Bariatric Surgery

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Instructions for Use

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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)
Louisiana	Bariatric Surgery (for Louisiana 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 age 18 years or older, bariatric surgery using one of the procedures identified above for treating obesity is proven and medically necessary when all of the following criteria are met:
- **One** of the following:

- BMI ≥ 40 kg/m^2 (or BMI ≥ 37.5 kg/m^2 in individuals of Asian descent); or
- BMI ≥ 35 kg/m^2-39.9 kg/m^2 (or BMI ≥ 32.5 kg/m^2-37.4 kg/m^2 in individuals of Asian descent) in the presence of one or more of the following co-morbidities:
  - 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 mmHg or diastolic blood pressure 90 mmHg or greater, despite pharmacotherapy), coronary artery disease, hyperlipidemia]; or
  - History of cardiomyopathy; or
  - Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30; or
  - Evidence of Nonalcoholic Fatty Liver Disease (NAFLD); 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 age 12-17 years, the bariatric surgical procedures identified above are proven and medically necessary for treating obesity when all of 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 co-morbidities:
    - Insulin resistance or Type 2 diabetes; or
    - Poorly controlled hypertension (systolic blood pressure greater than 140 mmHg or diastolic blood pressure 90 mmHg or greater, despite pharmacotherapy); or
    - Hyperlipidemia; or
    - Obstructive Sleep Apnea confirmed on polysomnography with an AHI or RDI of ≥ 30; or
    - Evidence of Nonalcoholic Fatty Liver Disease (NAFLD); 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 (MBSAQIP) or can demonstrate similar programmatic components.

A planned two-stage procedure is proven and medically necessary when all of the following criteria are met:

- Initial BMI ≥ 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 compliant with nutrition and exercise; and
- Individual meets medical necessity criteria listed above at time of 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
- Uncontrollable reflux related to sleeve gastrectomy when all the following criteria are met:
  - Maximum nonpharmacological medical management failure (e.g., positional, dietary modification, and behavioral changes); and

- Maximum pharmacological medical management failure (e.g., at least one month of double dose PPI, H2 blocker, and/or sucralfate); and
- Severe esophagitis (grade C or D) confirmed by endoscopy despite maximum medical management

Removal of 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 (BAE)
  - Gastric electrical stimulation with an implantable gastric stimulator (IGS)
  - Intragastric balloon
  - Laparoscopic greater curvature plication, also known as total gastric vertical plication
  - Mini-gastric bypass (MGB)/laparoscopic mini-gastric bypass (LMGBP)/one-anastomosis gastric bypass (OAGB)
  - Single-anastomosis duodenal switch [also known as duodenal switch with single anastomosis or stomach intestinal pylorus sparing surgery (SIPS)]
  - Stomach aspiration therapy
  - Transoral endoscopic surgery [includes TransPyloric Shuttle® (TPS®) device, endoscopic sleeve gastroplasty]
  - Vagus nerve blocking (VBLOC®)
  - Gastrointestinal liners

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 a person having origins from the Far East, Southeast Asia, or the Indian subcontinent (e.g., Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) (United States Census Bureau, 2012).

Body Mass Index (BMI): A person's weight in kilograms divided by the square of height in meters. 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 (CDC), 2017].

The National Heart, Lung, and Blood Institute's (NHLBI) Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults classifies the ranges of BMI in adults as follows:

- < 18.5 – Underweight
- 18.5 to 24.9 kg/m^2 – Normal Weight
- 25-29.9 kg/m^2 – Overweight
- 30-34.9 kg/m^2 – Obesity Class I
- 35-39.9 kg/m^2 – Obesity Class II
- ≥ 40 kg/m^2 – Obesity Class III

The American Society of Metabolic and Bariatric Surgeons (ASMBS; 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 35-39.9 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

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

Los Angeles (LA) 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 involve less than 75% of the circumference
- Grade D: One (or more) mucosal break which involves at least 75% of the esophageal circumference

(Lundell, et al. 1999)

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 patient. Building the Multidisciplinary team includes staff such as the bariatric surgeon, obesity medicine specialist, registered dietician, specialized nursing, behavioral health specialist, exercise specialist, and support groups [American Society for Metabolic and Bariatric Surgery (ASMBS) textbook of bariatric surgery].

Nonalcoholic Fatty Liver Disease (NAFLD): Condition that is evidenced by hepatic steatosis (HS) diagnosed either by imaging or histology without a secondary cause of hepatic fat accumulation such as significant alcohol consumption, long-term use of steatogenic medication, or monogenic hereditary disorders (Chalasani et al., 2018).

Obstructive Sleep Apnea (OSA): The American Academy of Sleep Medicine (AASM) defines OSA as a sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. OSA severity is defined as:

- Mild for AHI or RDI ≥ 5 and < 15
- Moderate for AHI or RDI ≥ 15 and ≤ 30
- Severe for AHI or RDI > 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 or adjustable gastric band converted to Roux-en-Y (RYGB)]. Note: This is not the same as an intraoperative conversion (e.g., converting from laparoscopic approach to an open procedure)
- Corrective – A procedure that corrects or modifies 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, re-sleeve gastrectomy, limb length adjustments in RYGB, and 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.

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

CPT Code	Description
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
43999	Unlisted procedure, stomach
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 II 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 cancer, renal cell carcinoma, and non-Hodgkin's lymphoma.

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

Bariatric Surgery in the Adolescent Population

For adolescents, physical development and maturation may be determined utilizing the gender specific growth chart and BMI chart developed by the CDC, 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, as well as to 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 patient's unique situation.

Roux-en-Y Bypass (RYGB)/Gastric Bypass

The 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 (LAGB)

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 (VSG)

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 60-75% of the stomach, leaving a narrow gastric "tube" or "sleeve." This small remaining "tube" cannot hold as much food and produces less of the appetite-regulating hormone ghrelin, lessening a patient's desire to eat. VSG is not a purely malabsorptive procedure, so there is no requirement for lifetime nutritional supplementation (California Technology Assessment Forum, 2015).

Biliopancreatic Diversion With Duodenal Switch (BPD/DS) (also known as the Scopinaro Procedure)

BPD is primarily malabsorptive but has a temporary restrictive component. As in 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 measuring only 50 to 100 cm, thereby permitting relatively little absorption.

Robotic-Assisted Surgery

Robotic surgery provides surgeons with three-dimensional vision, increased dexterity and precision by downscaling surgeon's movements enabling a fine tissue dissection and filtering out physiological tremor. It overcomes the restraint of torque on ports from 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 (NOTES) is performed via a natural orifice (e.g., mouth, vagina, etc.), and in some cases eliminates the need for abdominal incisions. This form of surgery is being investigated as an alternative to conventional surgery.

Transoral restorative obesity surgery (ROSE) 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® (TPS®) device is a non-balloon, space occupying device with a 12-month treatment duration that is proposed as a new endoscopic bariatric therapy. The TPS device is comprised of 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, 2014;). The device was granted FDA premarket approval on April 16, 2019, and was approved for up to 12 months weight loss therapy in individuals with a BMI of 35.0 kg/m^2 to 40.0 kg/m^2 or a BMI of 30.0 kg/m^2 to 34.9 kg/m^2 with 1 or more obesity-related comorbid condition. The device is intended to be used in conjunction with a diet and behavior modification program (ECRI, 2019).

Endoscopic sleeve gastroplasty (ESG) 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. ESG 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 (LMGBP)/One-Anastomosis Gastric Bypass (OAGB)

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

Implantable Gastric Stimulator (IGS)

IGS is a small, battery-powered device similar to a cardiac pacemaker, in a small pocket, created beneath the skin of the abdomen using laparoscopy. The IGS 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 (VBLOC)

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

VBLOC 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 (IGB)

IGBs 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 6 months to be the current standard duration of therapy from insertion to removal (ASMBS, 2016).

Laparoscopic Greater Curvature Plication (LGCP) [also known as Total Gastric Vertical Plication (TGVP)]

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

Stomach Aspiration Therapy

Stomach aspiration therapy, such as with the AspireAssist®, uses a surgically placed tube (endoluminal device) designed to aspirate a portion of the stomach contents after every meal (Hayes, 2021). The AspireAssist® is intended for long-term use in conjunction with lifestyle therapy (to help individuals develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Individuals must be monitored regularly for weight loss progress, stoma site heath, and metabolic and electrolyte balance.

Bariatric Artery Embolization (BAE)

BAE is a minimally invasive procedure which is the percutaneous, catheter-directed, trans-arterial embolization of the left gastric artery (LGA). 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, utilize an endoscopically implanted sleeve into the stomach to reduce the stomach size. The sleeve is then removed after weight loss has been achieved. The EndoBarrier is not approved for use by the U.S. Food and Drug Administration (FDA) in the United States; it is limited by federal law to investigational use only.

Single-Anastomosis Duodenal Switch (SADS)

SADS is also called single-anastomosis loop duodenal switch, single-anastomosis duodenoileal bypass with sleeve gastrectomy, or stomach intestinal pylorus-sparing surgery – is a modification of biliopancreatic diversion with duodenal switch (BPD-DS). 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 the 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 from revisional surgery (Brethauer et al., 2014). It is important to determine if the poor response to primary bariatric surgery is due to anatomic causes that led to inadequate weight loss or weight regain or to the patient'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 GERD after bariatric surgery includes dietary and lifestyle modification, 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 (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) combined their individual accreditation programs into a single unified program. MBSAQIP works to advance safe, high-quality care for bariatric surgical patients 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).

Clinical Evidence

In a 2022 systematic review and meta-analysis, Alghamdi compared the results of Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) on the obesity comorbidities of diabetes, hypertension, dyslipidemias, obstructive sleep apnea (OSA) and GERD. Sixteen randomized controlled trials in adults with a BMI > 27.5 kg/m^2 with a follow up of 1-5 years were included (no trials with revision or conversion procedures were included). The results showed that for diabetes remission, 14 trials reported no statistically significant differences. There were statistically significant differences for hypertension (8 trials) and dyslipidemia (5 trials) remission in favor of LRYGB with substantial heterogeneity for dyslipidemia seen. Obstructive sleep apnea was assessed by 4 trials and showed equal efficacy. Two trials reported on GERD and showed that LRYGB was better for remission but there were no significant differences with regard to new onset GERD. Surgical complications were assessed and showed that LSG is associated with fewer early and late complications including dumping syndrome and fewer nutritional deficiencies. There was inconsistent reporting on the effects of the procedures on gut hormones and liver enzymes that contribute to nonalcoholic fatty liver disease. The authors concluded that the results of the two procedures are similar with LRYGB showing superiority to LSG for GERD, hypertension, and dyslipidemia remission.

Khalaj et al. (2020) conducted a cohort study comparing gastric bypass (GB) to sleeve gastrectomy (SG) and the effectiveness and safety of these two procedures. The authors evaluated 2,202 patients that underwent laparoscopic SG and 1,085 patients who underwent laparoscopic GB. The SG procedure was performed over a 36-F bougie and reinforced with an omental pouch; the GB procedure was performed as either RYGB or one anastomosis (OAGB). Evaluation of weight loss included body mass index change, percent of total weight loss, and percentage of excess weight loss. Type 2 diabetes mellitus (T2DM), hypertension (HTN), and dyslipidemia, as obesity-associated comorbidities were assessed in all patients. There were no major complications identified which was recognized by a return to the operating room, prolonged hospital stays beyond 7 days, or the need for re-admission. Quality of life (QoL) was assessed using the Iranian version of the Short-Form Health Survey which measured physical, social, and mental aspects of health. Patient 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; patients that underwent SG had a lower FPG and HbA1C when compared to the GB group. BMI was not significantly different between the two groups. Excess weight loss (EWL)% was 61.9 ±15.7, 74.8 ±19.1, and 75.0 ±21.9 in the SG group and 62.7 ±15.3, 77.5 ±18.4, and 80.1 ±20.8 in the GB group at 6-, 12-, and 24-month follow-ups, respectively. All patient comorbidities and QoL improved. The authors concluded that bariatric surgery is effective and safe for treatment of obesity; while both procedures are effective for weight loss, remission of obesity-associated comorbidities, and QoL, SG is associated with fewer complications and nutritional deficiencies.

Jung et al. (2020) conducted a systematic review and meta-analysis of 22 studies with 2,141 patients to comprehensively evaluate the efficacy of different endoscopic bariatric procedures compared to lifestyle modification in the treatment of morbid obesity. Intragastric balloon, duodenal-jejunal bypass liner (DJBL), aspiration therapy, primary obesity surgery endoluminal (POSE) procedure, and botulinum toxin injection to the stomach were included and the meta-analysis determined the percentage of weight loss (%weight loss) and percentage of excess weight loss (%EWL). The results showed that the Obalon Balloon system was shown to have efficacy for both %weight loss and %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 when compared to lifestyle modification. Gas-filled balloon and botulinum toxin injection did not show a significant difference in %weight loss or %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 show superior short-term efficacy compared with lifestyle modification. These findings are limited by 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 2015b, Chang 2014, Courcoulas 2017, Gersin 2010, Schouten 2010, Sullivan 2013, Thompson 2017.)

O'Brien et al. (2019) performed a systematic review and meta-analysis on 33 reports containing ten or more years of follow-up for patients that underwent bariatric surgery. The authors evaluated the long-term effectiveness of Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), or BPD/DS. Results for gastric bypass surgery showed a weighted mean % 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 for the patients receiving LAGB showed patient 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 lead to substantial weight loss which continued for at least 10 years. Due to patient education and lap band design changes, revisional surgery has decreased significantly over the past eleven years. The findings are limited by lack of direct comparison between techniques and lack of comparison groups not undergoing surgical treatments. (The following publications previously cited in this policy, are included in this systematic review: Maciejewski 2016, Salminen 2018, Schauer 2017, Sethi 2016, Sheikh 2017, Topart 2017, Vinzens 2017.)

Zhao and Jiao (2019) conducted a systematic review to determine whether LRYGB and LSG are equivalent for mid- and long-term weight loss, resolution of comorbidities and adverse events (AEs). Eleven RCTs were included in the meta-analysis and the authors found no significant difference in excess weight loss between LRYGB and LSG nor any significant difference for T2D improvement. This analysis did identify more postoperative early complications for LRYGB, but no difference between the two procedures in later postoperative period. Future studies should focus on the comparison of complication and comorbidities. Limitations included the variation in sample size among the included studies which may have created a bias, variation of patient age and preoperative BMIs which may have led to heterogeneity, and failure of subgroup analysis for reoperation rate. Additional studies are needed to determine the relative long-term efficacy of different bariatric surgeries. (Publication by Salminen 2018, which was previously cited in this policy, is included in this systematic review.)

Lager et al. (2017) retrospectively studied 30-day postoperative complications as well as changes in weight, blood pressure, cholesterol, hemoglobin, hemoglobin A1C, and creatinine from baseline to 2, 6, 12, and 24 months postoperatively in 383 patients undergoing RYGB and 336 patients undergoing SG. Follow-up rates were 706/719 at 2 months, 566/719 at 6 months, 519/719 at 12 months, and 382/719 at 24 months. Baseline characteristics were similar in both groups except for higher weight and BMI in the SG group. The RYGB group experienced greater total body weight loss at 6, 12, and 24 months (41.9 vs. 34.6 kg at 24 months, $p < 0.0001$). Excess weight loss was 69.7 and 51.7% following RYGB and SG respectively at 24 months ($p < 0.0001$). Blood pressure improved significantly in both groups. Surgical complication rates were greater after RYGB (10.1 vs. 3.5%, $p = 0.0007$) with no significant difference in life-threatening or potentially life-threatening complications. Weight loss was greater following RYGB compared to SG at 2 years. The authors recommend that surgical intervention be tailored to surgical risk, comorbidities, and desired weight loss. Limitations included retrospective design which may have impacted patient selection and other biases, incomplete biochemical data as some patients did not return to clinic for routine blood draws and performed at specific institution.

Polega et al. (2017) conducted a matched cohort study of laparoscopic BPD/DS and SG to compare 30-day outcomes. Of the 741 patients who underwent BPD/DS or SG, 2 cohorts of 167 patients each were matched for age, sex, and BMI. Length of stay (LOS) was longer in the BPD/DS cohort (2.5 ±9 days versus 2.1 ±7 days, $p < .001$). There were no significant differences between the groups in relation to 30-day postoperative rates of leak (0.3% versus 0.6%, $p > 0.99$), bleed (0% versus 0.3%, $p > 0.99$), reoperation (1.2% versus .6%, $p > .99$), or readmission (3% versus 1.2%, $p = .45$). There were no mortalities. After matching for age, sex, and BMI, the authors found no significant differences between BPD/DS and SG with regard to 30-day postoperative rates of leak, bleed, reoperation, readmission, or mortality.

Risstad et al. (2017) conducted a randomized clinical trial with 60 patients with body mass index 50-60 kg/m^2 to investigate bile acid profiles up to 5 years after RYGB and BPD/DS. Total bile acid concentrations increased substantially over 5 years after both RYGB and BPD/DS, with greater increases in total and primary bile acids after BPD/DS. Higher levels of total bile acids at 5 years were associated with lower body mass index, greater weight loss, and lower total cholesterol.

Xie et al. (2016) prospectively evaluated Apnea-Hypopnea Index (AHI) and Functional Outcomes of Sleep Questionnaires Scores (FOSQ) pre- and post-operatively in patients undergoing bariatric surgery. A total of 167 subjects were studied. The median age was 46 (14-75) years and BMI 49 (36-69) kg/m^2. Ninety-two (55.0%) patients were diagnosed with OSA preoperatively. Fifty (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. Eighty (87.9%) reported improved sleep quality 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 and without OSA. Thirty-nine (90.7%) patients 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 patients with and without OSAS. The findings are however limited by lack of comparison group without bariatric surgery.

Giordano (2015) conducted retrospective comparative study of consecutive super-obese patients. Patients either underwent RYGB (n = 102) or LAGB (n = 79). Early complications and weight loss outcomes were comparable between the two groups in the short term. However, weight loss and excess weight loss percent at 6 and 12 months of follow-up was significantly higher in patients who underwent RYGB than LAGB.

Magallares et al. (2015) conducted a meta-analysis of 21 studies evaluating the mental and physical health-related quality of life (HR-QOL) measures with the Short Form-36 (SF-36) before and after bariatric surgery. Study authors reported that obese patients scored less in the mental health component of 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 SF-36. Study authors concluded that obese patients experienced strong improvement in mental and physical QOL measures following surgery. The findings are limited by lack of comparison group.

A 2014 Cochrane Systematic Review of RCTs by Colquitt et al. found that surgery results in greater improvement in weight loss outcomes and weight associated comorbidities compared with non-surgical interventions, regardless of the type of procedures used. They noted the overall quality of evidence in this analysis to be moderate. When compared with each other, certain procedures resulted in greater weight loss and improvements in comorbidities than others. Outcomes were similar between RYGB and SG, and both of these procedures had better outcomes than AGB. However, in one RCT, the LRGYB procedure resulted in greater duration of hospitalization in two RCTs (4/3.1 versus 2/1.5 days) and a greater number of late major complications (26.1% versus 11.6%). For people with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than RYGB. Duodenojejunal bypass with sleeve gastrectomy and LRYGB had similar outcomes; however, this was based on one small trial. Isolated SG led to better weight-loss outcomes than AGB after three years follow-up. This was based on one trial only. Weight-related outcomes were similar between laparoscopic gastric imbrication and LSG in one trial. Across all studies adverse event rates and reoperation rates were generally poorly reported. The authors also found that most trials followed participants for only one or two years, therefore the long-term effects of surgery remain unclear. In addition, open RYGB, LRYGB and LSG led to losses of weight and/or BMI but there was no consistent picture as to which procedure was better or worse in the seven included trials. (The following publications previously cited in this policy, are included in this systematic review: Dixon 2008, Mingrone 2012.)

Biliopancreatic Diversion/Biliopancreatic Diversion With Duodenal Switch (BPD/DS)

Kapeluto et al. (2020) assessed long-term glycemic outcomes in 132 patients with type 2 diabetes (T2D) that received biliopancreatic diversion with duodenal switch (BPD/DS) surgery versus other bariatric surgeries. Inclusion criteria consisted of patients with diagnosis of T2D and those that had underwent BPD/DS surgical procedure. Patient follow up consisted of post-surgical assessments at week 3 and then at 4, 8, 12, 18, and 24 months and annually thereafter. Fifteen patients were lost to death during the 10 years follow-up and two more beyond 10 years. 90% of the patients had clinical remission of their diabetes; 3 patients had partial remission, 21 had improvement and 3 were unchanged in their status. The authors found that BPD-DS maintained a remission rate of 10 years postop in the vast majority of patients with advanced diabetes. The authors concluded patients that 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 included late arrival of the standard use of the HbA1C test, incomplete weight parameters due to lack of self-reported weights and retrospective analysis.

Strain et al. (2017) reported nine-year outcomes of BPD/DS. Initially 284 patients received a BPD/DS; 275 patients (69.8% women) age 42.7 years, BMI 53.4 kg/m^2 qualified for baseline analysis. Two hundred seventy-five patients were available in year 1; 275 patients in year 3; 273 patients in year 5; 259 patients in year 7; and 228 patients in year 9. Gender distribution was not different. BMI was 30.1 at 1 year and 32.0 at 9 years. Body fat was reduced to 26% after 2 years. Nutritional problems developed in 29.8% of patients over the course of observation. There were significant positive changes in quality of life between baseline and year 1 for most patients. Data showed that after surgery, the resolution of comorbidities continued for the 9-year follow-up period. Weight loss during the first year was well maintained, resolving comorbidities, and improving quality of life. According to the authors, rates of surgical complications resemble other bariatric procedures; however long-term nutritional deficiencies are of concern. The findings are limited by lack of 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 a hemoglobin A1c (HbA1c) level of 8.0% or higher and a BMI between 30.0 and 39.9. 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. Ninety-eight (82%) patients completed 5 years of follow-up. At 5 years, 13 participants (23%) in the gastric bypass group and 2 (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 5th year, 31 patients (55%) in the gastric bypass group vs. 8 (14%) in the lifestyle-medical management group achieved an HbA1c level of less than 7.0% (difference, 41%; 95% CI, 19%-63%; p = 0.002). Participants undergoing RYGB had more serious adverse events than did the lifestyle-medical management intervention, 66 events versus 38 events, most frequently gastrointestinal events, and surgical complications such as strictures, small bowel obstructions, and leaks. The authors concluded that in this patient population there remained a significantly better composite triple end point in the surgical group 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 patients thus unsure if study results would be the same with a group of better controlled glycemic patients. Additional limitations included incomplete follow up creating opportunity for bias and testing of a single type of bariatric surgery therefore unable to apply conclusions to other bariatric surgical approaches.

In a matched observational cohort study, Liakopoulos et al. (2017) evaluated 6,132 patients with a baseline BMI of 42 kg/m2 and T2D who underwent RYGB compared to patients who had not undergone RYGB. Over a 6-year follow-up period, beneficial changes in BMI, hemoglobin A1C, blood lipids 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 type 2 diabetes, 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 (BQoL) scores for 56 patients who underwent RYGB. The enrolled patients were divided into two groups: stable weight and weight regain with a review of the BQoL Index scores for each. The authors demonstrated and found in addition to a return to comorbid illness, weight regain was associated with worsening QoL thus showing the importance of close follow-up, early recognition, and intervention. Limitations included lack of established definition of weight regain in the current literature, the imbalance of weight regain and weight stable patients, and the retrospective nature of the study.

In a systematic review and meta-analysis, Yan et al. (2016) compared RYGB surgery versus medical treatment for type 2 diabetes mellitus T2D in obese patients. Six RCTs with a total of 410 patients 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 significant lower BMI in individuals who underwent RYGB than those who received medical therapy alone. Based on the results, the authors conclude 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 recommend well-designed studies with consistent definition of adverse events, as well as a larger number of RCTs with long-term follow-up (> 60 months) to evaluate the safety and long-term benefits of RYGB surgery on obese patients with T2D.

Cooper et al. (2015) assessed weight loss and occurrence of weight regain among patients (n = 300) at 1 year follow-up who underwent RYGB at a single institution. The mean weight regain for all patients was 23.4% of maximum weight loss. Using categorical analysis, mean weight regain in the < 25, 25-30, 30-35, 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 patients. Despite the percentage of weight loss over the first year, all cohort patient groups regained on average between 21 and 29% of lost weight. Excessive weight gain was experienced by over one third of patients. 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 peri-operative outcomes of patients with obesity undergoing robotic gastric bypass versus laparoscopic gastric bypass surgery. Twenty-eight studies (1 RCT, 1 prospective study, and 26 retrospective studies) comprised of 82,155 individuals were included. Robotic bypass surgery (RBS) was performed on 9,051 participants versus 73,104 laparoscopic bypass surgery (LBS). 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 (LOS). Secondary outcomes included operative time, estimated blood loss, conversion, and readmission rates. The results showed that of the 26 articles reporting overall complications, there were no differences. In the 10 that reported intraoperative complications, there were also no differences between the procedures. There were no significant differences seen in anastomotic leak or stricture, surgical site infection or 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 to 3.4% for LBS. Secondary outcomes also showed no significant differences, but there was heterogeneity among reporting this outcome. The authors concluded that there are no significant differences in outcomes between the two procedures, with RBS findings at risk of bias. Prospective trials to validate the advantages and limitations of robotic bariatric surgery are needed. (Publication by Ayloo 2016, which was previously cited in this policy, is included in this systematic review.)

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

Ahmad et al. (2016) conducted a retrospective review to compare the operative and early peri-operative outcomes between laparoscopic and robotic-assisted RYGB. There were no statistically significant differences in complication rates, estimated blood loss, or length of stay between the two groups. There was a significant difference between the total operative times (135.30 ±37.60 min for the laparoscopic procedure versus 154.84 ±38.44 min for the robotic procedure, $p < 0.05$). There were no adverse intraoperative events, conversions to open procedures, leaks, strictures, returns to the operating room within 30 days, or mortalities in either group. The authors concluded that both techniques are comparable in terms of safety, efficacy, and operative and early perioperative outcomes. The findings are however limited by lack of randomization.

Laparoscopic Adjustable Gastric Banding (LAGB)

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 patients with T2D. A total of 200 patients [age 47 ±9.7 years; body mass index (BMI) 52.8 ±9.2 kg m^{-2}; glycosylated hemoglobin (HbA1c) 7.9 ±1.9% (62.8 mmol mol^{-1}); 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). There were significant reductions in body weight [-24.4 ±12.3% (38 ±22.7 kg)], HbA1c (-1.4 ±2.0%), systolic blood pressure (BP) (-11.7 ±23.5 mmHg), total cholesterol and triglyceride levels. The proportion of patients requiring insulin reduced from 36.2% to 12.3%. The overall band complication rate was 21% (21 patients). The authors concluded that LAGB, when combined with multidisciplinary medical care, significantly improved metabolic outcomes in patients with T2D independent of diabetes duration, and baseline BMI over 5 years. Diabetes duration and baseline BMI did not predict changes in glycemic control, BP or lipids following LAGB. The findings are limited by lack of 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 mellitus (13.5%), hypertension (32%), hyperlipidemia (12.1%), obstructive sleep apnea (5.4%), joints disease (10.8%), mood disorders (5.4%), and gastro-esophageal reflux disease (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 ($p < 0.001$), and the % TWL was 21.0 ±0.13. There was no improvement in any of the comorbidities. GERD symptoms worsened at long-term follow-up ($p < 0.001$). Undergoing another bariatric procedure was associated with a higher weight loss (OR 12.8; CI 95% 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, patients 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 from a cohort of 208 patients who underwent LAGB. Complete follow-up was available for 90% at one year (186/207), 80% at five years (136/171), and 71% at ten years (10/14). Percentage of EWL at one, five, and ten years was 29.9, 30, and 16.9, respectively. LAGB failure occurred in 118 (57%) and 48 patients (23.1%) required a reoperation. Higher baseline BMI was the only independently associated factor (OR 1.1; 95% CI 1.0-1.1; p = 0.016).

Giet et al. (2018) conducted a retrospective study of 2,246 patients who underwent LAGB. Patients were followed for a minimum of 2 years, and up to 9 years post-procedure. Operative mortality was zero and there were no in-hospital re-operations. Mean preoperative weight and BMI were 111.2 ±22.1 kg and 39.9 ±6.7 kg/m^{2,} respectively. Mean 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. There was no significant difference in mean excess % BMI loss between those < 50 or ≥ 50 years old (p value = 0.23) or between patients with an initial BMI of < or ≥ 50 kg/m^2 (p value = 0.65). Complications over nine years occurred in 130 (5.8%) patients and included: 39 (1.7%) slippage or pouch dilatation, 2 (0.04%) erosions and 76 (3.4%) complications related to the access port or LAGB tubing. The overall re-operation rate for LAGB complications was 4.2% over 9 years with a LAGB explanation rate of 1.5%. Thirty-nine LAGBs were converted to a sleeve or gastric bypass procedure, 11 of these due to complications.

Vinzens et al. (2017) evaluated the long-term results of 405 patients (age 41 ±10 years), with a BMI of 44.3 ±6 kg/m^2, who were treated with LAGB. Mean follow-up was 13 ±3 years, with a follow-up rate of 85% (range 8-18 years), corresponding to 343 patients. One hundred patients exceeded 15-year follow-up. In 216 patients (63%), sleeve gastrectomy, gastric bypass, or biliopancreatic diversion with duodenal switch was performed as revisional surgery. Twenty-seven patients (8%) refused revisional surgery after band removal. Finally, 100 patients (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 (BAROS), the failure rate was 25%, and 50% had what was considered to be a good to excellent outcome. The authors concluded that more than 10 years after LAGB, 71% of patients lost their bands and only 15% of the 343 followed patients with the band in place had a good to excellent result. The findings are limited by lack of comparison group.

Sleeve Gastrectomy (Vertical Gastrectomy)

Clapp et al. (2018) conducted a meta-analysis to evaluate long-term (7 or more years) outcomes of LSG. Nine studies met the inclusion criteria, with a total of 2,280 patients included initially. Only 652 patients 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 (5 studies) and 2.9% (I^2 = 60.8%; 95% CI: 1%-4.9%) due to gastroesophageal reflux disease (5 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 of the sleeve gastrectomy, especially regarding revisions and weight regain. (Publication by Noel 2017, which was previously cited in this policy, is included in this systematic review.)

Felsenreich et al. (2017) evaluated long-term outcomes and complications following SG. 53 patients did not have symptomatic reflux or hiatal hernia preoperatively and of the 43 patients available for follow-up, six patients (14.0%) were converted to RYGB due to intractable reflux over a period of 130 months. Ten out of the remaining non-converted patients (n = 26) also suffered from symptomatic reflux. Gastroscopies revealed de novo hiatal hernias in 45% of the patients and Barrett's metaplasia in 15%. SG patients suffering from symptomatic reflux scored significantly higher in the RSI (p = 0.04) and significantly lower in the GIQLI (p = 0.02) questionnaire. This study shows a high incidence of Barrett's esophagus and hiatal hernias at more than 10 years after SG. Its results therefore suggest maintaining pre-existing large hiatal hernia, GERD, and Barrett's esophagus as relative contraindications to SG. The limitations of this study include its small sample size as well as the fact that it was based on early experience with SG-make drawing any general conclusions about this procedure inconclusive.

Fløլo et al. (2017) presented 5-year outcomes after VSG, including complications and revisions, weight change, obesity-related diseases, and health-related quality of life (HRQOL). Of 168 operated patients (mean age, 40.3 ±10.5 years; 71% females), 92% completed 2-year and 82% 5-year follow-up. Re-intervention for complications occurred in four patients, whereas revision surgery was performed in six patients for weight regain and in one patient 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 T2DM and hypertension occurred in 79 and 62% at 2 years, and 63 and 60% at 5 years, respectively. The percentage of patients treated for GERD increased from 12% preoperatively to 29% at 2 years and 35% at 5 years. Preventing weight regain and GERD are important considerations with this procedure. The findings are limited by lack of comparison group.

Nocca et al. (2017) reported 5-year outcomes from a cohort of 1,050 patients who underwent SG (mean preoperative BMI was 44.58 kg/m^2) either as the 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 of %EBL was, respectively, 75.95% (±29.16) (382 patients), 73.23% (±31.08) (222 patients) and 69.26% (±30.86) (144 patients). The success rate at 5 years was 65.97% (95 patients). The improvement or remission of comorbidities was found, respectively, in 88.4 and 57.2% of diabetic patients; 76.9 and 19.2% for hypertensive patients and 98 and 85% for patients with sleep apnea syndrome. The authors conclude that five-year results are very convincing for SG, although GERD is the main long-term complication. The findings are limited by lack of comparison group.

El Chaar et al. (2017) evaluated the incidence, indications, and outcomes of revisional surgery following LSG in adult patients. Of the 630 LSGs performed, 481 patients were included in the analysis (mean age and BMI = 46.2 and 44.3, respectively; 79.5% female; 82.3% white). A total of 12/481 patients underwent conversion to a different bariatric procedure due to inadequate weight loss, GERD, or both. The 6/12 patients with GERD-related symptoms and failed medical management underwent conversion to RYBG following preoperative wireless Bravo pH monitoring (Given Imaging) to confirm the diagnosis objectively. The other 6/12 patients with inadequate weight loss received either RYBG or BPD/DS based on personal choice. Overall, 9/12 patients underwent conversion to RYBG, and 3/12 underwent conversion to BPD/DS. Median time from the initial surgery to conversion was 27 months (range 17-41). Median operating room time was 168 min (range 130-268). Median length of stay was 48 h (range 24-72). The follow-up rate at 3 months was 100% (12/12 patients). The authors conclude that conversion to RYBG or BPD/DS may be done safely and effectively in patients present following LSG with refractory GERD or inadequate weight loss. Longer term outcomes are needed. The findings are limited by lack of comparison group.

Brethauer et al. (2009) performed a systematic review (n = 36 studies) of the evidence on SG as a primary or staged procedure. Studies included a single nonrandomized matched cohort analysis, RCTs (n = 2 studies) and uncontrolled case series (n = 33 studies). Of these studies, 13 differentiated that the SG was used as a staged procedure or as a management strategy for a high-risk patient population. Those patients who underwent SG as a planned staged procedure went on to receive RYGB or BPD/DS within 2 years of SG after improvement of their co-morbidities 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 for the high-risk patients (range 49.1-69.0) and 60.4 kg/m^2 for the primary SG patients (range 37.2-54.5). The follow-up period ranged from 3-60 months. The mean %EWL after SG reported in 24 studies was 33-85%, with an overall mean %EWL of 55.4%. The mean postoperative BMI was reported in 26 studies and decreased from a baseline mean of 51.2 kg/m^2 to 37.1 kg/m^2 postoperatively. Improvement or remission of T2D was found in more than 70% of patients. 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 high risk/staged procedure was 9.4%. The overall mortality rate for all studies was 0.19% which included 0.24% for high risk/staged procedure. Despite the high surgical risk of this patient population, report complication rates were acceptably low. The authors conclude that SG is an effective weight loss procedure that can be performed safely as a first stage or primary procedure. Limitations include lack of long-term follow-up for the high-risk group mainly due to patients who refused a second-stage operation or had sufficient weight loss and co-morbidity reduction with SG alone.

Revision Surgery

Axer et al. (2023) conducted a systematic review to compare revisional procedures for weight non-response after SG. Primary outcomes included weight change after revisional surgery, measured as BMI, %TBWL, %EWL, or percental excess BMI loss (%EMBI). There were 12 studies included in the review which included 1046 individuals. There were no RCTs, 2 studies at serious risk of bias and 10 studies 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 non-response after SG cannot be established. The authors note 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 of revisional procedures (RYGB and OAGB) following a failed laparoscopic sleeve gastrectomy (SG). The primary outcome was the total percent weight loss following the revisional surgery. Secondary outcomes included overall weight loss, diabetes remission and post-operative complications. Seven articles comprised of 404 patients who underwent OAGB and 413 who underwent RYGB were included. Five were retrospective studies, one randomized trial and one case cohort study. The results showed a significantly greater rate of diabetes remission in the OAGB group was seen in four separate studies that reported this in 130 participants. However, both procedures have a significant ability to achieve this. Total weight loss after revisional surgery was measured in 4 studies and showed a more pronounced body weight reduction. Similarly, the global TWL was reported in five studies and showed significantly greater weight loss in the OAGB group. The rate of complications was reported in 5 articles and showed 7 in the RYGB group compared to 4 in the OAGB group, which was not considered statistically significant. Postoperative gastroesophageal reflux disease (GERD) was significantly higher in the OAGB group, and there were no significant differences in the development of Barrett's esophagus. The authors concluded that for individuals that achieve insufficient weight loss or weight regain following SG, OAGB and RYGB are safe and effective. This systematic review and meta-analysis is limited by a relatively small sample size and limited relevant publications. Furthermore, there was differing reports of long-term outcomes 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 Embase, PubMed, Cochrane Library, and Scopus databases which returned 39 retrospective and prospective comparative studies. Inclusion criteria included patients undergoing revisional bariatric surgery after a failed primary restrictive surgery of LAGB, VBG, or SG. The authors confirmed SG continues to have a low rate of immediate postoperative complications. The authors found duodenal switch (DS) and biliopancreatic diversion (BPD) were superior when it came to %EWL and %TWL, but not free from the risk of weight regain. Secondary SG ensures the lowest rate of early and late complications when compared to single-anastomosis duodeno-ileal bypass (SADI) and one-anastomosis gastric bypass (OAGB), but it also provides the worst benefits for either 1 and 3 years %EWL and %TWL thus should not be considered when planning revisional surgery unless there are exceptional circumstances that warrants 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 when compared to SG. In addition, RYGB is more frequently associated with early and late complications when compared to SG, OAGB, and SADI. Finally, the authors found 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 included retrospective design, surgical intervention allocation bias, heterogeneity, and lack of evaluation of important outcomes like GERD or malabsorption which could affect the patient's quality of life. (Publication by Qiu 2018, which was previously cited in this policy, is included in this systematic review.)

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

Janik et al. (2019) assessed the safety of revisional surgery to LSG compared to LRYGB after failed LAGB. Converted LSG cases were matched (1:1) with converted LRYGB patients by age (± year), body mass index (±kg/m), sex, and comorbidities including diabetes, hypertension, hyperlipidemia, venous stasis, and sleep apnea. A total of 2,708 patients (1,354 matched pairs) were included in the study. The mean operative time in conv-LRYGB was significantly longer in comparison to conv-LSG patients (151 ±58 vs. 113 ±45 minutes, $p < 0.001$). No mortality was observed in either group. Patients 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%, $p < 0.001$). Thirty-day readmission rate was significantly higher in conv-LRYGB patients (7.46% vs. 3.69%, $p < 0.001$), as was 30-day reoperation rate (3.25% vs. 1.26%, $p < 0.001$). The length of hospital stay was longer in 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 versus LSG in the first 30 days postoperatively. 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 versus revisional LRYGB for insufficient weight loss after VBG or adjustable gastric banding. Three hundred forty-two LRYGB operations were performed, 245 were primary, and 97 revisional. Median follow-up was 30 months (range 0-108 months). Mean BMI (kg/m^2) before bypass was 45.2 for primary LRYGB (pLRYGB) and 41.1 for revisional laparoscopic RYGB (rLRYGB). Median operative time and length of stay were longer for rLRYGB 157.5 versus 235 min ($p < 0.001$) and 6 versus 6.5 days ($p = 0.05$). Conversion to laparotomy was performed in eight patients, 0.4% of primary and 7.2% of revisional. Morbidity rate was 6.5% in pLRYGB versus 10% in rLRYGB (NS). There was one death in the primary group. 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 % 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 or conversions (RC) in patients who originally underwent RYGB, LSG, or LAGB. Patients were followed for at least 4 years. There were 40,994 bariatric procedures with 16,444 LAGB, 22,769 RYGB, and 1,781 LSG. Rate of RC was 26.0% for LAGB, 9.8% for SG, and 4.9% for RYGB. Multiple RCs were more common for LAGB (5.7% for LAGB, 0.5% for RYGB, and 0.2% for LSG). Band revision/replacements required further procedures compared with patients who underwent conversion to RYGB/SG (939 compared with 48 procedures). The majority of RCs were not performed at the initial institution (68.2% of LAGB patients, 75.9% for RYGB, 63.7% of SG). Risk factors for multiple procedures included surgery type, as LAGB was more likely to have multiple RCs. The authors concluded that reoperation was common for LAGB, but less common for RYGB (4.9%) and SG (9.8%). The RC rate is almost twice after SG than after RYGB. LAGB had the highest rate (5.7%) of multiple reoperations. Conversion was the procedure of choice after a failed LAGB.

Gray et al. (2017) conducted a retrospective review of adult patients undergoing laparoscopic revisional bariatric surgery (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 AGB in 39/84 (46%), sleeve gastrectomy (VSG) in 23/84 (27%), RYGB in 13/84 (16%), and vertical banded gastroplasty (VBG) in 9/84 (11%). For patients undergoing conversion from AGB ($n = 39$), there was no difference in operative time, length of stay, or complications by surgical approach. For 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 post-operative complications. There were three leaks in the LRBS group and none in the RRBS group ($p = 0.36$). Major complications occurred in 3/39 (8%) of patients undergoing conversion from AGB and 2/45 (4%) of patients 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 is anticipated.

Wijngaarden et al. (2017) identified that non-responders of LAGB showed inferior weight loss results after revisional LRYGB compared with responders of LAGB, and primary LRYGB at all moments of follow-up (12, 24, 36 months). This is based on an observational study of 96 non-responders, and 120 responders. In addition, the failure rate was significantly higher after revisional LRYGB compared with primary LRYGB (10.9% no responders, 8.5% responders, and 2.5% primary, $p = 0.001$).

In a retrospective review of primary LRYGB (pLRYGB) versus revisional LRYGB (rLRYGB) after failed LSG, Malinka et al. (2017) evaluated 3-year outcomes. There were no significant differences in patient demographics or median BMI (kg/m^2) for 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 excess weight loss (74.4 ±23.3 vs. 52.0 ±26, respectively; $p = 0.007$) was higher for pLRYGB than rLRYGB, while similar improvements of 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 to pLRYGB, resolution or improvement of coexisting comorbidities appears 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 in 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 recommend that particular attention be paid to surgical candidates with a history of difficulties in 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 in revision patients compared with 45.7 ±7.6 in primary bariatric surgery patients.

Most revision patients had a prior VBG (48%) or a LAGB (24%). Bands were removed in 36% of all LAGB patients presenting to 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 to 33.8 ±7.5, $p < 0.001$); their BMI at 12-month follow-up was similar to that of primary clinic patients (34.5 ±7.0, $p = 0.7$). The authors identified that complications were significantly more frequent in revision patients than primary patients (41% v. 15%, $p < 0.001$).

Sharples et al. (2017) conducted a systematic review and meta-analysis of outcomes after revisional bariatric surgery. 2,617 patients in 36 studies underwent either adjustable gastric band to Roux-en-Y gastric bypass (B-RYGB) or band to sleeve gastrectomy (B-SG). There was no difference between the B-RYGB and B-SG groups in morbidity, leak rate or return to surgery. %EWL following the revisional procedure for all patients combined at 6, 12 and 24 months was 44.5, 55.7 and 59.7%, respectively. There was no statistical difference in %EWL between B-RYGB and B-SG at any time point. The rates of remission of diabetes, hypertension and obstructive sleep apnea were 46.5, 35.9 and 80.8%, respectively. Available observational evidence does suggest 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 quality of life outcomes.

Tran et al., (2016) conducted a systematic review of 24 studies and 866 patients to evaluate outcomes and complications of different surgical methods of revision that were done after failed primary RYGB. All patients in the studies reported significant early initial weight loss after revisional surgery. However, of the five surgical revision options considered, biliopancreatic diversion/duodenal switch, 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 (MBSAQIP) database from 2015 to 2018. Participants included patients 19 years old and younger with a BMI ≥ 30 kg/m^2 and underwent laparoscopic RYGB or SG. Primary outcomes included mortality and overall complications; secondary outcomes included rates of readmission and reoperation. A total of 5,068 individuals met inclusion criteria for the study with 78.5% being females and 70.4% being white. Patients between the ages of 10 to 14 years comprised 1.5% of participants, 15 to 17 years 18.5%, and 18 to 19 years 79.9%. The mean BMI was 47.3 kg/m^2 and the most prevalent comorbidities were HTN, OSA, GERD, and diabetes. The 30-day analysis following surgery demonstrated intraoperative or postop complications in only 1.2% of patients and the death of two patients which was likely due to internal hernia. The authors concluded that bariatric surgery for adolescents was a safe and effective procedure with low complication rate and a recommendation of future robust studies to evaluate the long-term outcomes in this age group of patients.

Alqahtani et al. (2021) analyzed the long-term results and adverse events associated with LSG in children and adolescents with severe obesity. 2,504 children and adolescents that 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, %EWL, change in BMI, and BMI for age percentile along with assessment of comorbidity conditions. The mean standard deviation (SD) %EWL for one to three years was 82.3%, for 4 to 6 years was 76.3% and 7 to 10 years was 71.1%; 10-year results demonstrated that 30% of total weight was lost permanently. Prior to surgery 263 patients were diagnosed with T2D, 227 with dyslipidemia, and 377 had hypertension. After more than 7 years of follow-up, complete remission was observed in 188 patients for T2D, 130 patients for dyslipidemia, and 219 patients for HTN. Only 1% of the patients were readmitted within the first 90 days after the operation; two patients 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 younger than age 14 years. The authors concluded long-term follow-up after LSG in children and adolescents demonstrates positive weight loss and comorbidity resolution. The findings are however limited by lack of comparison group.

Lainas et al. (2020) conducted a study to assess whether bariatric surgery was successful for adolescents under the age of 18. The authors evaluated 84 adolescent patients (57 females, 27 males) that underwent LSG. Surgical postop care included blood work and diet restrictions with a discharge when oral diet was well tolerated. Patient follow-up included 4 outpatient visits the first year then annually; complete metabolic screening was done at 3 months, again at one year and annually thereafter. The quality of life was evaluated prior to surgery using the French version of the Short Form 36 questionnaire which assessed general health, physical function, social function, emotional and mental status, and bodily pain. The scoring ranged from 0-100 with higher scores indicating better wellbeing. All patients were contacted one-year post-surgery to answer the same questions. Comorbidities assessed included HTN, T2D, OSA, dyslipidemia, arthralgia, and GERD. According to the authors, the study showed LSG is a safe and effective procedure for patients under the age of 18, resulting in significant weight loss, comorbidity remission, and improvement in quality of life. In addition, it was felt that adherence to the medical team was an essential component for successful treatment in this group of patients.

Limitations included small sample size, retrospective design, substantial loss to follow-up thus affecting long-term outcomes and lack of comparison group.

A Hayes (2019, updated 2022) comparativeness effective review for bariatric surgeries for treatment of obesity in adolescents analyzed nineteen studies which compared AGB, 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. AGB was inferior to the others, but all three types are associated with low to moderate risk of postop 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-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 2 years, mean hemoglobin A1c 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. Twenty-three percent 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 type 2 diabetes 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 factors associated with long-term weight-loss maintenance following bariatric surgery in adolescents (n = 50) with severe obesity who underwent RYGB. Follow-up visits 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+) visit. A non-surgical comparison group (n = 30; mean ±s.d. age and BMI = 15.3 ±1.7 years and BMI = 52 ±8 kg m^{-2}) was recruited to compare weight trajectories over time. The BMI of 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 of the comparison group increased from baseline to the FABS-5+ visit (+10.3 ±20.6%). When the surgical group was split into maintainers and re-gainers, no differences in weight-related and eating behaviors, health responsibility, physical activity/inactivity, or dietary habits were observed between groups. However, at FABS-5+, maintainers had greater overall QOL scores than re-gainers (87.5 ±10.5 vs. 65.4 ±20.2, $p < 0.001$) and in each QOL sub-domain ($p < 0.01$ all).

In a retrospective review of 79 adolescents who underwent LSG, Elhag et al. (2018) assessed preoperative levels and postoperative changes in 4 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 33.3%, respectively). Low hemoglobin levels (29.3%) were reported only in females. Trace elements were not deficient. Significant reductions in percentage of adolescents with elevated low-density lipoprotein (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. Inclusion criteria included the following: age 13-18 years and BMI > 35 kg/m^2. Patients underwent dual-energy X-ray absorptiometry and serum bone marker analyses preoperatively and annually for 2 years. Differences in body fat and lean mass proportions were observed according to sex following RYGB. 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, 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 (BMD-Z) at baseline were within or above the normal range. The mean (SD) BMD-Z was 2.02 (1.2) at baseline, decreasing to 0.52 (1.19) at 2 years. Higher concentrations of serum CTX ($p < 0.001$) 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 girls. Bone turnover increased, and BMD decreased to levels approaching a norm for age. Long-term outcome 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 quality of life in adolescents with obesity. A total of 49 studies with 3,007 patients 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% confidence interval (CI): 14.84-18.01] and 31% (95% CI: 28%-34%) reduction in BMI. There were significant improvements in glycemic and lipid profiles including glycosylated hemoglobin A1C, fasting blood insulin, fasting blood glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, postoperatively 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. (Publications by Manco 2017, Serrano 2016, Inge 2016, Olbers 2017, Shah 2017, Hervieux 2017, and O'Brien 2010, which were previously cited in this policy, are included in this systematic review.)

The Teen-Longitudinal Assessment of Bariatric Surgery (LABS) Study was a prospective, multicenter, observational study, which enrolled 242 adolescents (≤ 19 years of age) who were undergoing bariatric surgery from March 2007 through February 2012, at 5 U.S. adolescent bariatric surgery centers. The patients underwent RYGB (n = 161), SG (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 (HR), immediate posttest HR, and HR difference (resting HR minus posttest HR) 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 HR and HR difference were further adjusted for changes in time to completion). Compared with the baseline, the post-surgery data showed an improvement in all measurements at all times measured. The authors conclude that bariatric surgery in adolescents with extreme obesity is associated with significant improvement in functional mobility and in the reduction of walking-related musculoskeletal pain up to 2 years after surgery. Findings are however limited by lack of comparison group.

Bariatric Artery Embolization (BAE)

There is insufficient evidence for bariatric artery embolization and its outcomes for weight loss; additional robust RCTs are warranted for safety and efficacy along with long-term follow up.

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 sham procedure (n = 20) or TBE targeting the left gastric artery using embolic beads (n = 20). The primary efficacy endpoint was the difference in TBWL between the two groups at 6 months. All patients entered a lifestyle counseling program and follow-up was completed by physicians that were masked to allocated therapy. At 6 months, the TBWL for TBE in the intention to treat (ITT) population was 7.4 kg compared to 3.0 kg for sham procedure. The change in BMI at 6 months for ITT was -2.6 in TBE versus -1.1 in sham. The TBE ITT population did maintain the weight loss at 12 months. Patients within the sham group were unblinded at 6 months and permitted to crossover to TBE and then only initial group was followed for 12 months. Limitations included small sample size, single center, no control group after 6 months, and possibility that the efficacy of TBE was related to subject participation in weight management counseling as it is unknown if TBE alone would have an impact on obesity without lifestyle counseling. Additionally, four subjects withdrew consent after randomization and another three prior to the 6-month visit. Furthermore, the clinical significance of the effect, its long-term sustainability, and safety are unclear.

Hafezi-Nejad et al. (2019) conducted a systematic review and meta-analysis of case series investigating the safety and efficacy of left gastric artery (LGA) embolization as a bariatric procedure. Meta-regression was performed to assess associations of age, sex, body mass index, and ghrelin and leptin levels with weight change after LGA embolization were selected. Six case series published between January 2014 and April 2019, comprising 47 patients investigating the safety and/or efficacy of LGA embolization for weight loss were included in the meta-analysis. The results showed a mean weight loss of 8.68 kg (19.14 lbs.) 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 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. There were considerable variations in patient age, sex distribution, and baseline characteristics among the studies. Significant variation was observed in the duration of follow-up, which ranged from 3 months to 20-24 months. Limitations of this study include variations in the indications for LGA embolization, study designs, embolization techniques, follow-up plans, dietary assessments, patient comorbidities, and availability of control subjects, 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. (Publications by Bai 2018, Syed 2016, and Weiss 2017, which were 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 twelve months following surgery in 20 severely obese patients [five of which are identified below in the Weiss et al. (2017) case series]. The primary endpoint was weight loss with additional end points assessed. Bariatric embolization was performed successfully in all participants. Participants experienced mean excess weight loss of 8.2% at one month, 11.5% at 3 months, 12.8% at six months and 11.5% at twelve months. The mean total weight loss was 7.6 kg at twelve months. As a result of loss to follow-up, 18 participants remained at three months, 16 at six months, and 15 at twelve months. No major adverse events (AE) were identified and only eleven minor AE occurred in eight participants. The authors found bariatric embolization is well tolerated and promotes clinically relevant weight loss in adults with severe obesity. Limitations included lack of comparison group, small sample size, insufficient data due to lack of continuous follow up for several participants, required weight management compliance before the embolization procedure on the first five participants only and a large portion of participants were African American thus overrepresenting that population.

Gastric Electrical Stimulator (GES)

While gastric electrical stimulation may provide benefit for obesity, 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 the 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 patients. Meal intake and gastric emptying and motility were also evaluated. In this study, 20 obese patients were implanted with the Exilis system and amplitude was individually set during 4 amplitude titration visits. Subjects underwent two blinded baseline test days (GES ON vs. OFF), after which long-term, monthly follow-up continued for up to 52 weeks. The results suggested that this device is safe and caused no patient 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 EWL of 14% at 52 weeks. The authors conclude that the data were comparable with studies of subjects on diet and/or exercise alone, but disappointing when compared to 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 included small sample size, lack of control group, and lack of long-term outcomes.

In a 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 system (CLGES). Weight loss, safety, quality of life (QOL), and cardiac risk factors were analyzed. Weight regain was limited in the 35 (74%) participants remaining enrolled at 24 months. Mean %TBWL changed by only 1.5% between 12 and 24 months, reported at 14.8% (95% CI 12.3 to 17.3) and 13.3% (95% CI 10.7 to 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 thru 24 months. The authors conclude that during the 24-month follow-up, CLGES was shown to limit weight regain with strong safety outcomes, including no serious AEs in the second year. They hypothesize that CLGES and objective sensor-based behavior data combined to produce behavior change, and in their opinion supports GES as a safe obesity treatment with potential for long-term health benefits. Larger well-designed randomized controlled trials are needed to further evaluate the safety and efficacy of GES therapy in the treatment of obesity.

In a post-implant analysis, Alarcón Del Agua I, et al. (2017) evaluated possible preoperative predictors for obtaining clinically meaningful weight loss with GES. Ninety-seven obese participants in a prospective multicenter study conducted in nine European centers were implanted laparoscopically with the abiliti® CLGES system. The mean 12-month %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 BMI < 40 kg/m^2 and age ≥ 50 years, increasing 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, BMI < 40, and age ≥ 50 (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 closed-loop GES and may be used for patient selection.

In a systematic review, Cha et al. (2014) evaluated the current state regarding implantable gastric stimulators. Thirty-one 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 that 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 HbA1c, respectively. The authors conclude 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. (Publications by Shikora 2009, Sarr 2012, and Camilleri 2008, which were previously cited in this policy, are included in this systematic review.)

Intragastric Balloon (IGB)

There is mixed evidence regarding the long-term efficacy and safety for intragastric balloons and their use with 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 assessing weight loss and adverse events for Spatz3® in adults with obesity revealed short-term clinically significant weight loss but whether these results were long-term remains to be seen. Limitations included small sample sizes, retrospective design of studies, lack of randomization, masking, and controls along with 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 intragastric balloon (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 participants in total). The results showed that over time, IGB therapy significantly improved the serum markers homeostasis model assessment of insulin resistance (HOMA-IR), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma-glutamyl transpeptidase (GGT) levels from baseline to follow-up. The authors concluded that IGB has the potential to become a multidisciplinary management tool of MAFLD, however IGB is a temporary measure, and if the patient cannot maintain an active lifestyle after the first balloon is removed, relapse of MAFLD is expected. Limitations include lack of comparison group; further RCTs are needed.

Hayes (2018, updated 2022) low-quality evidence suggests that IGB 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 high AE and all studies analyzed lacked long term follow up on maintaining weight loss and safety concerns.

A 2021 ECRI clinical evidence assessment on the Orbera® Intragastric Balloon System concluded that the evidence is inconclusive with mixed results, and shows the use of Orbera results in short-term, clinically significant weight loss in most patients; however, most patients regain weight, and by 1 year, the sustained weight loss has unclear clinical significance. Additional randomized studies are needed to determine whether Orbera use can reduce bariatric surgery risks for patients who are not surgery candidates and/or use the device to lose weight to become eligible for surgery. Additional studies that directly compare Orbera with other IGBs would also be useful.

In a multicenter, open-label industry-sponsored RCT, Abu Dayyeh et al. (2021, included in ECRI 2022 report above) investigated the safety and efficacy of the Spatz IGB in adults with obesity. 288 patients were randomly assigned to receive either the IGB plus dietary and exercise counselling or dietary and exercise counselling alone for 32 weeks. Inclusion criteria were patients aged 22-65 years, BMI of 30 kg/m^2 or greater for past two years, history of unsuccessful non-surgical weight loss methods and willingness to participate in the required dietary restrictions. The IGB was implanted via esophagogastroduodenoscopy (EGD) under conscious or monitored anesthesia sedation; depending on the patient's height an initial volume of 400 ml, 450 ml, 500 ml, or 550 ml was utilized. During the 32 weeks, all patients followed a 1,000-1,200 kcal/day diet and exercise plan. After 32 weeks, the IGB was removed and patients were followed for another 24 weeks. Primary outcomes consisted of %TBWL and clinical responder rate, which was achieved by a decrease of at least 5% total bodyweight loss at 32 weeks. Mean %TBWL at 32 weeks was 15·0% (95% CI 13·9-16·1) in the IGB group versus 3·3% (2·0-4·6) in the control group ($p < 0·0001$). The authors found the adjustable IGB combined with lifestyle modification enabled significant weight loss over a period of 6 months with an observed acceptable safety profile. Limitations included 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.

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

Moore et al. (2019, included in the ECRI report above) performed a retrospective analysis of patients that underwent the Obalon Balloon System (OBS), a swallowable, gas-filled intragastric balloon system for weight loss. A web-based registry was accessed for the data on 1,343 patients with a starting BMI ≥ 25 kg/m^2. Nonserious and serious adverse events 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 other BMI categories was 8.2 ±5.6 kg or 10.3 ±7.0% total body weight loss for BMI 25 to 29.9 kg/m^2; and 11.6 ±7.8 kg or percent total body weight loss 9.3 ±6.0 for BMI > 40 kg/m^2. The authors concluded that the OBS safe and effective at stimulating weight loss and provides practitioners with another tool to treat obese patients who have failed other weight loss programs. Limitations included lack of comparison group, the possible bias of a manufacturer-sponsored study, variation with loss and behavior modification data collection, and lack of data collection for co-morbidities and metabolic data resulting in inability of data analysis for these areas.

Coffin et al. (2017, included in the Hayes 2021 report above) published findings from their multicenter randomized controlled trial, 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 patients (> 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 median BMI of 47.9 kg/m^2 for IGB patients and 50.7 kg/m^2 for control patients (p < 0.001). However, while the implanted IGB was effective on 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 versus standard care, 37.6 kg/m^2; p = 0.56). The authors concluded that IGB insertion before LGBP induced weight loss but did not improve the perioperative outcomes or affect postoperative weight loss. Limitations of the study included short duration of the IGB intervention, poor recruitment rate, a higher-than-expected use of ICU facilities, and the poor weight loss in the IGB group.

Nunes et al. (2017) conducted a retrospective review of 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%, excess weight loss 60.1% and a BMI reduction of 6.76 points. Six months after removal of the balloon 842 patients had continued follow-up (82.8%). At this time, weight loss was 19.84%, excess weight loss was 59.49%, and BMI reduction of 7.06 points. In all groups there was statistical difference between the times T0 and T1 and between T1 and T2 (p < 0.001). There was no statistical difference between T2 and T3, in any group. The authors concluded that IGB provided sustained weight loss in patients who remained in dietary follow-up for 1 year. The study is limited by lack of comparison group and high lost-to-follow up rate. Longer term outcomes with well-designed randomized clinical controlled trials 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 intragastric balloon (IGB) treatment. A total of 20 RCTs involving 1,195 participants were identified. Weight loss results before and after 3 months were analyzed separately. The weight loss results of patients with and 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 patients than among non-IGB control patients. No mortality was reported from IGB treatment. In the authors' opinion, IGB treatment, in addition to lifestyle modification, is an effective short-term modality for weight loss. However, there is not sufficient evidence confirming its safety or long-term efficacy.

The REDUCE pivotal trial (Ponce et al., 2015, included in the Hayes 2021 report above, and Jung 2020 systematic review) was a prospective, randomized controlled pivotal trial of a dual intragastric balloon to evaluate the safety and effectiveness of a dual balloon system plus diet and exercise in the treatment of obesity compared to diet and exercise alone. Participants (n = 326) with body mass index (BMI) 30-40 kg/m^2 were randomized to endoscopic dual balloon system (DBS) treatment plus diet and exercise (DUO, n = 187) or sham endoscopy plus diet and exercise alone (DIET, n = 139). Co-primary endpoints were a between-group comparison of %EWL and DUO subject responder rate, both at 24 weeks. Thereafter DUO patients had the DBS retrieved followed by 24 additional weeks of counseling; DIET patients were offered DBS treatment. Mean BMI was 35.4. Both primary endpoints were met. DUO weight loss was over twice that of DIET. DUO patients had significantly greater %EWL at 24 weeks [25.1% intent-to-treat (ITT), 27.9% completed cases (CC, n = 167) compared with DIET patients (11.3% ITT, p = .004, 12.3% CC, n = 126)]. DUO patients significantly exceeded a 35% response rate (49.1% ITT, p < .001, 54.5% CC) 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 non-ulcer 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 dual balloon system was significantly more effective than diet and exercise in causing weight loss with a low adverse event profile. Additional RCTs with longer follow-up are needed.

Laparoscopic Greater Curvature Plication (LGCP)

While laparoscopic greater curvature plication may appear to be safe for weight loss, 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 of 75 patients following laparoscopic gastric greater curvature plication (LGGCP) surgery. The results showed that 13 out 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 lbs. (±24) and 35.6 (±3.9 kg/m^2) respectively. Mean nadir body weight after LGGCP was 149 lbs. (±13), and BMI was 25.8 (±2.8 kg/m^2). At revision, mean body weight was 196 lbs. (±25) and BMI was 33.9 (±4.2 kg/m^2). The results showed that after 5 years, there was weight gain close to pre-surgery levels. The authors concluded that LGGCP as a primary surgery, results in high rate of weight gain and the need for revisional surgery.

Doležalova-Kormanova et al. (2017) reported outcomes in a cohort of LGCP patients at 5-year follow-up. Patients with complete weight data through 5-year follow-up was 86.9%, (212/244). The ANOVA database indicated a significant BMI reduction out to 2 years ($p < 0.001$), a plateau at 3 and 4 years, and a 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% (168/212) of patients were successful; 20.8% (44/212) experienced a suboptimal weight outcome; mean weight regain, 9.2%. Cluster analysis identified four distinct LGCP patient profiles. Diabetes improvement rate was 65.5%. There were 12 reoperations (4.9%): 4 emergency (1.6%) and 8 (3.3%) elective. There was no mortality. The authors concluded that based on their original cohort and a 56.8% Excess BMI loss and low rate of complications, LGCP proved to be safe and effective. The findings are limited by lack of comparison group. Additional long-term outcomes are needed to evaluate LGCP in comparison to other bariatric procedures.

In an 18-month prospective, observational, open-label study, Bužga et al. (2017) reported outcomes of 127 patients; 84 underwent LSG and 43, 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 an improved body composition resulted from either procedure vs. baseline (i.e., pre-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, falling from pre-surgery levels of 140.7 to 69.6 ng/L by 6 months ($p < 0.001$). Subsequently, ghrelin levels increased, reaching 107.8 ng/L by month 12. Conversely, after LGCP, a statistically significant increase in ghrelin was seen, 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 two-year outcomes in a European prospective randomized controlled trial comparing LGCP versus LSG. A total of 54 patients with morbid obesity were allocated either to LGCP group (n = 25) or LSG group (n = 27). Main exclusion criteria were ASA > III, age > 75 and BMI > 65 kg/m^2. There were 40 women and 12 men, and the mean age was 42.6 ±6.8 years (range 35-62). Data on the operation time, complications, hospital stay, BMI loss, %EWL, loss of appetite and improvement in comorbidities were collected during the follow-up examinations. One year after surgery, the mean %EWL was 59.5 ±15.4% in LSG group and 45.8 ±17% in LGCP group ($p > 0.05$). After 2 years, mean %EWL was 78.9 ±20% in the LSG group and 42.4 ±18% in the LGCP group ($p < 0.01$). After 3 years, mean %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 LGCP group and 76.9% in the LSG group ($p < 0.05$). The 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 the both procedures, but 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 randomized controlled trial and three non-randomized controlled trials involving 299 patients. The meta-analysis demonstrated a significantly greater %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 mellitus between these two approaches did not reach statistical significance ($p = 0.66$). According to the pooled data, LGCP was associated with more adverse events than was 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 (MGB)/Laparoscopic Mini-Gastric Bypass (LMGB)/One-Anastomosis Gastric Bypass (OAGB)

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

Robert et al. (2024) conducted a prospective, open-label, non-inferiority, randomized extension study aiming to report weight loss, metabolic, safety and efficacy of one anastomosis gastric bypass (OAGB) versus Roux-en-Y gastric bypass (RYGB) at the five-year follow-up. The original study, YOMEGA (NCT02139813) studied the outcomes at 24 months. Study criteria included individuals with a BMI of 40 kg/m^2 or more, or 35 kg/m^2 or more if at least one comorbidity such as hypertension, obstructive sleep apnea, dyslipidemia or arthritis is present. Ultimately, 253 participants were randomly assigned to OAGB (n = 129) or RYGB (n = 124). Five individuals did not undergo their assigned surgery and 14 were excluded from the post-protocol analysis. At the two-year follow-up point, the mean percentage excess BMI loss was -87.9% in the OAGB group and -85.8% in the RYGB group. After 5 years, the mean percentage excess BMI loss was -75.6% in the OAGB and -71.4% in the RYGB group. Remission of type 2 diabetes was similar in both groups. The most common adverse event was gastroesophageal reflux disease (GERD), occurring in 41% of the participants in the OAGB group versus 18% in the RYGB group. Although the mean percentage excess BMI weight loss was similar in both procedures, the study noted participants who were status post OAGB had a higher incidence of diarrhea, steatorrhea, and nutritional disorders. These adverse events suggest OAGB may result in a higher rate of malabsorptive effect. The higher rate of GERD after OAGB can be viewed as a limitation and raises the concern about the procedure's long-term outcomes. Therefore, OAGB and its long-term outcomes need to be further investigated.

In a 2023 systematic review and meta-analysis, Li et al. assessed the efficacy and safety outcomes of OAGB compared to the Roux-en-Y (RNY) procedure in eight randomized controlled trials that comprised a total of 931 patients. The mean preoperative BMI ranged from 42.6 to 53.5 kg/m^2. Due to inconsistent outcome measures being described in each study, the authors performed a meta-analysis using the post operative outcome measures of BMI, percent of excess weight loss (%EWL), or excess body mass index loss (EBMIL). The results showed that 6 months after surgery, BMI and %EWL did not show a statistically significant difference. Twelve months post-surgery, 4 articles showed OAGB resulted in better weight loss than RYGB for %EWL, and two articles showed OAGB had superior BMI reduction. Two articles reported 5-year outcomes and showed Five years no statistically significant differences in %EBIML and BMI. Two articles reported intraoperative complications for which there were no statistically significant differences between the two procedures. Three articles were included in the early postoperative complications OAGB showed fewer complications than RNY, 3 versus 8 serious complications, respectively. There was inconsistent reporting of obesity related illnesses across the studies, but articles that did report them, included diabetes, hypertension, hyperlipidemia, and gastroesophageal reflux disease (GERD), and all showed a high rate of remission. The authors concluded that OAGB is not inferior to RNY in terms of weight loss and remission of comorbidities during the first 2 years post operatively but may have a higher incidence of malnutrition. Additional large sample and long-term randomized controlled trials are needed to verify these findings. (Eskandaros 2021, and Musella 2017 previously cited in this policy were included in this review.)

Parmar et al. (2020) evaluated the role of one anastomosis/mini gastric bypass (OAGB-MGB) as a revisional/secondary procedure in patients who needed revisional bariatric surgery (RBS). A total of 17 studies were included in this systematic review with a total of 1,075 patients. 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 following identifies the breakout of primary procedures performed: LAGB – 569 patients, SG – 397 patients, VBG – 105 patients, and lap gastric plication – 5 patients. The most common reason for RBS was poor response in 81%, followed by gastric band failure in almost 36% of patients. The mean BMI prior to RBS was 41.6 kg/m^2. Following the OAGB-MGB procedure, the mean %EWL was 50.8% at 6 months, 65.2% at one year, 68.5% at 24 months and 71.6% at 5 years. The author's conclusion suggests that OAGB-MGB is a safe and an effective choice for revisional surgery, however randomized studies and large prospective studies with long term follow-up are needed to validate these findings. Limitations included lack of comparison group or RCTs in analysis along with race and ethnicity differences which may have impacted the patient's eating habits, education, compliance, and expectations.

In a comparative effectiveness review from Hayes (2019, updated 2023) for primary bariatric surgery, the mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB) was compared to RYGB and LSG separately. Data from two systematic reviews and 4 RCTs suggest an overall increase in percentage of weight loss with the MGB-OAGB procedure when compared to RYGB and LSG. The evidence also suggested MGB-OAGB may have a positive impact on resolution of T2D and HTN. 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 of 150 morbidly obese patients who underwent laparoscopic OAGB, lipid profiles were evaluated preoperatively and at different intervals during a 2-year follow-up. The authors (Carbajo et al., 2017) reported a mean weight loss of 48.85 kg ±15.64 and mean %EWL of 71.87 ±13.41. kg. Total cholesterol and low-density lipoprotein (LDL) levels significantly decreased, and high-density lipoprotein (HDL) levels significantly increased which the authors believe translate into theoretical relevant cardiovascular risk benefits. The findings are limited by lack of 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 mini-gastric bypass (MGB) and laparoscopic SG. Thirteen studies met the inclusion criteria of comparative studies between MGB and SG; patients were adults, with age ranging from 20 to 70 years old; at least one of the following endpoints 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 %EWL or 5-year %EWL. The authors observed that patients receiving mini-gastric bypass had more advantageous indexes than patients receiving sleeve gastrectomy, such as higher 1-year EWL% (excess weight loss), higher 5-year 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 on overall early complications rate, bleed rate, vomiting rate, anemia rate, and operation time between MGB and SG. 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 samples sizes are needed to compare the effectiveness and safety between MGB and SG. (Publications by Kansou 2016 and Plamper 2017, which were previously cited in this policy, are included in this systematic review.)

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

There is insufficient evidence regarding the safety and efficacy of the single-anastomosis duodenal switch (SADS) for obesity; additional robust RCTs with comparison groups along with long-term results are needed. Several clinical trials are in progress for the single-anastomosis duodenal switch; information can be found at https://www.clinicaltrials.gov.

Esparham et al. (2023) conducted a systematic review evaluating 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 included studies in regard to surgical technique and reported variables, the authors were unable to perform a meta-analysis. The percentage of excess weight loss (EWL) was 70.9%-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, obstructive sleep apnea, and dyslipidemia were 62.9%, 81.3%, 53.2%, 60.9%, and 69.7%, respectively. While the authors conclude that SADI-S/SADS is a safe and effective surgical technique with durable weight loss and a high rate of comorbidity resolution, they also note 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 (DADS), and single-anastomosis duodenal switch (SADS). Data of 107 patients was collected in the Ontario Bariatric Registry from a Canadian bariatric center of excellence between 2010 and 2019, with the primary outcome measurement weight loss at 1- and 2-years post-surgery. Short-term secondary outcomes included operative times, intra- and early postoperative complications, hospital LOS, and 30-day readmissions. 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 DADS. Follow up data was available for 59 patients at one year, and 47 after 2 years. The results showed similar %TWL at 1 year (23.6 versus 26.2) and 2 years (24.8 versus 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 large rate of lost-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 of 112 patients receiving SADS or BPD/DS. Primary endpoints were BMI and TWL, and secondary endpoints included remission of obesity related disorders (T2D, hypertension and dyslipidemia), nutritional deficiencies and post-operative complications. 83 patients received SADS and 29 BPD/DS. There were no statistically significant differences between groups' demographic characteristics or 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, respectively. The results showed no significant differences in BMI and percent excess BMI loss (%EBMIL) between the groups, although the percentages of total weight loss observed from 12, 24, and 36 months were significantly higher after BPD/DS. Obesity related comorbidities resolved 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 was shorter for the SADS group. The authors concluded SADS is a simpler technique and shows similar results to BPD/DS. They acknowledged several limitations, including that there was a considerable numerical imbalance between the two groups, and the number of patients with a follow-up was small. Large-scale, randomized controlled clinical trials with long-term data are needed to confirm these results.

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

In a retrospective cohort study, Surve et al. (2017) compared biliopancreatic diversion with duodenal switch (BPD-DS) with single anastomosis duodenal switch (SIPS-stomach intestinal pylorus sparing surgery) at a single institution with two-year follow-up. One-hundred eighty-two patients received either a BPD-DS (n = 62) or SIPS (n = 120) procedure. BPD-DS and SIPS had weight loss at 3 months that were not statistically significantly different but %EWL was more with BPD-DS than SIPS at 6, 9, 12, 18, and 24 months. Patient lost a mean BMI of 23.3 (follow-up: 69%) and 20.3 kg/m^2 (follow-up: 71%) at 2 years from the BPD-DS and SIPS surgery, respectively. However, patients who had undergone SIPS procedure had significantly shorter operative time, shorter length of stay, fewer perioperative and postoperative complications than BPD-DS ($p < 0.001$). There was no statistical difference between 2 groups for postoperative nutritional data such as vitamins D, B1, B12, serum calcium, fasting blood glucose, glycosylated hemoglobin (HbA1C), insulin, serum albumin, serum total protein, and lipid panel. The authors noted that as the BPD-DS procedures were done prior to SIPS, learning curve and experience may account for the post-operative complications. RCTs with larger patient 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. One-hundred eight patients received either a RYGB (n = 54) or SADS (n = 54). 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. 5), diagnostic endoscopies (EGD) (21 vs. 3) and ulcers (6 vs. 0) with the RYGB than the SADS. The 2-year outcomes for this same patient cohort had similar results (Cottam et al., 2017). RCTs with larger patient populations and longer follow-up periods are needed to validate these findings.

Stomach Aspiration Therapy

Currently there is insufficient evidence regarding the safety and efficacy of stomach aspiration therefore additional robust RCTs with comparison groups are needed along with long-term results.

A 2021 ECRI clinical evidence assessment on AspireAssist Gastric Aspiration Port (Aspire Bariatrics, Inc.) noted that evidence is somewhat favorable for AspireAssist when adding to lifestyle modification. It was noted to improve weight loss at 1 year which was maintained at up to 4 years, however, these findings are based on low-quality evidence from 2 systematic reviews and 1 single-arm extension of an RCT. It is unknown if AspireAssist therapy contributes to abnormal eating behaviors as only one single-arm extension of RCT reported too few events. Evidence limitations included risk of bias in most studies included in the systematic reviews due to small study size, lack of control group, or both. Additional larger RCTs are needed to confirm findings, especially in the long term, as well as to compare AspireAssist with other minimally invasive treatments.

Jirapinyo et al. (2020) conducted a systematic review and meta-analysis of 5 studies with a total of 590 patients to assess the outcomes of aspiration therapy (AT) (AspireAssist®) on obesity related comorbidities at one year follow up. Comorbidities included hypertension, hyperlipidemia, T2D, and NAFLD. Secondary outcomes were the amount of weight loss up to four years post operatively, and pooled serious adverse events (SAEs). The results showed after one year hypertension, hyperlipidemia, HbA1C, and NAFLD significantly improved. Weight loss at one year was 17% TWL (296 patients), 2 years 18.3% (174 patients), 3 years 18.6% (88 patients), and 4 years 18.6% (27 patients). The pooled SAEs rate was 4.1% and included buried bumper, peritonitis severe abdominal pain, abdominal pain secondary to pre-pyloric ulcer and device malfunction requiring A tube replacement. Two studies reported a rate of persistent fistula following A-tube removal. The authors concluded that at 1 year AT resulted in significant improvement in metabolic function parameters and 4 years, patients maintained their significant weight loss of 18.6% of their baseline weight, meeting the definition of successful weight loss maintenance, and may improve access to treatment in obese patients with concomitant comorbidities. The authors acknowledge the limitations of this study. The number of studies is small (to account for this, conference abstracts that met the a priori inclusion criteria were included in the analysis), and most of them were retrospective and observational in nature. Larger, high-quality studies with longer follow-up are required to validate these findings. (Publications by Sullivan 2013, Thompson 2017, and Nyström 2018, which were previously cited in this policy, are included in this systematic review.)

In the post study of the PATHWAY Trial, Thompson et al. (2019) provide 4-year outcomes of the AT patients from the initial trial. 58 participants were enrolled in the follow up study; of these 55 had achieved at least 10% TWL at the end of the first year. Of the 58 patients who enrolled in the follow-up study, 15, 21, and 7 patients elected to have the A tube removed between years 1 and 2, 2 and 3, and 3 and 4, respectively, thus withdrawing from the study but no loss to follow-up. The 43 patients who withdrew from the study between years 2 and 4, 25 (58.1%) achieved at least 10% TWL. The mean %EWL of AT participants at years 1, 2, 3, and 4 was 37.1 ±27.6 (n/n = 81/110), 40.8 ±25.3 (n/n = 42/55), 44.7 ±29.7 (n/n = 22/55), and 50.8 ±31.9 (n = 15/55), respectively. The clinical success rate for patients participating in the follow-up study was 40/58 (69%) at 4 years from A-tube placement. The authors concluded the AT is a safe and effective intervention for people with class II and III obesity and can achieve weight loss along with improvement of quality of life. Limitations of this study are the relatively small number of participants by the fourth year, participant commitment and the absence of weight loss data after A-tube removal. Additionally, the findings are limited by the design that only allowed continued follow-up of participants maintained at least 10% TWL from baseline at each year end and lack of comparison group for the long-term.

Norén and Forssel (2016) reported 1 and 2-year outcomes from their prospective observational study of 25 obese subjects to evaluate weight reduction and safety of AT with AspireAssist™. Twenty of the original 25 subjects completed the initial 1-year treatment. These 20 subjects lost mean 54% of their excess weight. At 2 years, 15 subjects had lost mean 61% of their excess weight. This weight loss surpassed expectations and is nearly at the level of gastric bypass procedure and other major abdominal surgery for obesity. The subjects reported improved quality of life during treatment. There was neither mortality nor any event more severe than grade III-a according to Clavien-Dindo grading system. Limitation of this study is the combination of AT and cognitive behavioral therapy (CBT) without any control group. Long term patency is still unknown.

Transoral Endoscopic Surgery [Including Transpyloric Shuttle® (TPS) Device]

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

In a brief from ECRI (2019), the evidence for the Transpyloric Shuttle® (TPS) device is inconclusive. The evidence is limited indicating longer-term follow-up data is warranted. The RCT 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 small sample size, lack of a control group and randomization, and blinding. Both the RCT and case series report relatively short follow-up.

In a prospective, multicenter, single-arm, feasibility trial, Sandler et al. (2018) evaluate 32 obese subjects with a trans-oral 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. Baseline data collected included bodyweight, vital signs, AEs, medications, HbA1c, fasting glucose, and lipids in addition to follow-up visits. The device status was endoscopically assessed every 6 months. At 12 months, the 32 subjects 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 this study demonstrated the feasibility, safety, and efficacy of a fully trans-oral gastrointestinal bypass implant and that this endoscopic device may provide a valuable addition to the available treatment for the management of morbid obesity. However, this study is limited by lack of 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 performed to evaluate the safety and efficacy of the transpyloric shuttle (TPS) device. The study enrolled twenty patients meeting the criteria in 2 cohorts with treatment periods of 3 and 6 months. Patients were required to be ≥ 18 and ≤ 55 years of age with a BMI between 30 and 50 kg/m^2. Before device placement, patients were provided with nutritional guidelines for a low-calorie diet and no additional dietary counseling was given after the initial consultation. Patients were placed under general anesthesia and the devices were deployed and retrieved with no complications. All 20 patients enrolled in the study had lost weight at the time of device removal. Both the 3- and 6-month patients had statistically significant improvements to the overall IWQOL-Lite score that exceeded the 7.7- to 12-point threshold to define a clinical change. All but two patients completed the planned treatment period; both patients had the device removed due to complaints of epigastric pain. Limitations of the study were small participant size and short treatment duration. The authors concluded the TPS is a promising technology that has potential to benefit obese patients 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. a sham procedure for revisional surgery in RYGB patients 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 patients. One-year follow-up was completed by 45 patients treated with StomaphyX and 29 patients in the sham treatment group. Primary efficacy outcome was achieved by 22.2% (10) with StomaphyX vs. 3.4% (1) with the sham procedure ($p < 0.01$). Patients undergoing StomaphyX treatment experienced significantly greater reduction in weight and BMI at 3, 6, and 12 months ($p \leq 0.05$). There was one causally related adverse event with StomaphyX, that required laparoscopic exploration and repair.

Endoscopic Sleeve Gastroplasty (OverStitch)

There is insufficient quality evidence regarding the safety and efficacy of endoscopic sleeve gastroplasty for obesity. Future studies including RCTs are needed to assess the safety and efficacy of this procedure along with long-term results.

In a 2024 evolving evidence review, Hayes evaluated the endoscopic sleeve gastroplasty (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 7 and 35 studies, and five practice guidelines. It was noted that there are ongoing clinical trials, however, it is unclear if these trials will provide useful information on the place of Apollo ESG System in the bariatric surgery landscape.

Weitzner et al. (2023) performed a systematic review to evaluate various endoscopic bariatric procedures using only randomized controlled trials (RCTs) and observational studies. The authors evaluated weight loss compared with conservative management, lifestyle modification and bariatric surgery. A total of thirty-seven studies which included a total of 15,639 individuals were included in the review. The primary outcomes included the percentage of total body weight loss (%TBWL), percentage of excess body weight loss (%EBWL) and adverse events. Secondary outcomes included data related to quality of life, and differences in hemoglobin A1C (HgcA1c) levels. ESG had less %TBWL, 4.7-14.4% compared to 18.8-26.5% after LSG at 6 months and 4.5-18.6% as compared to 28.4-29.3%, respectively, at the one-year follow-up. Additionally, the study did not demonstrate that endoscopic therapies resulted in significant differences in HgbA1c reduction compared to lifestyle modification. Despite endoscopic therapies resulting in greater weight loss compared to lifestyle modification, it did not result in greater weight loss when compared to 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) adverse events (AEs), readmissions, reoperations, and reinterventions in patients that underwent endoscopic sleeve gastroplasty (ESG) compared to sleeve gastrectomy (SG). A total of 6,054 patients underwent ESG, and 597,463 SG. 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 for black patients after SG. This retrospective study is limited by a very short follow up period. The authors concluded that further prospective long-term evaluations of ESG versus SG with regards to safety and efficacy are needed.

Current evidence in an evolving technology report from Hayes (2022) identified four comparative studies and two systematic reviews which revealed minimal support for endoscopic sleeve gastroplasty (ESG) with the OverStitch device. Even though the OverStitch device is associated with clinically significant weight loss and fewer AEs, studies did not suggest the weight loss was more beneficial than an LSG.

Abu Dayyeh et al. (2022) conducted a randomized clinical trial to explore the safety and efficacy of endoscopic sleeve gastroplasty (ESG) with lifestyle modifications compared to lifestyle modification alone for the treatment of Class 1 and 2 obesity. Inclusion criteria was aged 21-65 with a BMI of 30 to less than 40 with a history of failure with non-surgical weight loss methods, and who agreed to comply with lifelong dietary restrictions required by this procedure. The primary outcome on efficacy was %EWL at 52 weeks. Secondary efficacy outcomes included proportion of patients with 25% or more EWL, % of total weight loss, and the proportion of patients with 5% or more and 10% or more of total weight loss. The effect of ESG on obesity related comorbidities and safety were also assessed. Seventy-seven participants were randomized to the ESG plus moderate-intensity lifestyle modifications (ESG group), and 110 to the 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 ESG with lifestyle modifications, compared with lifestyle modifications alone, resulted in significant improvements in terms of weight loss, and metabolic comorbidities with no GERD incidence as seen with other bariatric surgeries. Adverse events included gastrointestinal symptoms such as pain, heartburn, nausea and vomiting which is not unexpected when acclimating post procedure. Three participants had a Clavien-Dindo grade 3 device or procedure related adverse event requiring intervention and included abscess, GI bleeding and one case of malnutrition requiring 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 that prefer a non-surgical 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 versus ESG. The authors selected a total of sixteen studies for a total of 2,188 participants. One randomized study and seven observational studies on LSG were selected and eight observational studies on ESG were included. The authors reviewed studies which included obese individuals with a baseline Body Mass Index (BMI) between 30-40 kg/m^2 and a minimum of one year follow-up. The mean BMI was 34.34 and 34.72 kg/m^2 for LSG and ESG, respectively. The mean percentage end weight loss was 80.32% for the LSG group and 62.20% for the ESG group. The mean adverse events rate was 0.19%. The study results indicated a moderate superiority of LSG versus ESG. Although the recent emergence of bariatric endoscopic techniques is 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 there are very few comparative studies available. Therefore, there remains a need for a proper meta-analysis that combines data from the two different techniques. The studies revealed notable biases including the type of design, the loss to follow-up rate was not always reported in some studies and 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 additionally, valid studies to base guidelines on are necessary.

Singh (2020) conducted a systematic review and found eight studies addressing the OverStitch™ device which included a total of 1,859 patients. Studies were all observational and included single center and multicenter experiences. Primary outcomes measured were %TWL), %EWL, and SAE. The authors found the pooled mean %TWL at 6, 12, and 24 months was 14.86, 16.43, and 20.01. Similarly, %EWL at 6, 12, and 24 months was 55.75, 61.84, and 60.40. The incidence of SAE 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 included lack of controlled studies, lack of standardization definition for SAE and lack of long-term follow up data. (Publication by Lopez-Hava 2017, which was previously cited in this policy, was included in this systematic review.)

Hedjoudje et al. (2020) conducted a systematic review and meta-analysis from eight studies which included 1,772 patients that underwent ESG. Primary outcome measurements included relative weight loss, decrease in BMI and relative estimated weight loss. Serious adverse events were reported in all studies with an occurrence of 2.2% and included 18 patients with pain or nausea that required hospitalization, 9 patients that experience upper GI bleeding, 8 patients with perigastric leak or collection, one patient experienced pneumoperitoneum and one patient had a pulmonary embolism. The authors found the data suggested ESG gave way to significant sustained weight loss and safety. Patients had a BMI decrease of 5.6 kg/m^2, mean TBWL was 15.1% and relative EWL of 57.7%. These results appear to be sustained through 18-24 months of follow-up. Limitations included lack of control group, large loss to follow-up, lack of reporting for mild adverse events and lack of long-term outcomes; future studies are warranted.

Vagus Nerve Blocking

Currently there is insufficient quality evidence supporting the long-tern effectiveness of vagus nerve blocking for obesity treatment; additional robust studies including randomization are warranted.

Apovian et al. (2017) reported the two-year outcomes from the ReCharge study among participants initially randomized to an active intervention. At 24 months, 123 (76%) vBloc participants 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), HbA1c (-0.3%), and systolic (-11 mmHg) and diastolic blood pressures (-10 mmHg). QOL measures were significantly improved. Heartburn/dyspepsia and implant site pain were the most frequently reported AEs. The primary related serious AE rate was 4.3%. The findings are limited by lack of comparison group.

Morton et al. (2016) reported 12-month outcomes from the ReCharge study. Fifty-three 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 %EWL of 33% (11% %TWL) compared to 19% EWL (6% TWL) with sham at 12 months (treatment difference 14 percentage points, 95% CI, 7-22; $p < 0.0001$). Common AEs of 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 among participants with moderate obesity and comorbidities, and with a well-tolerated safety profile. Longer-term outcomes are needed to demonstrate the continued durability of this procedure.

Shikora et al. (2016) reported two-year outcomes from the VBLOC DM2 study, a prospective, case series of 28 subjects with T2D and BMI between 30 and 40 kg/m^2 who underwent a VBLOC procedure. At 24 months, the mean percentage of EWL was 22% (95% CI, 15 to 28, $p < 0.0001$) or 7.0% TWL (95% CI, 5.0 to 9.0, $p < 0.0001$). Hemoglobin A1c decreased by 0.6 percentage points (95% CI, 0.2 to 1.0, $p = 0.0026$) on average from 7.8% at baseline. Fasting plasma glucose declined by 15 mg/dL (95% CI, 0 to 29, $p = 0.0564$) on average from 151 mg/dL at baseline. Among subjects who were hypertensive at baseline, systolic blood pressure declined 10 mmHg (95% CI, 2 to 19, $p = 0.02$), diastolic blood pressure declined by 6 mmHg (95% CI, 0 to 12, $p = 0.0423$), and mean arterial pressure declined 7 mmHg (95% CI, 2 to 13, $p = 0.014$). Waist circumference was significantly reduced by 7 cm (95% CI, 4 to 10, $p < 0.0001$) 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 lack of comparison group. Randomized controlled studies with larger patient populations are needed to validate these findings.

The ReCharge pivotal study, sponsored by the manufacturer, (Ikramuddin et al., 2014), was a prospective, randomized, double-blind, sham-controlled, multicenter trial to evaluate the safety and effectiveness of the Maestro system in treating obesity. The trial enrolled subjects who had a BMI 40-45 kg/m^2 or a BMI 35-39.9 kg/m^2 with at least one obesity-related co-morbid condition, and who had failed a more conservative weight reduction alternative. A total of 239 subjects were enrolled at 10 investigational sites; 162 subjects were randomized to the device group, and 77 were randomized to the sham control group. Subjects randomized to the sham control group underwent a surgical procedure consisting of anesthesia, implantation of a non-functional 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 endpoint and helped more than half of patients 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 excess weight loss to sham by a 10-point margin with at least 55% of patients in the vagal block group achieving a 20% loss and 45% achieving a 25% loss.

Gastrointestinal Liner (EndoBarrier®)

Currently there is insufficient evidence regarding the effectiveness and safety of gastrointestinal liners for obesity and weight loss; additional well designed RCTs are needed along with 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.

Ruban et al. (2022) conducted an RCT to study the clinical efficacy and safety of the duodenal-jejunal bypass liner (DJBL). Participants aged 18 to 65 years, with a BMI of 30 to 50 kg/m^2 and confirmed diagnosis of T2D for at least 1 year with inadequate glycemic control and on glucose-lowering medications were included in the trial. 170 patients were originally selected but due to several participants dropping out, 55 and 58 patients (DJBL and control arms, respectively) were included in the primary analysis at one year and 58 and 51 patients were included at year two. All participants received dietary and physical activity counselling. The primary outcome was to achieve an HbA1c reduction of 20% at 12 months post intervention. Secondary outcomes included lowered blood pressure, and a reduction in total body weight loss and the number of medications taken. The authors found that while the addition of the DJBL resulted in superior weight loss and improvement in cardiovascular risk factors, it did not make a significant impact on the patients' HbA1c. The findings are limited by the open-label design of the study and large loss to follow up that could have introduced biases.

Quezada et al. (2018) conducted a single-arm, open-label, case series to evaluate the safety and efficacy of endoscopically placed DJBL over a 3-year period. Of 80 patients enrolled in the study, (age: 35 ±10 years; 69% female; weight: 109 ±17 kg; BMI: 42 ±5.4 kg/m^2), 72 AEs were observed in 55 patients (68%). Nine subjects required a prolonged hospital stay and three subjects required major interventions. At 52 weeks (71 patients), 104 weeks (40 patients), and 156 weeks (11 patients), the mean %EWL were 44 ±16, 40 ±22, and 39 ±20, respectively ($p < 0.001$). This study shows significant and sustained weight loss after 3 years of treatment with the new DJBL. However, the high frequency and severity of AEs preclude the use of this prototype for periods longer than 1 year.

Forner et al. (2017) evaluated the outcomes of 114 obese patients treated with a DJBL. Mean total body weight change from baseline was 12.0 kg (SD 8.5 kg, $p < 0.001$). Over an average of 51 weeks, the mean %TWL was 10.5% (SD 7.3%). Mean HbA1c was not significantly improved, but of 10 patients on insulin, 4 ceased insulin and 4 reduced insulin dosages. There was a significant decrease in hemoglobin and total cholesterol and a significant increase in serum alkaline phosphatase. Seventy-four percent of patients experienced at least one AE, some of them serious including 6 device obstructions, 5 gastrointestinal hemorrhages, 2 liver abscesses, and 1 acute pancreatitis. Seventy-four percent of patients experienced weight gain after removal with a mean 4.5 ±6.1 kg ($p < 0.0001$) within the first 6 months after explanation. The authors conclude that the DJBL provides significant but highly variable weight loss, and variable glycemic control. Most patients experienced an adverse event and most regained significant weight after device removal. In addition, the authors observed that major adverse events can occur, including the potentially life-threatening complications of hepatic abscess and gastrointestinal hemorrhage. The findings are limited by lack of comparison group. Further studies are needed to determine the long-term safety and efficacy of this procedure.

In a retrospective review, Betzel et al. (2017) evaluated the efficacy and safety profile of the DJBL. Inclusion criteria for treatment with a DJBL were age 18-70 years, BMI 28-45 kg/m^2, and T2D with a HbA1c > 48 mmol/mol. Primary outcomes were changes in HbA1c and body weight. Secondary outcomes included changes in blood pressure, lipids, and anti-diabetic medication. Predictive factors for success of treatment with the DJBL were determined. The authors reported that 185 out of 198 patients successfully underwent a DJBL implantation procedure, with an intended implantation time of 12 months. In these 185 patients, body weight decreased by 12.8 ±8.0 kg (total body weight loss of 11.9 ±6.9%, $p < 0.001$), HbA1c decreased from 67 to 61 mmol/mol ($p < 0.001$) despite a reduction in anti-diabetic medication, and blood pressure and serum lipid levels all decreased. In total, 57 (31%) DJBLs were explanted early after a median duration of 33 weeks. AE occurred in 17% of patients. C-peptide ≥ 1.0 nmol/L and body weight ≥ 107 kg at screening were independent predictive factors for success. The authors concluded that treatment with the DJBL in patients with T2D and obesity resulted in improvement in glucose control, a reduction in anti-diabetic medication, and significant weight loss. The largest changes are observed within the first 3-6 months. Initial C-peptide levels and body weight may help to select patients with the greatest chance of success. The findings are limited by lack of comparison group.

Vilarrasa et al. (2017) evaluated the efficacy and safety of Endobarrier® in grade 1 obese patients with T2D and poor metabolic control and the role of gastro-intestinal hormone changes on the metabolic outcomes. Twenty-one patients aged 54.1 ±9.5 years, diabetes duration 14.8 ±8.5 years, BMI 33.4 ±1.9 kg/m^2, and HbA1c 9.1 ±1.3%, under insulin therapy, were implanted with Endobarrier®. Fasting concentrations of PYY, ghrelin and glucagon, and AUC for GLP-1 after a standard meal test were determined prior to and at months 1 and 12 after implantation. They found that the Endobarrier® in in this subset of patients is associated with significant weight decrease and moderate reduction in HbA1c at month 12. Longer term outcome data is needed, and the findings are limited by lack of comparison group.

In a systematic review and meta-analysis, Rohde et al. (2016) evaluated the efficacy and safety of the DJBS. Five RCTs (235 subjects) and 10 observational studies (211 subjects) were included. The risk of bias was evaluated as high in all studies. The mean BMI ranged from 30 to 49.2 kg/m^2 and 10-100% of the subjects had T2D. Meta-analysis showed that the DJBS was associated with significant mean differences in body weight and excess weight loss of -5.1 kg [95% confidence interval (CI) -7.3, -3.0; four trials; n = 151; I(2) = 37%] and 12.6% (95% CI 9.0, 16.2; four trials; n = 166; I(2) = 24%), respectively, compared with diet modification. The mean differences in glycated hemoglobin (-0.9%; 95% CI -1.8, 0.0) and fasting plasma glucose (-3.7 mM; 95% CI -8.2, 0.8) among subjects with T2D did not reach statistical significance. Adverse events consisted mainly of abdominal pain, nausea, and vomiting. No deaths occurred. Future high-quality long-term RCTs are needed to further assess efficacy and safety of the DJBS for obesity.

Clinical Practice Guidelines

American Diabetes Association (ADA)

The American Diabetes Association (ADA) *Standards of Medical Care in Diabetes – 2024* states that metabolic surgery should be considered as a weight and glycemic management approach for individuals with diabetes with a BMI ≥ 30.0 kg/m^2 (or ≥ 27.5 kg/m^2 in Asian American individuals) 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 individuals after surgery.

The joint statement by international diabetes organizations on metabolic surgery in the treatment algorithm for type 2 diabetes (American Diabetes Association, International Diabetes Foundation, Diabetes UK, Chinese Diabetes Society, and Diabetes India) made 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 and 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 an ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease (Katz, et al. 2022), the following recommendations are made:

- For refractory GERD, recommend optimization of PPI therapy as the first step in 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 intragastric balloons (IGB) 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 include long-term efficacy of IGB therapy compared with SOC beyond 1 year, variables such as the filling medium (fluid vs. gas) the potential efficacy of an ongoing dietary intervention, pharmacotherapy, or the need for sequential balloon placement for sustained weight loss, and the role of exercise in weight-loss sustainability. Although the risk of serious adverse events appears to be relatively low, early removal due to device intolerance seems to be relatively common. The AGA makes the following recommendations:

- In individuals with obesity seeking a weight-loss intervention who have failed 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 individuals 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 individuals undergoing IGB therapy, recommend prophylaxis with proton pump inhibitors. (Strong recommendation, moderate certainty)
- In individuals 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 individuals undergoing IGB therapy, suggest against perioperative laboratory screening for nutritional deficiencies. (Conditional recommendation, low certainty)
- Suggest daily supplementation with 1–2 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 patient’s context and comorbidities following a shared decision-making approach. (Conditional recommendation, low certainty)

American Society for Gastrointestinal Endoscopy (ASGE)

The ASGE Technology Committee conducted a systematic review and meta-analysis to evaluate whether endoscopic technologies have met appropriate thresholds outlined by ASGE by the Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) document (Abu Dayyeh et al., 2015a). The study authors evaluated Orbera intragastric balloon (IGB) (Apollo Endosurgery) and the EndoBarrier duodenal-jejunal bypass sleeve (DJBS) (GI Dynamics). Results of the meta-analysis (17 studies, n = 1,683) indicate that the Orbera IGB satisfies the PIVI thresholds for therapy for primary and non-primary bridge obesity. The percentage of EWL (%EWL) associated with the Orbera IGB at 12 months was 25.44% (95% CI, 21.45 to 29.41%) with a mean difference over controls of 26.9% (%EWL) (95% CI, 15.66% to 38.24%; p ≤ 0.01) in a total of 3 RCTs. The pooled %TWL after use of Orbera IGW was 13% at 6 months (95% CI, 12.37% to 13.95%) and 11.27% (95% CI, 8.17% to 14.36%), both which exceed 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 FDA and meet thresholds of efficacy and safety as defined in the ASGE/ASMBS Preservation and Incorporation of Valuable Endoscopic Innovations should be included in the obesity treatment algorithm as adjunctive therapies to a lifestyle intervention program as outlined in the 2013 American Heart Association(AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) guidelines for the management of overweight and obesity in adults. ASGE advises that endoscopists performing EBT have a mechanism to enroll patients in long-term follow-up care for weight loss maintenance (Sullivan et al., 2015).

American Association of Clinical Endocrinologists (AACE)/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 ≥ 40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible.
- Patients with a BMI ≥ 35 kg/m^2 and one or more severe obesity-related complications remediable by weight loss, including type 2 diabetes (T2D), high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, obstructive sleep apnea, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure.
- Patients with the following comorbidities and BMI ≥ 35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable: obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; gastroesophageal reflux disease; severe venous stasis disease; impaired mobility due to obesity; and considerably impaired quality of life.
- Patients with BMI of 30-34.9 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 body mass index criterion for bariatric procedures should be adjusted for ethnicity (e.g., 18.5 to 22.9 kg/m^2 is normal range, 23 to 24.9 kg/m^2 overweight, and ≥ 25 kg/m^2 obesity for Asians).
- Interventions should first include a multidisciplinary approach, including dietary change, physical activity, behavioral modification with frequent follow up; and then if appropriate, pharmacologic 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 is to include 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 the ACE developed comprehensive clinical practice guidelines for the medical care of patients with obesity (Garvey, et al., 2016) based on diligent review of clinical evidence with “transparent incorporation of subjective factors.” The final recommendations recognize that obesity is a complex, adiposity-based chronic disease, where management targets both weight-related complications and adiposity to improve overall health and quality of life. 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 guideline are the following recommendations pertaining to BMI:

- 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 1 or more severe obesity-related complications, including T2DM, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease,

severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure.
- Patients with a BMI of 30-34.9 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 CVD risk reduction alone.

American Heart Association (AHA)/American College of Cardiology (ACC)/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 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 use of bariatric surgery for patients with a BMI ≥ 40, or BMI ≥ 35 with comorbidities.

In a scientific statement on severe obesity in children and adolescents the American Heart Association (Kelly et al., 2013), summarized that RYGB has been associated with improvement or resolution of numerous comorbid conditions, including OSAS, T2DM, features of metabolic syndrome, pseudotumor cerebri, and psychosocial functioning. Controlled, prospective adult studies demonstrate 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 & 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 to 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 noted that there is no data from any randomized controlled trial, large prospective study, or meta-analysis to support the practice of mandated preoperative weight loss. Further, there is no Level I data in the surgical literature, or 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 co-morbid 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 preoperatively. 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 the norm in the majority of WLS practices. Screening is important because it is common for patients who present for WLS to have at least 1 vitamin or mineral deficiency preoperatively.

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.

Indications for Surgery

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

- MBS is recommended for individuals with a BMI ≥ 35 kg/m^2, regardless of presence, absence, or severity of comorbidities.
- MBS should be considered for individuals with metabolic disease and BMI of 30-34.9 kg/m^2.
- BMI thresholds should be adjusted in the Asian population such that a BMI ≥ 25 kg/m^2 suggests clinical obesity, and individuals with BMI ≥ 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.

Specific Bariatric Procedures

The ASMBS (2016, updated 2019) has approved, and supports the use of the following bariatric procedures and associated devices:
- Roux-en-Y gastric bypass
- BPD/duodenal switch
- Intragastric balloon
- Sleeve gastrectomy
- Adjustable gastric banding
- Single anastomosis duodeno-ileostomy with sleeve

In a position statement (Ghiassi et al., 2024), the ASMBS indicated that the adoption of OAGB outside of the United States has resulted in numerous publications that report on the early, 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 RYGB or SG. Evidence has also shown that OAGB is effective as a revision option after restrictive operations such as LAGB, VBG, and SG. 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 the single-anastomosis duodenal switch (SADS), the ASMBS has concluded that single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) provides for similar outcomes to those for the classic biliopancreatic diversion with duodenal switch (BPD-DS) procedure and therefore should be recognized. The society conclusion is that the current available peer-reviewed literature does not suggest outcomes will differ substantially from those seen with classic DS procedure. While the ASMBS endorses SADI-S as an appropriate bariatric surgical procedure, the society indicates publication of long-term safety and efficacy outcomes is still needed and is 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 (SG) as a bariatric procedure (Ali et al., 2017) summarized that:
- Substantial long-term outcome data published in the peer-reviewed literature including studies comparing outcomes of various surgical procedures, confirm that sleeve gastrectomy (SG) provides significant and durable weight loss, improvements in medical co-morbidities, improved quality of life, and low complication and mortality rates for obesity treatment.
- SG is now the most commonly performed procedure in the United States (~53.8% of all bariatric procedures), followed by Roux-en-Y gastric bypass (RYGB; 23.1% of all procedures) (Chaar et al., 2018).
- In terms of initial early weight loss and improvement of most weight-related co-morbid conditions, SG and RYGB appear similar.
- SG 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 SG 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 SG.
- Based on safety and efficacy data, there is a trend toward SG as the procedure of choice for adolescents, although both RYGB and SG are routinely performed in teen weight loss surgery programs.
- As with any bariatric procedure, long-term weight regain can occur after SG and may require one or more of a variety of re-interventions.

The ASMBS Clinical Issues Committee position statement on intragastric balloon therapy endorsed by SAGES (Ali, et al., 2016) includes the following summary and recommendations:
- Level 1 data regarding the clinical utility, efficacy, and safety of intragastric balloon therapy for obesity are derived from randomized clinical studies.
- Implantation of intragastric balloons can result in notable weight loss during treatment.

- Although utilization of intragastric balloons results in notable weight loss, separating the effect of the balloon alone from those of supervised diet and lifestyle changes may be challenging. Of note, recent FDA pivotal trials demonstrated a benefit to balloon use compared with diet alone in their study populations. In general, any obesity treatment, including intragastric balloon 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 for intragastric balloons 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 intragastric balloons 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 intragastric balloon therapy position statement in response to the FDA's warnings on complications not identified during initial clinical trials, and worldwide mortalities associated with intragastric balloons. They recommend that:
- As with all procedures, it is important that patients give informed consent and are aware of potential adverse events. Laypeople may need to be counseled to correct a misperception that endolumenal treatments are nonsurgical and thus risk-free.
- When less powerful treatments are chosen, behavioral modification increases in importance and there is risk of weight regain after the device is retrieved. The ASMBS routinely advocates for multidisciplinary care and support of the weight loss patient, and this recommendation is even more crucial for intragastric balloon recipients.

The ASMBS, in their 2015 position statement on vagal blocking therapy for obesity (Papasavas et al., 2016), conclude that the quantity of the data available at this time (6 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 patient tolerance of this device.

Bariatric Surgery in Adolescents

The updated ASMBS pediatric metabolic and bariatric surgery 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 physiologic 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.

The summary of major changes in the guideline includes:
- Patient selection criteria of a BMI ≥ 20% of the 95th percentile with a co-morbidity or a BMI ≥ 140% of the 95th percentile should be used when determining weight cut offs for adolescents to undergo metabolic and bariatric surgery (MBS). In their opinion, Tanner stage and linear growth should not be used to determine readiness for MBS.
- Preoperative attempts at diet and exercise: there are no data that the number of weight loss attempts correlates with success after MBS. Compliance with a multi-disciplinary preoperative program may improve out-comes after MBS but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity.
- Requiring adolescents with a BMI > 40 to have a co-morbidity (as in the old guidelines) puts children at a significant disadvantage to attaining 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 co-morbidities.
- Certain co-morbidities 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 of medical therapies for type 2 diabetes in children, these co-morbidities may be considered an indication for MBS in younger adolescents or those with lower obesity percentiles.
- Nonalcoholic fatty liver disease (NAFLD) and steatohepatitis (NASH): NAFLD may be present in at least 59% of adolescent patients referred for MBS. Given complete resolution of NASH 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 quality of life (HRQoL) with 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 suffer from severe obesity and have failed medical management of idiopathic intracranial hypertension should be considered for MBS.
- Adolescents with severe obesity have significant risk factors for cardiovascular disease (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 long term.
- Multidisciplinary teams should stabilize and treat preexisting eating disorders, assure 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 (MBSAQIP) 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 of untreated or inadequately treated obesity for 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 is lower might decrease the operative risk, morbidity, and mortality. Additionally, earlier surgical intervention alters the natural course of many obesity-related co-morbidities 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 (ACOG) and the Obesity Society (Kominiarek et al., 2017), the ASMBS summarized 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 is 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 systematic review of reoperative bariatric surgery, the ASMBS Revision Task Force (Brethauer et al., 2014) states that the indications and outcomes for reoperative bariatric surgery are procedure-specific, but the current evidence does support additional treatment for persistent obesity, co-morbid disease, and complications. Additional surgical therapy may benefit patients who present with insufficient weight loss, continued co-morbid disease, or weight gain after the index bariatric procedure. A thorough evaluation should be conducted by a multi-disciplinary program to determine the potential causes for their poor responses.

As the risks of reoperative bariatric surgery are higher than 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, the patient’s anatomy, the patient’s weight and co-morbidities, and the 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 which 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 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 was compared to that from patients who had initial bariatric operations but did not undergo reoperations. Reoperations were subdivided into corrective operations and conversions.

- Out of 449,753 bariatric operations, 28,720 (6.3%) underwent reoperations of which 19,970 (69.5%) were corrective and 8,750 (30.5%) were conversions.

- The mean % EBWL after conversion to a different bariatric operation was 39.3% and was 35.9% after a corrective operation. Although this % 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 laparoscopic adjustable gastric band for band intolerance or dilated esophagus or reversing a duodenal switch or a gastric bypass for severe malabsorption, may in fact result in weight gain and return of comorbidities.
- Elderly patients (> 60 years of age) comprised 11% of the primary and 12% of the reoperative group of patients. The data suggests an overall improvement in the rates of morbidity and mortality after bariatric operations in recent years, even for 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 primary procedures.

American Academy of Pediatrics (AAP)

In 2023, the AAP published the first edition of the clinical practice guideline for evaluation and management of children and adolescents with overweight and obesity. This document recommends metabolic and bariatric surgery for pediatric patients over the age of 12 for the following:
- Class II obesity, BMI ≥ 35 or 120% of the 95th percentile for age and sex, whichever is lower with clinically significant disease, including but not limited to:
  - T2DM
  - Idiopathic intracranial hypertension
  - Non-alcoholic steatohepatitis
  - Blount’s disease
  - Slipped capital femoral epiphysis
  - GERD
  - OSA with an AHI > 5
  - Cardiovascular disease risks
  - Depressed health related QOL
- Class III obesity, BMI ≥ 40 or 140% of the 95th percentile for age and sex, whichever is lower

Furthermore, the following is stated:
- The determination of eligibility for metabolic and bariatric surgery should rely heavily on a multicomponent and individualized approach between members of the metabolic and bariatric surgery team, the patient, and the patient’s parents or guardians.
- A referral should be to a comprehensive metabolic and bariatric surgery center with experience and expertise in treatment of patients younger than 18 years.
- Evaluation for metabolic and bariatric surgery 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 2-part joint scientific statement on lipids and bariatric procedures. Part 1 concluded 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. Among the mechanisms by which bariatric procedures may improve dyslipidemia includes 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 summarized 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 3-6 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 utilized when evaluating children or adolescents for obesity.
- Bariatric surgery is suggested only under the following conditions:
    - The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of > 40 kg/m^2 or has a BMI of > 35 kg/m^2 and significant, extreme comorbidities.
    - T2DM, moderate to extreme sleep apnea, pseudotumor cerebri, debilitating orthopedic problems, and nonalcoholic steatohepatitis with advanced fibrosis.
    - Extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy.
    - 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).
    - Psychological evaluation confirms the stability and competence of the family unit [psychological distress due to impaired quality of live (QOL) from obesity may be present, but the patient does not have an underlying untreated psychiatric illness].
    - The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.
    - There is 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 breast-feeding adolescents (and those planning to become pregnant within 2 years of surgery), and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder.

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

In a 2024 position statement (Ponce de Leon-Ballesteros et al.), the IFSO conducted a systematic review of evidence evaluating the 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, there were a total of 93 articles included. Among the articles included, there were 1 RCT, 14 cohort studies, 25 case-control studies, 42 case series, and 11 case reports. The authors note that SADI-S/SADS demonstrated efficacy in weight loss and medium-to-long-term control of type 2 diabetes, as well as positive outcomes regarding hypertension and hyperlipidemia. The impact of SADI-S/SADS on other comorbidities remained inconclusive. The authors also note that there were frequent nutritional deficiencies identified included fat-soluble vitamins, anemia, and hypoalbuminemia. Limitations included considerable variation in the length of the common channel which may lead to differences in terms of weight loss outcomes as well as late complications and over-estimation of data due to the duplication of patients in the different studies. Despite significant efforts, there is a scarcity of high-quality evidence on SADI-S/SADS and the authors acknowledged that limited data was 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 for 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 co-morbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group. The benefits in patients with BMI > 30 is less clear and needs 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 fail to 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 suffering with progressive or poorly controlled obesity-related comorbidities if the risk-versus-benefit analysis favors surgery. Laparoscopic RGB, AGB, and BPD 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 versus tolerance of risk and lifestyle change.

Further, the 2008 guidelines state that there are no absolute contraindications to bariatric surgery. 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's disease may be a relative contraindication to Roux-en-Y gastric bypass and biliopancreatic diversion.

Multidisciplinary Care Task Group

Greenberg et al. (2005) found a high incidence of depression, negative body image, eating disorders, and low quality of life (QoL) in patients with severe obesity and that perceived obesity-related health problems, motivation, and sense of coherence (SoC) predicted better weight loss. Although their investigation showed 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 working with a multidisciplinary team. Although research supports the association of psychological problems such as depression and personality disorder with less successful obesity surgery outcomes, rarely are the psychological problems cited as contraindications for surgery (Greenberg et al., 2005).

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) 2014 (updated 2023) guideline on obesity identification, assessment and management offers bariatric surgery as a treatment option for people with obesity when they 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, type 2 diabetes or high blood pressure) that could be improved if they lost weight; have a multi-disciplinary team approach; and the individual agrees to necessary long-term follow-up after surgery. In addition, the NICE guideline notes that bariatric surgery should be expedited for individuals 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) type 2 diabetes and is receiving or will receive assessment in a specialist weight management service. Additionally, the guideline suggests consideration for individuals 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 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.

A 2015 NICE interventional procedure guidance on managing type 2 diabetes states that current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes 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 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 type 2 diabetes, both when the device is in place and after its removal; and control of type 2 diabetes 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 single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity shows that there are well-recognized complications. 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.

A 2020 NICE interventional procedure guidance on 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.

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

American Academy of Sleep Medicine (AASM)

The American Academy of Sleep Medicine 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, 2021). The following are recommendations intended as a guide for clinicians who treat overweight adults with OSA:

- Recommend clinicians discuss referral to a sleep surgeon with adults with OSA and BMI < 40 who are intolerant or unaccepting of CPAP (Strong).

- Recommend clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class II/III, BMI ≥ 35) who are intolerant or unaccepting of PAP (Strong).
- Suggest clinicians discuss referral to a sleep surgeon with adults with OSA, BMI < 40 and persistent inadequate PAP adherence due to pressure-related side effects (Conditional).
- Suggest clinicians recommend PAP as an initial therapy for adults with OSA and a major upper airway anatomic 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 or recommendations:
- In patients with a body mass index of ≥ 30 kg/m^2 and type 2 diabetes mellitus, suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention.
- In adult patients with a body mass index ≥ 40 kg/m^2 or those with body mass index ≥ 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 (body mass index ≥ 30 kg/m^2) who prioritize short-term (up to six months) weight loss, suggest offering intragastric balloons in conjunction with a comprehensive lifestyle intervention.
- There is insufficient evidence to recommend for or against metabolic/bariatric surgery to patients over age 65.
- There is insufficient evidence to recommend for or against percutaneous gastrostomy devices for weight loss in patients with obesity.
- There is insufficient evidence to recommend for or against intragastric balloons for long-term weight loss to support chronic weight management or maintenance.

Thoracic Society

In a clinical practice guideline from the Thoracic Society (Hudgel, 2018), the following recommendations are made for patients who are overweight and suffer from 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 BMI ≥ 30 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 failed conservative weight reduction strategies, such as supervised diet, exercise, and 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 October 2, 2024)

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 FDA for marketing under the premarket approval process. According to the FDA labeling, this is approved for surgical treatment for severely obese adults for 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 a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe co-morbid conditions, or those who are 100 lbs. 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 failed 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, with a body mass index (BMI) of at least 40 kg/m^2 or less obese patients who have at least a body mass index (BMI) of 30 kg/m^2 and one or more additional obesity-related co-morbid condition, such as diabetes or hypertension. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf. (Accessed October 2, 2024)

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 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, product code GDW and GAG, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm. (Accessed October 2, 2024)

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 within the gastrointestinal tract. The device can utilize either a single- or dual-channel endoscope. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181141.pdf. (Accessed October 2, 2024)

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 with a BMI of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with one or more obesity related comorbid conditions and intended to be used in conjunction with a diet and behavior modification program. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180024a.pdf. (Accessed October 2, 2024)

In August of 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 October 2, 2024)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2025	**Template Update** • Removed content/language pertaining to the state of Mississippi
06/01/2025	**Application** ***Idaho*** **and** ***Kansas*** • Added language to indicate this Medical Policy does not apply to the states of Idaho and Kansas; refer to the state-specific policy versions **Medical Records Documentation Used for Reviews** • Updated reference link to the guidelines titled *Medical Records Documentation Used for Reviews*
04/01/2025	**Applicable Codes** • Added CPT code 43999

Date	Summary of Changes
	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS007.V

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.