UnitedHealthcare®

UnitedHealthcare® Commercial
*Medical Policy*

# Bariatric Surgery

**Policy Number:** 2020T0362FF
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Instructions for Use

Table of Contents | Page



**Related Commercial Policies**

- Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia
- Obstructive Sleep Apnea Treatment
- Robotic-Assisted Surgery Policy

**Community Plan Policy**

- Bariatric Surgery

**Medicare Advantage Coverage Summary**

- Obesity: Treatment of Obesity, Non-Surgical and Surgical (Bariatric Surgery)

## Coverage Rationale

See Benefit Considerations

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

- Biliopancreatic bypass/ Biliopancreatic diversion with duodenal switch
- Gastric bypass (includes robotic-assisted gastric bypass)
- Laparoscopic adjustable gastric banding 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)
- Vertical banded gastroplasty

In adults, 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:

- Class III obesity; or
- Class II obesity in the presence of one or more of the following co-morbidities:
  - Type 2 diabetes; or
  - Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or
  - History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty; or
  - History of cardiomyopathy; or
  - Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥30

  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 multi-disciplinary surgical preparatory regimen

In Adolescents, the bariatric surgical procedures identified above are proven and medically necessary for treating obesity when all of the following criteria are met:

- Class III obesity; or
- Class II obesity in the presence of one or more of the following co-morbidities:
    - Type 2 diabetes; or
    - Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or
    - History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty; or
    - History of cardiomyopathy; or
    - Obstructive Sleep Apnea confirmed on polysomnography with an AHI or RDI of ≥30

  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.

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 bariatric procedure.

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 surgical 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)
    - Single-Anastomosis Duodenal Switch (also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery [SIPS])
    - Stomach aspiration therapy (AspireAssist®)
    - Transoral endoscopic surgery (includes TransPyloric Shuttle® (TPS®) Device)
    - Vagus Nerve Blocking (VBLOC®)

Gastrointestinal liners (EndoBarrier®) are investigational, unproven and not medically necessary for treating obesity due to lack of U.S. Food and Drug Administration (FDA) approval, and insufficient evidence of efficacy.

# Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

| CPT Codes* | Required Clinical Information |
|---|---|
| **Bariatric Surgery** | |
| 0312T, 0313T, 0314T, 0315T, 0316T, 0317T, 43644, 43645, 43647, 43648, 43659, 43770, 43771, 43772, 43773, 43774, 43775, 43842, 43843, 43845, 43846, 43847, 43848, 43881, 43882, 43886, 43887, 43888, 64590, 64595 | Medical notes documenting all of the following:<br>• Height<br>• Weight<br>• Current and five year history of BMI (body mass index)<br>• Diet history<br>• Co-morbidities<br>• Medical treatment tried and failed including diet and exercise<br>• Psychological evaluation by a licensed behavioral health professional<br>• Nutritional consult<br>• Name of the facility where the procedure will be performed |
| **Subsequent Bariatric Surgery** | |
| 43860<br>43865 | Medical notes documenting all of the following:<br>• Height<br>• Weight<br>• BMI (body mass index)<br>• Diet history<br>• Co-morbidities<br>• Previous unsuccessful medical treatment<br>• Name of the facility where the procedure will be performed<br>• Initial bariatric surgery performed and date and subsequent complications that require further surgical intervention |

*For code descriptions, see the Applicable Codes section.

# Definitions

Adolescent: Individuals 12-21 years of age (Hardin and Hackell [American Academy of Pediatrics], 2017). For the purposes of this policy, adults are considered $\geq$18 years of age.

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 (NHLBI) (Jensen et al., 2013) 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
- $\geq$ 40 kg/$m^2$ – Extreme 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 $95^{th}$ percentile height, or an absolute BMI of 35-39.9 kg/$m^2$, whichever is lower*
- Class III obesity – 140% of the $95^{th}$ percentile height, or an absolute BMI of $\geq$40 kg/$m^2$, whichever is lower

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

Multidisciplinary: 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).

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/hr

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

Revisional Bariatric Surgery:
- Conversion – A second bariatric procedure that changes the bariatric approach from the index 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 to the same as an intraoperative conversion (e.g., converting from laparoscopic approach to an open procedure).
- Revision or Corrective – A procedure that corrects or modifies anatomy of a previous bariatric procedure to improve the intended 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.

(Hayes, 2018)

Technical Failure or Major Complication: Potential issues related to bariatric procedures 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

# 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 the member specific benefit plan document 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 |
|---|---|
| 0312T | Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming |
| 0313T | Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator |
| 0314T | Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator |

| CPT Code | Description |
|---|---|
| 0315T | Vagus nerve blocking therapy (morbid obesity); removal of pulse generator |
| 0316T | Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator |
| 0317T | Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed |
| 43644 | Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less) |
| 43645 | Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption |
| 43647 | Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum |
| 43648 | Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum |
| 43659 | Unlisted laparoscopy procedure, stomach |
| 43770 | Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components) |
| 43771 | Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only |
| 43772 | Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only |
| 43773 | Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only |
| 43774 | Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components |
| 43775 | Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy) |
| 43842 | Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty |
| 43843 | Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty |
| 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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |

| CPT Code | Description |
|---|---|
| 64595 | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver |

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# Description of Services

## Obesity

Obesity and weight are 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, osteoarthritis, certain types of cancer, Obstructive Sleep Apnea and 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/m2 or higher to intensive, multicomponent behavioral interventions (USPSTF, 2012).

The National Center for Health Statistics (Centers for Disease Control and Prevention [CDC], 2017) reports that in 2015-2016, the prevalence of obesity was 39.8% in adults and 18.5% in children. The observed change in prevalence between 2013–2014 and 2015–2016 was not significant among adults and youth.

The National Heart, Lung, and Blood Institute (NHLBI) Obesity Expert Panel (2013) estimates that 8.1% of women, and 4.4% of men in the U.S. population has a BMI over 40. The NHLBI clarified that the term Class III or Extreme Obesity has replaced the term "morbid obesity." The American Society for Metabolic and Bariatric Surgery (American Society of Metabolic and Bariatric Surgery [ASMBS]) (English et al., 2016) estimates there were over 216,000 bariatric surgery procedures in 2016.

## 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 (2017).

## First-Line Treatments for Obesity

First-line treatments for obesity include dietary therapy, physical activity, behavior modification, and medication management; all of which have generally 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 patients 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).

### *Vertical Banded Gastroplasty (VBG)*

VBG restricts the size of the stomach using a stapling technique; there is no rearrangement of the intestinal anatomy. VBG has been abandoned by many due to a high failure rate, a high incidence of long-term complications, and the newer adjustable gastric band (AGB) and sleeve gastrectomy (van Wezenbeek et al., 2015). David et al. (2015) estimated the failure rate to be approximately 50% based on results from long-term studies.

### *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; Hayes, 2019). The device was granted FDA premarket approval on April 16, 2019 and was approved for up to 12 months weight loss therapy in patients with a BMI of 35.0 kg/m2 to 40.0 kg/m2 or a BMI of 30.0 kg/m2 to 34.9 kg/m2 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).

### *Laparoscopic Mini Gastric Bypass (LMGBP)*

LMGBP 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. 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 (such as via the Maestro® System; Enteromedics, Inc.) 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 via an endoscope 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, 2019). 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®, is a relatively new type of treatment for obesity which uses a surgically-placed tube to drain a portion of the stomach contents after every meal.

The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Patients 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 (Hayes, 2018).

### 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, patients 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).

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).

## Benefit Considerations

Most Certificates of Coverage and many Summary Plan Descriptions explicitly exclude benefit coverage for bariatric surgery.

Some states may require coverage for bariatric surgery. Refer to the member specific benefit plan document to determine availability of benefits for these procedures. As in all benefit adjudication, state legislated mandates must be followed. Therefore, the applicable state-specific requirements and the member specific benefit plan document must be reviewed to determine what benefits, if any, exist for bariatric surgery.

### For Fully Insured Group Policies in Maryland Only

Use the following criteria as specified in the Code of Maryland Regulations (COMAR 31.10.33.03B. April 2006):

1. A Body Mass Index (BMI) above 40 kg/m2 without co-morbidity; or
2. A BMI of 35 kg/m2 or greater with obesity-related co-morbid medical conditions including:
    a. Hypertension
    b. Cardiopulmonary condition
    c. Sleep apnea
    d. Diabetes
    e. Any life threatening or serious medical condition that is weight induced
3. Documentation that dietary attempts at weight control have been ineffective through completion of a structured diet program, such as Weight Watchers or Jenny Craig. Either of the following in the two-year period that immediately precedes the request for the surgical treatment of morbid obesity meets the indication:
    a. One structured diet program for six consecutive months; or
    b. Two structured diet programs for three consecutive months
4. A carrier or a private review agent acting on behalf of a carrier shall use flexibility with regard to defining a structured diet program
5. Completion of a psychological examination of the member's readiness and fitness for surgery and the necessary postoperative lifestyle changes

## Clinical Evidence

The criteria for patient selection for bariatric surgery are relatively uniform among clinical studies published in the peer-reviewed literature and broadly correspond to criteria recommended by the American Association of Clinical Endocrinologists (AACE), the Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMB) (Mechanick et al., 2019):

- Patients with a BMI≥40 kg/m2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk.

- Patients with a BMI≥35 kg/m2 and 1 or more severe obesity-related co-morbidities.
- Demonstration that a multidisciplinary approach with dietary, other lifestyle modifications (such as exercise and behavioral modification), and pharmacological therapy, if appropriate, have been unsuccessful.

Refer to the Professional Societies section of the policy for additional information.

The American Diabetes Association (ADA) *Standards of Medicare Care in Diabetes – 2018* states that metabolic surgery should be recommended as an option to treat type 2 diabetes in appropriate surgical candidates with a BMI of 40 kg/m2 (BMI 37.5 kg/m2 in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with a BMI of 35.0–39.9 kg/m2 (32.5–37.4 kg/m2 in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy. Metabolic surgery should be considered as an option for adults with type 2 diabetes and a BMI of 30.0–34.9 kg/m2 (27.5–32.4 kg/m2 in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin). They strongly recommend that long-term lifestyle support and routine monitoring of micronutrient and nutritional status be provided to patients after surgery, according to guidelines for postoperative management of metabolic surgery by national and international professional societies. The ADA's 2017 *Standards of Medicare Care in Diabetes* noted that the ADA now refers to bariatric surgery as metabolic surgery.

Salminen et al. (2018) reported 5-year outcomes from the SLEEVEPASS multicenter, open-label, randomized clinical equivalence trial. The purpose of the trial was to determine whether laparoscopic sleeve gastrectomy (LSG) (n=121) and laparoscopic Roux-en-Y gastric bypass (n=119) are equivalent for weight loss at 5 years in patients with morbid obesity. Among 240 patients randomized (mean age, 48 [SD, 9] years; mean baseline body mass index, 45.9, [SD, 6.0]; 69.6% women), 80.4% completed the 5-year follow-up. Based on the results, the authors concluded that the use of laparoscopic sleeve gastrectomy compared with use of laparoscopic Roux-en-Y gastric bypass did not meet criteria for equivalence in terms of percentage excess weight loss at 5 years. Although gastric bypass compared with sleeve gastrectomy was associated with greater percentage excess weight loss at 5 years, the difference was not statistically significant, based on the prespecified equivalence margins. Limitations included a small number of bariatric procedures performed along with technical complications which may have resulted in a higher reoperation rate accompanied by 20% of patients lost to followup.

Chaar et al. (2018) reported 30-day outcomes of SG versus RYGB based on the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database. The authors' evaluation showed that the incidence of postoperative complications in the first 30 days after surgery is low for both RYGB and SG. However, SG seems to have a better safety profile in the first 30 days postoperatively compared with RYGB. These findings should be considered in the preoperative evaluation and counseling of bariatric patients. Long-term follow-up is needed to compare safety and efficacy of SG versus RYGB.

Jambhekar et al. (2018) evaluated demographic and socioeconomic factors in the United States that are predictors of long-term weight loss after LSG. Prospectively collected data on 713 consecutive primary LSG operations was included in this study. Multiple regression analyses were done to determine if gender, race, or socioeconomic factors such as insurance and employment status correlated with postoperative weight loss. The presence of chronic comorbidities affecting quality of life such as Type II diabetes and obstructive sleep apnea (OSA) were also recorded and analyzed. All studied groups had similar preoperative body mass index (BMI) (mean 46 $kg/m^2$). Race was not significantly associated with weight loss at any postoperative interval. Male gender was associated with increased weight loss through the first three months (48.2 +/- 12.5 lbs vs. 40.5 +/- 11 lbs; p = 0.0001). Patients with diabetes had significantly less weight loss at the 6 through 18 month intervals (50.4 +/- 17.9 lbs vs. 59.6 +/- 15.6 lbs at six months; p = 0.00032; 53.3 +/- 25.4lbs vs. 80.5 +/- 31.3lbs at 18 months; p = 0.008). Patients with obstructive sleep apnea had significantly less weight loss at the two-year interval (57.5 +/- 29.2 lbs) vs. those without obstructive sleep apnea (69.6 +/- 23.5 lbs; p = 0.047). Finally, those patients who were students had the greatest weight loss at two years postoperatively with the least weight loss seen in retired patients followed by those on disability (108.0 +/-21.5 lbs vs. 26.0 lbs vs. 46.0 +/-19.7 lbs; p = 0.04). Further studies are needed to evaluate whether demographic differences impact long term weight loss. Limitations included loss to follow-up, identification and testing of only selected predictive factors, thus underrepresenting other socioeconomic factors, and conflicting results were identified between the model variables.

Schauer et al. (2017) reported 5-year outcomes from the STAMPEDE clinical trial which included 150 patients who had type 2 diabetes and a BMI of 27 to 43 were randomly assigned to receive intensive medical therapy alone or intensive medical therapy plus RYGB or SG. The primary outcome was a glycated hemoglobin level of 6.0% or less with or without the use of diabetes medications. Of the 134 of the remaining 149 patients (90%) who completed 5 years of follow-up, a glycated hemoglobin level of 6.0% or less at 5 years was achieved in 2 of 38 patients (5%) in the medical-therapy group, as compared with 14 of 49 patients (29%) in the RYGB (P = 0.01) and 11 of 47 patients (23%) in the SG group (P = 0.03). Changes from baseline observed in the RYGB and SG groups were deemed as superior by the authors as compared to the changes seen in the medical-therapy group with respect to body weight (-23%, -19%, and -5% in the RYGB, SG, and medical-therapy groups, respectively), triglyceride level (-40%, -29%, and -8%), high-density lipoprotein cholesterol level (32%, 30%, and 7%), use of insulin (-35%, -34%, and -13%), and quality-of-life measures (general health score increases of 17, 16, and 0.3; scores on the RAND 36-Item Health Survey ranged from 0 to 100, with higher scores indicating better health) (P<0.05 for all comparisons). No major late surgical complications were reported except for one reoperation. The authors concluded that five-year outcome data showed that, among patients with type 2 diabetes and a BMI of 27 to 43, bariatric surgery plus intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia.

Shoar and Saber (2017) conducted a systematic review and meta-analysis to compare long-term and midterm outcomes of laparoscopic sleeve gastrectomy versus RYGB. Fourteen studies comprising 5264 patients were eligible. Follow-up ranged from 36 months to 75.8±8.4 months. The pooled result for weight loss outcomes did not show any significant difference in midterm weight loss (standardized mean difference = -0.03; 95% confidence interval (CI), -0.38-.33; P = .88) but a significant difference in the long-term weight loss outcome favoring LRYGB (standardized mean difference = .17; 95% CI, .05-.28; P= .005). The pooled results demonstrated no significant difference for resolution of type 2 diabetes mellitus, hypertension, hyperlipidemia, and hypertriglyceridemia. Despite the insignificant difference between LRYGB and LSG in midterm weight loss, LRYGB produced better weight loss in the long-term. There was no significant difference between the 2 procedures for co-morbidity resolution. A major limitation of this study was the inclusion of short-term studies in the pooled analysis of midterm studies but claimed to be a long-term meta-analysis.

Kang and Le (2017) conducted a systematic review and meta-analysis to determine the effectiveness of bariatric surgical procedures. Eleven RCTs that met the criteria were included in the review. Of 9 trials (n=765), the differences in mean BMI reduction were -0.76 (95% CI: -3.1 to 1.6) for RYGB versus SG, -5.8 (95% CI: -9.2 to -2.4) for RYGB versus LAGB, and -5.0 (95% CI: -9.0 to -1.0) for SG versus LAGB. Eight RCTs (n=656) reported percentage excess weight-loss (%EWL), the mean differences between RYGB and SG, RYGB and LAGB, and SG and LAGB were 3.8% (95% CI: -8.5% to 13.8%), -22.2% (95% CI: -34.7% to -6.5%), and -26.0% (95% CI: -40.6% to -6.4%), respectively. The meta-analysis indicated low heterogeneity between studies, and the node splitting analysis showed that the studies were consistent between direct and indirect comparisons (P>.05). The authors concluded that the RYGB and SG were similar in weight-loss effect and both were superior to LAGB. Other factors such as complications and patient preference should be considered during surgical consultations.

In a systematic analysis, Osland et al. (2017a) evaluated the postoperative impact on type 2 diabetes resolution following laparoscopic vertical sleeve gastrectomy (LVSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB). Seven RCTs involving a total of 732 patients (LVSG n = 365, LRYGB n = 367) met inclusion criteria. Significant diabetes resolution or improvement was reported with both procedures across all time points. Similarly, measures of glycemic control (HbA1C and fasting blood glucose levels) improved with both procedures, with earlier improvements noted in LRYGB that stabilized and did not differ from LVSG at 12 months postoperatively. Early improvements in measures of insulin resistance in both procedures were also noted in the studies that investigated this. The authors suggest that both procedures are effective in resolving or improving preoperative type 2 diabetes in obese patients during the reported 3-to -5 year follow-up periods. However, further studies are required before longer-term outcomes can be elucidated. Areas identified that need to be addressed for future studies on this topic include longer follow-up periods, standardized definitions and time point for reporting.

Osland et al. (2017b) conducted a systematic review of non-diabetic comorbid disease status following LRYGB and LVSG. Six RCTs involving a total of 695 patients (LVSG n = 347, LRYGB n = 348) reported on the resolution or improvement of comorbid disease following LVSG and LRYGB procedures. The authors concluded that this systematic review of RCTs suggests that both LVSG and LRYGB are effective in resolving or improving preoperative nondiabetic comorbid diseases in obese patients. While results are not conclusive, in the authors' opinion, LRYGB may provide superior results compared to LVSG in mediating the remission and/or improvement in some conditions such as dyslipidemia and arthritis.

In a review of findings from retrospective or cohort studies on bariatric surgery and impact on nonalcoholic fatty liver disease (NAFLD), Aguilar-Olivos et al. (2016) remarked that bariatric surgery is the most effective treatment for morbid obesity and its associated metabolic comorbidities. There is evidence indicating that bariatric surgery improves histological and biochemical parameters of NAFLD, but currently is not considered a treatment option for NAFLD. The aim of this work is to review the evidence for the effects of bariatric surgery on NAFLD and the metabolic syndrome (MetS). The authors found that insulin resistance, alterations in glucose metabolism, hypertension, plasma lipids, transaminases, liver steatosis, steatohepatitis and fibrosis improve after bariatric surgery. Weight loss and improvement of NAFLD are greater after RYGB than after other interventions. The authors conclude that patients with indications for bariatric surgery will most likely benefit from the improvements in the MetS and NAFLD.

Spaniolas et al. (2016) found that patients with complete follow-up (3, 6, and 12 months) were compared to patients who had one or more prior missed visits. There were 51,081 patients with 12-month follow-up data available. After controlling for baseline characteristics, complete follow-up was independently associated with excess weight loss ≥50%, and total weight loss ≥30%. Adherence to postoperative follow-up is independently associated with improved 12-month weight loss after bariatric surgery. The authors urge that bariatric programs should strive to achieve complete follow-up for all patients.

Maciejewski et al. (2016) examined 10-year weight changes in a large, multisite, clinical cohort of veterans who underwent Roux-en-Y gastric bypass (RYGB) compared with nonsurgical matches and the 4-year weight change in veterans who underwent RYGB, adjustable gastric banding (AGB), or sleeve gastrectomy (SG). The 1787 patients undergoing RYGB had a mean (SD) age of 52.1 (8.5) years and 5305 nonsurgical matches had a mean (SD) age of 52.2 (8.4) years. Patients undergoing RYGB and nonsurgical matches had a mean body mass index of 47.7 and 47.1, respectively, and were predominantly male (1306 [73.1%] and 3911 [73.7%], respectively). Patients undergoing RYGB lost 21% (95% CI, 11%-31%) more of their baseline weight at 10 years than nonsurgical matches. A total of 405 of 564 patients undergoing RYGB (71.8%) had more than 20% estimated weight loss, and 224 of 564 (39.7%) had more than 30% estimated weight loss at 10 years compared with 134 of 1247 (10.8%) and 48 of 1247 (3.9%), respectively, of nonsurgical matches. Only 19 of 564 patients undergoing RYGB (3.4%) regained weight back to within an estimated 5% of their baseline weight by 10 years. At 4 years, patients undergoing RYGB lost 27.5% (95% CI, 23.8%-31.2%) of their baseline weight, patients undergoing AGB lost 10.6% (95% CI, 0.6%-20.6%), and patients undergoing SG lost 17.8% (95% CI, 9.7%-25.9%). Patients undergoing RYGB lost 16.9% (95% CI, 6.2%-27.6%) more of their baseline weight than patients undergoing AGB and 9.7% (95% CI, 0.8%-18.6%) more than patients undergoing SG. The authors concluded that surgical patients lost substantially more weight than nonsurgical matches and sustained most of this weight loss in the long term. Roux-en-Y gastric bypass induced significantly greater weight loss among veterans than SG or AGB at 4 years. Limitations included lack of randomization, lack of specificity in disease severity, bias due to loss of follow-up and lack of systematic weight data collection.

Blackledge et al. (2016) conducted a retrospective analysis of 300 patients who underwent laparoscopic Roux-en-Y bypass. There were no significant demographic differences among the quartiles however, there was an increased time to operation for patients who gained or lost ≥5 % excess body weight (p < 0.001). Although there was no statistical significance in postoperative complications, there was a higher rate of complications in patients with ≥5 % EWG compared to those with ≥5 % EWL (12.5 vs. 4.8 %, respectively; p = 0.29). Unadjusted and adjusted generalized linear models showed no statistically significant association between preoperative % excess weight change and weight loss outcomes at 24 months. This was a single-center study and may not be representative of all patient populations.

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) states that sufficient clinical and mechanistic evidence exists to support inclusion of metabolic surgery among antidiabetes interventions for people with type 2 diabetes and obesity. The organizations note that additional studies are needed to further demonstrate long-term benefits (Rubino et al., 2016).

Arterburn et al. (2015) evaluated the association between bariatric surgery and long-term survival in a retrospective cohort study of obese patients treated at the Veterans Administration (VA) health system. A cohort of surgical patients (n=2500; mean age, 52 years; mean body mass index [BMI] of 47), undergoing any bariatric surgery procedure, were compared with control patients (n=7462). At the end of 14 years, there were a total of 263 deaths in the surgical cohort group (n=2500) and 1277 deaths in the matched controls (n=7462). Based on Kaplan-Meier estimates, mortality rates were 2.4% at 1 year, 6.4% at 5 years, and 13.8% at 10 years for surgical cohort patients. In the matched controls, mortality rates were 1.7% at 1 year, 10.4% at 5 years, and 23.9% at 10 years. Bariatric surgery was associated with reduced mortality compared controls after 1 to 5 years (hazard ratio [HR], 0.45; 95% CI, 0.36 to 0.56) and after 5 years (HR, 0.47; 95%CI, 0.39 to 0.58). Across different subgroups based on diabetes diagnosis, sex, and period of surgery, there were no significant differences between surgery and survival at the mid- and long-term evaluations. Limitations include lack of randomization and retrospective design, lack of disease specificity due to inaccurate identification of comorbid conditions with ICD-9 classification, and a small amount of cases missing preoperative BMI data which may have affected the results.

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=2680) compared with after surgery (n=2251). 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.

A retrospective cohort study was conducted by Yska et al. (2015) within the Clinical Practice Research Datalink involving 2978 patients with a record of bariatric surgery, with a BMI of > 35. They identified 569 patients with type 2 diabetes (T2DM) and matched them to 1881 patients with diabetes without bariatric surgery. Data on the use of medication and laboratory results were evaluated. Among patients undergoing bariatric surgery, the authors found a prevalence of 19.1% for T2DM. Per 1000 person-years, 94.5 diabetes mellitus remissions were found in patients who underwent bariatric surgery compared with 4.9 diabetes mellitus remissions in matched control patients. Patients with diabetes who underwent bariatric surgery had an 18-fold increased chance for T2DM remission (adjusted relative rate [RR], 17.8; 95% CI, 11.2-28.4) compared with matched control patients. The authors conclude that bariatric surgery strongly increases the chance for remission of T2DM with gastric bypass and sleeve gastrectomy having a greater effect than gastric banding. Limitations included discrepancy between the patient's actual use of medication and what was recorded along with incomplete recording of clinical and laboratory testing.

The National Institute for Health and Care Excellence (NICE) 2014 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/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight; all appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss; have a multi-disciplinary team approach; the person is generally fit for surgery and anesthesia; and the person commits to the need for long-term follow-up. In addition, the NICE guideline notes that bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m2 when other interventions have not been effective. 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.

In a systematic review and meta-analysis, Osland et al. (2016) evaluated the early postoperative complication rate (i.e. within 30-days) in 6 RCTs involving a total of 695 patients (LVSG n = 347, LRYGB n = 348). A statistically significant reduction in relative odds of early major complications favoring the LVSG procedure was noted (p = 0.05). Five RCTs representing 633 patients (LVSG n = 317, LRYGB n = 316) reported early minor complications. A non-statically significant reduction in relative odds of 29 % favoring the LVSG procedure was observed for early minor complications (p = 0.4). However, other outcomes directly related to complications which included reoperation rates, readmission rate, and 30-day mortality rate showed comparable effect size for both surgical procedures. The authors concluded that this meta-analysis and systematic review of RCTs suggests that fewer early major and minor complications are associated with LVSG compared with LRYGB procedure. However, this does not translate into higher readmission rate, reoperation rate, or 30-day mortality for either procedure.

Shoar and Saber (2017) conducted a systematic review and meta-analysis to compare long-term and midterm outcomes of laparoscopic sleeve gastrectomy versus RYGB. Fourteen studies comprising 5264 patients were eligible. Follow-up ranged from 36 months to 75.8±8.4 months. The pooled result for weight loss outcomes did not show any significant difference in midterm weight loss (standardized mean difference = -0.03; 95% confidence interval (CI), -0.38-.33; P = .88) but a significant difference in the long-term weight loss outcome favoring LRYGB (standardized mean difference = .17; 95% CI, .05-.28; P= .005). The pooled results demonstrated no significant difference for resolution of type 2 diabetes mellitus, hypertension, hyperlipidemia, and hypertriglyceridemia. Despite the insignificant difference between LRYGB and LSG in midterm weight loss, LRYGB produced better weight loss in the long-term. There was no significant difference between the 2 procedures for co-morbidity resolution.

Jambhekar et al. (2018) evaluated demographic and socioeconomic factors in the United States that are predictors of long-term weight loss after LSG. Prospectively collected data on 713 consecutive primary LSG operations was included in this study. Multiple regression analyses were done to determine if gender, race, or socioeconomic factors such as insurance and employment status correlated with postoperative weight loss. The presence of chronic comorbidities affecting quality of life such as Type II diabetes and obstructive sleep apnea (OSA) were also recorded and analyzed. All studied groups had similar preoperative body mass index (BMI) (mean 46 kg/$m^2$). Race was not significantly associated with weight loss at any postoperative interval. Male gender was associated with increased weight loss through the first three months (48.2 +/- 12.5 lbs vs. 40.5 +/- 11 lbs; p = 0.0001). Patients with diabetes had significantly less weight loss at the 6 through 18 month intervals (50.4 +/- 17.9 lbs vs. 59.6 +/- 15.6 lbs at six months; p = 0.00032; 53.3 +/- 25.4lbs vs. 80.5 +/- 31.3lbs at 18 months; p = 0.008). Patients with obstructive sleep apnea had significantly less weight loss at the two-year interval (57.5 +/- 29.2 lbs) vs. those without obstructive sleep apnea (69.6 +/- 23.5 lbs; p = 0.047). Finally, those patients who were students had the greatest weight loss at two years postoperatively with the least weight loss seen in retired patients followed by those on disability (108.0 +/-21.5 lbs vs. 26.0 lbs vs. 46.0 +/-19.7 lbs; p = 0.04). Further studies are needed to evaluate whether demographic differences impact long term weight loss.

A 2014 Cochrane Systematic Database Review 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 sleeve gastrectomy, and both of these procedures had better outcomes than adjustable gastric banding. For people with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than RYGB. Duodenojejunal bypass with sleeve gastrectomy and laparoscopic RYGB had similar outcomes; however this is based on one small trial. Isolated sleeve gastrectomy led to better weight-loss outcomes than adjustable gastric banding after three years follow-up. This was based on one trial only. Weight-related outcomes were similar between laparoscopic gastric imbrication and laparoscopic sleeve gastrectomy 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 a systematic review and meta-analysis, Chang et al. (2014) examined the effectiveness and risks of bariatric surgery using up-to-date, comprehensive data and appropriate meta-analytic techniques. A total of 164 studies were included (37 randomized clinical trials and 127 observational studies). Analyses included 161,756 patients with a mean age of 44.56 years and body mass index of 45.62. In randomized clinical trials, the mortality rate within 30 days was 0.08% (95% CI, 0.01%-0.24%); the mortality rate after 30 days was 0.31% (95% CI, 0.01%-0.75%). Body mass index loss at 5 years postsurgery was 12 to 17. The complication rate was 17% (95% CI, 11%-23%), and the reoperation rate was 7% (95% CI, 3%-12%). Based on this review, the authors found that gastric bypass was more effective in weight loss but associated with more complications, adjustable gastric banding had lower mortality and complication rates (yet, the reoperation rate was higher and weight loss was less substantial than gastric bypass), sleeve gastrectomy appeared to be more effective in weight loss than adjustable gastric banding and comparable with gastric bypass. The authors concluded that bariatric surgery provides substantial and sustained effects on weight loss and ameliorates obesity-attributable comorbidities in the majority of bariatric patients, although risks of complication, reoperation, and death exist. Death rates were lower than those reported in previous meta-analyses.

Cohort studies show that bariatric surgery reduces all-cause mortality by 30% to 50% at seven to 15 years postsurgery compared with patients with obesity who did not have surgery (Schroeder et al., 2016).

Adams et al. (2015) reviewed the association between bariatric surgery and long-term mortality. They concluded that the general consensus is that bariatric surgical patients have: 1) significantly reduced long-term all-cause mortality when compared to extremely obese non-bariatric surgical control groups; 2) greater mortality when compared to the general population, with the exception of one study; 3) reduced cardiovascular-, stroke-, and cancer-caused mortality when compared to extremely obese non-operated controls; and 4) increased risk for externally caused death such as suicide.

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/m2. Ninety two (55.0%) patients were diagnosed with Obstructive Sleep Apnea (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/m2 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.

According to an NHLBI Obesity Expert Panel evidence report on managing overweight and obesity in adults (Jensen et al., 2013), the pattern of weight loss over time with dietary intervention shows the average weight loss is maximal at 6 months with smaller losses maintained for up to 2 years while treatment and follow-up tapers. Weight loss achieved by dietary techniques aimed at reducing daily energy intake ranges from 4 to 12 kg at a 6-month followup. Thereafter, slow weight regain is observed, with a total weight loss of 4 to 10 kg at 1 year and 3 to 4 kg at 2 years. The authors cited both psychological and biologic factors as responsible for weight regain, and recommend future studies to identify strategies that prevent or minimize weight regain after successful dieting.

The NHLBI Obesity Expert Panel (2013) completed a systematic evidence review to evaluate critical questions regarding overweight and obesity management in adults. On the topic of bariatric surgical procedures, they concluded that in obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight. For patients with obesity who have obesity-related comorbid conditions or who are at high risk for their development, bariatric surgery offers the possibility of meaningful health benefits, albeit with significant risks.

The NHLBI Obesity Expert Panel (2013) also considers that the evaluation of efficacy end points for weight loss and change in cardiovascular diease (CVD) risk factors and other health outcomes requires studies with a minimum post-surgical followup of 2 years and inclusion of a nonsurgical comparator group. Studies evaluating predictors of weight change or medical outcomes, including patient factors (e.g., presence vs. absence of diabetes) or surgical factors (e.g., RYGB vs. BPD), require direct comparison of these factors plus a minimum 2-year followup. Studies evaluating complications of bariatric surgery require at least a 30-day post-surgical followup. For observational studies with 10 or more years of followup or for studies on BPD or SG procedures, the work group agreed to require a sample size ≥100 and for all other observational studies to require a sample size >500. This sample size requirement was instituted because the most important complications are infrequent (e.g., perioperative mortality rates are <1 percent) so that smaller studies could give inaccurate estimates of complication rates.

A randomized, nonblinded, single-center trial, Schauer et al. (2012) evaluated the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes. The mean age of the patients was 49±8 years, and 66% were women. The average glycated hemoglobin level was 9.2±1.5%. The primary end point was the proportion of patients with a glycated hemoglobin level of 6.0% or less 12 months after treatment. In obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery achieved glycemic control in significantly more patients than medical therapy alone. Further study will be necessary to assess the durability of these results.

In a systematic review and meta-analysis, Kadeli et al. (2012) evaluated whether preoperative weight loss before gastric bypass correlates to weight loss up to 1 year post-surgery. Of the 186 studies screened, 12 were identified. A meta-analysis was performed to further classify studies (A class, B class, regression, and rejected). The authors conclude that losing weight leads to better outcomes because a patient entering surgery with a lower weight than someone entering surgery without weight loss will have more weight loss in total.

Dixon et al. (2008) conducted an unblinded randomized controlled trial to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control. A total of 60 patients were randomized into the 2 groups; 30 receiving surgical treatment and 30 receiving conventional treatment. Remission of type 2 diabetes, at 2 year follow-up, was reduced 73% in the surgical group and 13% in the conventional therapy 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. Although their investigation showed there are no predictive relationships between preoperative psychological evaluations and postoperative weight loss, they 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. In another study of clients followed for 1 year after weight loss surgery, perceived obesity-related health problems, motivation, and sense of coherence (SoC) predicted better weight loss. . 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). Furthermore, the goal of psychological assessment should be the development of pre- and postsurgical treatment plans that address psychosocial barriers to postoperative success. Professional consensus is that bariatric surgery should be performed only in motivated, educated patients who have participated in a combined multidisciplinary assessment and only after behavior-based interventions have failed (Bachman et al., 2005).

Christou el al. (2004) concluded that bariatric surgery not only decreased risk factors, but also decreased overall mortality. They performed a matched cohort study of 1,035 patients who had bariatric surgery with 5,746 obese patients who did not have surgery. Subjects with medical conditions other than morbid obesity were not included. The participants were followed for 5 years. The mortality rate in the treatment group was 0.68% compared with 6.17% of the controls which results in a reduction in the relative risk of death by 89%.

Shen et al. (2004) studied the impact of patient follow-up on weight loss after bariatric surgery. They found that weight loss was correlated with the number of follow-up visits completed in the first year post surgery. They concluded that patient follow-up plays a significant role in the amount of weight loss after bariatric surgery and that patient motivation and surgeon commitment for long term follow-up is critical for successful weight loss after bariatric surgery.

Still et al. (2007) conducted a prospective, longitudinal assessment of characteristics and outcomes of gastric bypass patients to analyze whether modest, preoperative weight loss improved perioperative outcomes among high-risk, morbidly obese patients undergoing Roux-en-Y gastric bypass. Patients (n=884) were required to participate in a standardized multidisciplinary preoperative program that encompassed medical, psychological, nutritional, and surgical interventions and education. In addition, patients were encouraged to achieve a 10% loss of excess body weight prior to surgical intervention. A total of 425 (48%) lost more than 10% of their excess body weight prior to the operation. After surgery (mean follow-up, 12 months), this group was more likely to achieve 70% loss of excess body weight (P.001). Those who lost more than 5% of excess body weight prior to surgery were statistically less likely to have a length of stay of greater than 4 days (P=.03). The authors noted that because of the older age, high disease burden, and high BMIs of this population, these results may not be applicable to all preoperative candidates for bariatric surgery. Further studies to extend these results and to evaluate the effects on preoperative weight loss of specific surgical outcomes as well as its correlation with long-term weight loss are ongoing.

## Biliopancreatic Diversion with Duodenal Switch (BPD/DS)

Topart et al. (2017) reported weight loss and nutritional outcomes in a 10-year follow-up of 80 patients who underwent BPD/DS. A follow-up of 141 ± 16 months was available for 87.7% of the patients at least 10 years from surgery. Preoperative BMI decreased from 48.9 ± 7.3 to 31.2 ± 6.2 kg/m2 with an EWL of 73.4 ± 26.7% and a TWL of 35.9% ± 17.7%. Despite weight regain ≥10% of the weight loss in 61% of the cases, 78% of the patients maintained a BMI <35. Fourteen percent of the patients had a revision. Normal vitamin D levels were found in 35.4%. The overall PTH level was 91.9 ± 79.5 ng/mL, and 62% of the patients had hyperparathyroidism. Other deficiencies were less frequent but fat-soluble deficiencies as well as a PTH >100 ng/mL were significantly associated with the absence of vitamin supplementation. Based on the results of their study, the authors conclude that although BPD/DS maintains a significant weight loss at 10 years, it is associated with side effects that in some cases led to revision and multiple vitamin deficiencies. The most severe deficiencies are related to the lack of supplementation compliance.

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. 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 (.3% versus .6%, P>.99), bleed (0% versus .3%, P>.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, BPD/DS found no significant differences from 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/m2) to investigate bile acid profiles up to 5 years after Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch. Total bile acid concentrations increased substantially over 5 years after both gastric bypass and duodenal switch, with greater increases in total and primary bile acids after duodenal switch. Higher levels of total bile acids at 5 years were associated with lower body mass index, greater weight loss, and lower total cholesterol.

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/m2 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.

In a retrospective review, Sethi et al. (2016) evaluated the long-term weight loss, co-morbidity remission, complications, and quality of life in patients (n=100) after BPD (34%) and BPD/DS (64%). Outcomes included weight loss measures at 2, 5, and 10-15 years postoperatively; co-morbidity remission; long-term complications; nutritional deficiencies; and patient satisfaction. Mean preoperative BMI was 50.2 kg/m2. Mean follow up was 8.2 years (range: 1-15 yrs.) with 72% of eligible patients in active follow up at 10-15 years postoperatively. Excess weight loss (EWL) was 65.1% at 2 years, 63.8% at 5 years, and 67.9% at 10-15 years. Approximately 10% higher %EWL was achieved for those with preoperative BMI <50 kg/m2 versus≥50 kg/m2 and patients who underwent BPD/DS versus BPD. Although co-morbidities improved, 37% of patients developed long-term complications requiring surgery. There were no 30-day mortalities; however, there was one mortality from severe malnutrition. Nutritional deficiencies in fat-soluble vitamins, anemia, and secondary hyperparathyroidism were common. The authors observed that higher levels of excess weight loss are achieved by patients with a lower preoperative BMI and BPD/DS. Although nutritional deficiencies and postoperative complications are common, and according to the authors the patient satisfaction remains high.

A single-center, nonblinded, randomized, controlled trial performed by Mingrone et al (2012), with 60 patients between the ages of 30 and 60 years with a body-mass index BMI of 35 or more, a history diabetes for at least 5 years, and a glycated hemoglobin level of 7.0% or more were randomly assigned to receive conventional medical therapy or undergo either gastric bypass or biliopancreatic diversion. The primary end point was the rate of diabetes remission at 2 years (defined as a fasting glucose level of <100 mg per deciliter [5.6 mmol per liter] and a glycated hemoglobin level of <6.5% in the absence of pharmacologic therapy). In severely obese patients with type 2 diabetes, bariatric surgery resulted in better glucose control than did medical therapy. Preoperative BMI and weight loss did not predict the improvement in hyperglycemia after these procedures.

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

Laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) are the most common procedures performed during bariatric surgery and both have demonstrated a significant efficacy for morbid obesity. Zhao and Jiao (2019) conducted a comparative analysis 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 Type II DM 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.

Ikramuddin et al. (2018) conducted an observational follow-up of a multi-center randomized clinical trial involving 120 participants 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 = .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 = .002). Gastric bypass 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 6132 patients with a baseline BMI of 42 kg/m2 and type 2 diabetes who underwent RYGB. Over a 6 year follow-up period, beneficial changes in body mass index (BMI), hemoglobin A1C, blood lipids and blood pressure were seen compared with control persons. 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.

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 sleeve gastrectomy (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 risk for surgical complications was greater following RYGB. 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.

In a retrospective analysis, Jirapinyo et al. (2017) evaluated the Bariatric Quality of Life (BQoL) scores for 56 patients. 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 (T2DM) in obese patients. Six RCTs with 410 total obese T2DM patients were included and follow-up ranged from 12 to 60 months. The pooled analysis of T2DM 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 T2DM, 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 T2DM.

Cooper et al. (2015) assessed weight loss and occurrence of weight regain among patients (n=300) at 1 year follow-up who underwent Roux-en-Y gastric bypass (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.

Giordano (2015) conducted retrospective comparative study of consecutive super-obese patients. Patients either underwent laparoscopic Roux-en-Y gastric bypass procedure (n=102) or laparoscopic adjustable gastric banding (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 Roux-en-Y surgery than gastric banding.

A 2014 Cochrane Systematic Database Review by Colquitt et al. found that in comparison with laparoscopic adjustable gastric banding (LAGB), 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%) in one RCT. In addition, open RYGB, LRYGB and laparoscopic sleeve gastrectomy (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.

Griffith et al. (2012) reviewed the major perioperative and late complications that can arise in patients who have undergone LRYGB. Postoperative complications following LRYGB can be broadly grouped into early and late complications. By definition, early complications occur within the immediate perioperative period — the first 2 weeks post-LRYGB. Early complications may include anastomotic or staple line leak (ASL), postoperative hemorrhage, bowel obstruction and incorrect Roux limb reconstructions. Anastomotic or staple line leaks are the most dreaded and potentially devastating early complication of this procedure, with a mortality rate of nearly 50%. Late complications arise after the second postoperative week. Aside from the formation of internal hernias, a range of other complications can develop over the long term in patients who have undergone LRYGB. These complications include anastomotic stricture, marginal ulcer formation, fistula formation, weight gain and nutritional deficiencies.

## Robotic-Assisted Gastric Bypass Surgery

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 adjustable gastric banding (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.

Ayloo et al. (2016) retrospectively reviewed their experience with robotic approaches to RYGB using prospectively maintained data. Procedures were categorized into three groups: laparoscopic, hybrid robotic (HR), and total robotic (TR). The study included 192 RYGB consecutive patients who underwent laparoscopic, HR, or TR surgery. Mean patient age, preoperative body mass index, and preoperative weight were 40.4 ± 9.3 years (range 22-64), 46. 2 ± 5.9 kg/m(2) (range 35-64), and 130. 3 ± 22.1 kg (range 76.7-193.4) respectively. Ninety-two patients (47.9 %) had undergone previous abdominal surgery. Mean operative time, estimated blood loss, and length of stay were 223.4 ± 39.2 min (range 130-338), 21.9 ± 18.8 mL (range 5-10), and 2.6 ± 1.1 days (range 2-15), respectively. There were 248 concomitant procedures such as upper endoscopy, cholecystectomy, etc., 7 revisional surgeries, and 2 conversions to open surgery. Intraoperative complications included one liver laceration and one bowel injury. There were two cases each of bowel obstruction, transfusions, and deep vein thrombosis/pulmonary embolus, but no deaths or anastomotic leaks. Although there were variables such as different concomitant procedures, the authors conclude that early experience with a total robotic approach for RYGB appears to be safe, with similar outcomes to the laparoscopic approach.

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.

In a systematic review and meta-analysis, Bindal et al. (2015) evaluated the role of robotics in bariatric surgical procedures compared with laparoscopic approaches. Several studies showed a lower complication rate with the robotic platform including leaks, hemorrhage and stricture. Another advantage noted by the authors for the use of the robotic system is improved ergonomics and lesser operator fatigue. The authors observed that the use of robotics may provide specific advantages in some situations, and overcome limitations of laparoscopic surgery. With the advent of newer technologies in robotics the authors conclude that it will provide an empowering tool to the surgeons, which can potentially change the way surgery is practiced.

Economopoulos et al. (2015) conducted a systematic review and meta-analysis to evaluate the available literature on patients treated with robotic RYGB and compared the clinical outcomes of patients treated with robotic RYGB with those treated with the standard laparoscopic RYGB. Fourteen comparative and 11 non-comparative studies were included in this study, reporting data on 5145 patients. Based on their review they found robotic-assisted RYGB was associated with significantly less frequent anastomotic stricture events, reoperations, and a decreased length of hospital stay compared with the standard laparoscopic procedures; however, these findings should be interpreted with caution given the low number and poor quality of the studies currently available in the literature.

## Laparoscopic Adjustable Gastric Banding (LAGB)

In a longitudinal analysis, Mistry et al. (2018) reported changes in glycemic control, blood pressure and lipids 5 years following LAGB combined with medical care in patients with type 2 diabetes (T2DM). 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 T2DM 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.

Froylich et al. (2018) conducted a retrospective follow-up 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/m2. 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 % total weight loss 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 review, 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 excess weight loss 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 2246 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 explantation 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/m2, who were treated with laparoscopic adjustable gastric banding (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/m2, 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.

Angrisani et al. (2013) retrospectively evaluated the efficacy and safety of laparoscopic adjustable gastric banding (LAGB) in moderately obese subjects with or without obesity-related co-morbidities. Thirty-four patients with BMI between 30 and 35 kg/m(2) and mean percentage excess weight 48.7 ± 9 %) who underwent LAGB were included. Good response was defined as BMI <30 kg/m(2) or percentage estimated weight loss (%EWL) >50. Poor response was defined as BMI >30 kg/m(2) or %EWL less than 50 after a minimum of 1 year. Mean weight, BMI and %EWL were recorded at 1, 3, 5 and 7 years and were 77.4 ± 7.6, 69.9 ± 10.8, 70.9 ± 9.3 and 73.3 ± 12.0 kg; 28.8 ± 2.9, 26.4 ± 3.2, 26.5 ± 3.4 and 27.4 ± 5.0 kg/m(2); and 36 ± 23, 46.1 ± 33.8, 58.6 ± 31.5 and 45 ± 57, respectively (p < 0.01). Co-morbidities were diagnosed in 17/34 (50 %) patients at baseline and underwent remission or improvement in all cases after 1 year. The authors concluded that LAGB is a safe and effective procedure in patients with a BMI <35 kg/m(2). Small sample size was a limitation to this study.

## Sleeve Gastrectomy (Vertical Gastrectomy)

Clapp et al. (2018) conducted a meta-analysis to evaluate long-term (7 or more years) outcomes of LSG. Nine cohort studies met the inclusion criteria, with a total of 2280 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.

Noel et al. (2017) conducted a retrospective analysis of a prospective cohort of 168 patients who underwent laparoscopic sleeve gastrectomy (LSG) to present the 8-year outcome concerning weight loss, modification of co-morbidities, and occurrence of revisional surgery. Follow-up was available for 116 patients (69%). Of the remainder, 23 patients underwent revisional surgery and 29 were lost to follow-up. For the entire cohort, the mean excess weight loss (EWL) was 76% (0-149) at 5 years and 67% (4-135) at 8 years, respectively. Of the 116 patients with 8 years of follow-up, 82 patients had>50% EWL at 8 years (70.7%). Percentages of co-morbidities resolved were hypertension, 59.4%; type 2 diabetes, 43.4%; and obstructive sleep apnea, 72.4%. Twenty-three patients had revisional surgery for weight regain (n = 14) or for severe reflux (n = 9) at a mean period of 50 months (9-96). Twelve patients underwent repeat LSG, 6 patients underwent conversion to a bypass, and 5 patients to duodenal switch (1 single anastomosis duodeno-ileostomy). A total of 31% of patients reported GERD symptoms at 8 years.

Felsenreich et al. (2017) evaluated long-term outcomes and complications following SG. Besides weight regain, GERD is the most common reason for conversion to Roux-en-Y gastric bypass. Patients (53) did not have symptomatic reflux or hiatal hernia preoperatively. Of 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.

Flølo et al. (2017) presented 5-year outcomes after vertical sleeve gastrectomy (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 gastroesophageal reflux disease (GERD). Mean body mass index (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 type 2 diabetes mellitus (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.

Nocca et al. (2017) reported 5-year outcomes from a cohort of 1050 patients who underwent SG (mean preoperative BMI was 44.58 kg/m$^2$) either as the primary or revisional surgical procedure. The overall reoperative 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.

Stenard and Iannelli (2017) conducted a systematic review to evaluate GERD in association with SG and other bariatric procedures. GERD is described as either de novo or as being caused by aggravation of preexisting symptoms. Some cases are caused by the large compliant stomach being transformed into a long and narrow tube. Other factors are related to dismantling of the anatomical antireflux mechanisms, including disruption to the Hiss angle and resection of the sling fibers in the distal part of the lower sphincter, which results in low esophageal-sphincter pressure. The final shape of the sleeve also plays a role as it may favor GERD and regurgitation when it is funnel-shaped. Technical mistakes include narrowing at the junction between the vertical and horizontal parts of the sleeve, twisting of the sleeve, anatomical stenosis, and persistence of the gastric fundus and/or a hiatal hernia that has not been diagnosed before surgery. The role of the gastric antrum has not been fully clarified but it is thought that extensive resection of the antrum may impair gastric emptying and favor GERD. The presence of other factors, such as a HH or an impaired LES, may lead to the appearance of de novo GERD or aggravate a preexisting GERD. Based on their review, the authors conclude that when patients develop GERD after a SG resistant to PPI, a RYGB remains the operation of choice, whereas some patients with residual fundus after a SG may be suitable candidates for a redo fundectomy or a redo SG.

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 Roux-en-Y gastric bypass (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 bilio-pancreatic diversion with duodenal switch (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.

In a retrospective study of prospectively collected data, Garofalo et al. (2017) assessed the safety and efficacy of laparoscopic sleeve gastrectomy (LSG) performed in older patients (≥65 years old). A total of 27 (90%) primary LSG and 3 revisional LSG (10%) were performed. Thirty-day morbidity included 3 cases of self-limiting nausea and vomiting and 1 case of gastric sleeve stenosis necessitating conversion to gastric bypass. No mortality reported. The overall mean percentage of excess weight loss (±SD) and percentage of total weight loss (±SD) at 12 months were 53.8±19.8 and 23.9±8.4; 52.9±21.8 and 24±9.9 at 36 months, respectively. No patients were lost to follow-up but 5 were excluded because they underwent revisions. Age-adjusted mixed model analyses revealed that baseline BMI (P = .018), BMI>45 kg/m2 (P = .001), and having diabetes (P = .030) were associated with excess weight loss<50% across follow-up. Their conclusion is that LSG seems to be effective and safe for patients≥65 years old and that obesity related co-morbidities have improved across follow-up.

Lopez-Nava et al. (2016) conducted a prospective single-center follow-up study of 25 patients (5 men, 20 women) who underwent flexible endoscopic suturing for endoluminal gastric volume reduction. All patients had failed lifestyle modification efforts. A multidisciplinary team provided post-procedure care. Patient outcomes were recorded at 1 year after the procedure. Linear regression analysis was done to evaluate the variables associated with best results at 1 year of follow-up. Mean body mass index (BMI) was 38.5 ± 4.6 kg/m2 (range 30 – 47) and mean age 44.5 ± 8.2 years (range 29 – 60). At 1 year, 22 patients continued with the follow-up (2 dropped out at 6 months and 1 at 3 months). There were no major intra-procedural, early, or delayed adverse events. Mean BMI loss was 7.3 ± 4.2 kg/m2, and mean percentage of total body weight loss was 18.7 ± 10.7 at 1 year. In the linear regression analysis, adjusted by initial BMI, variables associated with %TBWL involved the frequency of nutritional (β = 0.563, P = 0.014) and psychological contacts (β = 0.727, P = 0.025). The number of nutritional and psychological contacts was predictive of good weight loss results. The authors concluded that endoscopic sleeve gastroplasty is a feasible, reproducible, and effective procedure to treat obesity. Nutritional and psychological interactions are predictive of success.

Brethauer et al. (2009) performed a systematic review (n=36 studies) of the evidence on sleeve gastrectomy (SG). Studies included a single nonrandomized matched cohort analysis, RCTs (n=2 studies) and uncontrolled case series (n=33 studies). 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 % of excess weight loss (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 type 2 diabetes 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 major postoperative complication rate ranged from 0%-23.8%.

## Vertical Banded Gastroplasty (VBG)

van Wezenbeek et al. (2015) retrospectively evaluated a total of 392 patients (80% female) with a mean body mass index of 44 ± 5 kg/m(2) who underwent primary VBG. Mean follow-up after VBG was 66 ± 50 months and showed a mean excess weight loss (EWL) of 53 ± 27% and comorbidity reduction of 54%. One hundred fifty-two patients (39%) out of 227 patients (58%) with long-term complaints underwent revisional surgery. Main reasons for revision were weight regain and vomiting/food intolerance. Analysis before revision showed an outlet dilatation (17%), pouch dilatation (16%), and outlet stenosis (10%). After revision, an additional EWL of 23% and 33% further reduction in comorbidities was seen. They concluded that primary VBG has an acceptable EWL of 53% and 55% of comorbidities were improved however, the high complication rate, often necessitating revision, underlines the limits of this procedure.

David et al. (2015) reported their experience in laparoscopic conversion of failed VGB to RYGB or BPD (n=39), noting that the reoperation rate for VGB in long-term studies is approximately 50%. Most (89%) of the conversions were completed laparoscopically. The mean operative time was 195 and 200 min for RYGB and BPD, respectively. There was no mortality. Complications occurred in 11 patients (28%), 5 in RYGB (19%) and 6 in BPD (42%). At the 3-year follow-up, the mean body mass index decreased from 47±8 kg/m(2) to 26±4 kg/m(2) for BPD, and from 43 kg/m(2) to 34 kg/m(2) (P = .05) for RYGB. Weight (kg) decreased from 110 to 84 and to 92, and from 123 to 81 and 68, at 1 and 3 years for RYGB and BPD, respectively. The weight loss for RYGB and BPD was equal at 1 year but tended to be better for BPD at 3 years postoperatively. Laparoscopic conversion of failed VBG to RYGB or BPD was feasible, but it was followed by prohibitively high complication rates in BPD patients. The authors concluded that the risk:benefit ratio of these procedures in this series is questionable.

A Cochrane Database Systematic Review by Colquitt et al. (2009) found that while complication rates for vertical banded gastroplasty are relatively rare, revision rates requiring further surgical intervention are approximately 30%. Complication rates for VBG were not included in their updated 2014 Cochrane Database Systematic Review.

## Revision Surgery

Janik et al. (2019) assessed the safety of revisional surgery to LSG compared to laparoscopic Roux-Y LRYGB after failed LAGB. Converted LSG cases were matched (1:1) with converted LRYGB patients by age (±1 year), body mass index (±1kg/m), sex, and comorbidities including diabetes, hypertension, hyperlipidemia, venous stasis, and sleep apnea. A total of 2708 patients (1354 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.

Qiu et al. (2018) reviewed prospectively-collected data on revisional bariatric procedures. Patients (n=84) included in this review underwent surgery for weight regain (WR), and underwent surgery to address refractory complications (RC) related to their primary bariatric procedure. Demographics, indications, and outcomes of each group were compared using Fisher's exact test, Mann-Whitney rank sums, and chi-square tests. WR patients were divided based on their primary index procedure. Forty-three patients (53.6%) underwent surgery for WR and 41 (46.4%) for RC. The variety and distribution of primary bariatric procedures were gastric band (40%), gastric bypass (35.4%), sleeve gastrectomy (22%), and vertical banded gastroplasty (3.7%). The indications for revisional surgery due to RC included gastroesophageal reflux disease, internal hernia, gastro-gastric fistula, marginal ulcer, excess weight loss, and pain. Overall complication rate was 14.3% (three early, nine late); there was one leak. Five patients required a reoperation (5.9%; two early, three late). Excess weight loss varied from 31.5-79.1% 12 months after revision. The authors concluded that revisional bariatric surgery can be performed with low complication rates and with acceptable 12-month weight loss, though not with the same safety as primary procedures.

Dardamanis et al. (2018) conducted a retrospective comparative study of primary versus revisional LRYGB. Three hundred forty-two laparoscopic gastric bypass operations were performed, 245 were primary, and 97 revisional. Median follow-up was 30 months (range 0-108 months). Mean BMI (kg/m2) 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 1781 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, .5% for RYGB, and .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.

Angrisani et al. (2017) reported 5-year outcomes for RYGB versus LSG as revisional procedures after LAGB in 51 patients. Twenty-four patients were converted to LRYGBP (LRYGBP group) and 27 to LSG (LSG group). Indication for conversion was weight loss failure in 34 (67%) patients and band complications in 17 (33%) patients. No significant difference in age, BMI, and body weight in the two groups was found at the time of revision. One patient converted to RYGB had an internal hernia; one patient initially scheduled for LSG was intraoperatively converted to RYGB due to staple line leak. No other major perioperative complication was observed. Follow-up rate at 5 years was 84.3% (43 patients out of 51 patients) Delta-BMI and percentage of excess weight loss (%EWL) were not significantly different in the two groups at 1, 3, and 5 years ($p > 0.05$). The authors concluded that RYGB or LSG are feasible and effective surgical options after LAGB. Satisfactory weight loss was achieved after both procedures.

Wijngaarden et al. (2017) identified that nonresponders 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 nonresponders, and 120 responders. In addition, the failure rate was significantly higher after revisional LRYGB compared with primary LRYGB (10.9% nonresponders, 8.5% responders, and 2.5% primary, $P = .001$).

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/m2) 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 reoperative 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 2769 patients. The mean preoperative body mass index (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 vertical banded gastroplasty (VBG; 48%) or a laparoscopic adjustable gastric band (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. 2617 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. Percentage excess weight loss (%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.

Switzer et al. (2016) found that revisional bariatric procedures are increasingly common. With more primary procedures being performed to manage extreme obesity and its complications, 5% to 8% of these procedures will fail, requiring revisional operation. Reasons for revisional bariatric surgery are either primary inadequate weight loss, defined as less than 25% excess body weight loss, or weight recidivism, defined as a gain of more than 10 kg based on the nadir weight; however, each procedure also has inherit specific complications that can also be indications for revision. This article reviews the history of each primary bariatric procedure, indications for revision, surgical options, and subsequent outcomes.

Quezada et al. (2016) conducted a retrospective analysis of laparoscopic sleeve gastrectomy (SG) conversion to Roux-en-Y gastric bypass (n=50) due to the observation of increased complications of SG as the number of procedures increase. Revisions were done due to weight regain, GERD, or gastric stenosis. At follow-up (over a 3 year period), the authors reported median excess weight loss was 60.7 lbs., all gastric stenosis symptoms had resolved, and over 90% of GERD patients reported either a resolution or improvement in symptoms. Despite their findings, long term follow-up on this patient population is needed.

Felsenreich et al. (2016) reviewed 10-year outcomes from patients (n=53) who underwent a laparoscopic sleeve gastrectomy. Nineteen of the 53 patients (36%) were converted to Roux-en-Y gastric bypass (n=18) or duodenal switch (n=1) due to significant weight regain (n=11), reflux (n=6), or acute revision (n=2) at a median of 36 months. Within a long-term follow-up of 10 years or more after SG, a high incidence of both significant weight regain and intractable reflux was observed, leading to conversion, most commonly to Roux-en-Y gastric bypass.

Mann et al. (2015) conducted a systematic review to identify definitions of failure related to revisional bariatric surgery. A total of 60 articles underwent analysis. Fifty-one studies included inadequate weight loss or weight regain as an indication for revision: 31/51 (61%) gave no definition of failure, 7/20 quoted <50% of excess weight loss at 18 months and 6/20 used <25% excess weight loss. The authors concluded that the majority of published studies do not define failure of bariatric surgery, and <50% excess weight loss at 18 months was the most frequent definition identified.

Refer to the Professional Societies section of the policy for additional information.

## Pediatric and Adolescent Bariatric Surgery

Adolescent severe obesity is associated with numerous comorbidities, and persists into adulthood. Bariatric surgery is the most effective treatment available, resulting in major weight loss and resolution of important comorbid conditions (Desai et al., 2016).

Clinical practice guidelines for pediatric obesity treatment recommend consideration of surgery after failure of behavioral approaches. Careful screening and postoperative management of patients by a multidisciplinary team is required. Adolescent obesity is associated with preventable chronic health conditions such as type two diabetes mellitus (T2DM), hypertension, obstructive sleep apnea syndrome (OSAS), dyslipidemia, nonalcoholic steatohepatitis, polycystic ovary syndrome, and various musculoskeletal diseases. Obese adolescents are likely to suffer from psychological morbidity, loss of self-esteem, and social exclusion which has the potential for life-long effects. The risk of dying from any obesity-related cause increases by 6–7% for every 2 years lived with obesity. Presently, adolescent obesity is mostly managed by combined lifestyle interventions focusing on behavioral and dietary modifications. These treatments are typically initiated and evaluated by a multidisciplinary team including a pediatrician, dietician, psychologist, and a physiotherapist. While often effective in short term, long-term effects are relatively disappointing. Potential adverse effects on growth and development in prepubertal patients who have not reached full maturity raise concerns. However, bariatric surgery relatively early in life intervenes before comorbidities become irreversible and reduces the risk of surgical complications (Paulus et al., 2015).

Inge et al. (2018) compared glycemic control in cohorts of severely obese adolescents with type 2 diabetes 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. Data from 30 participants from Teen-LABS (mean [SD] age at baseline, 16.9 [1.3] years; 21 [70%] female; 18 [66%] white) and 63 from TODAY (mean [SD] age at baseline, 15.3 [1.3] years; 28 [44%] female; 45 [71%] white) were analyzed. 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 body mass index 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 type 2 diabetes, 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 Roux-en-Y gastric bypass surgery. 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 type 2 diabetes cases were observed. The slight worsening of preexisting nutritional deficiencies warrants careful preoperative surveillance and appropriate postoperative nutritional supplementation.

In a systematic review, Rajjo et al. (2017) reported that surgical interventions (laparoscopic adjustable gastric banding, Roux-en-Y gastric bypass, sleeve gastrectomy) resulted in the largest BMI reduction in this patient population (moderate quality of evidence). According to the authors, combined interventions consisting of dietary modification, physical activity, behavioral therapy, and education appear to have the best overall results.

Benedix et al. (2017) compared the perioperative course, weight loss and resolution of comorbidities after primary sleeve gastrectomy (LSG) for morbid obesity between adolescents (n=362) and adults (n=15,428). Pre-procedure BMI was similar between these populations, but the adult cohort had a higher incidence of co-morbidities. In the authors' opinion, the results at 12 and 24 months demonstrate that LSG is a safe therapeutic option that can be performed in adolescents without mortality. Late adolescents experienced the highest weight loss; resolution rate of comorbidities was lower in adults.

In a prospective, non-randomized controlled study of 81 adolescents (aged 13–18 years) with severe obesity who underwent Roux-en-Y bypass, Olbers et al. (2017) compared clinical outcomes with those of matched adolescent controls undergoing conservative treatment and of adult controls undergoing Roux-en-Y gastric bypass. The primary outcome measure was change in BMI over 5 years. The change in bodyweight in adolescent surgical patients over 5 years was −36·8 kg (95% CI −40·9 to −32·8), resulting in a reduction in BMI of −13·1 $kg/m^2$ (95% CI −14·5 to −11·8). Mean BMI rose in adolescent controls (3·3 $kg/m^2$, 95% CI 1·1–4·8) over the 5-year study period, whereas the BMI change in adult controls was similar to that in adolescent surgical patients. Comorbidities and cardiovascular risk factors in adolescent surgical patients showed improvement over 5 years and compared favorably with those in adolescent controls. 20 (25%) of 81 adolescent surgical patients underwent additional abdominal surgery for complications of surgery or rapid weight loss and 58 (72%) showed some type of nutritional deficiency; health-care consumption (hospital visits and admissions) was higher in adolescent surgical patients compared with adolescent controls. 20 (25%) of 81 adolescent controls underwent bariatric surgery during the 5-year follow-up. The authors' interpretation was that although the adolescents who underwent Roux-en-Y gastric bypass had substantial weight loss over 5 years alongside improvements in comorbidities and risk factors, gastric bypass was associated with additional surgical interventions and nutritional deficiencies. Conventional non-surgical treatment was associated with weight gain and a quarter of patients had bariatric surgery within 5 years.

Inge et al. (2017) conducted a prospective follow-up analysis of long-term (>5 years) outcomes of Roux-en-Y gastric bypass in a cohort of young adults 13-21 years of age (n=58) who underwent the procedure during adolescence, in the Follow-up of Adolescent Bariatric Surgery at 5 Plus Years (FABS-5+) extension study. Outcomes assessed included BMI, comorbidities, micronutrient status, safety, and other risks. At baseline, the mean age of the cohort was 17·1 years (SD 1·7) and mean BMI was 58·5 $kg/m^2$ (10·5). At mean follow-up of 8·0 years (SD 1·6; range 5·4–12·5), the mean age of the cohort was 25·1 years (2·4) and mean BMI was 41·7 $kg/m^2$ (12·0; mean change in BMI −29·2% [13·7]). From baseline to long-term follow-up, significant declines were recorded in the prevalence of elevated blood pressure (27/57 [47%] vs 9/55 [16%]; p=0·001), dyslipidemia (48/56 [86%] vs 21/55 [38%]; p<0·0001), and type 2 diabetes (9/56 [16%] vs 1/55 [2%]; p=0·03). At follow-up, 25 (46%) of 58 patients had mild anemia (not requiring intervention), 22 (45%) had hyperparathyroidism, and eight (16%) had low amounts of vitamin B12 (below the normal cutpoint). The authors conclude that Roux-en-Y gastric bypass surgery resulted in substantial and durable bodyweight reduction and cardiometabolic benefits for young adults. In addition, they recommend that long-term health maintenance after Roux-en-Y gastric bypass should focus on adherence to dietary supplements and screening and management of micronutrient deficiencies.

Manco et al. (2017) evaluated the benefit of sleeve gastrectomy in ninety-three obese (BMI ≥ 35 kg/m2) adolescents with nonalcoholic steatohepatitis (NAFLD) and hepatic fibrosis. Obese adolescents (13-17 years of age) with biopsy-proven NAFLD underwent laparoscopic sleeve gastrectomy (LSG)(n=20), lifestyle intervention plus intragastric weight loss devices (IGWLD) (n=20), or lifestyle intervention only (n=13) . One year after treatment, patients who underwent LSG lost 21.5% of their baseline body weight, whereas patients who underwent IGWLD lost 3.4%, and patients who underwent NSWL increase 1.7%. In patients who underwent LSG, NASH reverted completely in all patients and hepatic fibrosis stage 2 disappeared in 18 patients (90%). After IGWLD, NASH reverted in 6 patients (24%) and fibrosis in 7 (37%). Patients who received the NSWL intervention did not improve significantly. Hypertension resolved in all patients who underwent LSG with preoperative hypertension (12/12) versus 50% (4/8) of the patients who underwent IGWLD (P = .02). The cohort-specific changes in impaired glucose metabolism were similar: 100% (9/9) of affected patients who underwent LSG versus 50% (1/2) of patients who underwent IGWLD (P = .02). LSG was also more affective in resolving dyslipidemia (55% [7/12] vs 26% [10/19]; P = .05) and sleep apnea (78% [2/9] vs 30% [11/20]; P = .001). Based on these findings, the authors determined that LSG was more effective than lifestyle intervention, even when combined with intragastric devices, for reducing NASH and liver fibrosis in obese adolescents after 1 year of treatment.

Shah et al. (2017) reported 8-year outcomes related to lipid changes after RYGB in adolescents with severe obesity (FABS-5+ study). A non-operative group was recruited for comparison. Surgical participants (n=58) at long-term follow-up showed that BMI decreased by 29% and all lipids (except total cholesterol) significantly improved (P<0.01). In the non-operative group, BMI increased by 8% and lipid parameters were unchanged. The authors concluded that weight loss maintenance over time was significantly associated with improvements in lipid profile over 5 years.

Jaramillo et al. (2017) conducted a retrospective study on 38 adolescents who underwent laparoscopic sleeve gastrectomy (LSG). Mean age was 16.8 years, mean weight was 132.0 kg and mean BMI was 46.7. There were no reported surgical complications. Mean %EWL was 19.4%, 27.9%, 37.4%, 44.9%, and 47.7% at 1.5, 3, 6, 9, and 12 month follow up visits, respectively. Comorbidity resolution rates were 100% for hypertension and nonalcoholic fatty liver disease, 91% for diabetes, 44% for prediabetes, 82% for dyslipidemia and 89% for OSA. The authors concluded that based on their current data, LSG is an effective and safe method of treatment of morbid obesity in adolescents as it can significantly decrease excess body weight and resolve comorbid conditions. Further studies are needed to investigate the long-term effects of LSG in adolescents.

Brissman et al. (2017) evaluated 2-year outcomes in cardiorespiratory fitness, body composition, and functional capacity in a subset of adolescents (n=41) from the Adolescence Morbid Obesity Surgery (AMOS) study who had Roux-en-Y gastric bypass. In addition to anthropometric measurements, participants performed a submaximal bicycle test, 6-min walk test, dual-energy X-ray absorptiometry, and a short interview at baseline, 1 and 2 years after surgery. Relative improvements in maximal oxygen consumption (VO2max) per kilogram body mass (+62 %) and per kilogram fat-free mass (+21 %), as well as walking distance (+13 %) were observed after 1 year, and persisted 2 years after surgery. Despite a reduction of fat-free mass (-15 %), absolute VO2max was maintained across the full group (+8 %, p = ns) and significantly increased in non-smokers. Body mass and fat mass were significantly decreased (-45.4 and -33.3 kg, respectively). Self-reported physical activity was significantly increased, and pain associated with movement was reduced. In adolescents with obesity, Roux-en-Y gastric bypass improved VO2max more than could be explained by fat mass loss alone. In combination with improved functional capacity and body composition, these results suggest that surgery in adolescence might add specific benefits of importance for future health. However, longer term outcomes are needed.

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/m2. 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/m2. 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 complication and quality of life in adolescents with obesity. A total of 49 studies with 3007 patients were included. Roux-en-Y gastric bypass (n = 1216), laparoscopic adjustable gastric banding (n = 1028), and laparoscopic sleeve gastrectomy (n = 665) were the most common bariatric surgeries performed. At the longest follow-up (range, 12-120 mo), bariatric surgery led to an overall 16.43 kg/m2 (95% confidence interval [CI]: 14.84-18.01) and 31% (95% CI: 28%-34%) reduction in body mass index. 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. Roux-en-Y gastric bypass 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.

In a retrospective study of prospectively collected data, Vilallonga et al. (2016) evaluated long term outcomes after LRYGB in patients <18 years. This group of patients (ChG) was matched with an adult control group (AdG) of randomly chosen patients with similar characteristics who underwent LRYGB during the same period. Nineteen of the original 28 patients (67.9%) were available for follow-up. Preoperatively, 3 had type 2 diabetes mellitus (T2DM), 1 arterial hypertension, 5 dyslipidemia and 1 sleep apnea. In the ChG, average BMI after 7 years dropped from 38.9 kg/m2 preoperatively to 27.5 kg/m2. In the AdG, average BMI decreased from 39.4 to 27.1 kg/m2 in the same time period (nonsignificant between groups). One patient in the ChG needed a reoperation (internal hernia) versus 3 patients in the AdG (1 leak, 2 obstructions). All patients resolved their initial comorbidities. The authors concluded that LRYGB seems to be safe, provide good weight loss, and cure comorbidities in an adolescent population. Small patient population was a limitation to this study.

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 Roux-en-Y gastric bypass (n=161), sleeve gastrectomy (n=67), or laparoscopic adjustable gastric band (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 body mass index (calculated as weight in kilograms divided by height in meters squared), 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.

Inge et al. (2016) reported 3-year outcomes from the TEEN-LABS study of adolescents (n=242) undergoing Roux-en-Y gastric bypass (161 participants) or sleeve gastrectomy. Changes in body weight, coexisting conditions, cardiometabolic risk factors, and weight-related quality of life and postoperative complications were evaluated. The mean weight had decreased by 27% (95% confidence interval [CI], 25 to 29) in the total cohort, by 28% (95% CI, 25 to 30) among participants who underwent gastric bypass, and by 26% (95% CI, 22 to 30) among those who underwent sleeve gastrectomy. By 3 years after the procedure, remission of type 2 diabetes occurred in 95% (95% CI, 85 to 100) of participants who had had the condition at baseline, remission of abnormal kidney function occurred in 86% (95% CI, 72 to 100), remission of prediabetes in 76% (95% CI, 56 to 97), remission of elevated blood pressure in 74% (95% CI, 64 to 84), and remission of dyslipidemia in 66% (95% CI, 57 to 74). Weight-related quality of life also improved significantly. However, at 3 years after the bariatric procedure, hypoferritinemia was found in 57% (95% CI, 50 to 65) of the participants, and 13% (95% CI, 9 to 18) of the participants had undergone one or more additional intraabdominal procedures. The authors found significant improvements in weight, cardiometabolic health, and weight-related quality of life at 3 years after the procedure. Risks associated with surgery included specific micronutrient deficiencies and the need for additional abdominal procedures.

Ejaz, et al. (2016) reported outcomes following laparoscopic sleeve gastrectomy (LSG) as a first-line bariatric procedure among adolescents under 21 years of age (n=18). BMI among all patients was 48.6±7.2kg/m2 and did not differ by gender (P=0.68). One patient (5.6%) experienced a 30-day perioperative complication (pulmonary embolism). Median LOS following LSG was 3days (IQR: 2, 3). 2 patients (11.1%) were readmitted within 30-days because of feeding intolerance that resolved without invasive intervention. At a median follow-up of 10.6 (range: 0-38) months, percent excess weight loss (%EWL) among all patients was 35.6%. Among patients with at least 2 years follow-up (n=3), %EWL was 50.2%. The authors conclude that laparoscopic sleeve gastrectomy in morbidly obese adolescents is a safe and feasible option. Short- and long-term weight loss appears to be successful following LSG.

In a prospective study, Hervieux et al. (2016) compared 2-year results between adolescent patients and young adult controls that underwent LAGB. Follow-up program were similar, weight loss and comorbid disease were analyzed. During this period, insulin resistance and dyslipidemia decreased similarly in both groups, although there was no difference between overall weight loss and BMI. The authors' overall assessment is that provided there is careful selection of patients and a supportive multidisciplinary team, satisfying results can be obtained after LAGB in adolescents, comparable to those obtained in young adults at 2-year follow-up.

Serrano et al. (2016) evaluated patients ≤21 years old to determine the safety and efficacy of bariatric surgery in this population. The primary end point was excess weight loss (EWL). Secondary end points included surgical morbidity, improvement in obesity-related metabolic parameters, and subjective obesity-related symptoms at 1 year. Fifty-four patients were identified who had a laparoscopic Roux-en-Y gastric bypass (LGBP) or laparoscopic sleeve gastrectomy (LSG). Fourteen patients were male

(25.9 %), and 40 patients were female (74.1 %). Thirty-seven patients (68.5 %) underwent LGBP, and 17 patients (31.5 %) underwent LSG. Median follow-up was 13.3 months. The baseline BMI was 51.7 kg/m2 for the LGBP group and 51.0 kg/m2 for the LSG group. EWL was 35.2, 47.6, 62.4, 58.1, and 61.8 % for the LGBP group; 29.7, 44.7, 57.4, 60.3, and 59.0 % for the LSG group at 3, 6, 12, 24, and 36 months, respectively. They reported complications which included 1 anastomotic bleed, 1 postoperative stricture, and 1 patient who developed vitamin deficiency that manifested as a peripheral neuropathy in the LGBP group. LGBP was more successful than LSG in improving lipid panel parameters and HbA1c at 1 year, and it also seemed to offer better subjective improvement in obesity-related symptoms. Overall, they observed that LGBP and LSG seem to confer comparable weight loss benefit in patients ≤21 years old with acceptable surgical morbidity.

In a retrospective analysis of Roux-en-Y gastric bypass versus sleeve gastrectomy in adolescents, Maffazioli et al. (2016) found 1–6 months and 7–18 months reductions in BMI following both RYGB and SG, and no difference between the groups for changes in BMI and weight regain following surgery, indicating that in their opinion, both RYGB and SG are effective options for weight loss in adolescents. However, weight reduction at 7–18 months following RYGB trended higher than that following SG. Although surgical time and length of stay at the hospital were greater in the RYGB group, the rate of post-operative complications did not significantly differ between groups. This is in accordance with prior studies (23) and supports the safety profile of both procedures. The authors cite limitations in their study to be the retrospective analysis in which data elements were not uniformly collected; patients were not matched for some baseline measures, such as creatinine and LDL, which may have influenced some results of comparisons of post-surgical changes; relatively small sample size, and a limited time frame for evaluation of post-operative changes. Longer studies with larger sample sizes will be needed to confirm the present findings. However, in evaluating patients with pre-existing diabetes, the authors found that at least 67% of subjects had achieved remission and 22% had improved glycemic levels following surgery. This is consistent with previous studies showing remission of type 2 diabetes following bariatric procedures.

In a systematic review and meta-analysis, Paulus et al. (2015) evaluated the efficacy, safety, and psychosocial health benefits of various bariatric surgical techniques (RYGB, LAGB, LSG) as a treatment for morbid obesity in adolescents. A total of 37 peer-reviewed articles were included, although the studies were mainly observational and varied in quality. Authors of 9 studies were contacted for additional information. All three procedures lead to significant weight loss in morbidly obese adolescents, and weight loss is most pronounced after RYGB. This seems to persist after both RYGB and LAGB. For LSG studies, long-term follow-up were not yet available. While adverse events are relatively mild and long-term complication rates are acceptable, they are more frequent and more serious after RYGB than after LAGB. In the currently available follow-up after LSG, the rate of adverse events appears to be similar to that after LAGB. Although a healthy nutritional status in adolescents is important to prevent developmental and growth deficiencies, standard postoperative vitamin supplementation regimens and the occurrence of deficiencies are not reported in most studies (not at all in LSG studies). However, more and more severe deficiencies occur after RYGB than after LAGB. Reduction of comorbidity, which is pivotal for health gain, is impressive in all techniques, and QOL consistently showed improvement, although follow-up up to 24 months may not be enough to capture negative long-term effects in life after bariatric surgery. A limitation of this review is the lack of high-quality, prospective randomized controlled trials, which increases the risk of bias and therefore introduces heterogeneity.

Zitsman et al. (2015) studied a population of morbidly obese teenagers (n=137) who underwent LAGB to evaluate its safety and effectiveness. The mean weight gain between enrollment and LAGB was 4.7 kg. Mean preoperative weight, body mass index (BMI), and excess BMI were 136.1 kg, 48.3 kg/m2, and 23.6 kg/m2, respectively. Mean BMI at 6, 12, 18, 24, and 36 months was 43.8, 41.6, 41.5, 40.5, and 39.3. Excess BMI loss was 28.4%, 35.9%, and 41.1% at 1, 2, and 3 years postop. Co-morbid conditions improved or resolved with weight loss after LAGB. Thirty patients (22%) underwent one or more additional operations for complications. Twenty-seven patients (20%) converted to other weight loss procedures or had their bands removed. The authors concluded that morbidly obese adolescents can lose weight successfully and experience health improvement following LAGB, but the role of LAGB in the younger population requires long-term evaluation.

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.

Hsia et al. (2012) reviewed the epidemiology of pediatric obesity, indications for operative therapy in adolescents, surgical outcomes, and multidisciplinary management. The authors comment that the use of BMI as a marker of obesity in children is more complicated than it is in adults because age, sex, and growth patterns in children change the proportion of height to weight. Children have the additional factors of reliance on parents and psychosocial impact of family dynamics. Given the unknown long-term risks of surgery in the still-developing adolescent, more stringent criteria have been proposed for this population. In the authors' opinion, the unknown long-term risks of bariatric surgery in adolescents are counterbalanced by the potential benefits of improved quality and length of life. The review outlines the International Pediatric Endosurgery Group (IPEG) 2009 guidelines for bariatric procedures in adolescents. The criteria include a BMI >35 with severe comorbidities: Type 2 diabetes, moderate to severe sleep apnea, pseudotumor cerebri. BMI >40 with mild comorbidities: hypertension, dyslipidemia, mild obstructive sleep apnea, venous stasis disease, panniculitis, urinary incontinence, impairment in activities of daily living, steatohepatitis, GERD, severe psychosocial distress, weight-related arthropathies. Additional criteria include a Tanner stage of 4 or greater, 95% skeletal maturity, a demonstrated commitment to lifestyle change, and a stable psychosocial environment. Contraindications listed by IPEG include a medically correctable cause of obesity, documented substance abuse problem, disability that would impair adherence to postoperative treatment, current or planned pregnancy or breastfeeding, and unwillingness to understand and acknowledge the consequences of the procedure, particularly the nutritional concerns.

O'Brien et al. (2010) conducted a prospective, randomized controlled study of 42 adolescents to compare the outcomes of gastric banding (n=24) with an optimal lifestyle program (n=18) for adolescent obesity. Patients in the gastric banding group had an estimated weight loss of 78.8% compared to 13.2% in the optimal lifestyle program. Body mass index scores decreased from 42.3 to 29.6 in the gastric banding group compared with 40.4 to 39.1 in the optimal lifestyle program group. Prior to the study, 9 gastric banding patients and 10 lifestyle patients had metabolic syndrome. At 24 month follow-up, none of the patients in the gastric banding group had the metabolic syndrome compared with 4 in the lifestyle group. Eight reoperations were required in 7 patients due to proximal pouch dilatation or tubing injury during follow-up. The authors concluded that use of gastric banding compared with lifestyle intervention resulted in a greater percentage of excess weight loss. Study limitations include small number of study participants as well as a third of the gastric banding patients' required surgical revision due to complications.

A U.S. Food and Drug Administration (FDA) approved clinical trial by Nadler et al. (2009) evaluated the impact on metabolic health following laparoscopic adjustable banding in 45 morbidly obese adolescents. Thirty-one of the 45 patients had 85 identified co-morbidities. All patients completed a 1 year follow-up with 41 patients completing 2 year follow-up. Mean age was 16.1$\pm$1.2 years, preoperative weight was 299$\pm$57 lb, and BMI was 48$\pm$6.4 kg/m$^2$. The estimated weight loss at 6 months was 31$\pm$16; at 1 year 46$\pm$21; and 2 years 47$\pm$22. At 1-year follow-up, patients had a significant decrease in their total and android fat mass. At follow-up, 47 of the 85 identified co-morbidities (55%) were completely resolved and 25 (29%) were improved in comparison with baseline. Improvements in alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, hemoglobin A1c, fasting insulin, triglycerides, and high density lipoprotein, were also seen. The authors concluded that based on these results, laparoscopic adjustable banding is an appropriate surgical option for morbidly obese adolescents.

A retrospective study by Lawson et al. (2006) reported one-year outcomes of Roux-en-Y gastric bypass for morbidly obese adolescents (n=39) aged 13 to 21 years of age. Weight loss of the surgical group was compared to a non-surgical group (n=12). Other outcomes were metabolic changes and complications. Mean BMI in the surgical group decreased from 56.5kg/m$^2$ to 35.8kg/m$^2$ at 12 months postoperatively compared to the nonsurgical group at 47.2kg/m$^2$ to 46.0kg/m$^2$. Surgical patients showed significant improvements in triglycerides (-65 mg/dL), total cholesterol (-28 mg/dL), fasting blood glucose (-12 mg/dL), and fasting insulin (-21 microM/mL]). Fifteen patients experienced complications. Nine had minor complications with no long-term consequences (food obstruction, wound infection, nausea, diarrhea, hypokalemia, or deep vein thrombosis), 4 had at least 1 moderate complication (persistent iron deficiency anemia, peripheral neuropathy secondary to vitamin deficiency, reoperation due to staple line leak, obstruction, or gastrostomy revision, shock or internal hernia) for at least 1 month, and 2 had at least 1 severe medical complication with long-term consequences (including beriberi and death). The authors concluded that postoperatively, adolescents lose significant weight and realize major metabolic improvements. Complication rates and types are similar to those of adults; however, the small sample size of this precludes calculation of complication rates.

## 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.

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 7.6kg 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. Of note, 5% weight loss is defined by the FDA as clinically relevant and is the benchmark by which low-risk drugs and devices are judged; the weight loss results for this study were consistent with those of previous studies. No major adverse events (AE) were identified and only eleven minor AE occurred in eight participants. Results included analysis for hunger assessments, quality of life and lab values. The authors found bariatric embolization is well tolerated and promotes clinically relevant weight loss in adults with severe obesity. Limitations included 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.

The BEAT Obesity Trial, a U.S. Food and Drug Administration (FDA)-approved prospective investigational device exemption study, is being conducted to evaluate the feasibility, safety, and short-term efficacy of bariatric artery embolization (BAE) (Weiss et al., 2017). In the initial phase of the study, 5 severely obese patients (four women, one man) who were 31-49 years of age and who had a mean body mass index of 43.8 kg/m2 ± 2.9 with no clinically significant comorbidities were enrolled in this study and received BAE. There were no major adverse events (AEs), 2 minor AEs healed prior to the time of the 3-month endoscopy. Mean change in serum ghrelin was 8.7% ± 34.7 and -17.5% ± 29 at 1 month and 3 months, respectively. Mean changes in serum glucagon-like peptide 1 and peptide YY were 106.6% ± 208.5 and 17.8% ± 54.8 at 1 month. There was a trend toward improvement in QOL parameters. Hunger/appetite scores decreased in the first 2 weeks after the procedure and then rose without reaching preprocedure levels. The authors concluded that in this initial phase of the study, BAE is feasible and appears to be well tolerated in severely obese patients. In this small patient cohort, it appears to induce appetite suppression and may induce weight loss. Further expansion of this study will provide more insight into the long-term safety and efficacy of bariatric embolization.

In a small case series (N=5), Bai et al. (2018) investigated the safety and 9-month effectiveness of transcatheter left gastric artery (LGA) embolization for treating patients with obesity (mean BMI 38.1 kg/m2 ± 3.8 [range, 32.9-42.4 kg/m2]). Average body weight loss at 3, 6, and 9 months was 8.28 ± 7.3 kg (p = 0.074), 10.42 ± 8.21 kg (p = 0.047), and 12.9 ± 14.66 kg (p = 0.121), respectively. The level of serum ghrelin decreased by 40.83% (p = 0.009), 31.94% (p = 0.107), and 24.82% (p = 0.151) at 3, 6, and 9 months after LGAE, respectively. In the authors' opinion, this study with 9-month data in 5 patients indicates that bariatric embolization of the LGA is safe and may be a promising strategy to suppress the production of ghrelin and results in weight loss and abdominal fat reduction. Randomized controlled trials with larger patient populations and longer-term outcomes are needed to further evaluate BAE in the treatment of obesity.

In the GET LEAN trial, Syed et al. (2016) reported 6-month safety and efficacy results from a pilot study of LGA embolization for the treatment of morbid obesity in 4 patients with a mean BMI of 42.4 kg/m(2) [range, 40.2-44.9 kg/m(2)]). Three minor complications (superficial gastric ulcerations healed by 30 d) occurred that did not require hospitalization. There were no serious adverse events. Average body weight change at 6 months was -20.3 lbs (n = 4; range, -6 to -38 lbs), or -8.5% (range, -2.2% to -19.1%). Average excess body weight loss at 6 months was -17.2% (range, -4.2% to -38.5%). Patient 4, who had diabetes, showed an improvement in hemoglobin A1c level (7.4% to 6.3%) at 6 months. QOL measures showed a general trend toward improvement, with the average physical component score improving by 9.5 points (range, 3.2-17.2) and mental component score improving by 9.6 points (range, 0.2-19.3) at 6 months. The authors' conclude that preliminary data support LGA embolization as a potentially safe procedure that warrants further investigation for weight loss in morbidly obese patients. Study limitations include small patient sample and non-randomization.

## Gastric Electrical Stimulator (GES)

While gastric electrical stimulation may provide benefit for obesity, additional well designed RCTs with long-term effects along with safety and efficacy are warranted.

In a in a 12-month prospective multicenter randomized study, Morales-Conde et al. (2018) monitored all participants (n = 47) up to 24 months after laparoscopic implantation of a closed-loop GES system. 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 percent total body weight loss (%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 adverse events 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. During the 24 month follow-up, CLGES was shown to limit weight regain with strong safety outcomes, including no serious adverse events in the second year. The authors hypothesize that closed-loop GES 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 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 randomized study conducted in nine European centers were implanted laparoscopically with the abiliti® closed-loop GES 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.

Lebovitz (2016) reviewed interventional treatment of obesity and type 2 diabetes with gastric electrical stimulation. Gastric electrical stimulation for effectively treating moderate (class 1 and class 2) obesity has remained elusive in part due to the constellation of causes of obesity which may differ among obese individuals. Combining lifestyle modification with gastric electrical stimulation frequently complicates the interpretation of the results and requires that the studies be double blind and inactive implanted device controlled. The relationship between the metabolic benefits of gastric electrical stimulation in improving glycemic control and lowering systolic blood pressure needs further analysis through randomized controlled studies.

The Screened Health Assessment and Pacer Evaluation (SHAPE) trial by Shikora et al. (2009) compared gastric stimulation therapy to a standard diet and behavioral therapy regimen in a group of obese patients. The difference in excess weight loss between the control group and the treatment group was not found to be statistically significant at 12 months of follow-up. These results suggest that this technology is not effective in achieving significant weight loss in severely obese individuals.

Shikora (2004a) reported an update of the two U.S. clinical trials for gastric stimulation in obesity. The first was an RCT in 2000 that included patient's age 18–50 who had a BMI of 40–55. No statistical difference in the weight loss between study and control groups was found at six-month follow-up. The second trial, the Dual-Lead Implantable Gastric Electrical Stimulation Trial (DIGEST), was a non-randomized, open-label study of patients with a BMI 40–55 $kg/m^2$ or 35–39 $kg/m^2$ and one or more significant comorbidities. At the 12-month follow-up point, 71% of participants lost weight (54% lost >10% of excess, and 29% lost >20% excess). At the 16-month follow-up, mean EWL was 23%.

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 mo, 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 GES 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 GES on obesity.

## Intragastric Balloon (IGB)

There is mixed evidence regarding the efficacy and safety for intragastric balloons and their use with obesity; additional well designed RCTs and long-term data are warranted.

Hayes (2020) low-quality evidence suggests that IGBs have mixed results with regard to weight loss over the short term when used as an adjunct to diet and exercise. These devices are consistently associated with high adverse events and all studies analyzed lacked long term follow up on maintaining weight loss and safety concerns.

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 adverse event (AE) risks. Available clinical guideline recommendations on IGBs are mixed and none pertain to ingestible IGBs. 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 .15% of patients, respectively. Weight loss in the indicated use (BMI 30-40 kg/m2) was 9.7 ± 6.1 kg and 10.0 ± 6.1% total body weight loss (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/m2; and 11.6 ± 7.8 kg or percent total body weight loss 9.3 ± 6.0 for BMI >40 kg/m2. The authors found 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 the bias of a manufactured 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.

In a multicenter randomized controlled trial, Courcoulas et al. (2017, included in Hayes 2020 report above) included obese (BMI 30-40 kg/m2) patients who underwent lifestyle interventions for 12 months. Patients were randomized to receive an IGB for the first 6 months (n=137) or to lifestyle intervention alone (n=136). Data from 44 run-in patients were also included in the safety analyses. The investigators found that IGB patients had a mean %EWL of 26.5% at 9 months; this was not statistically significantly greater than the 25% EWL threshold (P=0.32). The mean differences in %EWL were significantly greater among IGB patients than control group patients. At 9 months, the adjusted mean difference was 16.2% in favor of IGB (P<0.001); and the difference at 12 months was 13.8% (P<0.001). Nearly half of IGB patients (45.6%) achieved at least 15% EWL more than the mean %EWL in control patients (P<0.001). Total body WL was also significantly greater among IGB patients at both 9 and 12 months (both P≤0.001). The authors concluded that although intragastric balloon achieved greater short-term weight loss at 3 and 6 months postballoon removal than lifestyle intervention alone, adverse gastrointestinal events were common. Additional RCTs with longer follow-up periods are needed to further evaluate IGBs in this patient population.

Coffin et al. (2017, included in the Hayes 2020 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/m2). 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/m2 for IGB patients and 50.7 kg/m2 for control patients (P<0.001). However, while the implanted IGB was effective, having the IGB before surgery did not impact postsurgical outcomes after 12 months (approximately 6 months postsurgery), the groups' BMIs were not significantly different at this time point (median BMI:IGB, 38.1 kg/m2 versus standard care, 37.6 kg/m2; 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 poor recruitment rate, a higher than expected use of ICU facilities, and the poor weight loss in the IGB group.

The REDUCE pivotal trial (Ponce et al., 2015, included in the Hayes 2020 report above) 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 percent excess weight loss (%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 nonulcer intolerance occurred in 9%. Gastric ulcers were observed; a minor device change led to significantly reduced ulcer size and frequency (10%). The authors concluded that the dual balloon system was significantly more effective than diet and exercise in causing weight loss with a low adverse event profile. Additional randomized controlled studies are needed.

In a Cochrane review by Fernandes et al. (2007), nine randomized controlled trials involving 395 patients comparing intragastric balloon with conventional weight loss management. Six out of 9 studies had a follow-up of less than one year with the longest study duration was 24 months. Compared with conventional management, IGB did not show convincing evidence of a greater weight loss. On the other hand, complications of intragastric balloon placement occurred, however few of a serious nature. The relative risks for minor complications like gastric ulcers and erosions were significantly raised.

Melissas et al. (2006) studied 140 morbidly obese patients who underwent intragastric balloon placement. These patients refused bariatric surgery because of fear of complications and mortality and were followed over a 6- to 30-month period (mean 18.3 months) after balloon extraction. Of the 140 patients in the study, 100 patients lost ≥ 25% of their excess weight on balloon extraction and were categorized as successes, while 40 patients did not achieve that weight loss and were categorized as failures. During the follow-up period, 44 of the originally successful patients (31.4%) regained weight and were categorized as recurrences, while the remaining 56 patients (40%) maintained their EWL of ≥ 25% and were considered long-term successes. In addition, during follow-up, 45 patients (32.1%) requested and underwent bariatric surgery for their morbid obesity (21 adjustable gastric band, 11 laparoscopic sleeve gastrectomy, 13 laparoscopic gastric bypass). Of these, 13 (32.5%) were from the group of 40 patients categorized as failures upon intragastric balloon removal, 28 (63.6%) were from the group of 44 patients whose obesity recurred, and 4 (7.1%) were from the 56 patents who although they maintained successful weight loss requested further weight reduction. The authors concluded that use of the intragastric balloon served as a first step and a smooth introduction to bariatric surgery for morbidly obese patients who initially refused surgical intervention; however; the incidence of surgical intervention was double in patients who initially experienced the benefits of weight loss and then had obesity recurrence, compared with patients in whom the method failed.

Nunes et al. (2017) conducted a retrospective review of 2002 patients who underwent an intragastric balloon (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 1016 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. 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 1195 patients 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.

In a systematic review, Tate and Geliebter (2017) evaluated 8 randomized controlled trials comparing percentage total body weight loss (%TBWL) between intragastric balloon (IGB) and control groups. Five of the eight studies had balloon treatment duration of 6 months. IGB showed lower efficacy than bariatric surgery (median weight loss of 27% for RYGB). The weighted mean reported incidence of serious adverse events (SAEs) in the IGB group across all eight studies was 10.5%. Only 6 of the 8 reviewed studies reported adverse events (AEs) in the IGB group, with a pooled reported incidence of 28.2%. Based on the available evidence, the authors conclude that it is unlikely that IGB use will supplant other forms of obesity treatment. Collectively, a relatively small control-subtracted %TBWL and the potential for serious complications make the IGB unlikely to become widely adopted. Neylan et al. (2016) reviewed the literature on endoscopic treatments for obesity. The authors' evaluation is that intragastric balloons are the best-studied of all the treatments and although they show 30%-50% excess weight loss after device removal, there is a lack of significant long-term follow-up.

Vyas et al. (2017) evaluated advances in endoscopic balloon therapy for weight loss and its limitations. One of the biggest concerns noted by the authors is that the balloons are unable to provide long term, substantial weight loss when compared with traditional bariatric procedures. The RYGB and the sleeve gastrectomy provide up to 60%-75% EWL at 1 year, when compared to the 25%-30% EWL with the balloon. In addition, the authors report that co-morbidity resolution profiles of the gastric bypass and sleeve gastrectomy are superior to that of the balloons.

Popov et al. (2017) conclude that based on their systematic review and meta-analysis, IGBs are more effective than diet in improving obesity-related metabolic risk factors with a low rate of adverse effects, however the strength of the evidence is limited given the small number of participants and lack of long-term follow-up.

## 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.

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 ($p < 0.01$). EBMIL 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% EBMIL and low rate of complications, LGCP proved to be safe and effective. 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 laparoscopic sleeve gastrectomy (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 a reduced 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, body mass index loss, percentage of excess weight 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 the 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.

In a retrospective review, Khidir et al. (2017) evaluated the efficacy, effects on associated comorbidities, safety and the rate of complications, and patient satisfaction with LGCP's outcomes among extremely obese patients. Mean preoperative BMI was 40.7 kg/m2 that decreased at 2 years to 34.6 kg/m2; 7.6% of patients experienced resolutions of their comorbidities. There were no reported mortality or postoperative complications that required reoperation. Six patients (23%) were satisfied with the outcomes while 10 patients (38.5%) underwent sleeve gastrectomy subsequently. The authors concluded that LGCP demonstrated acceptable short term weight loss results, exhibited almost no postoperative complications, and improved patients' comorbidities. Despite the durability of the gastric fold, some patients regained weight. Future research may assess the possibility of an increase in the gastric pouch size post-plication associated with weight regain. Limitations included small sample size and retrospective design thus inability to evaluate LGCP effect on diabetes mellitus.

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 % excess weight loss 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.

Additional evidence evaluating the safety and effectiveness of laparoscopic greater curvature plication consists primarily of case series with patient populations ranging from 26-244. (Niazi et al., 2013; Fried et al., 2012; Taha, 2012; Talebpour et. al., 2012; Skrekas et al., 2011; Ramos et al., 2010). Limitations in these studies include lack of a randomized controlled study design and short-term follow-up.

## Mini-gastric bypass (MGB)/Laparoscopic Mini-Gastric Bypass (One Anastomosis Gastric Bypass)

Currently there is insufficient evidence regarding the effectiveness of mini-gastric bypass for obesity and weight loss; additional well designed RCTs are needed along with long-term effects, and safety and efficacy results.

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 1075 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 percentage excess weight loss (%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 RCTs in analysis along with race and ethnicity differences which may have impacted the patient's eating habits, education, compliance and expectations.

Carbajo et al. (2018) conducted a prospective, single-center observational study to analyze weight evolution in 100 patients from the first pre-surgery appointment through a 2-year follow-up after one anastomosis gastric bypass. No surgical complications were observed in the patients studied. The patients' mean pre-surgery BMI was 42.61 ± 6.66 kg/m$^2$. Greatest weight loss was observed at 12 months postsurgery (68.56 ± 13.10 kg). Relative weight loss showed significant positive correlation, with greatest weight loss at 12 months and %excess BMI loss > 50% achieved from the 3-month follow-up in 92.46% of patients. The authors reported that in this series of patients, 48% of patients had normal weight (BMI > 18.5 < 25 kg/m$^2$) at 24 months postsurgery. A limitation of this study is the short-term follow-up of the sample selected; patient evolution should be completed with medium- and long-term data. In addition, a possible bias to consider is non-randomization of patients.

In a prospective, observational and descriptive study of 150 morbidly obese patients who underwent laparoscopic one anastomosis gastric bypass, 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 % excess weight loss 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. Long-term randomized studies are needed to fully evaluate the impact of this procedure.

Lessing et al. (2017) conducted a retrospective analysis of all patients (n=407) who underwent one anastomosis gastric bypass (OAGB), reporting an average excess weight loss 1 year following surgery as 88.9 ± 27.3 and 72.8 ± 43.5% in patients that underwent primary and revision OAGB, respectively. Study limitations include single center data analysis and non-randomization.

Musella et al. (2017) retrospectively evaluated complications of 2678 patients who underwent a mini/one anastomosis gastric bypass (MGB/OAGB). Follow-up at 5 years was 62.6%. Intraoperative and early complication rates were 0.5 and 3.1%, respectively. The late complication rate was 10.1%. A statistical correlation was found for postoperative duodenal-gastro-esophageal reflux (GERD) in patients with pre-existing GERD or with a gastric pouch shorter than 9 cm. The authors conclude that MGB/OAGB is a reliable bariatric procedure in comparison with more mainstream procedures (Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy). Additional long-term outcomes are needed to evaluate this procedure.

Long-term outcomes (up to 11 years) in a cohort of 156 patients undergoing silastic ring mini gastric bypass were evaluated by Sheikh et al. (2017). Computer-based hospital information was available on a total of 139 patients; 92 patients responded to the follow-up questionnaires. The authors concluded that the data supports the mini gastric bypass to be durable, with favorable excess weight loss at up to 11 years post-surgery (84.3%). Seven patients had alterations of the original silastic ring and 9.4% of the original cohort required conversion to a Roux-en-Y gastric bypass. The number of patients on anti-reflux medications increased from 5.1% to 44.6% at 11 years. In the authors' opinion, patients who are poorly controlled medically will require conversion to a different bariatric procedure.

Kansou et al. (2016) retrospectively evaluated one year outcomes for patients who underwent either a sleeve gastrectomy (n=261) or LMGBP (n=161) as an alternative to a Roux-en-Y gastric bypass. At one year, rate of follow-up was 88.4%. Main outcome was % of Total Weight Loss (%TWL) at one year. Propensity score matching and multivariable analyses were used to compensate for differences in some baseline characteristics. After matching sleeve gastrectomy (N = 136) and LMGBP (N = 136) groups did not differ for initial BMI, % of female patients, age (years) and diabetes. At one year, %TWL, change in BMI and rate of stenosis were higher for the LMGBP group, respectively: 38.2 ± 8.4 vs. 34.3 ± 8.4 (P < 0.0001); -16.5 ± 4.6 vs. -14.9 ± 4.4 (P = 0.005) and 16.9% vs. 0% (P < 0.0001). In multivariate analyses (β coefficient), LMGBP was a positive independent factor of %TWL (2.8; P = 0.008). The authors concluded that LMGBP appears to have better weight loss at one year compared to sleeve gastrectomy, with higher gastric complications.

Obese patients who underwent either a LMGBP (n=169) or SG (n=118) were retrospectively analyzed by Plamper et al. (2017) for short-term for perioperative and early postoperative outcomes. Both groups were comparable for BMI at baseline (MGB = 54.1 kg/m2 vs. SG = 54.6 kg/m2, p = 0.657). Mean operation time (81.7 vs. 112.1 min, p < 0.0001) as well as hospital stay was lower in the MGB-group (4.5 vs. 7.2 days, p < 0.0001). Perioperative (30 days) mortality was 0 % in MGB versus 0.8 % in SG (one patient). Perioperative complication rate was also lower in the MGB-group (3.0 vs. 9.3 %, p = 0.449). %EWL was significantly better after 1 year in MGB: 66.2 % (±13.9 %) versus 57.3 % (±19.0 %) in SG (p < 0.0001), as well as BMI which was 34.9 kg/m2 (±4.8 kg/m2) in MGB versus 38.5 kg/m2 (±8.6 kg/m2) in SG (p = 0.001). The authors concluded that MGB achieved superior weight loss at 1 year and had a lower 30-day complication rate in comparison with SG for super-obese patients.

Piazza et al. (2015) reported their experience with laparoscopic mini-gastric bypass (LMGB) as a revisional procedure for failed primary laparoscopic adjustable gastric banding (LAGB). From June 2007 to November 2012, 48 patients, who had undergone LAGB, underwent revisional surgery to LMGB. The revisions to a mini-gastric bypass (MGB) were completed laparoscopically in all cases except in four, when the MGB was deferred because of gastric tube damage. Mean age was 38 years (range 20-59) and BMI was 43.4 ± 4.2 kg/m(2); 82 % of patients were females. Revision was performed after a mean of 28.6 months. The mean hospital stay was 3.25 days. Within 60 days of the MGB, mortality and morbidity were nil. They observed a significant difference in mean BMI after 6 months' follow-up (P < 0.001). Diabetes remission was observed in 88 % of patients, apnea remission in 66 %, and hypertension remission in 66 % after LMGB (p < 0.001). Moreover, four patients with GERD reported symptom resolution. All LAGB patients had positive outcomes after the conversion to MGB, with a mean gain of 1.7 points in the bariatric analysis and reporting outcome system questionnaire. The authors suggest that based on their results, LMGB is a safe, feasible, effective and easy-to-perform revisional procedure for failed LAGB.

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 sleeve gastrectomy (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 T2DM remission rate, higher hypertension remission rate, higher obstructive sleep apnea (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 mini-gastric bypass and sleeve gastrectomy. In their opinion, due to the biased data, small sample size and short follow-up time, the results of this review may be unreliable. RCTs with larger samples sizes are needed to compare the effectiveness and safety between mini-gastric bypass and sleeve gastrectomy.

## Single-Anastomosis Duodenal Switch (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.

In a Hayes (2020) report, the overall limited low-quality body of evidence suggests that single-anastomosis duodenal switch (SADS) was more effective at promoting weight loss in patients than the Roux-en-Y gastric bypass or vertical sleeve gastrectomy procedures. However, the poor to very poor-quality evidence is limited by small sample sizes, retrospective design, and other methodological flaws. In addition, a significant limitation was that 4 of the 5 studies were conducted in the same bariatric center and utilized the same patient pool. While the available evidence for SADS in treatment of obesity appears to be safe, substantial uncertainty remains.

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/m2 with one obesity related comorbidity or a BMI of 40-60 kg/m2 with no related comorbidity. Weight loss, comorbidities, quality of life, and adverse events 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 analysis, Surve et al. (2017) compared biliopancreatic diversion with duodenal switch 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 statistically similar weight loss at 3 months but percent excess weight loss (%EWL) was more with BPD-DS than SIPS at 6, 9, 12, 18, and 24 months. Patient lost a mean body mass index (BMI) of 23.3 (follow-up: 69%) and 20.3 kg/m2 (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<.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. Randomized controlled trials 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 showed that both procedures had statistically similar 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). Randomized controlled trials 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.

In the post study of the PATHWAY Trial, Thompson et al. (2019) provide 4-year outcomes of the AT patients from the initial trial (see Thompson 2017 below). 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.

In a post-market study, Nyström et al. (2018) evaluated the long-term safety and efficacy of aspiration therapy in 5 European clinics using the AspireAssist®.A total of 201 participants (mean BMI 43.6 ± 7.2 kg/m2) participated. Mean percent total weight loss at 1, 2, 3, and 4 years, respectively, was 18.2% ± 9.4% (n/N = 155/173), 19.8% ± 11.3% (n/N = 82/114), 21.3% ± 9.6% (n/N = 24/43), and 19.2% ± 13.1% (n/N = 12/30), where n is the number of measured participants and N is the number of participants in the absence of withdrawals or lost to follow-up. Clinically significant reductions in HbA1C, triglycerides, and blood pressure were observed. For participants with diabetes, HbA1C decreased by 1% (P < 0.0001) from 7.8% at baseline to 6.8% at 1 year. The only serious complications were buried bumpers, experienced by seven participants and resolved by removal/replacement of the A-Tube, and a single case of peritonitis, resolved with a 2-day course of intravenous antibiotics. Although the authors concluded that aspiration therapy is a safe, effective, and durable weight loss therapy in people with classes II and III obesity, randomized controlled trials comparing aspiration therapy to other bariatric procedures are needed to validate these findings.

In the pivotal PATHWAY study, Thompson et al. (2017) conducted a 52-week randomized controlled trial at 10 leading institutions across the United States. 207 participants with a body-mass index (BMI) of 35.0–55.0 kg/m 2 were randomly assigned in a 2:1 ratio to treatment with AspireAssist plus Lifestyle Counseling (n =137; mean BMI was 42.2±5.1 kg/m 2) or Lifestyle Counseling alone (n =70; mean BMI was40.9±3.9 kg/m 2 ). The co-primary end points were mean percent excess weight loss and the proportion of participants who achieved at least a 25% excess weight loss. At 52 weeks, participants in the AspireAssist group, on a modified intent-to-treat basis, had lost a mean (±s.d.) of 31.5±26.7% of their excess body weight (12.1±9.6% total body weight), whereas those in the Lifestyle Counseling group had lost a mean of 9.8±15.5% of their excess body weight (3.5±6.0% total body weight) (P <0.001). A total of 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight (P <0.001). The most frequently reported adverse events were abdominal pain and discomfort in the perioperative period and peristomal granulation tissue and peristomal irritation. A total of 46 subjects are available for the extended follow-up study. Outcomes of the post-approval study may provide more solid evidence regarding the longer term efficacy of the AspireAssist.

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 aspiration therapy 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 our expectation 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 aspiration therapy and cognitive behavioral therapy (CBT) without any control group. Long term patency is still unknown.

Forssell and Norén (2015) conducted an observational study of 25 obese patients (BMI 39.8 ± 0.9 kg/m(2)) who after following a very low calorie diet for 4 weeks had the AspireAssist gastrostomy tube placed. A low-profile valve was installed 14 days later and aspiration of gastric contents was performed approximately 20 minutes after meals three times per day. Cognitive behavioral therapy was also started. At 6 months, mean weight lost was 16.5 ± 7.8 kg in the 22 subjects who completed 26 weeks of therapy (P = 0.001). The mean percentage excess weight lost was 40.8 ± 19.8% (P = 0.001). Two subjects were hospitalized for complications: one subject for pain after gastrostomy tube placement, which was treated with analgesics, and another because of an aseptic intra-abdominal fluid collection 1 day after gastrostomy tube placement. No clinically significant changes in serum potassium or other electrolytes occurred. The authors concluded that the results suggest the potential of the AspireAssist as an attractive therapeutic device for obese patients. Further research with randomized controlled trials is needed to validate these findings.

Sullivan et al. (2013) conducted a pilot study of 18 obese subjects who were randomly assigned (2:1) to groups that underwent aspiration therapy for 1 year plus lifestyle therapy (n = 11; mean body mass index, 42.6 ± 1.4 kg/m(2)) or lifestyle therapy only (n = 7; mean body mass index, 43.4 ± 2.0 kg/m(2)). Lifestyle intervention comprised a 15-session diet and behavioral education program. Ten of the 11 subjects who underwent aspiration therapy and 4 of the 7 subjects who underwent lifestyle therapy completed the first year of the study. After 1 year, subjects in the aspiration therapy group lost 18.6% ± 2.3% of their body weight (49.0% ± 7.7% of excess weight loss [EWL]) and those in the lifestyle therapy group lost 5.9% ± 5.0% (14.9% ± 12.2% of EWL) (P <.04). Seven of the 10 subjects in the aspiration therapy group completed an additional year of therapy and maintained a 20.1% ± 3.5% body weight loss (54.6% ± 12.0% of EWL). The authors reported that there were no adverse effects of aspiration therapy on eating behavior (including binge eating) and no evidence of compensation for aspirated calories with increased food intake. The small sample size does not allow a conclusion to be made as to whether the outcomes can be generalized to a larger population. Lack of long-term follow-up data is another study limitation.

## Transoral Endoscopic Surgery (including Transpyloric Shuttle® (TPS) Device)

The evidence for transoral endoscopic surgery is limited for bariatric surgery; 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 followup 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 followup.

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 ($P < .01$). Patients undergoing StomaphyX treatment experienced significantly greater reduction in weight and BMI at 3, 6, and 12 months ($P \leq .05$). There was one causally related adverse event with StomaphyX, that required laparoscopic exploration and repair.

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, adverse events, 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. This endoscopic device may provide a valuable addition to the available treatment for the management of morbid obesity, however this study is limited by small sample size and short term follow-up.

Many patients do not maintain weight loss after gastric bypass. Buttelmann et al. (2015) compared outcomes for patients undergoing diet/exercise intervention with patients undergoing surgical intervention through restorative obesity surgery-endolumenal (ROSE), band over bypass, and endoscopic gastro gastric fistula closure. A retrospective analysis of 60 patients was performed on those who underwent gastric bypass and failed to lose weight. Records were reevaluated at 3, 6, and 12 months after intervention for primary outcomes of, weight loss and comorbidity resolution. The authors concluded ROSE, band over bypass, and endoscopic fistula closure results in greater weight loss and trend toward greater comorbidity resolution compared with diet and exercise. This study is limited by small sample size and short term follow-up.

A case series by Mullady et al. (2009) evaluated 20 patients who underwent restorative obesity surgery, endoluminal (ROSE) procedure due to weight regain post gastric bypass, with a confirmed dilated pouch and gastrojejunal anastomosis (GJA) on endoscopy. Seventeen of 20 (85%) patients had an average reduction in stoma diameter of 16 mm (65% reduction) and an average reduction in pouch length of 2.5 cm (36% reduction). The mean weight loss in successful cases was 8.8 kg at 3 months. The authors concluded that the ROSE procedure is effective in reducing not only the size of the gastrojejunal anastomosis but also the gastric pouch and may provide an endoscopic alternative for weight regain in gastric bypass patients. This study is limited by small sample size and short term follow-up.

Marinos et al. (2014) conducted/published 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. The study was registered at www.clinicaltrials.gov (NCT01386905). Patients were required to be ≥18 and ≤55 years of age with a body mass index (BMI) between 30 and 50 kg/m2. 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.

## Vagus Nerve Blocking

Currently there is insufficient evidence regarding the effectiveness of vagus nerve blocking for obesity; additional robust studies including randomization are warranted.

The ReCharge pivotal study, sponsored by the manufacturer, (Ikramuddin et al., 2014), was a prospective, randomized, double-blind, sham-controlled, multi-center 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.

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 type 2 diabetes (8%). The vBloc group achieved a percentage excess weight loss (%EWL) of 33% (11% total weight loss (%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 adverse events 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.

Apovian et al. (2017) reported the two-year outcomes from the ReCharge study. At 24 months, 123 (76%) vBloc participants remained in the trial. Participants who presented at 24 months (n = 103) had a mean excess weight loss (EWL) of 21% (8% total weight loss [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 adverse events. The primary related serious adverse event rate was
4.3%.

Shikora et al. (2016) provided two-year outcomes from the VBLOC DM2 study, a prospective, observational study of 28 subjects with T2DM and BMI between 30 and 40 kg/m(2) who underwent a VBLOC procedure. At 24 months, the mean percentage of excess weight loss was 22% (95% CI, 15 to 28, p <0.0001) or 7.0% total body weight loss (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 adverse events 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. Randomized controlled studies with larger patient populations are needed to validate these findings.

Sarr et al. (2012) conducted a randomized, prospective, double-blind multicenter trial to evaluate use of intraabdominal vagal blockade (VBLOCTherapy). Five hundred three subjects were enrolled at 15 centers. After informed consent, 294 subjects were implanted with the vagal blocking system and randomized to the treated or control group. Main outcome measures were percent excess weight loss (percent EWL) at 12 months and serious adverse events. Subjects controlled duration of therapy using an external power source; therapy involved a programmed algorithm of electrical energy delivered to the subdiaphragmatic vagal nerves to inhibit afferent/efferent vagal transmission. Devices in both groups performed regular, low-energy safety checks. Study subjects consisted of 90% females, body mass index of 41±1 kg/m$^2$, and age of 46±1 years. There was no mortality. 12-month percent EWL was 17±2% for the treated and 16±2% for the control group. Weight loss was related linearly to hours of device use; treated and controls with ≥12 h/day use achieved 30±4 and 22±8% EWL, respectively. The authors concluded that VBLOC® therapy to treat morbid obesity was safe, but weight loss was not greater in treated compared to controls; clinically important weight loss, however, was related to hours of device use. Post-study analysis suggested that the system electrical safety checks (low charge delivered via the system for electrical impedance, safety, and diagnostic checks) may have contributed to weight loss in the control group.

In an open-label study, Camilleri and associates (2008) evaluated the effects of vagal blocking by means of a new medical device that uses high-frequency electrical algorithms to create intermittent vagal blocking (VBLOC therapy) on EWL. Electrodes were implanted laparoscopically on both vagi near the esophago-gastric junction to provide electrical block. Patients (obese subjects with body mass index [BMI] of 35 to 50 kg/m$^2$) were followed for 6 months. The authors concluded that VBLOC therapy is associated with significant EWL and a desirable safety profile. They noted that these findings have resulted in the design and implementation of a randomized, double-blind, prospective, multi-center trial in an obese subject population.

Hwang et al. (2016) summarized current surgical options in weight loss reporting that initial studies in the use of the Maestro Rechargeable System show that although the VBLOC device is not as effective for weight loss as the laparoscopic vertical sleeve gastrectomy or laparoscopic Roux-en-Y gastric bypass, it appears to be a viable option for weight loss in obese patients desiring a “less invasive” procedure for weight loss, or who would not be able to tolerate a more invasive procedure. Well-designed studies are needed to determine the best usage of the Maestro Rechargeable System.

## Gastrointestinal Liner

Currently there is insufficient evidence regarding the effectiveness of gastrointestinal liners for obesity and weight loss; additional well designed RCTs are needed along with long-term effects, and safety and efficacy results.

Quezada et al. (2018) conducted a single-arm, open-label, prospective trial to evaluate the safety and efficacy of endoscopically placed duodenal-jejunal bypass liner (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 severe adverse events (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.

Schouten et al. (2010) conducted a randomized controlled trial of an endoscopically placed duodenal-jejunal bypass sleeve or EndoBarrier Gastrointestinal Liner in 30 patients. An additional 11 patients served as a diet control group with all patients following the same low-calorie diet during the study period. Twenty-six devices were successfully implanted. In 4 patients, implantation could not be achieved and the devices were explanted prior to the initial protocol end point because of migration (1), dislocation of the anchor (1), sleeve obstruction (1), and continuous epigastric pain (1). The remaining patients all completed the study. Mean excess weight loss after 3 months was 19.0% for device patients versus 6.9% for control patients. Of 8 patients with diabetes, 7 patients showed improvement at follow-up. The authors concluded that the EndoBarrier Gastrointestinal Liner was a safe noninvasive device with excellent short-term weight loss results; however, long-term randomized studies are necessary to determine the role of the device in the treatment of morbid obesity.

A prospective, randomized trial by Gersin et al. (2010) compared 21 patients receiving the duodenojejunal bypass liner (DJBL) with 26 patients undergoing a sham procedure. Primary outcomes measured the difference in the percentage of EWL at week 12 between the 2 groups. Thirteen duodenojejunal bypass liner subjects and 24 sham subjects completed the 12-week study.

The duodenojejunal bypass liner group had a EWL of 11.9% compared to 2.7% in the sham group. Eight patients in the duodenojejunal bypass liner group dropped out of the study early because of GI bleeding (n=3), abdominal pain (n=2), nausea and vomiting (n=2), and an unrelated preexisting illness (n=1). The authors concluded that duodenojejunal bypass liner promotes a more significant weight loss beyond a minimal sham effect in candidates for bariatric surgery. This study is limited by small patient sample, short term follow-up, and relatively high complication rates.

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 percent total body weight loss (%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 adverse event, 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 explantation. 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. 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 T2DM 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. Adverse events 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 T2DM patients with (morbid) 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.

Vilarrasa et al. (2017) evaluated the efficacy and safety of Endobarrier® in grade 1 obese T2DM patients with 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/m2, 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.

In a systematic review and meta-analysis, Rohde et al. (2016) evaluated the efficacy and safety of the DJBS. Five randomized controlled trials (RCTs; 235 subjects) and 10 observational studies (211 subjects) were included. The risk of bias was evaluated as high in all studies. The mean body mass index 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.

A 2015 National Institute of Health and Care Excellence (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.

## Professional Societies

### *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=1683) 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.

The ASGE Bariatric Endoscopy Task Force and the ASGE Technology Committee reviewed endoscopic bariatric therapies (EBT) and summarized that EBTs hold the promise of providing the next major breakthrough in the management of obesity. They commented that the development of a variety of new endoscopic therapies that replicate the physiological benefits of bariatric surgery in a safe, cost-effective, and minimally invasive fashion may potentially offer the best path to making a meaningful impact on the obesity epidemic, as less than 1% of qualified patients actually undergo bariatric surgery. Currently investigated devices have established promising outcomes in short-term weight loss and in control of the metabolic and other medical adverse events of obesity. Further studies will help define their optimal role in the comprehensive management of obesity (Abu Dayyeh et al., 2015b).

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/m2 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/m2 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/m2 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/m2 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.
- 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/m2 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/m2 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/m2 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.

The AACE and the ACE define obesity as a chronic disease caused by an interaction between biological factors, environmental factors, and behavior (Garvey et al., 2014).

The AACE/ACE diagnostic algorithm for obesity has the following 2 main components:

- Screening with body mass index (BMI) with adjustments for ethnic differences to better identify people with increased adipose tissue.
- Clinical evaluation for the presence and severity of obesity-related complications such as metabolic syndrome, type 2 diabetes mellitus (T2DM), dyslipidemia, hypertension, nonalcoholic fatty liver disease, polycystic ovary syndrome, obstructive sleep apnea, osteoarthritis, urinary stress incontinence, gastroesophageal reflux disease (GERD), disability and immobility, psychological disorder, and stigmatization.

### *American Heart Association/American College of Cardiology (AHA/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.

## *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 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 weight loss surgery (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.

### Specific Bariatric Procedures

The ASMBS (2016) has approved, and supports the use of the following bariatric procedures and associated devices:
- Roux-en-Y Gastric Bypass
- Duodenal Switch
- Intragastric Balloon
- Sleeve Gastrectomy
- Adjustable Gastric Banding
- Bariatric Reoperative Procedures
- Open procedures as deemed appropriate by the surgeon

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.
- 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.

In an updated statement 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 (Kallies, 2020).

The ASMBS Clinical Issues Committee position statement on intragastric balloon therapy endorsed by SAGES (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., 2015), 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.

In a 2015 position statement on intragastric balloon therapy endorsed by SAGES, the ASMBS acknowledges that 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 (Ali et al., 2015).

## 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 ≥120% 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/m2) 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.
- Overview of 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.
- Overview of 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.
- 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.

A comparative effectiveness review indicates bariatric surgical procedures such as Roux-en-Y gastric bypass (RYGB), gastric banding and vertical sleeve gastrectomy (VSG) for adolescents are superior to nonsurgical interventions for promoting weight loss. In addition, further support demonstrates adolescent patients who undergo RYGB or VSG procedures show similar efficacy outcomes as adult patients undergoing the same procedure (Hayes, 2019).

## 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 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/m2
- 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/m2 or has a BMI of >35 kg/m2 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/m2 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

### *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.

### *American Academy of Sleep Medicine (AASM)*

In its 2009 *Clinical Guideline for the Evaluation, Management, and Long-Term Care of Obstructive Sleep Apnea in Adults*, the AASM Adult Obstructive Sleep Apnea Task Force (Epstein, et al., 2009) states that bariatric surgery may be adjunctive in the treatment of obstructive sleep apnea (OSA) in obese patients. There is a consensus that bariatric surgery should be considered as an adjunct to less invasive and rapidly active first-line therapies such as PAP for patients who have OSA and meet the currently published guidelines for bariatric surgery. The remission rate for OSA two years after bariatric surgery, related to the amount of weight lost, is 40%, emphasizing the need for ongoing clinical follow-up of these patients.

## 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/m2. 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, see:

- 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 August 19, 2020)

The FDA approved the implantable EnteroMedics Maestro Rechargeable System to be marketed on January 4, 2015) .The Maestro Rechargeable System is an implantable pacemaker-like device for patients who are morbidly obese or who are obese with one or more obesity-related conditions. For more information, see: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130019. (Accessed August 19, 2020)

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/m2 or less obese patients who have at least a body mass index (BMI) of 30 kg/m2 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 August 19, 2020)

On September 28, 2007, the FDA approved the REALIZE™ Adjustable Gastric Band (REALIZE Band) manufactured by Ethicon Endo-Surgery, Inc. The REALIZE Band also consists of a silicone band, tubing, and an injection port. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070009b.pdf. (Accessed August 19, 2020)

In October 2010, the manufacturer voluntarily recalled the REALIZE Band due to the potential for a small ancillary component called the Strain Relief to move out of its intended position. The device was changed to add a silicone adhesive to bond the strain relief sleeve and the locking connector components of the injection port. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95101. (Accessed August 19, 2020)

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 August 19, 2020)

StomaphyX was granted 510(k) marketing approval on March 9, 2007. EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is substantially equivalent in intended use and method of operation to a combination of the LSI Solutions Flexible Suture Placement Device and the Bard Endoscope Suturing System/Bard Endocinch. According to the FDA, the StomaphyX system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062875.pdf.
(Accessed August 19, 2020)

According to EndoGastric Solutions, StomaphyX is no longer being manufactured.

The AspireAssist received FDA pre-market approval on June 14, 2016 for adults who are at least 22 years old and are obese, with a BMI of 35.0-55.0 kg/m$^2$ who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150024. (Accessed August 18, 2020)

Transoral gastroplasty (TOGA) is not currently FDA approved.

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/m2 or a BMI of 30.0 to 34.9 kg/m2 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 August 19, 2020)

# Centers for Medicare and Medicaid Services (CMS)

Medicare covers certain surgical services for the treatment of obesity when criteria are met. Refer to the National Coverage Determinations (NCDs) for Bariatric Surgery for Treatment of Morbid Obesity (100.1), Surgery for Diabetes (100.14), Intestinal Bypass Surgery (100.8), Gastric Balloon for Treatment of Obesity (100.11), Treatment of Obesity (40.5) and Intensive Behavioral Therapy for Obesity (210.12).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; see the LCDs/LCAs for Bariatric Surgical Management of Morbid Obesity, Surgical Management of Morbid Obesity and Laparoscopic Sleeve Gastrectomy for Severe Obesity.
(Accessed November 5, 2020)

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## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 12/01/2020 | **Coverage Rationale**<br>• Updated list of proven and medically necessary bariatric surgical procedures; replaced "*gastric* sleeve *procedure*" with "sleeve *gastrectomy* (*vertical* sleeve *gastrectomy*)"<br>• Updated list of unproven and not medically necessary bariatric surgical procedures; replaced "VBLOC® *vagal* blocking *therapy*" with "*vagus nerve* blocking (VBLOC®)"<br>**Supporting Information**<br>• Updated *Clinical Evidence*, *FDA*, *CMS*, and *References* sections to reflect the most current information<br>• Archived previous policy version 2020T0362EE |

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. 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.