of this study include the risk of bias, as most of the studies included were observational; high heterogeneity across studies; and potential bias due to financial conflicts of interest.

The ASGE Technology Committee conducted a systematic review and meta-analysis to evaluate whether endoscopic technologies have met appropriate thresholds outlined by the ASGE by the PIVI document (Abu Dayyeh et al., 2015a). The study authors evaluated Orbera IGB (Apollo Endosurgery) and the EndoBarrier duodenal-jejunal bypass sleeve (GI Dynamics). Results of the meta-analysis (17 studies; n = 1,683) indicated that the Orbera IGB satisfies the PIVI thresholds for therapy for primary and nonprimary bridge obesity. The percentage of EWL associated with the Orbera IGB at 12 months was 25.44% (95% CI, 21.45%-29.41%), with an MD over controls of 26.9% (percentage of EWL; 95% CI, 15.66%-38.24%; $p \leq 0.01$) in a total of three RCTs. The pooled percentage of TWL after use of the Orbera IGB was 13% at 6


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months (95% CI, 12.37%-13.95%) and 11.27% (95% CI, 8.17%-14.36%), both of which exceeded the PIVI threshold of 5% TBWL for nonprimary bridge obesity therapy.

In its position statement on EBTs in clinical practice, the ASGE states that EBTs that have been approved by the U.S. Food and Drug Administration (FDA) and meet thresholds of efficacy and safety, as defined in the ASGE/American Society for Metabolic and Bariatric Surgery PIVI, should be included in the obesity treatment algorithm as adjunctive therapies to a lifestyle intervention program, as outlined in the 2013 American Heart Association/American College of Cardiology/The Obesity Society Guidelines for the Management of Overweight and Obesity in Adults. The ASGE advises that endoscopists performing EBT have the ability to enroll patients in long-term follow-up care for weight loss maintenance (Sullivan et al., 2015).

## American Association of Clinical Endocrinologists (AACE)/The Obesity Society/American Society for Metabolic and Bariatric Surgery (ASMBS)

In a clinical practice guideline for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient, the AACE, The Obesity Society, and the ASMBS (Mechanick et al., 2019) cite the following:

- Patients with a BMI of ≥ 40 kg/m$^2$, without coexisting medical problems and in whom bariatric surgery would not be associated with excessive risk, should be eligible.
- Patients with a BMI of ≥ 35 kg/m$^2$ and one or more severe obesity-related complications that are remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, nonalcoholic fatty liver disease (NAFLD)/nonalcoholic steatohepatitis, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure. Patients with the following comorbidities and a BMI of ≥ 35 kg/m$^2$ may also be considered for a bariatric procedure, although the strength of evidence is more variable: obesity-hypoventilation syndrome and Pickwickian syndrome after careful evaluation of operative risk; idiopathic intracranial hypertension; GERD; severe venous stasis disease; impaired mobility due to obesity; and considerably impaired QOL.
- Patients with a BMI of 30 to 34.9 kg/m$^2$ and T2D, with inadequate glycemic control despite optimal lifestyle and medical therapy, should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity.
- The BMI criteria for bariatric procedures should be adjusted for ethnicity (i.e., 18.5-22.9 kg/m$^2$ is normal range, 23-24.9 kg/m$^2$ is overweight, and ≥ 25 kg/m$^2$ is obesity in Asian patients).
- Interventions should first include a multidisciplinary approach, including dietary change, physical activity, behavioral modification with frequent follow-up, and then, if appropriate, pharmacological therapy and/or surgical revision.
- Selection of a bariatric procedure should be based on the individualized goals of therapy [e.g., weight loss and/or metabolic (glycemic) control], available local-regional expertise (surgeon and institution), patient preferences, and personalized risk stratification.

In addition, they recommend that all patients seeking bariatric surgery have a comprehensive preoperative evaluation. This assessment includes an obesity-focused history, physical examination, and pertinent laboratory and diagnostic testing. A detailed weight history should be documented, including a description of the onset and duration of obesity, the severity, and recent trends in weight. Causative factors to note include a family history of obesity, use of weight-gaining medications, and dietary and physical activity patterns.

A brief summary of personal weight loss attempts, commercial plans, and physician-supervised programs should be reviewed and documented, along with the greatest duration of weight loss and maintenance. This information is useful in substantiating that the patient has made reasonable attempts to control weight before considering obesity surgery. The guidelines state that preoperative weight loss should be considered for patients in whom reduced liver volume can improve the technical aspects of surgery.

## American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE)

The AACE and ACE developed comprehensive clinical practice guidelines for the medical care of patients with obesity (Garvey et al., 2016), based on a diligent review of clinical evidence with “transparent incorporation of subjective factors.” The final recommendations recognize that obesity is a complex, adiposity-based chronic disease, for which management targets both weight-related complications and adiposity to improve overall health and QOL. The detailed evidence-based recommendations allow for nuanced clinical decision-making that addresses real-world medical care of patients with obesity, including screening, diagnosis, evaluation, selection of therapy, treatment goals, and individualization of care. The goal is to facilitate high-quality care of patients with obesity and provide a rational, scientific approach to management that optimizes health outcomes and safety. Included in their clinical guidelines are the following recommendations pertaining to BMI:


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- Patients with a BMI of ≥ 40 kg/m$^2$, without coexisting medical problems and for whom the procedure would not be associated with excessive risk, should be eligible for bariatric surgery.
- Patients with a BMI of ≥ 35 kg/m$^2$ and one or more severe obesity-related complications, including T2D, hypertension, OSA, obesity-hypoventilation syndrome, Pickwickian syndrome, NAFLD or nonalcoholic steatohepatitis, pseudotumor cerebri, GERD, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, and considerably impaired QOL, may also be considered for a bariatric surgery procedure.
- Patients with a BMI of 30 to 34.9 kg/m$^2$, with diabetes or metabolic syndrome, may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.
- Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease (CVD) risk reduction alone.

## American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society

The AHA/ACC and The Obesity Society published an updated 2013 Practice Guideline and Management of Overweight and Obesity in Adults (Jensen et al., 2014). The updated guidelines reflect such consensus and offer an update regarding treatment for patients who are overweight or obese. While the focus remains on sustained weight loss and decreased waist circumference, the authors also recommend the use of bariatric surgery for patients with a BMI of ≥ 40 kg/m$^2$ or a BMI of ≥ 35 kg/m$^2$ with comorbidities.

In a scientific statement on severe obesity in children and adolescents, the AHA (Kelly et al., 2013) summarized that RYGB has been associated with improvement or resolution of numerous comorbid conditions, including OSA, T2D, features of metabolic syndrome, pseudotumor cerebri, and psychosocial functioning. Controlled, prospective, adult studies have demonstrated a marked effect of bariatric surgery on mortality, comorbidity reversal, and prevention of comorbidity over ensuing decades; these beneficial effects of bariatric surgery help to inform clinical decision-making for severely obese adolescents when no other treatments have demonstrated long-term effectiveness.

## American Society for Metabolic and Bariatric Surgery (ASMBS)

### *Presurgical Evaluations*

The ASMBS published Recommendations for the Presurgical Psychosocial Evaluation of Bariatric Surgery Patients (Sogg et al., 2016). They recommend that bariatric behavioral health clinicians, with specialized knowledge and experience, be involved in the evaluation and care of patients both before and after surgery. Given the importance of long-term follow-up after weight loss surgery (WLS), the preoperative psychosocial assessment provides a valuable opportunity for patients to establish a trusted connection with a behavioral health provider as an additional resource and integral participant in their postoperative care. The need to ensure that postoperative psychosocial care is available has been noted in established practice guidelines, and evidence suggests that such care is associated with better outcomes after surgery.

In a 2016 position statement on preoperative supervised weight loss requirements, the ASMBS notes that no data from any RCT, large, prospective study, or meta-analysis are available to support the practice of mandated preoperative weight loss. Further, no level I data exist in the surgical literature nor is there consensus in the medical literature (based on over 40 published RCTs) that has clearly identified any one dietary regimen, duration, or type of weight loss program that is optimal for patients with clinically severe obesity. Finally, they recommend that patients seeking surgical treatment for clinically severe obesity should be evaluated based on their initial BMI and comorbid conditions.

### *Nutritional Impact of Bariatric Surgery*

In an updated guideline on the Integrated Health Nutritional Guidelines for Surgical Weight Loss, the ASMBS (Parrott et al., 2017) states that optimizing postoperative patient outcomes and nutritional status begins prior to the operation. Patients should be educated before and after WLS on the expected nutrient deficiencies associated with alterations in physiology. Although surgery can exacerbate preexisting nutrient deficiencies, preoperative screening for vitamin deficiencies has not been normalized in the majority of WLS practices. Screening is important because it is common for patients who present for WLS to have at least one vitamin or mineral deficiency prior to the operation.

Data continue to suggest that the prevalence of micronutrient deficiencies is increasing, while monitoring of patients at follow-up is decreasing. The ASMBS recommends that their guideline be considered a reasonable approach to patient nutritional care, based on the most recent research, scientific evidence, resources, and information available. It is the responsibility of the registered dietitian nutritionist and WLS program to determine individual variations as they relate to patient nutritional care.


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## *Indications for Surgery*

In a joint update, the ASMBS and the International Federation for the Surgery of Obesity and Metabolic Disorders released revised guidelines on indications for metabolic and bariatric surgery (MBS) (Eisenberg et al., 2023). Updates to the guidelines include:

- MBS is recommended for patients with a BMI of ≥ 35 kg/m$^2$, regardless of presence, absence, or severity of comorbidities.
- MBS should be considered for patients with metabolic disease and a BMI of 30 to 34.9 kg/m$^2$.
- BMI thresholds should be adjusted in the Asian population such that a BMI of ≥ 25 kg/m$^2$ suggests clinical obesity, and patients with a BMI of ≥ 27.5 kg/m$^2$ should be offered MBS.
- Long-term results of MBS consistently demonstrate safety and efficacy.
- Appropriately selected children and adolescents should be considered for MBS.
- Severe obesity is a chronic disease requiring long-term management after primary MBS, which may include revisional surgery or other adjuvant therapy to achieve the desired treatment effect.

## *Specific Bariatric Procedures*

The ASMBS (2016; updated 2025) has endorsed and supports the use of the following bariatric procedures and associated devices:

- Sleeve gastrectomy
- RYGB
- BPD/DS
- SADI-S
- OAGB
- Bariatric reoperative procedures
- Adjustable gastric banding
- ESG
- IGB

Endorsement acknowledges that obesity is a complex, chronic disease and that no single procedure is appropriate for every patient. By endorsing a procedure, the ASMBS is stating that it is one of many tools that qualified providers may use to deliver individualized, evidence-based care. The society recognizes that thoughtful debate exists within their membership. While the majority of survey respondents supported endorsement, we also respect the strong perspectives of those who raised concerns. The endorsement reflects ASMBS's responsibility to balance innovation, evidence, patient access, and clinical judgment while continually evaluating emerging data and outcomes. The ASMBS remains committed to supporting its members, advancing safe and effective obesity care, and ensuring that patients have access to appropriate treatment options delivered within accredited, high-quality programs (ASMBS, 2025).

In a position statement (Ghiassi et al., 2024), the ASMBS indicates that the adoption of OAGB outside the United States has resulted in numerous publications that report on the early and mid- and long-term results. OAGB results in effective weight loss at 5 years and beyond as well as metabolic effects that are comparable to those with RYGB or sleeve gastrectomy. Evidence has also shown that OAGB is effective as a revision option after restrictive operations such as LAGB, VBG, and sleeve gastrectomy. The authors note that since the majority of the peer-reviewed evidence on OAGB is retrospective, with a few RCTs, well-designed RCTs to compare OAGB with other established bariatric procedures are encouraged.

In an updated statement (Kallies and Rogers, 2020) on SADS, the ASMBS has concluded that SADI-S provides similar outcomes to those with the classic BPD/DS procedure and therefore should be recognized. The society's conclusion is that the current available peer-reviewed literature does not suggest that outcomes will differ substantially from those seen with the classic duodenal switch procedure. While the ASMBS endorses SADI-S as an appropriate bariatric surgical procedure, the society indicates that the publication of long-term safety and efficacy outcomes is still needed and strongly encouraged; concerns remain about intestinal adaptation, nutritional issues, and long-term weight loss/regain following this procedure.

A 2017 ASMBS updated position statement on sleeve gastrectomy as a bariatric procedure (Ali et al., 2017) summarizes the following:

- Substantial long-term outcome data published in the peer-reviewed literature, including studies comparing outcomes of various surgical procedures, confirm that sleeve gastrectomy provides significant and durable weight loss, improvements in medical comorbidities, improved QOL, and low complication and mortality rates for obesity treatment.


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- Sleeve gastrectomy is now the most commonly performed procedure in the United States (~53.8% of all bariatric procedures), followed by RYGB (23.1% of all procedures) (Chaar et al., 2018).
- In terms of initial early weight loss and improvement of most weight-related comorbid conditions, sleeve gastrectomy and RYGB appear similar.
- Sleeve gastrectomy is an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned, staged approach.
- The effect of sleeve gastrectomy on GERD is less clear because GERD improvement is less predictable, and GERD may worsen or develop de novo. Preoperative counseling specific to GERD-related outcomes is recommended for all patients undergoing sleeve gastrectomy.
- Based on safety and efficacy data, there is a trend toward sleeve gastrectomy as the procedure of choice for adolescents, although both RYGB and sleeve gastrectomy are routinely performed in teen WLS programs.
- As with any bariatric procedure, long-term weight regain can occur after sleeve gastrectomy and may require one or more of a variety of reinterventions.

The ASMBS Clinical Issues Committee position statement on IGB therapy, endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (Ali et al., 2016), includes the following summary and recommendations:
- Level 1 data regarding the clinical utility, efficacy, and safety of IGB therapy for obesity are derived from randomized clinical studies.
- Implantation of IGBs can result in notable weight loss during treatment.
- Although the use of IGBs results in notable weight loss, separating the effects of the balloon alone from those of supervised diet and lifestyle changes may be challenging. Of note, recent FDA pivotal trials demonstrated a benefit with balloon use compared with diet alone in their study populations. In general, any obesity treatment, including IGB therapy, would benefit from a multidisciplinary team that is skilled and experienced in providing in-person medical, nutritional, psychological, and exercise counseling.
- The safety profiles of IGBs indicate a safe intervention, with serious complications being rare. Early postoperative tolerance challenges can be significant but can be controlled with pharmacotherapy in the majority of patients, thereby minimizing voluntary balloon removals. These early symptoms should be discussed with the patient before the procedure.
- Although therapy with prolonged balloon in situ time and the use of sequential treatments with multiple balloons have been studied, awareness and adherence to absolute and relative contraindications of use and timely removal optimize device safety.
- Based on current evidence, balloon therapy is FDA approved as an endoscopic, temporary (maximum 6 months) tool for the management of obesity. Further review will evaluate the impact of diet, lifestyle changes, and pharmacotherapy during and after balloon removal.
- The ability to perform appropriate follow-up is essential when IGBs are used for weight loss to enhance their safety and avoid complications related to spontaneous deflation and bowel obstruction.

The ASMBS (Moore and Rosenthal, 2018) released an addendum to their IGB therapy position statement in response to the FDA's warnings on complications not identified during initial clinical trials and worldwide mortalities associated with IGBs. They recommend the following:
- As with all procedures, it is important that patients give informed consent and are aware of potential AEs. Laypeople may need to be counseled to correct a misperception that endoluminal treatments are nonsurgical and thus risk free.
- When less powerful treatments are chosen, behavioral modification increases in importance, and a risk of weight regain after the device is retrieved is present. The ASMBS routinely advocates for multidisciplinary care and support of the weight loss patient, and this recommendation is even more crucial for IGB recipients.

The ASMBS, in their 2015 position statement on vagal blocking therapy for obesity (Papasavas et al., 2016), concludes that the quantity of the data available at this time (six published studies; approximately 600 implanted devices) and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies, with longer follow-up, are required to establish the clinically significant efficacy and patients' tolerance of this device.

### *Bariatric Surgery in Adolescents*

The updated ASMBS pediatric MBS guidelines (Pratt et al., 2018) state that the disease of obesity has become recognized as a metabolic disease controlled by genetic factors, with clear evidence that the physiological control of weight is through neuroendocrine pathways that regulate body mass by affecting satiety, hunger, and metabolism. The recognition that weight is largely not under volitional control leads to a strong need to offer effective, sustainable, proven therapies to children with obesity.


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The summary of major changes in the guideline includes:

- Patient selection criteria of a BMI of ≥ 20% of the 95th percentile with a comorbidity or a BMI of ≥ 140% of the 95th percentile should be used when determining weight cutoffs for adolescents to undergo MBS. In their opinion, Tanner stage and linear growth should not be used to determine readiness for MBS.
- Regarding preoperative attempts at diet and exercise, no data show that the number of weight loss attempts correlates with success after MBS. Adherence to a multidisciplinary preoperative program may improve outcomes after MBS, but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity.
- Requiring adolescents with a BMI of > 40 kg/m$^2$ to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage when attempting to attain a healthy weight. Earlier surgical intervention (at a BMI < 45 kg/m$^2$) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end-organ damage from comorbidities.
- Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes with medical therapies for T2D in children, these comorbidities may be considered an indication for MBS in younger adolescents or those with lower obesity percentiles.
- Regarding NAFLD and nonalcoholic steatohepatitis, NAFLD may be present in at least 59% of adolescent patients referred for MBS. Given complete resolution of nonalcoholic steatohepatitis in approximately 85% of patients who undergo VSG or RYGB, NAFLD should be considered a strong indication for MBS in adolescents with severe obesity.
- OSA has been shown to cause significantly decreased health-related QOL, with an increased risk of morbidity and mortality in adolescents. MBS in adolescents results in significant improvement or resolution of OSA. Thus, OSA should be considered a strong indication for MBS.
- Adolescents who have severe obesity and have experienced failure of medical management for idiopathic intracranial hypertension should be considered for MBS.
- Adolescents with severe obesity have significant risk factors for CVD, including hyperlipidemia, elevated inflammatory markers, hypertension, and insulin resistance. MBS significantly improves these risk factors and therefore would be expected to decrease morbidity and mortality from CVD in the long term.
- Multidisciplinary teams should stabilize and treat preexisting eating disorders, ensure stable social support, assess and assist with nutrition and activity knowledge, and consider the addition of medications when appropriate.
- The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program guidelines should be followed when building an adolescent MBS program. It is the responsibility of the adolescent MBS program to have a transition plan in place for adolescents to transition to an adult MBS program for lifelong care.

The ASMBS Pediatric Committee (Michalsky et al., 2012) Best Practice Guidelines state that the associated risk-benefit analysis of bariatric surgery in adolescents should also include the consideration of the potential long-term health risks with untreated or inadequately treated obesity in the individual candidate. In addition, patients with a greater BMI and more serious medical illness are at increased risk of complications after bariatric surgery. Providing access to bariatric surgery earlier in life, when the disease burden and severity are lower, might decrease the operative risk, morbidity, and mortality. Additionally, earlier surgical intervention alters the natural course of many obesity-related comorbidities that otherwise would put the patient at risk of long-term complications and early mortality.

### *Impact of Obesity and Obesity Treatment on Fertility and Fertility Therapy*

In a position statement endorsed by the American College of Obstetricians and Gynecologists and The Obesity Society (Kominiarek et al., 2017), the ASMBS summarizes that:

- Bariatric surgery is effective in achieving significant and sustained weight loss in morbidly obese women and has been shown in case-control studies to improve fertility.
- Pregnancy is not recommended during the rapid weight loss phase after bariatric surgery; therefore, counseling and follow-up regarding contraception during this period are important.
- The specific impact of either medical weight loss treatments or bariatric surgery on the responsiveness to subsequent treatments for infertility in both men and women is not clearly understood at this time.

### *Revisional Bariatric Surgery*

In a literature review evaluating the RYGB limb lengths on outcomes (Aleassa et al., 2023), the ASMBS states that type 1 distalization as a revisional procedure, lengthening the biliopancreatic limb length and shortening the common channel (CC), results in significant weight loss but caries a risk of severe macro- and micronutrient deficiencies, especially if the CC is < 200 cm and a total alimentary limb length (TALL) (AL plus CC) is < 400 cm. Additionally, patients who undergo distalization of an RYGB as a revisional procedure should adhere to aggressive vitamin supplementation and regular nutrition monitoring in order to avoid nutritional complications.


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In a systematic review of reoperative bariatric surgery, the ASMBS Revision Task Force (Brethauer et al., 2014) states that the indications for and outcomes with reoperative bariatric surgery are procedure specific, but the current evidence supports additional treatment for persistent obesity, comorbid disease, and complications. Additional surgical therapy may benefit patients who present with insufficient weight loss, continued comorbid disease, or weight gain after the index bariatric procedure. A thorough evaluation should be conducted by a multidisciplinary program to determine the potential causes of their poor responses.

As the risks of reoperative bariatric surgery are higher than those with the primary procedure, evidence suggests the need for careful patient selection. In addition, the specific type of reoperative procedure performed should be based on the patient's primary procedure, patient's anatomy, patient's weight and comorbidities, and experience of the surgeon.

An ASMBS task force (Sudan et al., 2015) on reoperative surgery provided the updated definitions for reoperative surgery, as follows:

- Any operation after the first bariatric operation that qualified toward center of excellence volume requirements is considered a reoperation. Reoperations were further divided into corrective operations or conversions.
- An operation is considered corrective when complications or the incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed.
- Conversions involve changing an index bariatric operation (first operation) to a different type of bariatric operation, and reversal restored original anatomy.

The task force also conducted a systematic review to evaluate morbidity, mortality, and weight loss outcomes after reoperative bariatric surgery. Data on reoperations were compared to those from patients who had initial bariatric operations but did not undergo reoperations. Reoperations were subdivided into corrective operations and conversions:

- Of 449,753 bariatric operations, 28,720 (6.3%) had reoperations, of which 19,970 (69.5%) were corrective and 8,750 (30.5%) were conversions.
- The mean percentage of EBWL after conversion to a different bariatric operation was 39.3% and was 35.9% after a corrective operation. Although this percentage of EBWL was lower than that after a primary operation (43.5%), it is still considered by the task force to be substantial and excellent weight loss. However, not all reoperations will result in further weight loss or resolution of comorbidity.
- Restorative operations necessitated by intolerable side effects or complications of the index procedure, such as removal of the LAGB for band intolerance or dilated esophagus or reversing a duodenal switch or a gastric bypass for severe malabsorption, may result in weight gain and the return of comorbidities.
- Older patients (> 60 years of age) comprised 11% of the primary and 12% of the reoperative group of patients. The data suggest an overall improvement in the rates of morbidity and mortality after bariatric operations in recent years, even in higher-risk populations.

The task force concluded that although most patients do not require reoperative surgery, among those who do, the complication rate is low, and outcomes are clinically comparable to those with primary procedures.

## American Academy of Pediatrics (AAP)

In 2023, the AAP published the first edition of the Clinical Practice Guideline for the Evaluation and Management of Children and Adolescents With Overweight and Obesity. This document recommends MBS for pediatric patients over the age of 12 years for the following:

- Class II obesity and a BMI of ≥ 35 kg/m$^2$ or 120% of the 95th percentile for age and sex, whichever is lower, with clinically significant disease, including but not limited to:
  - T2D
  - Idiopathic intracranial hypertension
  - Nonalcoholic steatohepatitis
  - Blount disease
  - Slipped capital femoral epiphysis
  - GERD
  - OSA with an Apnea-Hypopnea Index of > 5
  - CVD risks
  - Depressed health-related QOL
- Class III obesity and a BMI of ≥ 40 kg/m$^2$ or 140% of the 95th percentile for age and sex, whichever is lower

Furthermore, the following is stated:

- The determination of eligibility for MBS should rely heavily on a multicomponent and individualized approach between members of the MBS team, the patient, and the patient's parents or guardians.


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- A referral should be to a comprehensive MBS center that has experience with and expertise in the treatment of patients aged younger than 18 years.
- Evaluation for MBS should include a holistic view of the patient and family, including individual needs (physical and psychosocial) and social risk factors.

## American Society for Metabolic and Bariatric Surgery (ASMBS)/National Lipid Association (NLA)/Obesity Medicine Association (OMA)

The ASMBS, NLA, and OMA published a two-part joint scientific statement on lipids and bariatric procedures. Part 1 concludes that bariatric procedures reduce body fat and have favorable effects on adipocyte and adipose tissue function, which contributes to improvement in metabolic diseases such as dyslipidemia, high glucose levels, and high blood pressure. Mechanisms by which bariatric procedures may improve dyslipidemia include favorable alterations in endocrine and inflammatory homeostasis. Bariatric procedures may also have favorable effects on bile acid metabolism and the intestinal microbiome, which may also improve dyslipidemia (Bays et al., 2016a).

Part 2 of this joint scientific statement summarizes that the principles that apply to bariatric procedures and lipid levels include the following: (1) the greater the fat mass loss, the greater the improvement in lipid parameters such as triglycerides and especially LDL cholesterol; (2) bariatric procedures allow for a decrease in the use of drug treatment for dyslipidemia; and (3) after bariatric procedures, HDL cholesterol may transiently decrease for the first 3 to 6 months after the procedure, which is usually followed by an increase in HDL cholesterol above the baseline value before the bariatric procedure. Finally, the authors observed that data are scarce regarding the effects of bariatric procedures on some of the lipid parameters such as non-HDL cholesterol, apolipoprotein B, and lipoprotein particle number and remnant lipoproteins (Bays et al., 2016b).

## Endocrine Society

In its updated guideline for the assessment, prevention, and treatment of pediatric obesity (Styne et al., 2017), the Endocrine Society's recommendations include the following:

- Diagnose a child or adolescent > 2 years of age as overweight if the BMI is ≥ 85th percentile but < 95th percentile for age and sex; as obese if the BMI is ≥ 95th percentile; and as extremely obese if the BMI is ≥ 120% of the 95th percentile or ≥ 35 kg/m$^2$.
- Children or adolescents with a BMI of ≥ 85th percentile should be evaluated for potential comorbidities.
- Insulin concentrations should not be used when evaluating children or adolescents for obesity.
- Bariatric surgery is suggested only under the following conditions:
  - Tanner 4 or 5 pubertal development and final or near-final adult height; BMI of > 40 kg/m$^2$ or BMI of > 35 kg/m$^2$; and significant, extreme comorbidities.
  - T2D, moderate to extreme sleep apnea, pseudotumor cerebri, debilitating orthopedic problems, and nonalcoholic steatohepatitis with advanced fibrosis.
  - Extreme obesity and comorbidities despite adherence to a formal program of lifestyle modification, with or without pharmacotherapy.
  - A BMI of > 40 kg/m$^2$, with mild comorbidities (hypertension, dyslipidemia, moderate orthopedic problems, mild sleep apnea, nonalcoholic steatohepatitis, and extreme psychological distress that is secondary to their obesity).
  - Confirmation of the stability and competence of the family unit via psychological evaluation (psychological distress due to impaired QOL from obesity may be present, but the patient does not have an underlying untreated psychiatric illness).
  - Ability to adhere to the principles of healthy dietary and activity habits.
  - Access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- Bariatric surgery should not be performed in preadolescent children, pregnant or breastfeeding adolescents (and those planning to become pregnant within 2 years of surgery), and any patient who has not mastered the principles of healthy dietary and activity habits and/or has unresolved substance use, an eating disorder, or an untreated psychiatric disorder.

## International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)

In 2024, the IFSO Bariatric Endoscopy Committee conducted a systematic review and meta-analysis and developed a position statement (Dayyeh et al.) on ESG for obesity management. There were 44 articles included in the review, with 15,714 individuals who underwent an ESG. Of the identified studies, 29 articles were case series, 14 were cohort studies, and one was an RCT. The quality of evidence from the observational studies was assessed as very low, while the one RCT that was included was assessed as moderate-quality evidence. The outcomes reviewed were weight loss and safety


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data. The mean EWL at 6 months, 12 months, 18 months, 24 months, 36 months, and 60 months was 48.04%, 53.09%, 57.98%, 46.57%, 53.18%, and 45.3%. The mean TBWL at 6 months, 12 months, 18 months, 24 months, 36 months, and 60 months was 15.66%, 17.56%, 16.25%, 15.2%, 14.07%, and 15.9%. Among the 15,928 ESG procedures, there were 194 SAEs (1.25%). Based on the review, the authors endorsed ESG as an effective and valuable intervention for managing obesity, stating that ESG is particularly beneficial for individuals with class I and II obesity as well as for those with class III obesity who are not suitable candidates for traditional bariatric surgery. The authors also noted that this minimally invasive procedure not only achieves significant weight loss outcomes in the short term and mid-term but also maintains a favorable safety profile. Limitations of the review include the number of observational studies measured as low quality, lack of long-term outcomes greater than 5 years, and potential bias due to financial conflicts of interest.

In a 2024 position statement (Ponce de Leon-Ballesteros et al.), the IFSO conducted a systematic review of evidence evaluating SADI-S/SADS to guide clinical practice. While the IFSO endorsed the procedure in 2021 as safe and effective, they emphasized the need, at that time, for long-term multidisciplinary care and RCTs. For this review, a total of 93 articles were included. One RCT, 14 cohort studies, 25 case-control studies, 42 case series, and 11 case reports were included. The authors noted that SADI-S/SADS demonstrated efficacy in weight loss and medium- to long-term control of T2D as well as positive outcomes regarding hypertension and hyperlipidemia. The impact of SADI-S/SADS on other comorbidities remained inconclusive. The authors also noted that frequent nutritional deficiencies were identified, including deficiencies of fat-soluble vitamins, anemia, and hypoalbuminemia. Limitations include considerable variation in the length of the common channel, which may lead to differences in terms of weight loss outcomes and late complications, and overestimation of data due to the duplication of individuals in the different studies. Despite significant efforts, high-quality evidence on SADI-S/SADS is scarce, and the authors acknowledged that limited data were found beyond 5 years. The IFSO encouraged participation in national and international registries, publication of long-term follow-up studies, and RCTs to enhance the quality of evidence for SADI-S/SADS.

## Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

A 2010 guideline by SAGES states that due to concerns of higher failure rates after fundoplication in the morbidly obese patient (BMI > 35 kg/m$^2$) and the inability of fundoplication to address the underlying problem (obesity) and its associated comorbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group. The benefits in patients with a BMI of > 30 kg/m$^2$ are less clear and need further study (Stefanidis et al., 2010).

In its 2008 Guidelines for Clinical Application of Laparoscopic Bariatric Surgery, endorsed by the ASMBS, SAGES confirms that bariatric surgery is medically indicated for morbidly obese patients who do not respond to dietary, behavioral, nutritional, and medical therapies, with clear evidence of efficacy and safety. BMI- and age-based candidacy guidelines should not limit access for patients with progressive or poorly controlled obesity-related comorbidities if the risk-benefit analysis favors surgery. LRYGB, adjustable gastric banding, and biliopancreatic diversion have all been proven effective. They do not make a definitive recommendation for one procedure over another and note that at the present time, decisions are driven by patient and surgeon preferences as well as considerations regarding the degree and timing of necessary outcomes vs tolerance of risk and lifestyle change.

Further, the 2008 guidelines state that no absolute contraindications to bariatric surgery exist. Relative contraindications to surgery may include severe heart failure, unstable coronary artery disease, end-stage lung disease, active cancer diagnosis/treatment, cirrhosis with portal hypertension, uncontrolled drug or alcohol dependency, and severely impaired intellectual capacity. Crohn disease may be a relative contraindication to RYGB and biliopancreatic diversion.

## Multidisciplinary Care Task Group

Greenberg et al. (2005) found a high incidence of depression, negative body image, eating disorders, and low QOL in patients with severe obesity; additionally, they found that perceived obesity-related health problems, motivation, and sense of coherence predicted better weight loss. Although their investigation showed that there are no predictive relationships between preoperative psychological evaluations and postoperative weight loss, the Behavioral and Psychological subgroup of the Multidisciplinary Care Task Group recommended that all bariatric surgery candidates be evaluated by a licensed mental health care provider experienced in the treatment of severely obese patients and work with a multidisciplinary team. Although research supports the association of psychological problems such as depression and personality disorder with less successful obesity surgery outcomes, the psychological problems are rarely cited as contraindications for surgery (Greenberg et al., 2005).

## National Institute for Health and Care Excellence (NICE)

The NICE 2025 guideline on overweight and obesity management offers bariatric surgery as a treatment option for patients with obesity when they (1) have a BMI of 40 kg/m$^2$ or more or between 35 kg/m$^2$ and 39.9 kg/m$^2$, with a significant health condition (for example, T2D or high blood pressure) that could be improved if they lost weight, and (2)


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agree to necessary long-term follow-up after surgery. In addition, the NICE guideline notes that bariatric surgery should be expedited for patients with a BMI of 35 kg/m$^2$ or more or 30 kg/m$^2$ to 34.9 kg/m$^2$ who have recent-onset (diagnosed within the past 10 years) T2D and is receiving or will receive assessment in a specialist weight management service. Additionally, the guideline suggests consideration for patients of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean family background using a lower BMI threshold (reduced by 2.5 kg/m$^2$) to account for the fact that these groups are prone to central adiposity and that their cardiometabolic risk occurs at a lower BMI. Further, surgical intervention is not generally recommended in children or young people; however, it may be considered only in exceptional circumstances and if they have achieved or nearly achieved physiological maturity.

The 2015 NICE interventional procedure guidance on managing T2D states that current evidence on the safety and efficacy of implantation of a DJBL for managing T2D is limited in quality and quantity. Therefore, the procedure should only be used in the context of research. Further research should give details of patient selection, including information about the use of the procedure in patients with different levels of BMI. The research should provide information on complications; reasons for early removal of the device; medication used for treating T2D, both when the device is in place and after its removal; and control of T2D after device removal. In 2018, the following statement was added to this guidance: “The device used in this procedure (EndoBarrier) no longer has a current CE mark. The CE mark is necessary for medical devices to be marketed in the European Union. A non-CE marked device can only be used in the context of clinical investigations with MHRA and research ethical approval.”

Interventional procedures guidance (IPG569) from NICE (2016) states that the current evidence on the safety of SADI-S for treating morbid obesity shows that well-recognized complications exist. The evidence on efficacy is limited in both quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit, or research.

The 2020 NICE interventional procedure guidance on a swallowable gastric balloon for weight loss states that the evidence on efficacy is inadequate, and this procedure should only be done in a research setting.

The 2024 NICE interventional procedure guidance on ESG for obesity states that evidence on safety shows that this procedure is safe in the short and long term. Evidence of efficacy shows that, when combined with lifestyle changes, patients with a BMI of over 30 kg/m$^2$ who have the procedure lose weight.

## American Academy of Sleep Medicine (AASM)

The AASM commissioned a task force of experts in sleep medicine, otolaryngology, and bariatric surgery to develop recommendations based on a systematic review of the literature (Kent et al., 2021). The following are recommendations intended as a guide for clinicians who treat overweight adults with OSA:

- Recommend that clinicians discuss referral to a sleep surgeon with adults with OSA and a BMI of < 40 kg/m$^2$ who are intolerant or unaccepting of continuous PAP (STRONG)
- Recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class II/III, BMI ≥ 35 kg/m$^2$) who are intolerant or unaccepting of PAP (STRONG)
- Suggest that clinicians discuss referral to a sleep surgeon with adults with OSA, a BMI of < 40 kg/m$^2$, and persistent inadequate PAP adherence due to pressure-related side effects (CONDITIONAL)
- Suggest that clinicians recommend PAP as an initial therapy for adults with OSA and a major upper airway anatomical abnormality prior to consideration of referral for upper airway surgery (CONDITIONAL)

## Department of Veterans Affairs (VA)/Department of Defense (DOD)

The 2020 guideline from the VA/DOD (Mayer et al., 2020) for the management of adult overweight or obesity makes the following suggestions and recommendations:

- In patients with a BMI of ≥ 30 kg/m$^2$ and T2D, suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention
- In adult patients with a BMI of ≥ 40 kg/m$^2$ or those with a BMI of ≥ 35 kg/m$^2$ with obesity-associated condition(s), suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s)
- In patients with obesity (BMI ≥ 30 kg/m$^2$) who prioritize short-term (up to 6 months) weight loss, suggest offering IGBs in conjunction with a comprehensive lifestyle intervention
- Evidence to recommend for or against metabolic/bariatric surgery in patients over age 65 years is insufficient
- Evidence to recommend for or against percutaneous gastrostomy devices for weight loss in patients with obesity is insufficient
- Evidence to recommend for or against IGBs for long-term weight loss to support chronic weight management or maintenance is insufficient


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### Thoracic Society

In a clinical practice guideline from the Thoracic Society (Hudgel et al., 2018), the following recommendations are made for patients who are overweight and have OSA:

- Reduced-calorie diet; and
- Exercise or increased physical activity; and
- Behavioral guidance

In addition, it was stated that pharmacological therapy and bariatric surgery are appropriate for selected patients who require further assistance with weight loss.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Bariatric surgical procedures are not subject to FDA regulation. FDA approval information for several devices related to bariatric surgery is described below.

The FDA approved the Orbera Intragastric Balloon System (Apollo Endosurgery, Inc.) on August 5, 2015. The Orbera System is indicated for use as an adjunct to weight reduction in obese adults with a body mass index (BMI) of ≥ 30 kg/m$^2$ and ≤ 40 kg/m$^2$. It is to be used in conjunction with a long-term, supervised diet and behavior modification program designed to increase the likelihood of significant long-term weight loss and weight loss maintenance. It is indicated for adults who have experienced failure of conservative weight reduction strategies, such as supervised diet, exercise, and a behavior modification program. Orbera has a maximum placement period of 6 months. For more information, refer to:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140008
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140008S016

(Accessed September 16, 2025)

Gastric banding involves the use of an adjustable or nonadjustable gastric band, which is subject to FDA marketing approval. In 2001, the BioEnterics® LAP-BAND System was approved by the FDA for marketing under the premarket approval process. According to the FDA labeling, this is approved for surgical treatment in severely obese adults in whom more conservative treatments (e.g., diet, exercise, behavioral modification) have failed. The LAP-BAND System is indicated for use in weight reduction for severely obese patients with (1) a BMI of at least 40 kg/m$^2$ or at least 35 kg/m$^2$ with one or more severe comorbid conditions or (2) those who are 100 lb. or more over their estimated ideal weight, according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have experienced failure of more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.

In February 2011, the FDA approved the LAP-BAND Adjustable Gastric Banding System by Allergan for weight reduction in obese patients who have a BMI of at least 40 kg/m$^2$ or less obese patients who have at least a BMI of 30 kg/m$^2$ and one or more additional obesity-related comorbid conditions, such as diabetes or hypertension. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf. (Accessed September 16, 2025)

Adjustable gastric bands are contraindicated in patients younger than 18 years of age.

Surgical stapling devices are used in all bariatric surgical procedures, except gastric banding. These devices have been approved by the FDA for use in various general surgical procedures. One device is the Endo GIA Universal Auto Suture, which inserts six parallel rows of staples into tissue. Other surgical staplers are manufactured by Ethicon Endo-Surgery. Additional information and the product code GDW and GAG are available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm. (Accessed September 16, 2025)

The OverStitch Endoscopic Suturing System was granted 510(k) marketing approval on June 27, 2018. According to the FDA, it is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract. The device can use either a single- or dual-channel endoscope. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181141.pdf. (Accessed September 16, 2025)

The TransPyloric Shuttle/TransPyloric Shuttle Delivery Device was granted premarket approval on April 18, 2019, and is indicated for weight reduction in adult patients with obesity and a BMI of 35.0 to 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; it is intended to be used in conjunction with a diet and behavior


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modification program. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180024a.pdf. (Accessed September 16, 2025)

In August 2018, the FDA granted GI Dynamics Inc., Boston, MA, an investigational device exemption for the EndoBarrier gastrointestinal liner. Additional information is available at: https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide. (Accessed September 16, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 07/01/2026 | **Coverage Rationale**<br>• Replaced references to “Nonalcoholic Fatty Liver Disease (NAFLD)” with “Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)”<br>• Revised coverage criteria for a planned two-stage procedure; replaced criterion requiring the “individual has been *compliant with* nutrition and exercise” with “individual has been *adherent to* nutrition and exercise”<br>• Revised list of unproven and not medically necessary procedures: |


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| Date | Summary of Changes |
|---|---|
| | ○ Added:<br>▪ Silastic ring vertical gastric bypass<br>▪ Transoral endoscopic surgery including transoral outlet reduction (TORe)<br>○ Removed "stomach aspiration therapy"<br>○ Replaced:<br>▪ "Gastrointestinal liners" with "*transoral endoscopic surgery including* gastrointestinal liners"<br>▪ "Intragastric balloon" with "*transoral endoscopic surgery including* intragastric balloon"<br>▪ "Transoral endoscopic surgery (includes endoscopic sleeve gastroplasty)" with "transoral endoscopic surgery including endoscopic sleeve gastroplasty *(includes OverStitch™)*"<br>**Medical Records Documentation Used for Reviews**<br>• Updated list of Medical Records Documentation Used for Reviews:<br>○ Added:<br>▪ Indicate procedure being requested and if this request is for initial, planned two stage procedure, revision, or removal<br>▪ Preoperative evaluation<br>▪ Physical activity patterns<br>▪ Results of recent relevant diagnostic testing<br>▪ Physician's treatment plan<br>▪ For adolescents aged 12 to 17 years, in addition to the [listed required documentation], also include obesity class<br>○ Replaced:<br>▪ "Current and *five*-year history of Body Mass Index" with "current and *two*-year history of Body Mass Index"<br>▪ "*Medical* treatment tried and failed *including* diet and exercise" with "treatments tried, failed, *or contraindicated*; *include the dates, duration, and reason for discontinuation* (*e.g.,* diet and exercise)"<br>▪ "*Psychological* evaluation *by a licensed behavioral health professional*" with "*psychosocial behavioral* evaluation"<br>▪ "Nutritional consult" with "*participation in a Multidisciplinary surgical preparatory regimen, including* nutritional consult"<br>▪ "For subsequent bariatric surgery, *provide medical notes documenting all of the* [required documentation] in addition to the following: *previous unsuccessful medical treatment* and initial *bariatric* surgery performed and date and *subsequent* complications *that require further surgical intervention*" with "for subsequent bariatric surgery, in addition to the [required documentation], *also include*: date of initial surgery, *details of* complications, *if any*, and *complete (staged) surgical plan*"<br>**Definitions**<br>• Updated definition of:<br>○ Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD)<br>○ Multidisciplinary<br>**Applicable Codes**<br>• Updated list of applicable CPT codes to reflect annual edits; added 43889<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information<br>• Archived previous policy version CS007.W |

# Instructions for Use

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