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Bariatric Surgery

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members in Insured plans residing in the state of Indiana: § 27 13 7 14.1 and 14.5 requires coverage for nonexperimental, surgical treatment of morbid obesity. Morbid obesity is defined as a BMI of at least 35 with a comorbidity (such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes); or a BMI of at least 40 without a comorbidity. To qualify for coverage, the morbid obesity must have persisted for at least five years and must not have been successfully addressed through nonsurgical treatment supervised by a physician for at least six consecutive months. Coverage is not permitted for those less than age 21 unless two physicians determine that surgery is necessary to save the life of the enrollee or to restore the enrollee's ability to maintain a major life activity and each physician documents in the enrollee's medical record the reason for the physician's determination. This applies to Fully Insured Small Group, Mid-Market, Large Group HMO, EPO, PPO, POS.

Coverage

NOTE 1: Check member's contract for benefit coverage and/or exclusions for bariatric surgery and complications related to bariatric surgery. Not all benefit contracts cover bariatric surgery or complications of non-covered surgery.

This medical policy does NOT address Gender Reassignment Services (Transgender Services). This medical policy IS NOT TO BE USED for Gender Reassignment Services. Refer to SUR717.001, Gender Assignment Surgery and Gender Reassignment Surgery with Related Services

BARIATRIC SURGERY SELECTION CRITERIA FOR COVERAGE

For a member to be considered eligible for benefit coverage of bariatric surgery to treat obesity, the member must meet the following **two criteria**:

1. Diagnosis of Class III or Class II obesity, defined as a:

- Body mass index (BMI) equal to or greater than 40 kg/meter^2 (Class III obesity [formerly known as morbid obesity]) (* see Policy Guidelines below for BMI calculation); OR
- BMI equal to or greater than 35 kg/meters^2 (Class II obesity) with at least one (1) of the following clinically significant obesity-related diseases or complications that are not well controlled with medical management:
  - Hypertension, OR
  - Dyslipidemia, OR
  - Diabetes mellitus, OR
  - Coronary heart disease, OR
  - Obstructive sleep apnea, OR
  - Osteoarthritis in weight bearing joints;

NOTE 2: Individual consideration of other factors such as race/ethnicity may be given to adult individuals with type 2 diabetes and a BMI 32.5 to 35 kg/m^2 requesting bariatric surgery.

AND

2. Documentation from the requesting surgical program that:

- **Adult individuals** who are ≥ 18 years of age or have reached full expected skeletal growth; OR
- **Adolescent individuals** who have attained a Tanner 4 or 5 pubertal development and final or near-final adult height; **AND**
- Documentation from the surgeon attesting that the individual has been educated in and understands the post-operative regimen, which should include willingness to comply with ALL the following components:
  - Nutrition program, which may include a very low-calorie diet or a recognized commercial diet-based weight loss program; AND
  - Behavior modification or behavioral health interventions; AND
  - Counseling and instruction on exercise and increased physical activity; AND
  - Ongoing support for lifestyle changes to make and maintain appropriate choices that will reduce health risk factors and improve overall health; **AND**

- Individual has completed an evaluation by a master's level or higher behavioral healthcare provider acting within the scope of their licensure under applicable state law, within the 12 months preceding the request for surgery.
    - **Adult evaluation** should document:
        1. The absence of significant psychopathology that would hinder the ability of an individual to understand the procedure and comply with medical/surgical recommendations, AND
        2. The absence of any psychological comorbidity that could contribute to weight mismanagement or a diagnosed eating disorder, AND
        3. The individual's willingness to comply with preoperative and postoperative treatment plans.
    - **Adolescent evaluation** should document all requirements for the adult evaluation as well as documentation of consideration given to:
        1. Psychosocial evaluation (e.g., supportive family unit), AND
        2. Adequate developmental maturity, AND
        3. Assent to the procedure.

Bariatric surgery **is considered not medically necessary** for individuals not meeting the above criteria.

Bariatric Surgery in Adolescents

Bariatric surgery in adolescent members may be considered eligible for benefit coverage according to the same weight-based criteria used for adults.

NOTE 3: Forms of bariatric surgery performed without specific implantable devices (i.e., Roux-en-Y anastomosis or sleeve gastrectomy) are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA). In addition, any devices used for bariatric surgery must be used in accordance with the FDA-approved indications.

Bariatric Surgery in Preadolescent Children

Bariatric surgery **is considered experimental, investigational and/or unproven** for the treatment of obesity in preadolescent children.

COVERAGE STATEMENTS FOR SPECIFIC BARIATRIC SURGICAL PROCEDURES (Gastric Restrictive and Gastric Malabsorptive)

NOTE 4: For a member to be eligible for benefit coverage of any one of these procedures the member must meet the Bariatric Surgery Selection Criteria described above AND the member's contract or certificate of coverage must allow coverage of bariatric surgery.

- Gastric bypass using a Roux-en-Y anastomosis (up to and including 150 cm) **may be considered medically necessary** as an open or laparoscopic surgical treatment option for individuals with obesity who meet the eligibility criteria for surgery.
- Adjustable gastric banding (open or laparoscopic), consisting of an external adjustable band placed high around the stomach creating a small pouch and a small stoma**, may be**

considered medically necessary as a surgical treatment option for individuals with obesity who meet the eligibility criteria for surgery.

NOTE 5: If the original adjustable gastric banding procedure was a covered benefit, it is not necessary to request documentation for refill and maintenance procedures.

- Sleeve gastrectomy (open or laparoscopic) **may be considered medically necessary** as a surgical treatment option for individuals with obesity who meet the eligibility criteria for surgery.
- Biliopancreatic bypass (Scopinaro procedure) WITH duodenal switch (open or laparoscopic) **may be considered medically necessary** as a surgical treatment option for class III obese individuals with BMI of 50 kg/m² or greater who meet the other eligibility criteria for surgery.

Gastric bypass, as a primary procedure, using a Roux-en-Y anastomosis, adjustable gastric banding, sleeve gastrectomy, or biliopancreatic bypass (Scopinaro procedure) with duodenal switch **are considered not medically necessary** for the treatment of any condition other than class II/III obesity, including but not limited to gastroesophageal reflux disease and sleep apnea. (See **NOTE 6** below)

NOTE 6: See Miscellaneous Procedure Coverage Statements section under Complications for information on reoperation for intractable gastroesophageal reflux disease following sleeve gastrectomy.

The following procedures **are considered not medically necessary** as a treatment of obesity:

- Vertical banded gastroplasty is no longer standard of care.
- Biliopancreatic bypass with duodenal switch as a treatment for individuals with a BMI less than 50kg/m².

The following bariatric procedures **are considered experimental, investigational and/or unproven** as a treatment of obesity, include, but are not limited to:

- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass),
- Biliopancreatic bypass without duodenal switch,
- Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S),
- Long-limb gastric bypass procedure (i.e., >150 cm),
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time) (see **NOTE 7** below regarding staged procedures),
- Laparoscopic gastric plication,
- AspireAssist® device (aspiration therapy device),
- Embolization of gastric arteries as a treatment of obesity,
- Vagus nerve blocking (e.g., Maestro),
- Endoscopic bariatric procedures, either as a primary procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches). This includes, but is not limited to:

- Insertion of the StomaphyX™ device,
- Natural Orifice Transluminal Endoscopic Surgery (NOTES™),
- Transoral ROSE procedure (Restorative Obesity Surgery),
- Sclerotherapy of the stoma,
- Insertion of a gastric balloon,
- Endoscopic gastroplasty, or
- Use of an endoscopically placed duodenojejunal sleeve.

NOTE 7: A bariatric procedure that has to be aborted (i.e., no bariatric procedure is completed), but is then performed at a later date, is not considered a staged procedure. The individual must meet benefit coverage, contractual eligibility, and coverage criteria at the time the bariatric procedure is completed.

MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS

NOTE 8: Check member's contract for benefit coverage and/or exclusions for bariatric surgery and complications related to bariatric surgery.

Complications

- Reoperation related to previous bariatric surgery **may be considered medically necessary** for complications such as stricture, obstruction, or erosion except when the members benefit plan excludes coverage of such complications.
- Removal of an adjustable gastric band **may be considered medically necessary** for complications not resolved by band deflation, including but not limited to obstruction, erosion, aspiration pneumonia, GERD, night cough, Barrett's esophagus, persistent vomiting, or persistent pain except when the members benefit plan excludes coverage of such complications.
- Reoperation for intractable gastroesophageal reflux disease using Roux-en-Y anastomosis following a sleeve gastrectomy **may be considered medically necessary** for individuals who have objective historical documentation of diagnosed (e.g., upper endoscopy, 24-hour outpatient pH monitoring and Esophageal manometry) symptomatic gastroesophageal reflux disease that has either failed to respond to 6 months of medical therapy with proton pump inhibitors (PPIs) or the individual has a documented intolerance, FDA labeled contraindication, or hypersensitivity.

Repeat/Revisions

- Repeat/Revision of bariatric surgery: **may be considered medically necessary** only when specifically included as a benefit or covered service in the member's benefit plan, summary plan description or contract AND when **ALL** of the following criteria are met:
  - Technical surgical failure (e.g., dilatation of gastric pouch, gastrojejunal stoma, or gastrojejunostomy anastomosis; port leakage; or band slippage), has occurred that can only be addressed surgically, when the primary procedure was successful in inducing weight loss prior to the technical surgical failure, and the member has been compliant with a prescribed nutrition and exercise program; AND
  - The individual is requesting reinstitution of an acceptable bariatric surgical modality.

- Subsequent surgery for weight gain/failure to lose weight: When the indication is a weight gain OR a failure of the individual to lose a desired amount of weight due to the individual's non-compliance, then the individual must re-qualify and meet all of the initial preoperative criteria.

NOTE 9: When the initial bariatric surgical information is not available, medical information concerning the member's weight from other healthcare providers may be considered.

Procedures Performed Simultaneously with Bariatric Surgery

- Gallbladder removal during a bariatric surgery: **may be considered medically necessary** at the time of a covered gastric bypass surgical procedure, either for documented gallbladder disease or for prophylaxis.
- Repair of a hiatal hernia at the time of bariatric surgery **may be considered medically necessary** for individuals who have objective, historical documentation of a preoperatively-diagnosed (e.g., 24-hour outpatient pH monitoring and Esophageal manometry) symptomatic hiatal hernia that has either failed to respond to 6 months of medical therapy with proton pump inhibitors (PPIs) or the individual has a documented intolerance, FDA labeled contraindication, or hypersensitivity.
- Repair of a hiatal hernia at the time of bariatric surgery that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not have indications for surgical repair, **is considered not medically necessary**.
- Liver biopsy at the time of bariatric surgery **may be considered medically necessary** for individuals who have signs or symptoms of liver disease (e.g., history and physical, biochemical, and serological findings).

Policy Guidelines

Obesity Classifications

Per the Centers for Disease Control and Prevention (CDC), obesity is also frequently classified into the categories of:

- Class I: BMI of 30 to < 35 kg/m^2;
- Class II: BMI of 35 to < 40 kg/m^2; and
- Class III: BMI of 40 kg/m^2 or higher.

Class III obesity is sometimes categorized as "severe" obesity. (1)

*** Guidelines on how to calculate BMI**:

BMI can be calculated using pounds and inches with this equation:

BMI = [Weight (lbs) ÷ Height (in^2)] x 703

BMI can also be calculated using kilograms and meters:

BMI = Weight (Kg) ÷ Height (m^2)

To convert pounds to kilograms, multiply pounds by 0.45.
To convert inches to centimeters, multiply inches by 2.54.
To convert feet to meters multiply feet by 0.30.

Description

Bariatric surgery is performed to treat clinically severe obesity. Clinically severe obesity includes class III obesity, formerly referred to as morbid obesity, which is defined as a body mass index (BMI) greater than 40 kg/m^2 and class II obesity (BMI greater than 35 kg/m^2 to < 40kg/m^2) with associated high-risk complications including, but not limited to, type 2 diabetes (T2D), hypertension, or obstructive sleep apnea (OSA). Class III obesity results in a very high risk for weight-related complications, such as T2D, hypertension, OSA, and various types of cancers (for men: colon, rectum, prostate; for women: breast, uterine, ovarian), and a shortened life span. A man with class III obesity at age 20 can expect to live 13 fewer years than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of class III obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few individuals with class III obesity can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

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

Consideration for Bariatric Surgery

Rubino et al. (2016) reported on the 2nd Diabetes Surgery Summit (DSS-II), an international consensus conference that was convened in collaboration with six leading international diabetes organizations, one being the American Diabetes Association (ADA) and included endorsement of the consensus statements and guidelines from 45 leading professional societies across the globe, including the American Society for Metabolic and Bariatric Surgery (ASMBS). (161) The DSS-II made recommendations addressing BMI thresholds that included ancestry consideration. The following recommendations were noted:

- "Metabolic surgery should be a recommended option to treat T2D [type 2 diabetes] in appropriate surgical candidates with class III obesity (BMI ≥40 kg/m^2), regardless of the level of glycemic control or complexity of glucose-lowering regimens, as well as in patients with class II obesity (BMI 35.0–39.9 kg/m^2) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy."
- "All BMI thresholds should be reconsidered depending on the ancestry of the patient. For example, for patients of Asian descent, the BMI values above should be reduced by 2.5 kg/m^2."

Tanner Stages

The Tanner Staging or scale may be used to classify progression of puberty in children and adolescents. Stages of physical development/maturity are based on sex characteristics, for example – the development of genitalia in boys and the development of breasts in girls as well as pubic hair growth in both. Below the characteristic of each Tanner stage are described. (162-163)

Tanner Stages	Pubic Hair for both Male and Female	Female	Male
1	Pre-adolescent; no pubic hair.	Pre-adolescent; elevation of the papilla only.	Pre-adolescent; Testes, scrotum and penis about the same size and proportion as in early childhood.
2	Sparse growth of long, slightly pigmented, downy hair appearing at the base of the penis or along the labia.	Breast bud stage; elevation of breast and papilla. Enlargement of the diameter of the areola.	The scrotum and testes have enlarged. The scrotal skin has some reddening and change in texture.
3	Considerably darker, coarser, and more curled. Hair spreads sparsely over the junction of the pubes.	Further enlargement of breast and areola. No separation of their contours.	Growth of the penis first mainly in length; further growth of testes and scrotum.

4	Hair is adult in type, area of coverage is smaller than most adults. No spread to the medial surface of the thighs.	Areola and papilla form a secondary mound above the level of the breast.	Further enlargement in length and breadth of the penis with development of glans. Further enlargement of testes and scrotum. Darkening of the scrotal skin.
5	Adult in quantity and type; distributed in an inverse triangle. Spread to the medial surface of the thighs.	Mature stage: projection of papilla only, recession of the areola to the general contour of the breast.	Genitalia adult in size and shape.

Types of Bariatric Surgery Procedures

Open Gastric Bypass

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome," in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweets eaters." Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

NOTE 10: In 2005, CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared with the previous 100 cm. This change reflects the common practice in which the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

Laparoscopic Gastric Bypass

A CPT code was introduced in 2005, for laparoscopic gastric bypass which is the laparoscopic version of the open gastric bypass described above.

Adjustable Gastric Banding

Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting

stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two banding devices are approved by the U. S. Food and Drug Administration (FDA) for marketing in the United States. The first to receive FDA approval was the LAP-BAND (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). The labeled indications for this device are as follows: "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 comorbid conditions, or those who are 100 lb or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives."

In 2011, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m^2 with at least 1 obesity-related comorbid condition.

The second adjustable gastric banding device approved by the FDA through the premarket approval process is the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are:
“This [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a Body Mass Index of at least 40 kg/m^2, or a BMI of at least 35 kg/m^2 with one or more comorbid conditions. The Band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.”

Sleeve Gastrectomy

A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] with duodenal switch [DS]). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient’s overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., biliopancreatic diversion).

Biliopancreatic Diversion

The biliopancreatic diversion procedure (also known as the Scopinaro procedure), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:

- A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
- A 200-cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.
- A 300- to 400-cm "biliary tract" connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- A 50- to 100-cm "common tract" is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, creating selective malabsorption. The length of the common segment will influence the degree of malabsorption.

Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, several case reports have noted liver failure resulting in death or liver transplant.

Biliopancreatic Diversion With Duodenal Switch

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

Vertical-Banded Gastroplasty

Vertical-banded gastroplasty (VBG) was formerly one of the most common gastric restrictive procedures performed in the United States, but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is

segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter 2 requiring reoperation. Dilation of the stoma is a common reason for weight regain. VGB may be performed using an open or laparoscopic approach. Overall rates of revisions and reoperations at up to 10 years may be as high as 50%. (164-165) VBG is not included on the list of endorsed procedures by the American Society for Metabolic and Bariatric Surgery. (166)

Long-Limb Gastric Bypass (i.e., >150 cm)

Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways (e.g., resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses.

Laparoscopic Malabsorptive Procedure

This describes any of the malabsorptive/restrictive procedures done by laparoscopy.

Laparoscopic Gastric Plication

Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves 2 main steps mobilization of the greater curvature of the stomach and suture plication of the stomach.

Intragastric Balloon Devices

Intragastric balloon (IGB) devices are placed in the stomach via an endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2017, 2 IGB devices have U.S. FDA approval; each designed to stay in the stomach for no more than 6 months. The Obalon is a swallowable 3-balloon system and the OBERA Intragastric Balloon System (previously marketed outside of the United States as BioEnterics) is a saline-inflated silicone balloon.

Aspiration Therapy Device

Aspiration therapy (AT) involves an FDA-approved device (AspireAssist) that allows patients to drain a portion of the stomach contents after meals via an implanted tube connected to an external skin port.

Embolization of Gastric Arteries as a Treatment of Obesity

Bariatric arterial embolization (BAE) has been shown to modify body weight in animal models. The intent of BAE is to disrupt the arterial supply to the gastric fundus to reduce serum ghrelin levels; which stimulate appetite. Gastric artery embolization has recently been proposed as a minimally invasive intervention in the bariatric setting.

Vagus Nerve Blocking

Vagus nerve blocking therapy for obesity consists of an implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to intermittently block signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety. In January 2015, the FDA approved a medical device specifically designed to provide vagal nerve blocking therapy for regulation of weight in obese patients. This device, the Maestro Rechargeable System, includes a neuroblocking pulse generator that is implanted subcutaneously on the thoracic sidewall and flexible leads approximately 47 cm in length that are placed on the abdominal anterior and posterior vagal nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor, and customized software. The system delivers high-frequency pulses of electrical current to vagus nerve trunks; therapy parameters and the treatment schedule can be customized by a clinician.

Mini-Gastric Bypass

Recently, a variant of the gastric bypass, called the mini-gastric bypass, has been popularized. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. This unique aspect of this procedure is not based on its laparoscopic approach but rather the type of anastomosis used.

Endoluminal Bariatric Procedures

With endoluminal bariatric (also called endosurgical, endoscopic, or natural orifice) procedures, access to the relevant anatomic structures is gained through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce risks associated with open and laparoscopic interventions. Examples of endoluminal bariatric procedures studies include gastroplasty using a transoral endoscopically guided stapler and placement of devices such as a duodenojejunal sleeve and gastric balloon.

Weight Loss Outcomes

There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are the percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. Excess body weight is defined as actual weight minus “ideal weight” and

"ideal weight" and is based on 1983 Metropolitan Life Insurance height-weight tables for "medium frame."

These 2 reporting methods are generally preferred over the absolute amount of weight loss, because these methods reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 1 summarizes the variation in reporting weight loss outcomes.

Table 1. Weight Loss Outcomes

Outcome Measure	Definition	Clinical Significance
Decrease in weight	Absolute difference in weight pre- and post-treatment	Unclear relation to outcomes, especially in class III obesity
Decrease in body mass index (BMI)	Absolute difference in BMI pre- and post-treatment	May be clinically significant if change in BMI clearly leads to change in risk category
Percent of EBW loss	Amount of weight loss divided by EBW	Has anchor to help frame clinical significance; unclear threshold for clinical significance
Percent patients losing >50% of EBW	Number of patients losing >50% EBW divided by total patients	Additional advantage of framing on per patient basis. Threshold for significance (>50%) arbitrary
Percent ideal body weight	Final weight divided by ideal body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance

EBW: excess body weight

Durability of Weight Loss

Weight change (i.e., gain or loss) at yearly intervals is often reported. Weight loss at 1 year is considered the minimum length of time for evaluating these procedures; weight loss at 3 to 5 years is considered an intermediate time period for evaluating weight loss; and weight loss at 5 to 10 years or more is considered to represent long-term weight loss following bariatric surgery.

Short-Term Complications (Operative and Perioperative Complications <30 Days)

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative

complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (e.g., pneumonia, myocardial infarction).

Reoperation Rate

Reoperation may be required to either "take down" or revise the original procedure. Reoperation may be particularly common in vertical-banded gastroplasty (VBG) due to pouch dilation.

Long-Term Complications (Metabolic Adverse Effects, Nutritional Deficiencies)

Metabolic adverse effects are of particular concern in malabsorptive procedures. Other long-term complications include anastomotic ulcers, esophagitis, and procedure-specific complications such as band erosion or migration for gastric-banding surgeries.

Improved Health Outcomes in Terms of Weight-Related Comorbidities

Aside from psychosocial concerns, which may be considerable, one motivation for bariatric surgery is to decrease the incidence of complications of obesity, such as T2D, cardiovascular risk factors (i.e., increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, are not subject to regulation by the FDA.

Table 2 includes examples of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

Table 2: FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 mo treatment period.
AspireAssist System®	Aspire Bariatrics	June 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults

			>22 y, with a BMI of 35.0 to 55.0 kg/m^2 and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy
ORBERA® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30-40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
LAP-BAND® Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m^2 or a BMI of at least 30 kg/m^2 with ≥1 severe comorbid condition who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).
REALIZE® Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m^2, or a BMI of at least 35 kg/m^2 with ≥1 comorbid condition, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).

BMI: body mass index: FDA: Food and Drug Administration; mo: months; PMA: premarket approval.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intragastric balloons in response to reports of 2 types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. The second set of adverse event reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape (no longer marketed in the U.S.) and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers "instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications."

Rationale

Patient Selection Criteria for Coverage

A requirement that a candidate for bariatric surgery complete a formal, medically supervised weight loss programs of specified duration has been a fixture of Health Care Service Corporation (HCSC) bariatric surgery medical policy for some time. The rationale for this requirement was founded on review and interpretation of available evidence in the scientific medical literature, primarily national consensus guidelines. However, HCSC has decided to modify this requirement based on a current review of the bariatric surgery scientific literature related to required pre-surgery weight loss programs and including consideration of input from bariatric surgeons and their professional societies. The HCSC policy will no longer require documentation that a member with Class III obesity (morbidly obesity) must have completed a pre-surgery weight loss program of specified duration as one of the criteria for benefit coverage of bariatric surgery. This change does not mean, however, that HCSC no longer believes that successful bariatric surgery requires multi-disciplinary support from the member's bariatric surgery program and a life-long commitment to life-style changes.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The

quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Overview: Bariatric Surgery in Adults with Class III Obesity

There is a vast literature on bariatric surgery for adults with class III obesity. This literature is characterized by a preponderance of single-arm clinical series from individual institutions. These types of studies can be used to determine the amount of weight loss expected from surgery, the durability of the weight loss, and the rate of adverse events. However, these studies are not adequate for determining the comparative efficacy of bariatric surgery versus conservative treatment, or the comparative efficacy of different bariatric surgery techniques. Some comparative trials, including randomized and nonrandomized designs, compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedures. RCTs trials of bariatric surgery have been performed but are limited and insufficient to draw conclusions about comparisons of bariatric surgery and conservative treatments for weight loss. (2) RCTs are difficult in bariatric surgery because many experts consider it inappropriate or unethical to randomize patients to bariatric surgery. Also, most patients and clinicians have strong feelings about their preferences for treatment, which result in a select population that might agree to randomization and, therefore, limited generalizability. As a result, the emphasis for this policy is on comparative nonrandomized trials of bariatric surgery and nonsurgical therapy or of different types of bariatric surgery procedures.

Swedish Obese Subjects Trial

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34 kg/m^2 at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of comorbidities in the surgery group. A total of 2010 people chose surgery and 2037 people chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each surgeon chose the surgical procedure offered. Most procedures were vertical-banded gastroplasty (VBG; >70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. Patients were followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

Many publications from this trial have reported on methods, weight loss, and clinical outcomes. (3-6) The following general conclusions can be drawn from the SOS study:

- Weight loss was greater with bariatric surgery than with conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight compared with a weight gain of 1.6% in the conservative treatment group.
- There was significant improvement in glucose control for diabetics and reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors (e.g., hypertension, lipidemia) was also positive, but less marked than that seen for diabetes.
- Mortality was reduced by 29% after a mean follow-up of 10.9 years.
- Quality of life improved in the 2- to 10-year follow-up period, with the degree of improvement in quality of life correlated with the amount of weight loss.

Longitudinal Assessment of Bariatric Surgery Consortium

The Longitudinal Assessment of Bariatric Surgery Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass (RYGB) or laparoscopic adjustable gastric banding (LAGB) with follow-up through 3 years post-procedure. (7) The study enrolled 2458 subjects, with median a BMI 45.9 kg/m^2 (interquartile range [IQR], 41.7-51.5 kg/m^2). For their first bariatric surgical procedure, 1738 participants underwent RYGB, 610 LAGB, and 110 other procedures. At 3-year follow-up, for 1533 Roux-en-Y patients with available data, percentage of baseline weight lost was 31.5% (IQR, 24.6%-38.4%). For the 439 LAGB patients with available data at 3 years, the percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years post-surgery, 67.5% and 28.5% of RYGB and LAGB patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of RYGB and LAGB patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the RYGB patients and in 17.5% (95% CI, 13.8% to 21.9%) of LAGB patients.

National Patient-Centered Clinical Research Network - Bariatric Study

The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study is a large retrospective, comparative study of 65,093 patients aged 20 to 79 years who underwent RYGB (n= 32,208), LAGB (n=29,693), or sleeve gastrectomy (SG)(n=3,192) with follow-up through 5 years post-procedure. (8) Mean estimated percent total weight loss (%TWL) was calculated at 1, 3, and 5 years in addition to 30-day rates of major adverse events. Study results are summarized in Table 3. This study demonstrates that RYGB is associated with a greater weight loss than SG ($p<0.001$) and that LAGB is associated with the lowest amount of weight loss as observed in a large and diverse patient cohort.

Table 3. National Patient-Centered Clinical Research Network - Bariatric Study Results

	Mean TWL, % (95% CI)			**MAE Rate, % (95% CI)**
Group (n[a])	**1 Year**	**3 Years**	**5 Years**	**30 Days**
RYGB (19,029; 9225; 3676)	-31.2 (-31.3 to -31.1)	-29.0 (-29.2 to -28.8)	-25.5 (-25.9 to -25.1)	5.0 (NR)

LAGB (1681; 943; 337)	-13.7 (-14.0 to -13.3)	-12.7 (-13.5 to -12.0)	-11.7 (-13.1 to -10.2)	2.9 (NR)
SG (14,929; 5304; 1088)	-25.2 (-25.4 to -25.1)	-21.0 (-21.3 to -20.7)	-18.8 (-19.6 to -18.0)	2.6 (NR)

CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; MAE: major adverse event; NR: not reported; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; TWL: total weight loss.

[a] Number of patients evaluated at 1, 3, and 5 years, respectively.

Systematic Reviews

Numerous systematic reviews have compared the efficacy of bariatric surgery with conservative therapy or compared different types of bariatric surgery techniques, some of which are older and do not extend across the full range of available studies. (9-12)

Cosentino et al. (2021) performed a network meta-analysis of 43 RCTs comparing the efficacy of bariatric surgery versus medical therapy, as well as comparing different types of bariatric surgery techniques. (13) Most included trials were 1 year in duration, but a few extended to 5 years. Results demonstrated that surgery reduced BMI more effectively than medical therapy (mean difference [MD], -6.632 kg/m^2; 95% CI, -8.29 to -4.97), but increased risk for severe adverse events (odds ratio [OR], 3.06; 95% CI, 1.09 to 8.57). When comparing different procedures to medical therapy, duodenal switch (DS) and bilio-pancreatic diversion (BPD) appeared to be more effective than other procedures, whereas greater curvature plication, LAGB, and laparoscopic vertical banded gastroplasty (LVBG) produced a smaller weight loss than other interventions. When comparing different types of bariatric surgery techniques on BMI change, RYGB was superior to LAGB (MD, -4.26; 95% CI, -6.02 to -2.50; n=2 studies) and LVGB (MD, -3.05; 95% CI, -5.88 to -0.21; n=2 studies); the difference between RYGB and SG (n=12 studies), BPD (n=2 studies), gastric plication (n=3 studies), and one anastomosis/gastric bypass (OAGB; n=2 studies) did not reach statistical significance. Roux-en-Y gastric bypass was inferior to DS for BMI change (MD, 7.55; 95% CI, 6.35 to 8.75; 2 studies).

Park et al. (2019) conducted a systematic review with a network meta-analysis evaluating the comparative efficacy of various bariatric surgery techniques against standard-of-care in the treatment of morbid obesity and diabetes. (14) The literature search was conducted through February 2018, identifying 45 RCTs for inclusion on RYGB (2 studies versus control), SG (3 studies versus control), LAGB (5 studies versus control), and biliopancreatic diversion (BPD) with duodenal switch (BPD-DS; 3 studies versus RYGB). Based on 33 trials, superior efficacy for percent excess weight loss (EWL) compared to standard-of-care was seen for BPD-DS (mean difference [MD] 38.2%; 95% CI, 7.3% to 69.1%), RYGB (MD 32.1%; 95% CI, 3.1% to 61.1%), and SG (MD 32.5%; 95% CI, 5.5% to 59.5%) at 6 months post-procedure. LAGB was not superior to standard-of-care (MD -0.2%; -19.6% to 19.2%). At 3 years post-procedure, superior efficacy for percent EWL compared to standard-of-care was seen for RYGB (MD 45%; 95% CI, 21.8% to 68.2%) and SG (MD 39.2%; 95% CI, 15.2% to 63.3%). BPD-DS (relative risk [RR] 7.51; 95% CI, 1.91 to 29.54), RYGB (RR 7.51; 95% CI, 1.98 to 28.46), and SG (RR 6.69; 95% CI, 1.75 to 25.57) were all superior to standard-of-care with respect to remission rates at 3 to 5 years post-

procedure and remission rates were not significantly different among procedures. SG was found to have a relatively lower risk of adverse events compared to RYGB.

Kang et al. (2017) conducted a systematic review with a network meta-analysis that compared the 3 most common types of bariatric surgery techniques: RYGB, SG, and LAGB. (15) The literature search, conducted through July 2016, identified 11 RCTs for inclusion (8 RYGB versus SG; 2 RYGB versus LAGB; 1 SG versus LAGB). Quality of the trials was assessed using the Jadad score, based on allocation concealment, blinding, intention-to-treat analysis, power calculation, and funding. Most trials had a Jadad score of 3 (scale range, 1 to 5). A meta-analysis for the outcome of BMI reduction (6 trials) showed that there was no difference between SG and RYGB (0.7; 95% CI, -1.6 to 3.1). A meta-analysis of RYGB and LAGB (2 trials) and a single trial of SG and LAGB showed that LAGB was not as effective as RYGB or SG (5.8; 95% CI, 2.3 to 9.1; and 5.1; 95% CI, 0.9 to 8.9; respectively). Meta-analyses for the outcome of percent EWL showed the same pattern, no difference comparing SG and RYGB (5 trials; -4.0; 95% CI, -14.0 to 8.2), and both SG and RYGB more effective than LAGB (2 trials; 22.0; 95% CI, 6.5 to 34.0; 1 trial; 26.0; 95% CI, 6.4 to 41.0; respectively).

Colquitt et al. (2014) updated 2003 and 2009 Cochrane reviews of bariatric surgery for obesity. (16) The authors identified 22 randomized trials that compared bariatric surgery with nonsurgical obesity management or that compared different bariatric surgery procedures (N=1798 participants; sample size range, 15 to 250 participants). All 7 RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at 1- to 2-year follow-ups. However, reviewers noted that adverse event rates and reoperation rates were poorly reported across trials, and long-term follow-up (beyond 1 to 2 years) was limited. Gloy et al. (2013) conducted a systematic review and meta-analysis of RCTs comparing current bariatric surgery techniques with nonsurgical treatment for patients with a BMI of 30 kg/m^2 or more. (17) Eleven studies (N=796 patients) were included. Overall, patients after bariatric surgery lost more body weight than patients after nonsurgical treatment (MD, -26 kg; 95% CI, -31 to -21 kg; $p<0.001$). Remission of type 2 diabetes (T2D) was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of T2D remission, 22.1; 95% CI, 3.2 to 154.3; $p<0.000$); similarly, remission of metabolic syndrome was more likely for bariatric surgery patients (RR, 2.4; 95% CI, 1.6 to 3.6; $p<0.001$). After bariatric surgery, 21 (8%) of 261 patients required reoperations (5/124 after LAGB, 4/69 after RYGB, 1/49 after SG, 1/19 after BPD). Similar to the Colquitt et al. (2014) meta-analysis, no studies reported longer-term follow-up (>2 years) and heterogeneity between studies were high. Chang et al. (2014) published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery. (18) Reviewers included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean pre-surgery BMI was 45.62 kg/m^2 and, among the studies that provided information about obesity-related comorbidities, 26% of patients had T2D, 47% had hypertension, 28% had dyslipidemia, 7% had cardiovascular disease, and 25% had obstructive sleep apnea (OSA). Perioperative complications were relatively low, with a perioperative mortality rate in RCTs of 0.08% (95% CI, 0.01 to 0.24) and in observational studies of 0.22% (95% CI, 0.14 to 0.31). Complication rates were 17% (95% CI, 11 to 23) for RCTs and 10% for observational studies (95% CI, 7 to 13). At 1-year follow-up, mean change in BMI

was -13.53 kg/m^2 (95% CI, -15.51 to -11.55) in RCTs and -11.79 kg/m^2 (95% CI, -13.89 to -9.69 kg/m^2) in observational studies. Decreases in BMI were generally sustained over 2 to 4 years of follow-up among studies reporting this outcome. Puzziferri et al. (2014) conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies (total N=7,971 patients). (19) At follow-up, which ranged from 2 to 5 years post-procedure, the mean sample size–weighted percentage of excess weight loss (EWL) was higher for gastric bypass (65.7%) than for gastric banding (45.0%). Reviewers noted that few studies reported sufficient long-term results to minimize bias.

Many systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery. These reviews have relied primarily on the results of observational studies and included the outcomes of hypertension, T2D, hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease. (20-39)

Liu et al. (2021) performed a network meta-analysis of 35 RCTs (N=2,198) to compare the effects of bariatric surgery versus lifestyle/medical interventions on dyslipidemia and insulin resistance in patients who are overweight with or without T2D. (40) Compared with lifestyle/medical interventions, the Homeostasis Model Assessment for Insulin Resistance (HOMA-IR; a product of fasting circulating insulin and glucose concentrations divided by 22.5) was significantly lower with RYGB (MD, -3.93; 95% credible interval [CrI], -6.20 to -2.17), single anastomosis (mini-) gastric bypass (SAGB) (MD, -4.45; 95% CrI, -9.04 to -0.34), and SG (MD, -4.32; 95% CrI, -6.74 to -2.22). Compared with lifestyle/medical interventions, a statistically significant difference in the reduction of LDL-C was only reached with RYGB (MD, -0.51; 95% CrI, -0.85 to -0.16) and DS (MD, -0.90; 95% CrI, -1.66 to -0.16).

Wiggins et al. (2020) analyzed large-scale population studies to evaluate the association between bariatric surgery and long-term mortality and the incidence of new-onset obesity-related disease at a national level. (41) The analysis included 18 national or regional administrative database cohort studies involving patients who had undergone any bariatric procedure compared to an appropriate control group with a minimum follow-up of 18 months. Overall, 1,539,904 patients were included: 269,818 receiving a bariatric procedure and 1,270,086 controls. Results revealed that bariatric surgery was associated with a significant improvement in all-cause mortality (pooled odds ratio [POR], 0.62; 95% CI, 0.55 to 0.69; p<0.001), cardiovascular mortality (POR, 0.5; 95% CI, 0.35 to 0.71; p<0.001), T2D incidence (POR, 0.39; 95% CI, 0.18 to 0.83; p=0.01), hypertension (POR, 0.36; 95% CI, 0.32 to 0.4; p<0.001), dyslipidemia (POR, 0.33; 95% CI, 0.14 to 0.8; p=0.01), and ischemic heart disease (POR, 0.46; 95% CI, 0.29 to 0.73; p=0.001). Limitations of this analysis included inability to account for unmeasured variables, which may have not been equally distributed between patient groups due to the nonrandomized design of included studies, heterogeneity between studies regarding the nature of the control group utilized, and unexamined potential adverse effects related to bariatric surgery due to a lack of data.

Section Summary: Bariatric Surgery in Adults with Class III Obesity

There is a lack of large-scale RCTs with long-term follow-up comparing bariatric surgery with nonsurgical treatment for the general population of patients with morbid obesity. Evidence from nonrandomized comparative studies and case series and from meta-analyses of existing RCTs has consistently reported that bariatric surgery results in substantially greater weight loss than nonsurgical therapy. Data from the largest comparative study (the SOS study) has reported that bariatric surgery is associated with improvements in mortality, diabetes, cardiovascular risk factors, and quality of life.

Evidence for Specific Types of Bariatric Surgery Procedures

Gastric Bypass for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of gastric bypass is to provide a treatment option that is an alternative to or an improvement on existing therapies, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is gastric bypass. The procedure involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal); thus, food bypasses the duodenum and proximal small bowel.

Comparators

Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Negative outcomes can include surgical complications, including leakage and operative margin ulceration, and metabolic complications, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia.

The existing literature evaluating gastric bypass as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 10 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Cui et al. (2021) published a systematic review of 7 RCTs comparing long-term outcomes of RYGB (n=239) versus medical therapy (n=238) in obese patients with T2D. (42) Results demonstrated a higher likelihood of T2D remission with RYGB versus medical therapy at 1 year (RR, 18.01; 95% CI, 4.53 to 71.70), 3 years (RR, 29.58; 95% CI, 5.92 to 147.82), and 5 years (RR, 16.92; 95% CI, 4.15 to 69.00). The probability of achieving American Diabetes Association (ADA) treatment goals was also more likely with RYGB versus medical therapy at 1 year (RR, 3.99; 95% CI, 1.01 to 15.82), 3 years (RR, 3.16; 95% CI, 1.33 to 7.49), and 5 years (RR, 6.18; 95% CI, 1.69 to 22.68).

In 2016, Yan et al. published a systematic review of RCTs comparing gastric bypass and medical treatment in obese patients (i.e., BMI ≥30 kg/m^2) with T2D. (43) The primary study outcome was remission of T2D, which was reported in 5 of the 6 studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment (odds ratio [OR], 76.37; 95% CI, 20.70 to 271.73; p<0.001). In addition, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD = -6.54 kg/m^2; 95% CI, -9.28 to -3.80 kg/m^2; p<0.001).

Observational Studies

Arterburn et al. (2021) published a retrospective, matched cohort study to investigate weight loss among patients with severe obesity undergoing RYGB, SG, or nonsurgical treatment. (44) Among 17,258 RYGB, 13,900 SG, and 87,965 nonsurgical patients, the 5-year follow-up rate was 72.0%, 70.9%, and 64.5%, respectively. At 1, 5, and 10 years, RYGB patients had a %TWL of -28.35% (95% CI, -28.53 to -28.18), -21.74% (95% CI, -22.02 to -21.45), and -20.18% (95% CI, -21.00 to -19.34), respectively; at the same time points, nonsurgical patients had a %TWL of -0.22% (95% CI, -0.35 to -0.09), -2.24% (95% CI, -2.46 to -2.02), and -4.78% (95% CI, -5.51 to -4.04), respectively. At 1 and 5 years, SG patients had a %TWL of -22.98% (95% CI, -23.19 to -22.76) and -15.99% (95% CI, -16.58 to -15.40), respectively.

Wadden et al. (2019) reported on end-of-trial results from the Look AHEAD: Action for Health in Diabetes (Look AHEAD) trial, which evaluated outcomes in patients with T2D and obesity who

had self-selected to receive bariatric surgery after failing an assigned intensive lifestyle intervention (ILI) or a diabetes support and education (DSE) control therapy. (45) Patients who received bariatric surgery were significantly more likely to be female (p<0.001), younger (p<0.001), and have higher BMI at randomization (p<0.001). Patients underwent 127 RYGB, 58 LAGB, and 11 SG procedures, respectively. End-of-trial assessments were completed at 4.3 years post-surgery compared to 9.6 years post-randomization for the DSE and ILI participants. Patients undergoing RYGB, LAGB, or SG surgical procedures lost a mean of 22.4% ± 1.0%, 13.0% ± 1.5%, and 16.2% ± 3.3% of baseline weight, respectively. Twelve patients (6.1%) receiving bariatric surgery were randomized with a BMI <35 kg/m^2. The mean BMI was 37.0 ± 5.1, 37.1 ± 5.3, and 42.1 ± 5.8 for DSE, ILI, and surgery groups, respectively (p<0.001). Overall, surgically-treated patients lost a mean of 19.3% of baseline weight, compared with 5.8% and 3.3% for the ILI and DSE participants. Full diabetes remission was achieved by 7.6% of bariatric surgery participants compared to 1.1% of ILI and 1.1% of DSE participants. Full remission was significantly more common in surgically treated participants in ILI (RR 6.72; 95% CI, 3.35 to 13.48; p<0.001) or DSE (RR 7.07; 95% CI, 3.49 to 14.30; p<0.001) groups. Significantly greater reductions in waist circumference (p<0.001), triglyceride levels (ILI: p=0.03; DSE: p=0.02), and hemoglobin A1c (HbA1c) levels (p<0.001) were observed in surgically-treated patients compared to ILI or DSE groups. The study was limited by heterogeneity in baseline characteristics and choice of surgical procedure. Results were not stratified by surgery type or BMI range.

Section Summary: Gastric Bypass for Adults with Class III Obesity

Gastric bypass has been extensively studied. Systematic reviews found that gastric bypass improved health outcomes, including weight loss and remission of T2D.

Laparoscopic Adjustable Gastric Banding (LAGB) for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of LAGB is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is LAGB.

Comparators

Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating LAGB as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 2 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A publication by Ibrahim et al., (2017) reviewed 25,042 Medicare beneficiaries who underwent LAGB surgery; 18.5% (n=4,636) patients underwent 1 or more reoperation(s). Reoperation was prompted by the need for band removal (41.8%), band and port replacement (28.6%), and other requirements. (46) The rates of long-term complications reported raise concern about the impact of these events on the overall benefit-risk profile for LAGB.

In comparing LAGB with open gastric bypass, there are tradeoffs in terms of risks and benefits. LAGB is a less-invasive procedure associated with fewer procedural complications, decreased hospital stay, and earlier return to usual activities. However, benefits defined by the amount of weight lost are lower for LAGB. The patterns of long-term complications also differ between the 2 procedures. For LAGB, longer term adverse events related to the presence of a foreign body in the abdomen will occur and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

A 2012 systematic review by Chakravarty et al. (47) comparing LAGB with other bariatric surgery procedures included 5 RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (e.g., gastric bypass or sleeve gastrectomy [SG]). However, the short-term complication rate was lower with LAGB and no difference was found in quality of life after LAGB versus other procedures.

Prospective Studies
Dixon et al. (2018) published a prospective, industry-sponsored study of morbidly obese patients who underwent implantation of the adjustable gastric banding system (LAP-BAND) (48). Between 2009 and 2013, 652 patients with a mean BMI of 45.4 kg/m^2 were treated at 17 participating centers in the United States and Canada. At 5 years, the explant rate was 8.74% (95% CI: 6.6 to 10.9%). Excluding explants, 100 (15.3%) reoperations were necessary during the follow-up period. A mean weight loss of 18.7% was achieved by 2 years and maintained through 5-year follow-up. The study was limited by the lack of control group.

Section Summary: Laparoscopic Adjustable Gastric Banding for Adults with Class III Obesity
Systematic reviews of the literature have concluded that LAGB is a reasonable alternative to gastric bypass. There is less weight loss with LAGB; however, the procedure is associated with fewer serious adverse events.

Sleeve Gastrectomy (SG) for Adults with Class III Obesity
Clinical Context and Therapy Purpose
The purpose of SG is to provide a treatment option that is an alternative to or an improvement of existing therapies, such as standard medical care, in patients who are adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is SG, an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures. In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. This procedure can be done as an open or laparoscopic procedure.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating SG as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 5 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is

desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

SG may be performed as a stand-alone procedure or in combination with a malabsorptive procedure, such as the BPD with duodenal switch (BPD-DS). It has also been proposed as the first step in a 2-stage procedure, with gastric bypass or BPD as the second stage.

Numerous recent systematic reviews have compared SG and RYGB with regard to effects on weight, comorbidities, and complications. (49-54)

Lee et al. (2021) performed a meta-analysis evaluating long-term (5 years) outcomes of laparoscopic RYGB versus SG (Table 4). (55) A total of 33 studies (N=2,475) were included. Results demonstrated that RYGB resulted in a significantly greater decrease of BMI compared to SG at 1- and 3-years post-surgery; results at 5 years did not reach statistical significance (Table 5). A similar trend was seen for the resolution of dyslipidemia. Furthermore, neither RYGB nor SG was superior for the remission of T2D and hypertension at 5 years.

Gu et al. (2020) completed a meta-analysis of the medium- and long-term effects of laparoscopic SG and RYGB (Table 4). (49) The evaluation included 9038 patients from 28 studies. Overall, 5-year follow-up results revealed that laparoscopic RYGB was associated with an improvement in percentage of EWL and remission of T2D, hypertension, and dyslipidemia as compared to laparoscopic SG. Han et al. (2020) also published a systematic review and meta-analysis involving 18 studies (N=2917) that compared weight loss and comorbidity resolution between laparoscopic SG and RYGB (Table 4). (50) Results from this analysis revealed no significant difference in EWL or T2D resolution between the 2 procedures. Laparoscopic RYGB was found to be superior to SG with regard to dyslipidemia, hypertension, and gastroesophageal reflux disease (GERD) management; however, patients who underwent laparoscopic SG experienced fewer postoperative complications and reoperation rates.

Sharples et al. (2020) performed a systematic review and meta-analysis evaluating long-term (5 years) outcomes of RYGB and SG (Table 4). (51) Overall, both RYGB and SG resulted in sustained

weight loss and comorbidity control with RYGB associated with a greater percent EWL, improved dyslipidemia outcomes, and a reduced incidence of GERD (Table 5).

Shenoy et al. (2020) published a systematic review and meta-analysis of 9 studies that compared laparoscopic SG and RYGB in 2240 elderly (>55 years) patients. (52) Results revealed no significant differences between the 2 bariatric procedures with regard to the rate of early complications (3.6% LSG versus 5.8% LRYGB; p=0.15) and mortality (0.1% versus 0.8%; p=0.27). Additionally, there was no difference in EWL between the procedures at 1 year (Table 5); however, the authors recommended SG for high-risk elderly patients due to the reduced mortality and complication rates with this procedure. Another systematic review and meta-analysis by Xu et al. (2020) involving 19 studies also concluded that SG was the preferable option for elder obese patients 60 years and older as it was found to be non-inferior to RYGB with regard to efficacy, but overall had an improved safety profile. (56)

Osland et al. (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB (Table 4). (57) The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (N=865 patients). Four trials were included in meta-analyses comparing percent EWL between the 2 groups. Results at both 6- and 12-month follow-ups showed that the procedures are comparable (Table 5). Osland et al. (2020) recently published a continuation of their work that focused exclusively on long-term (5 year) weight outcomes of laparoscopic vertical SG versus RYGB. (58) This systematic review and meta-analysis included 5 studies (SG=520; RYGB=508) and results revealed that a statistically significant BMI loss was seen with both SG: -11.37 kg/m^2 (range: -6.3 to -15.7 kg/m^2) and RYGB: -12.6 kg/m^2 (range: -9.5 to -15.4 kg/m^2) at 5 years. However, differences in reporting parameters limit the ability to reliably compare outcomes using statistical methods and the results may have been impacted by large dropout rates and per protocol analyses of the 2 largest included studies.

A systematic review by Juodeikis and Brimas (2017) summarized evidence on long-term results after SG (Table 4). (59) Reviewers included an RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m^2. Mean duration of follow-up ranged from 5 to 11 years, and mean proportion of patients followed for 5 years was 68.5%. Seventeen studies (N=1501 patients) reported 5-year follow-up data. At 5 years, resolution of T2D, arterial hypertension, dyslipidemia, OSA, GERD, and degenerative joint diseases also improved in most patients (Table 5). Two studies reported weight loss after 7 and 8 years; percent EWL rates were 56.6% and 54.8%, respectively.

In a meta-analysis of 21 randomized and nonrandomized studies (N=18,766 patients) comparing SG with laparoscopic RYGB for morbid obesity, Zhang et al. (2015) reported no significant difference in percent EWL from 0.5- to 1.5-year follow-ups (Tables 4 and 5). (60) However, after 1.5 years, RYGB was associated with higher percent EWL (2-year MD=5.77; 95% CI, 4.29 to 7.25; p<0.05). Adverse events were more frequent following RYGB (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

Trastulli et al. (2013) conducted a systematic review of 15 RCTs (N=1,191 patients) that compared SG with other bariatric procedures (Table 4). (61) Summary statistics were provided; meta-analyses were not conducted (Table 5). Reviewers reported mean complication rates with SG of 12.1% (range, 10% to 13.2%) compared with 20.9% with LAGB (range, 10% to 26.4%). Percent EWL ranged from 49% to 81% with SG and from 62.1% to 94.4% with LAGB.

Brethauer et al. (2009) reviewed 36 studies (N=2,570 patients) in a systematic review of SG as a staged and primary procedure, the largest trials coming from European centers (Table 4). (62) Thirteen studies (n=821 patients) reported on high-risk patients having a staged approach and 24 studies (n=1,749 patients) on SG as the primary procedure. Mean percent EWL, reported in 24 studies (n=1,662 patients), was 55.4% overall. Mean postoperative BMI, reported in 26 studies (n=1,940 patients), decreased from a baseline of 51.2 to 37.1 kg/m^2. Other studies reported weight loss in terms of BMI decrease, the percentage of BMI lost, or percentage of total weight lost; all had significant reductions from baseline. Rates of major postoperative complications ranged from 0% to 23.8% for all studies and from 0% to 15.3% in studies with more than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies (n=2,570 patients). All extracted studies reported mortality data, with 5 deaths within 30 days of surgery (overall mortality rate, 0.19%; 2 in the high-risk/staged group, 3 in the primary procedure group).

Table 4. Systematic Review Characteristics for Sleeve Gastrectomy

Study	Dates	Studies	Participants	Design	Duration
Lee et al. (2021) (55)	Through Jan 2019	33	SG=1252; RYGB=1223	RCTs	1 to 5 years
Gu et al. (2020) (49)	Through Jan 2019	28	SG=4,597; RYGB=4,441	7 RCTs; 6 prospective; 15 retrospective	3 to 7 years
Han et al. (2020) (50)	Through Jan 2020	18	2,917	9 RCTs; 9 nonrandomized studies of interventions	1 to 82.2 months
Sharples et al. (2020) (51)	Through Dec 2018	5	729	RTCs	5 years
Shenoy et al. (2020) (52)	1991 to 2019	9	SG=683; RYGB=1,557	RCTs; observational studies	Minimum follow-up: 1 year
Osland et al. (2017) (57)	2000 to Nov 2017	9	SG=437; RYGB=428	RCTs	3 months to 5 years
Juodeikis et al. (2017) (59)	Through May 2016	20	1626	1 RCT; 19 retrospective	5 to 11 years

Zhang et al. (2015) (60)	Through Oct 2013	21	18,766	8 RCTs; 13 nonrandomized comparative	1 to 5 years
Trastulli et al. (2013) (61)	Through Nov 2012	15	1,191	RCTs	6 months to 3 years
Brethauer et al. (2009) (62)	1996 to 2009	36	2,570	2 RCTs; 1 cohort; 33 case series	3 months to 5 years

RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Table 5. Systematic Review Results for Sleeve Gastrectomy

Study	**BMI mean difference (95% CI)**	**Comorbidities (95% CI)**
Lee et al. (2021) (55)	Mean difference SG vs RYGB: 1 y (16 trials): -1.25 kg/m^2 (-2.01 to -0.49) 3 y (5 trials): -1.71 kg/m^2 (-2.68 to -0.74) 5 y (4 trials): -1.46 kg/m^2 (-3.15 to 0.23)	Remission, SG vs RYGB: T2D (1 y): RR, 0.86 (0.71 to 1.04) T2D (3 y): RR, 0.88 (0.72 to 1.07) T2D (5 y): RR, 0.79 (0.57 to 1.10) Hypertension (5 y): RR, 0.86 (0.68 to 1.10) Dyslipidemia (5 y): RR, 0.68 (0.46 to 1.23)
	Percent EWL (95% CI)	**Comorbidities (95% CI)**
Gu et al. (2020) (49)	Weighted mean difference, RYGB and SG: 3 y (13 trials): -4.37 (-8.10 to -0.64) 5 y (9 trials): -2.20 (-3.83 to -0.57)	Remission, RYGB and SG: T2D (3 y): OR, 0.68 (0.48 to 0.95) T2D (5 y): OR, 0.63 (0.41 to 0.96) Hypertension (5 y): OR, 0.51 (0.38 to 0.68) Dyslipidemia (5 y): OR, 0.3 (0.19 to 0.48)
Han et al. (2020) (50)	Mean difference, RYGB and SG: RCTs: -0.16 (-0.52 to 0.19)	Resolution, RYGB and SG: T2D: RR, 1.07 (0.89 to 1.28) Dyslipidemia: RR, 1.36 (1.17 to 1.59) Hypertension: RR, 1.23 (1.04 to 1.45) GERD symptoms: RR, 0.16 (0.06 to 0.44)
Sharples et al. (2020) (51)	5 years: RYGB: 65.7% SG: 57.3%	RYGB vs. SG at 5 years: T2D resolution: 37.4% vs. 27.5% Diabetes improvement: 77.5% vs. 74% Hypertension resolution: 60.1% vs. 48.4% Hypertension improvement: 86.4% vs. 76.6% Dyslipidemia resolution: 68.6% vs. 55.2% GERD remission: 60.4% vs. 25%
Shenoy et al. (2020) (52)	Mean difference, RYGB and SG: -7.79 (-23.96 to 8.38)	Resolution, RYGB and SG: T2D (5 studies): OR, 1.02 (0.63 to 1.66)

		Hypertension (4 studies): OR, 0.57 (0.35 to 0.93) Obstructive sleep apnea (2 studies): OR, 1.14 (0.55 to 2.34)
Osland et al. (2017) (57)	Mean difference, SG and RYGB: 6 months (3 trials): 0.5 (-5.0 to 6.0) 12 months (2 trials): 7.6 (-0.1 to 15.3)	NR
Juodeikis et al. (2017) (59)	Mean rates for SG: 5 y (17 trials): 58.4% 7 y (2 trials): 56.6% 11 y (1 trial): 62.5%	Remission/improvement: T2D: 77.8% Hypertension: 68.0% Dyslipidemia: 65.9% Sleep apnea: 75.8%
Zhang et al. (2015) (60)	Mean difference, RYGB and SG: 6 months (9 studies): 0.2 (-2.5 to 2.9) 12 months (15 studies): 2.9 (-0.2 to 6.0) 4 years (3 studies): 2.7 (0.2 to 5.2)	Mean difference resolution, RYGB and SG: T2D (10 studies): 3.3 (2.0 to 5.5) Hypertension (10 studies): 1.3 (0.7 to 2.4) Dyslipidemia (5 studies): 1.1 (0.3 to 1.3) Sleep apnea (7 studies): 1.5 (0.8 to 2.6)
Trastulli et al. (2013) (61)	Mean by procedure: SG: 49% to 81% LGB: 62% to 94% LAGB: 29% to 48%	T2D: SG, 67% to 100% LGB, 80% to 100%
Brethauer et al. (2009) (62)	Mean rate overall for SG: 55% (range, 33% to 85%)	Remission/improvement: T2D: >70% Significant reductions also seen in hypertension, hyperlipidemia, and sleep apnea

BMI: body mass index; CI: confidence interval; EWL: excess body weight loss; GERD: gastroesophageal reflux disease; LAGB: laparoscopic adjustable gastric banding; LGB: laparoscopic gastric bypass; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2D: type 2 diabetes; y: years.

Randomized Controlled Trials

Hofso et al. (2019) published the results of a single-center, triple-blind RCT comparing the efficacy of RYGB (n=54) versus SG (n=55) on diabetes remission and ß-cell function in patients with obesity and T2D. (63) Inclusion criteria included previously verified BMI ≥35 kg/m^2 and current BMI ≥33.0 kg/m^2, HbA1c ≥6.5% or use of antidiabetic medications with HbA1c ≥6.1%, and age ≥18 years. One-year follow-up was completed by 107 (98%) of 109 patients, with 1 patient in each group withdrawing after surgery. In the intention-to-treat population, diabetes

remission rates were superior in the gastric bypass group than in the SG group (risk difference 27%; 95% CI, 10 to 44; RR 1.57, 95% CI, 1.14 to 2.16; p=0.0054). Results were similar in the per-protocol population (risk difference 27%; 95% CI, 10 to 45; RR 1.57; 95% CI, 1.14 to 2.15; p=0.0036). The 2 procedures had a similar beneficial effect on ß-cell function.

Peterli et al. (2018) published a randomized study of adults with morbid obesity treated with either laparoscopic sleeve gastrectomy (LSG) or RYGB. (64) Two hundred five patients (mean age, 45.5 years; mean BMI, 43.9; 72% women) treated at 4 Swiss bariatric centers were randomly assigned to receive SG (n=101) or RYGB (n=104) with 5-year follow-up. Excess BMI loss was 61.6% for SG and 68.3% for RYGB (95% CI: -14.30 to -0.06; p=0.22). Gastric reflux remission was seen in 25.0% of SG and 60.4% of RYGB patients. Reoperations or interventions were necessary for 16/101 (15.8%) in the SG group and 23/104 (22.1%) of the RYGB group. The study was limited by the lack of analysis of diabetes remission information, and the results may not be generalizable.

Salminen et al. (2018) published a randomized trial, Laparoscopic Gastric Bypass vs. Laparoscopic Sleeve Gastrectomy in the Treatment of Morbid Obesity (SLEEVEPASS), comparing 5-year outcomes of morbidly obese patients (n=240; mean age, 48 years; mean baseline BMI, 45.9; 69.6% women) who underwent either LSG (n=121) or RYGB (n=119). (65) Five-year estimated mean percentage excess BMI loss was 49% (95% CI: 45 to 52) for SG and 57% (95% CI: 53 to 61) for gastric bypass. For SG and RYGB, respectively, rates of remission of T2D were 37% (n=15/41) and 45% (n=18/40; p>0.99). Medication for hypertension was discontinued in 20/68 (29%) SG patients and 37/73 (51%) RYGB patients (p=0.02). Overall, 5-year morbidity rate was 19% for SG and 26% for RYGB (p=0.19), and there was no significant difference in quality of life between groups (p=0.85). The study was limited by the following: 1) only a small number (n=430) of bariatric procedures were performed in Finland at trial initiation in 2008, meaning a learning curve could account for some earlier technical complications, 2) the study had a higher reoperation rate for SG than other trials reported, 3) approximately 20% of patients were lost to follow-up, and 4) there was a lack of reliable information for diabetes duration at baseline.

Wolnerhanssen et al. (2021) pooled 5-year outcomes data from the 2018 studies by Peterli et al. and Salminen et al. (66) Five-year follow-up was available for 199 of 228 patients after SG and 199 of 229 after RYGB. Patients who underwent SG had an estimated 7% greater excess BMI loss versus RYGB (p<.001). While remission rates for hypertension were better after RYGB versus SG (60.3% vs 44.9%; p<.049), between-group differences in rates of remission of T2D, OSA, or quality of life scores did not reach statistical significance. The rate of complications was higher after RYGB versus SG (37.2% vs 22.5%; p=.001), but there was no difference in mean Comprehensive Complication Index value (30.6 vs 31.0 points; p=.859).

An RCT comparing short-term outcomes of LSG with gastric bypass was published in 2012. (67) Trialists compared 30-day outcomes for 117 patients randomized to gastric bypass and 121 patients randomized to LSG. The rate of major complications (no deaths in either group) was 9.4% in the gastric bypass group compared to 5.8% in the LSG group (p=0.29). Minor

complications were more common in the gastric bypass group than in the LSG group (17.1% vs 7.4%, p=0.02), as were combined major and minor complications (26.5% vs 13.2%, p=0.01).

Karamanakos et al. (2008) carried out a double-blind RCT to compare outcomes of laparoscopic RYGB and laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery. (68) Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI were marked and comparable in each group. EWL was greater after LSG than laparoscopic RYGB at 6 months (55.5% vs 50.2%; p=0.04) and 12 months (69.7% vs 60.5%; p=0.05), all respectively. Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but decreased more after LSG.

Himpens et al. (2006) reported on a randomized trial comparing LAGB with isolated laparoscopic LSG in 80 patients and reported 3 year follow-up. (69) Median baseline BMI was 37 kg/m^2 (range, 30-47 kg/m^2) in the LAGB group and 39 kg/m^2 (range, 30-53 kg/m^2) in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, GERD, complications, and reoperations were recorded at 1- and 3-year follow-ups. Median decrease in BMI in the gastric bypass group was 15.5 kg/m^2 (range, 5-39 kg/m^2) after 1 year and 18 kg/m^2 (range, 0-39 kg/m^2) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m^2 (range, 0-45 kg/m^2) and 27.5 kg/m^2 (range, 0-48 kg/m^2) after 3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the difference was not statistically significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relation reversed at 3 years; between-group differences were not statistically significant at either time point. Two SG patients required reoperation for complications. Seven late complications required reoperation after LAGB, including pouch dilations treated by band removal (n=2) or conversion to RYGB (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 system disconnections that required reconnection. Four patients had reoperations for lack of efficacy (2 LAGB patients underwent conversion to RYGB, 2 SG patients underwent conversion to duodenal switch). The trialists noted that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.

Section Summary: Sleeve Gastrectomy for Adults with Class III Obesity

Systematic reviews of RCTs and observational studies, evaluating SG alone and comparing SG with RYGB, have found that SG results in substantial weight loss, comparable to RYGB and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG or gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events.

Biliopancreatic Diversion With Duodenal Switch (BPD-DS) for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of BPD-DS is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is BPD-DS. BPD may be performed with or without the duodenal switch procedure. In the BPD-DS, a SG is performed, preserving the pyloric sphincter. Preservation of the pyloric sphincter is intended to ameliorate dumping syndrome and to decrease the incidence of ulcers at the duodeno-ileal junction by providing a more physiologic transfer of stomach contents to the duodenum.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating BPD-DS as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 15 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Review

In a 2009 evidence-based review of literature, Farrell et al. summarized data on BPD with or without duodenal switch, RYGB (proximal), and LAGB, and reported that at a mean 1-year follow-up, EWL for BPD with or without duodenal switch (outcomes with and without duodenal switch not reported separately) was 72% (4 studies; n=896 patients), 67% for RYGB (7 studies; n=1627 patients), and 42% for LAGB (11 studies; n=4456 patients). (70) At mean follow-up of 5 years, EWL for BPD with or without duodenal switch was 73% (3 studies; n=174 patients), 58% for RYGB (3 studies; n=176 patients), and 55% for LAGB (5 studies; n=640 patients). Reviewers noted that "given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for 1 procedure over another."

Nonrandomized Comparative Studies

Skogar et al. (2017) published results from a retrospective mail survey of patients undergoing BPD-DS (n=113) or RYGB (n=98) (Table 6). (71) Reduction in BMI was statistically larger in patients receiving BPD-DS compared with patients receiving RYGB. Both groups experienced significant reductions in diabetes and OSA. Significant reductions in dyslipidemia were only seen in the group receiving BPD-DS. The overall complication rate was lower for patients undergoing RYGB.

Strain et al. (2007) published a smaller comparative study of 72 patients who underwent RYGB (n=50) or BPD (n=22) (Table 6). (72) Choice of surgery was by the surgeon and/or patient, and the patient populations differed by age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 10.6 kg/m^2 (23.3 lb) for BPD compared with 7.5 kg/m^2 (16.5 lb) for RYGB ($p<0.001$).

Prachand et al. (2006) published the largest comparative study of 350 super-obese patients with a BMI greater than 22.7 kg (50 lb) who underwent RYGB (n=152) or Scopinaro BPD combined with the DeMeester BPD-DS (n=198) (Table 6). (73) In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The BPD-DS patients differed from RYGB patients on baseline weight and BMI; mean weight was 167 kg (368 lb; range, 267 to 597 lb) in BPD-DS patients and 157 kg (346 lb; range, 240 to 505 lb) in the RYGB group, and mean BMI was 27 kg/m^2 (59 lb; range, 50 to 96 lb) in BPD-DS patients versus 26 kg/m^2 (56 lb; range, 50 to 84 lb) in the RYGB group. At 1 year, data were reported for 143 BPD-DS patients and 81 RYGB patients (Table 7). EWL was greater for BPD (64.1%) versus RYGB (55.9%; $p<0.01$), and the reduction in BMI was also greater with BPD (10.7 kg/m^2 [23.6 lb]) versus RYGB (8.8 kg/m^2 [19.4 lb]; $p<0.001$). Complications and data on the resolution of comorbidities were not reported.

Table 6. Nonrandomized Comparative Study Characteristics for Biliopancreatic Diversion with Duodenal Switch

Study	Country	Dates	Participants	Follow-Up
Skogar et al. (2017) (71)	Sweden	2003-2012	BPD-DS:113 RYGB: 98	4 years

Strain et al. (2007) (72)	United States	2002-2005	BPD-DS: 22 RYGB: 50	BPD-DS: 19 months RYGB: 15 months
Prachand et al. (2006) (73)	United States	2002-2005	BPD-DS:198 RYGB: 152	3 years

BPD-DS: biliopancreatic diversion with duodenal switch; RYGB: Roux-en-Y gastric bypass.

Table 7. Nonrandomized Comparative Study Results for Biliopancreatic Diversion with Duodenal Switch

Study	**Mean Reduction in BMI (SD)**		**Percent Achieving ≥50% EWL**			
	Presurgery, kg/m²	**Postsurgery, kg/m²**	**p[a]**	**1 Year**	**2 Years**	**3 Years**
Skogar et al. (2017) (71) BPD-DS RYGB	56 (6.7) 52 (4.0)	31 (5.5) 36 (7.1)	<0.01	NR NR		
Strain et al. (2007) (72) BPD-DS RYGB	54 (11.9) 48 (6.3)	30 (6.1) 31 (5.0)	<0.001	NR NR		
		Change in BMI				
Prachand et al. (2006) (73) BPD-DS RYGB	59 (6.7) 56 (6.8)	27.8 18.9	<0.01	83.9 70.4[b]	89.2 79.3	84.2 59.3[b]

BMI: body mass index; BPD-DS: biliopancreatic diversion with duodenal switch; EWL: excess weight loss; NR: not reported; RYGB: Roux-en-Y gastric bypass; SD: standard deviation.
[a] Between groups, difference in change.
[b] p<0.05.

Case Series

Strain et al. (2017) reported on the nutrient status of 190 patients receiving BPD-DS after 9 years of follow-up. (74) At baseline, the patients had a mean age of 43 years and mean BMI of 53 kg/m^2. All patients reported taking some supplements. Deficiencies in protein, iron, and calcium developed by year 3 and continued through the study. Zinc deficiencies developed by year 5. Folate levels increased during the study, probably due to the efficacy of the supplement.

The authors warned that interventions need to be implemented to improve nutrient status in patients receiving BDP-DS.

The largest case series of this procedure is by Marceau et al. (2009), who reported their 15-year experience with duodenal switch in 1423 patients from 1992 to 2005. (75) Follow-up evaluations were available for 97% of patients. Survival rate was 92%. After a mean of 7 years (range, 2-15 years), 92% of patients with an initial BMI of 50 kg/m^2 or less obtained a BMI of 35 kg/m^2 or less, and 83% of patients with BMI greater than 50 kg/m^2 achieved a BMI of less than 40 kg/m^2. Diabetes medication was discontinued in 92% and decreased in others. Use of continuous positive airway pressure was discontinued in 92% of patients, and the prevalence of cardiac risk index greater than 5 decreased by 86%. Operative mortality was 1%, the revision rate was 0.7%, and the reversal rate was 0.2%. Revision for failure to lose sufficient weight was needed in only 1.5% of patients. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage.

Section Summary: BPD with Duodenal Switch for Adults with Class III Obesity
Nonrandomized comparative studies have found significantly higher weight loss after BPB-DS compared with gastric bypass at 1 year. A large case series found sustained weight loss after 7 years.

Biliopancreatic Diversion without Duodenal Switch for Adults with Class III Obesity
Clinical Context and Therapy Purpose
The purpose of BPD without DS is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is BPD without DS.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating BPD without DS as a treatment for class III obesity has varying lengths of follow-up, ranging to 9 years. While studies described below all reported at least 1

outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized and Nonrandomized Studies

Complication rates have been poorly reported in these trials. The data have suggested that mortality is low (1%) and in the same range as for open gastric bypass. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data have suggested that long-term nutritional and vitamin deficiencies occur at a high rate following BPD. Slater et al. (2004) focused specifically on vitamin and calcium deficiencies following BPD. (76) The authors reported high rates of vitamin and calcium abnormalities in their population over a 4-year period. By year 4, 48% of patients had low calcium, and 63% had low levels of vitamin D. Other fat-soluble vitamins showed similar patterns of abnormalities. Low vitamin A was found in 69% of patients at 4 years, low vitamin K in 68%, and low zinc in 50%. Dolan et al. (2004) reported similar data in a study that compared several technical variations of BPD. (77) The authors reported low calcium levels in 12% to 34% of patients, low vitamin D in 22.2% to 70.6%, low vitamin A in 53% to 67%, and low vitamin K in 44% to 59%. Also, this study reported high rates of iron deficiency (11% to 47%) and anemia (11% to 40%).

Skroubis et al. (2006) randomized 130 patients with a BMI of 35 to 50 kg/m^2 to RYGB or BPB without duodenal switch using a variant of BPD that included Roux-en-Y gastrectomy in place of SG. (78) All patients were followed for at least 2 years. Weight loss outcomes were superior for the BPD group at every interval examined up to 2 years. EWL at 1 year was 73.7% for RYGB and 83.1% for BPD ($p<0.001$); at 3 years, EWL was 72.6% for RYGB and 83.1% for BPD ($p<0.001$). There were more early complications in the RYGB group, but this difference was not statistically significant (6 complications vs 1, respectively; $p=0.12$). Late complications also did not differ significantly between the RYGB group (16 complications) and BPD groups (22 complications; $p=0.46$).

Case Series

Numerous clinical series of BPD have been published but high-quality trials directly comparing outcomes of this procedure with gastric bypass are lacking. The largest experience with BPD (total N=1217 patients) was reported by Scopinaro et al. (1996), who developed the procedure. (79) With follow-up of up to 9 years, the authors reported a durable EWL of 75%, suggesting that weight loss is greater with this procedure than with gastric restrictive procedures. Also, most patients reported disappearance or improvement of complications such as OSA, hypertension, hypercholesteremia, and diabetes. The authors considered protein malnutrition the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication could require inpatient treatment with total parenteral nutrition. To address protein malnutrition, 4% of patients underwent reoperation to elongate the common limb (thus increasing protein absorption) or to have the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity and, presumably, patient eating habits, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients were encouraged to maintain an oral calcium intake of 2 g/d, with monthly vitamin D supplementation.

Section Summary: Biliopancreatic Diversion without Duodenal Switch for Adults with Class III Obesity

Weight loss was similar after BPD without the DS and gastric bypass. However, BPD without duodenal switch leads to complications, especially long-term nutritional and vitamin deficiencies.

Vertical-Banded Gastroplasty (VBG) for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of VBG is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is VBG. In this procedure, the stomach is segmented along its vertical axis, a plug of the stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. It can be performed using an open or laparoscopic approach.

Comparators

Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Negative outcomes associated with VBG include complications such as esophageal reflux, dilation, or obstruction of the stoma.

The existing literature evaluating VBG as a treatment for class III obesity has varying lengths of follow-up, ranging from 3 to 10 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 3 to 10 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Hseih et al. (2014) conducted a systematic review of studies reporting greater than 10-year follow-up for VBG, which included 3 studies with extractable data. (80) Mean EWL was 61.4% from baseline to follow-up in the 3 studies, but reviewers noted a lack of long-term evidence related to outcomes following VBG.

Randomized Controlled Trials
A small body of literature has compared outcomes between VBG and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study (1990), randomized 310 morbidly obese patients to gastric bypass, VBG, or horizontal gastroplasty. (81) The percentage of patients with greater than 50% EWL at 3-year follow-up was 67% for gastric bypass, 48% for VBG, and 17% for horizontal gastroplasty ($p<0.001$). There were no demonstrable differences in adverse events across groups.

A second, smaller RCT by Sugerman et al. (1987) randomized 40 patients to a VBG or a gastric bypass procedure. (82) After 9 months, the gastric bypass patients had significantly greater weight loss that was maintained at 3-year follow-up. The gastric bypass patients lost

approximately 64% of excess weight, whereas the gastroplasty patients lost 37% of excess weight.

Case Series
Relatively high rates of complications, revisions, and reoperations led to the abandonment of VBG as a bariatric surgery procedure in the United States. An example of these results is a large case series with long-term follow-up by MacLean et al. (1990), who reported on 201 patients undergoing VBG followed for a minimum of 2 years. (83) Staple line perforation occurred in 48% of patients, and 36% underwent reoperation either to repair the perforation or to repair a stenosis at the rate-limiting orifice. However, the more than 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight.

Section Summary: Vertical-Banded Gastroplasty for Adults with Class III Obesity
Weight loss was significantly greater with open gastric bypass than with VBG. Also, VBG has relatively high rates of complications, revisions, and reoperations.

Two-Stage Bariatric Surgery Procedures for Adults with Class III Obesity
Clinical Context and Therapy Purpose
The purpose of 2-stage bariatric surgery procedures is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is 2-stage bariatric surgery. Bariatric surgeries performed in 2 stages have been proposed as a treatment option, particularly for patients with "super-obesity" defined as a BMI greater than 50 kg/m^2. The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients who are extremely obese. Therefore, a procedure with low-risk (usually an SG) is performed first. After the patient loses some weight, thus lowering the surgical risk, a second more extensive procedure (e. g., BPD) is performed.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating 2-stage bariatric surgery as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 5 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 to 5 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trial

Coffin et al. (2017) published results on the use of intragastric balloon (IGB) prior to a laparoscopic gastric bypass in patients with super-obesity. (84) Patients with a BMI greater than 45 kg/m^2 were randomized to an IGB (n=55) or standard medical care (n=60) during the 6 months prior to a planned laparoscopic gastric bypass procedure. Five patients had the IGB removed earlier than 6 months due to complications (n=3) or patient request (n=2). Patients receiving IGBs during the first 6 months of the study experienced significantly more BMI reduction (2.8 kg/m^2; range 1.7 to 6.2 kg/m^2) than patients receiving standard care (0.4 kg/m^2; range 0.3 to 2.2 kg/m^2). Weight loss during months 6 through 12, after the laparoscopic gastric bypass procedure, was greater in the patients who received standard of care before the procedure. Duration of hospitalization after laparoscopic gastric bypass and quality of life did not differ between groups.

Case Series

Most of the evidence on 2-stage procedures consists of case series of patients undergoing SG as the initial procedure. Many do not report on the second-stage surgery. A minority of patients undergoing first-stage surgery proceed to second-stage surgery. Cottam et al. (2006) reported on 126 patients with a mean BMI of 65 kg/m^2 who underwent LSG as the first phase of a planned 2-stage procedure. (85) The incidence of major perioperative complications for LSG was 13%. After 1 year, mean EWL was 46%. Thirty-six (29%) patients proceeded to the second-stage procedure, which was laparoscopic gastric bypass. The incidence of major complications following the second procedure was 8%.

In a similar study, Alexandrou et al. (2012) reported on 41 patients who underwent SG as the first-stage of a planned 2-stage procedure. (86) After 1-year of follow-up, 12 (29%) patients achieved a BMI of less than 35 kg/m^2 and were ineligible for the second-stage procedure. Of the remaining 28 patients, 10 (24%) underwent the second-stage procedure. The remaining 18

(44%) patients were eligible for but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al. (2009) described the complication rates in 87 patients who underwent a stage 1 SG followed by BPD in 27 patients. (87) For the first stage, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, 29.6% had major complications, including bleeding, duodeno-ileal stenosis, and rhabdomyolysis.

Section Summary: Two-Stage Bariatric Surgery Procedures for Adults with Class III Obesity

The evidence from an RCT and several case series does not support a 2-stage bariatric surgery procedure for improving outcomes in patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year so that a second procedure is no longer indicated. Also, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.

Laparoscopic Gastric Plication for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of laparoscopic gastric plication is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is laparoscopic gastric plication. Laparoscopic gastric plication is a bariatric procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. To achieve gastric restriction the procedure requires 2 main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach.

Comparators

Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating laparoscopic gastric plication as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 12 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Li et al. (2021) reported on a systematic review of 18 studies (N=1,329) comparing outcomes after laparoscopic SG versus laparoscopic greater curvature gastric plication. (88) Results demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities such as T2D, hypertension, and OSA did not reach statistical significance between groups, nor did the risks of major complications or mortality.

Ji et al. (2014) reported on a systematic review of 14 studies reporting outcomes after laparoscopic gastric plication. (89) Reviewers included a nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports. The nonrandomized cohort study was small (N=19). Only 3 studies identified included more than 100 patients. Mean preoperative BMI ranged from 31.2 to 44.5 kg/m^2. Mean percent EWL after the procedure was reported in 9 studies (n=1,407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from 6 to 24 months. One study reported weight loss in terms of percent decrease in BMI, with a reported decrease at 6 and 12 months of 66.4% and 60.2%, respectively. One study compared anterior plication with greater curvature plication and reported increased weight loss with greater curvature plication (percent EWL, 53.7% versus 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no deaths were reported, and the rate of major postoperative complications requiring reoperation ranged from 0% to 15.4% (average,

3.7%), most commonly due to gastric obstruction or gastric perforation. Surgical techniques were not standardized.

In a systematic review, Abdelbaki et al. (2012) summarized outcomes from 7 studies of laparoscopic gastric plication, 2 of which enrolled more than 100 patients (N=307 patients). (90) All studies reported some incidence of nausea and vomiting, most of which were mild. Twenty (6.5%) patients were readmitted, of whom 14 (4.6%) patients required reoperation, most commonly for gastric obstruction (8/14 [57%]). Table 8 provides a comparison of the studies included in these systematic reviews. Tables 9 and 10 discuss characteristics and results, respectively.

Table 8. Comparison of Trials/Studies Included in Systematic Review (SR) & Meta-analysis (M-A)

Study	Li et al. (2021) (88)	Ji et al. (2014) (89)	Abdelbaki et al. (2012) (90)
Abdelbaki et al. (2014)	●		
Abdelnazer et al. (2016)	●		
Abouzeid et al. (2015)	●		
Atlas et al. (2013)		●	
Brethauer et al. (2011)		●	●
Buzga et al. (2017)	●		
Casajoana et al. (2017)	●		
Chouillard et al. (2015)	●		
Fried et al. (2012)		●	
Grubnik et al. (2015)	●		
Hi et al. (2012)		●	
Li et al. (2018)	●		
Lopeznava et al. (2020)	●		
Morshed et al. (2011)	●		
Miu et al. (2013)		●	
Nabil et al. (2018)	●		
Neagoe et al. (2019)	●		
Niazi et al. (2013)		●	
Park et al. (2017)	●		

Pujol Gebelli et al. (2011)		●	●
Ramos et al. (2010)		●	●
Sharma et al. (2014)	●		
Skrekas et al. (2011)		●	●
Shen et al. (2013)	●	●	
Taha et al. (2012)		●	
Talebpour et al. (2007)			●
Talebpour et al. (2017)	●	●	
Toprak et al. (2015)	●		
Tsang et al. (2012)		●	●
Verdi et al. (2015)	●		
Watkins et al. (2012)		●	●

M-A: meta-analysis; SR: systematic review.

Table 9. Systematic Review Characteristics for Laparoscopic Gastric Plication

Study	Dates	Studies	Participants	Design	Duration
Li et al. (2021) (88)	Dec 2020	18	1329	6 retrospective cohort; 7 prospective cohort; 5 RCTs	1 month to 3 years
Ji et al. (2014) (89)	Jun 2013	14	1450	1 matched cohort; 10 case series; 3 case reports	6 months to 10 years
Abdelbaki et al. (2012) (90)	NR	7	307	5 case series; 2 case reports	3 years

NR: not reported; RCT: randomized controlled trial.

Table 10. Systematic Review Results for Laparoscopic Gastric Plication

Study	% Excessive Weight Loss	Complication	Conclusions
Li et al. (2021) (88)	MD (95% CI) between SG and gastric plication: 6 mo: 5.37 (1.59 to 9.16) 12 mo: 13.23 (9.93 to 16.54) 24 mo: 19.62 (1.15 to 38.08) 36 mo: 24.63 (-1.94 to 51.21)	OR (95% CI) between SG and gastric plication: Bleeding: 1.37 (0.61 to 3.09) Stenosis: 0.57 (0.23 to 1.38)	SG is superior to gastric plication with regard to providing effective weight loss in the short- and mid-term. The procedures are similar in terms of major complications.

		Leak: 1.58 (0.61 to 4.15) Mortality: 1.39 (0.09 to 22.55)	
		Rate % (range)	
Ji et al. (2014) (89)	31.8 to 74.4	3.7 (0 to 15.4)	Favorable short-term efficacy and safety profile; long-term follow-up and prospective trials needed
Abdelbaki et al. (2012) (90)	6 mo: 51 to 54 12 mo: 53 to 67	8 (7 to 15.3)	Prospective randomized trials vs. gastric plication with established bariatric procedures needed

CI: confidence interval; MD: mean difference; mo: months; OR: odds ratio; SG: sleeve gastrectomy.

Randomized Controlled Trials

In additional to the studies included in the above-summarized systematic reviews, Sullivan et al. (2017) published results from the randomized, subject and evaluator-blinded, parallel-group, multicenter clinical trial using an endoscopic suturing device (G-CATH EZ™ suture anchor delivery catheter) for primary weight loss (ESSENTIAL), a randomized sham-controlled trial evaluating the efficacy and safety of endoscopic gastric plication (Table 11). (91) Patients (N=332) were randomized 2:1 to the active or sham procedure. All patients were provided low-intensity lifestyle therapy (LT). The primary endpoint was total body weight loss (TBWL) at 12-month follow-up. The MD in TBWL for patients receiving the procedure compared with patients receiving the sham procedure was 3.6% (95% CI, 2.1 to 5.1). Significant differences between the active and sham groups were also reported in a change in weight from baseline, percent excess weight loss, BMI, and improvement in diabetes (Table 12). No significant differences were detected in improvements in hyperlipidemia or hypertension between the treatment groups.

Table 11. RCT Characteristics for Laparoscopic Gastric Plication

					Interventions	
Study	**Countries**	**Sites**	**Dates**	**Participants**	**Active**	**Comparator**
Sullivan et al. (2017) (91)	United States	11	2013-2014	Patients 22 to 60 years BMI ≥30 kg/m^2 and ≥1 obesity-related comorbidity or BMI ≥35 kg/m^2 and with	Endoscopic gastric plication (n=221)	Sham procedure (n=111)

				or without obesity-related comorbidity Race (active, sham): White: 71%, 64.8% Indian: 0%, 0.9% Black: 28.1%, 31.5% Mixed: 0.9%, 2.8% Ethnicity (active, sham) Not Hispanic/ Latino: 93.7%, 92.8% Hispanic/Latino: 6.3%, 7.2%		

BMI: body mass index; RCT: randomized controlled trial.

Table 12. RCT Results for Laparoscopic Gastric Plication

Study; Trial Name	**BMI Reduction**	**Weight Loss[a]**		
	Mean Change (SD)[b]	**Difference (95% CI)**	**Mean (SD)[b]**	**Difference (95% CI)**
Sullivan et al. (2017) (91) ESSENTIAL		1.2 (0.6 to 1.9)		3.6 (2.1 to 5.1)
Endoscopic gastric plication	1.7		4.9 (7.0)	
Sham	0.5		1.4 (5.6)	

BMI: body mass index; CI: confidence interval; ESSENTIAL: The randomized, subject and evaluator-blinded, parallel-group, multicenter clinical trial using an endoscopic suturing device (G-CATH EZ™ suture anchor delivery catheter) for primary weight loss; SD: standard deviation.
[a] For Sullivan et al. (2017), percent total body weight loss at 12 months.
[b] At 12-month follow-up.

Study relevance, design, and conduct limitations are summarized in Tables 13 and 14.

Table 13. Study Relevance Limitations

Study	**Population[a]**	**Intervention[b]**	**Comparator[c]**	**Outcomes[d]**	**Duration of Follow-up[e]**
Sullivan et al. (2017) (91) ESSENTIAL	4. Majority White, not Hispanic/Latino	4. Low intensity lifestyle	2. Low-intensity		

	patients.	therapy used with procedure.	lifestyle therapy used.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 14. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Complete-ness[d]	Power[e]	Statistical[f]
Sullivan et al. (2017) (91) ESSENTIAL	5. Lead-in cohort of 34 subjects was not randomized but underwent the active treatment procedure for the purposes of investigator training.	1. Evaluator blinded only.			4. Weight loss results were lower in both the active and sham control groups than estimated in the power analysis.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Observational Study
In 2013, Pattanshetti et al. published results of a study that described the evolution of a LAGB plication procedure, a hybrid procedure involving both LAGB and greater curvature plication developed by the authors. (92) Eighty patients were included, with a baseline mean BMI of 38.05 kg/m^2. At 6, 12, 18, and 24 months postsurgery, mean percent EWL was 42.6%, 56.4%, 57.6%, and 65.8%, respectively. Five postoperative complications required reoperation.

Section Summary: Laparoscopic Gastric Plication for Adults with Class III Obesity
There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication with other bariatric surgery procedures. A 2021 systematic review demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. Longer-term follow-up and additional comparative studies are needed.

Single Anastomosis Duodeno-ileal Bypass With Sleeve Gastrectomy for Adults with Class III Obesity
Clinical Context and Therapy Purpose
The purpose of single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in patients who are adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is SADI-S.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating SADI-S as a treatment for morbid obesity has varying lengths of follow-up, ranging from 3 to 5 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

No controlled trials of SADI-S were identified. Some case series have reported on weight loss and other clinical outcomes up to 5 years post-surgery.

Systematic Review
In 2018, Shoar et al. published a systematic review of 12 studies, comprising 5 cohorts, 4 case series, and 3 case reports, that reviewed the efficacy and safety of SADI-S. (93) The studies included 581 patients who underwent SADI-S. These patients were between 18 and 71 years of age with a BMI between 33 to 71.5 kg/m^2. Of the total surgeries, 508 (87.4%) were primary and 73 (12.6%) were revisional. Follow-up was available between 6 and 60 months after the procedure. Results revealed the average percent EWL was 30% at 3 months, 55% at 6 months, 70% at 1 year, and 85% at 2 years. The comorbidity resolution rate was 74.1% for T2D, 96.3% for hypertension, 68.3% for dyslipidemia, 63.3% for OSA, and 87.5% for GERD. The most common complication was diarrhea (1.2%) and vitamin A, selenium, and iron deficiency were

the most common nutritional deficiencies. There was also the possibility of protein malnutrition in up to 34% of patients when measured. The authors concluded that SADI-S was associated with a promising short-term weight loss outcome and comorbidity resolution rate; however, RCTs are warranted to compare this procedure to more commonly performed bariatric procedures.

Observational Studies

Torres et al. (2017) published a retrospective chart review of patients from their center receiving bariatric procedures, evaluating outcomes at 3-year follow-up. (94) Outcomes were evaluated separately for patients with and without diabetes. For patients without diabetes, comparisons were made among patients who underwent RYGB (n=149) or SADI-S (n=106). For patients with diabetes, comparisons were made among patients who underwent RYGB (n=97), BPD-DS (n=77), or SADI-S (n=97). Among the patients without diabetes, significant differences favoring SADI-S over RYGB were found in: percent EWL; systolic blood pressure; total, high-density lipoprotein and low-density lipoprotein cholesterol; and insulin. Significant differences were not found in diastolic blood pressure or fasting glucose. Among the patients with T2D, remission rates using American Diabetic Association criteria were: 55%, 70%, and 76% for patients receiving RYGB, BPD-DS, and SADI-S, respectively. Patients with diabetes who underwent BPD-DS or SADI-S achieved significantly lower total cholesterol and triglyceride levels compared with those undergoing RYGB after 3 years of follow-up.

Case Series

One larger series, by Sanchez-Pernaute et al. (2015), reported on 97 patients with obesity and T2D who underwent SADI-S. (95) The authors reported that control of diabetes, defined as HbA1c levels less than 6.0%, was achieved by between 70% and 84% of patients at different time points. Remission rates were higher for patients on oral therapy than those on insulin and were higher in patients with a shorter duration of diabetes.

Section Summary: Single Anastomosis Duodeno-ileal Bypass With Sleeve Gastrectomy for Adults with Class III Obesity

A systematic review of 12 observational studies concluded that SADI-S was associated with promising weight loss and comorbidity resolution. No published controlled trials have evaluated SADI-S. A comparative chart review found that patients without diabetes experienced significantly better weight loss and lipid profiles with SADI-S than with RYGB and patients who had diabetes experienced significantly higher rates of remission with SADI-S than with RYGB. Long-term safety and efficacy outcomes and comparative RCTs are still needed.

Duodenojejunal Sleeve for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of the duodenojejunal sleeve procedure is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who are adults with class III obesity.

Interventions
The therapy being considered is the duodenojejunal sleeve procedure.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating duodenojejunal sleeve as a treatment for class III obesity has varying lengths of follow-up, ranging from 3 to 6 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Review
The EndoBarrier (GI Dynamics) is a fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and extends 80 cm into the small bowel, usually terminating in the proximal jejunum. A systematic review of the effect of EndoBarrier on weight loss and diabetes control outcomes was published in 2016. (96) It included 5 small RCTs (total N=235 patients; range, 18-77 patients), with follow-up ranging from 12 to 24 weeks. Comparators were diet and/or other lifestyle modifications, and 2 studies had sham controls. All studies were judged to be at high risk of bias using the Cochrane risk of bias tool. Combined results demonstrated that the EndoBarrier group had 12.6% greater EWL (95% CI, 9.0% to 16.2%) than medical therapy. For diabetes control outcomes, trends toward greater improvement in the EndoBarrier group were

not statistically significant. Mean difference in HbA1c level was -0.8% (95% CI, - 1.8% to 0.3%) and the relative risk of reducing or discontinuing diabetic medications was 3.28 (95% CI, 0.54 to 10.73).

Randomized Controlled Trial

The largest single trial was a multicenter RCT published in 2014; it included 77 patients with a BMI greater than 30 kg/m^2 and T2D. (97) Patients were treated for 6 months with EndoBarrier or medical therapy. At 6 months, the EndoBarrier was removed and patients were followed for an additional 6 months. Thirty-eight patients were randomized to the EndoBarrier group and 31 (82%) of 38 completed 12 months of treatment. Thirty-nine patients were randomized to medical treatment and 35 (90%) of 39 completed 12 months of treatment. At 6 months, the decrease in BMI was significantly greater in the EndoBarrier group than in the medical therapy group (3.3 kg/m^2 vs 1.8 kg/m^2, $p<0.05$), and at 12 months the difference in BMI was of marginal statistical significance (2.2 kg/m^2 vs 1.3 kg/m^2, $p=0.06$), respectively. HbA1c level was significantly lower in the EndoBarrier group at 6 months (7.0% vs 7.9%, $p<0.05$), but at 12 months the difference between groups did not differ significantly (7.3% vs 8.0%, $p=0.95$).

Observational Study

Obermayer et al. (2021) evaluated outcomes after treatment with EndoBarrier in 10 patients with T2D and an average BMI of 43.3 kg/m^2. (98) Results demonstrated that EndoBarrier reduced mean body weight from 121.2 ± 18.5 kg to 116.3 ± 18.2 kg (p=.006) 4 weeks after the start of therapy, and to 115.1 ± 21.4 kg (p=.075 vs. baseline) until explantation of the device after 36 weeks. There was an increase in weight to 117.2 ± 20.8 kg (p=0.117 vs. baseline) 24 weeks after explanation.

Section Summary: Duodenojejunal Sleeve for Adults with Class III Obesity

A systematic review of evidence on a duodenojejunal sleeve included 5 RCTs and found significantly greater short-term weight loss (12 to 24 weeks) with duodenojejunal sleeves compared with medical therapy. There was no significant difference in symptom reduction associated with diabetes. However, all RCTs had small sample sizes and were judged by the systematic reviewers to be at high-risk of bias.

Intragastric Balloon Devices (IGB) for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of IGB devices is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is IGB devices. IGB devices are placed in the stomach via endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2017, 2 IGB devices have U.S. Food and Drug Administration (FDA) approval, each designed to stay in the stomach for no more than 6 months. Obalon is a swallowable 3-balloon system and the OBERA Intragastric Balloon System (previously marketed outside of the United States as BioEnterics) is a saline-inflated silicone single balloon system.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating IGB devices as a treatment for morbid obesity has varying lengths of follow-up, ranging from 5 to 10 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Several systematic reviews of RCTs evaluating IGB devices for the treatment of obesity have been published; none was limited to FDA approved devices. (99-102)

Kotinda et al. (2020) published a systematic review and meta-analysis that evaluated the efficacy of IGB devices in comparison to sham or lifestyle interventions in overweight and obese adults. (102) Thirteen RCTs with 1523 patients were included. Results revealed that the mean percent EWL difference between the IGB and control groups was 17.98% (95% CI, 8.37 to 27.58; $p<0.00001$), significantly favoring IGB. IGB was also significantly favored when evaluating the mean percent TWL difference between the groups: 4.40% (95% CI, 1.37 to 7.43; $p<0.00001$).

Similarly, the difference in actual weight loss and BMI loss was 6.12 kg and 2.13 kg/m^2, respectively. Overall, IGB was found to be more effective than lifestyle intervention alone for weight loss; however, the majority of included RCTs used one fluid-filled IGB and there was significant heterogeneity between the included studies.

The systematic review by Tate et al. (2017) focused on RCTs, published between 2006 and 2016. (103) Additional inclusion criteria were: sham, lifestyle modification, or pharmacologic agent as a comparator; at least 1 outcome of body weight change; and study duration of 3 or more months. Eight RCTs were included in the review, with 4 contributing to the meta-analysis. The meta-analysis included 777 patients and showed a significant improvement in percent TBWL with IGB compared with control (5.5%; 95% CI, 4.3% to 6.8%). However, there was significant heterogeneity among the trials (I^2=62%), so interpretation of results is limited. The percent TBWL with IGB is lower than expected with RYGB (reported 27%) or with the most efficacious pharmacologic agent (reported 9%).

In 2017, Saber et al. identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention. (99) IGB was compared with sham in 15 trials, behavioral modification in 4 trials, and pharmacotherapy in 1 trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between 3 and 6 months. In a meta-analysis of 7 RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group compared with the control group (mean effect size [ES], 1.59 kg/m^2; 95% CI, -0.84 to 4.03 kg/m^2; p<0.001). Findings on other outcomes were similar. A meta-analysis of 4 studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%; p=0.02). In addition, a meta-analysis of 6 studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg; p=0.003).

Although the review was not limited to FDA-approved devices, older devices were air-filled and newer devices, including the 2 approved by FDA in 2015, are fluid-filled. Sufficient data were available to conduct a sensitivity analysis of 3-month efficacy data. A meta-analysis of 4 studies did not find a significant difference in weight loss with air-filled IGB devices or a control intervention at 3 months (ES= 0.26; 95% CI, -0.12 to 0.64; p=0.19). In contrast, a meta-analysis of 8 studies of fluid-filled devices found significantly better outcomes with the IGB than with control (ES=0.25; 95% CI, 0.05 to 045; p=0.02).

Randomized Controlled Trials
Pivotal trials on both FDA-approved devices have been published.

In 2017, Courcoulas et al. published a multicenter, pivotal RCT evaluating the Obera IGB in the United States (as noted, the device has been used in other countries). (104) A total of 317 patients were randomized and initiated 6 months of treatment with an IGB plus lifestyle therapy (n=137) or lifestyle therapy only (n=136). Patients were followed for an additional 6 months. Key eligibility criteria were age 18 to 65 years, baseline BMI between 30 and 40 kg/m^2, a history of obesity for at least 2 years, and having failed previous weight loss attempts.

Nineteen patients in the IGB group and 121 in the control group completed the 6-month treatment period.

Coprimary effectiveness outcomes, assessed at 9 months, were mean percent EWL and difference in mean weight loss. Mean percent EWL at 9 months was 26.4% in the IGB group and 10.1% in the control group (difference, 16.2%; 95% CI, 12.3% to 20.2%; p<0.001). Mean weight loss at 9 months was -8.8 kg (-19.4 lb) in the IGB group and -3.2 kg (-7.1 lb) in the control group (p<0.001). There were also significant between-group differences in mean weight loss and mean percent EWL at 6 and 12 months.

Most adverse events in the Obera pivotal trial were anticipated accommodative symptoms. A total of 139 (87%) patients reported nausea, 121 (76%) reported vomiting, and 92 (58%) reported abdominal pain. Fewer than 5% of these adverse events were serious; most were mild or moderate. Thirty patients in the device group had the IGB removed before month 6 because of an adverse event (n=15) or patient request (n=15). There were no deaths and 9 serious adverse events unrelated to device accommodation; among others, these included a case of gastric outlet obstruction and a case of gastric perforation with sepsis.

The Courcoulas et al. (2017) pivotal trial was not blinded or sham-controlled; however, a double-blind sham-controlled RCT evaluating the BioEnterics IGB (now called the Obera device) was published by Genco et al. in 2006. (105) This crossover trial included 32 obese patients ages 25 to 50 years with a mean BMI of 47.3 kg/m^2. Patients received, in random order, 3 months of an IGB and 3 months of sham. (Both groups underwent upper gastrointestinal endoscopy, but no device was placed in the sham group.) Patients who initially received the IGB had a mean BMI reduction of 5.8 kg/m^2 after 3 months; after crossover to sham, these patients had a mean additional BMI reduction of 1.1 kg/m^2. Patients initially in the sham group had an initial mean BMI reduction of 0.4 kg/m^2; after crossover to an active device, these patients had a mean BMI reduction of 5.1 kg/m^2. The between-group difference in BMI reductions was statistically significant (p<0.001). Findings on other outcomes (mean percent EWL, mean weight loss) were similar.

Case Series

A case series of patients treated with an IGB with up to 60-month follow-up was published by Kotzampassi et al. in 2012. (106) A total of 500 patients were treated with the BioEnterics IGB. Twenty-six patients did not complete the initial 6 months of treatment and another 77 patients did not comply with dietary restrictions and did not have satisfactory weight loss at 6 months. Among 352 patients with data available, BMI was 44.5 kg/m^2 at baseline, 35.7 kg/m^2 at device removal, 38.8 kg/m^2 12 months after device removal, and 40.1 kg/m^2 24 months after device removal. Mean percent EWL was 43.9% at device removal, 27.7% 12 months after device removal, and 17% 24 months after device removal. Among the 195 patients with available 5-year data, mean baseline BMI was 43.3 kg/m^2, mean BMI at device removal was 33.8 kg/m^2, and mean BMI at 5 years was 40.1 kg/m^2. Mean percent EWL at 5 years was 13.0%. Overall, patients who initially complied with 6 months of IGB device use and lost weight, slowly gained weight over time but weighed less at final follow-up than at baseline.

Section Summary: Intragastric Balloon Devices for Adults with Class III Obesity

Evidence includes RCTs, a case series with long-term follow-up on 1 of the devices, and systematic reviews on various IGB devices. RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or lifestyle therapy alone. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. A large case series with follow-up up to 5 years has suggested that patients regain weight over time. Additional long-term follow-up data are needed. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, 1 warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016 to 2017 following the IGB procedure. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S. Health care providers are encouraged to monitor patients receiving IGBs.

Aspiration Therapy Device for Adults with Class III Obesity

Clinical Context and Therapy Purpose

The purpose of the aspiration therapy (AT) device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity.

Interventions

The therapy being considered is the AT device.

Comparators

Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating AT device as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 2 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 to 2 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

AT involves an FDA-approved device (AspireAssist) that allows patients to drain a portion of the stomach contents after meals via an implanted tube connected to an external skin port. One RCT has been published. The Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) trial, by Thompson et al. (2017), randomized 207 participants to 52 weeks of AspireAssist therapy plus lifestyle counseling (n=127) or lifestyle counseling alone (n=70). (107) Participants were between 21 and 65 years of age, with a BMI ranging from 35 to 55 kg/m^2. Coprimary outcomes were mean EWL at 52 weeks and the proportion of patients with 25% or more EWL at 52 weeks. Investigators did a modified ITT analysis including all patients in the AspireAssist group who attempted tube placement (n=111) and all patients in the lifestyle counseling group who attended at least 1 therapy session (n=60). Mean EWL at 52 weeks was 31.5% in the AspireAssist group and 9.8% in the lifestyle counseling group. The difference between groups was 21.7% (95% CI, 15.3% to 28.1%), which was greater than the 10% difference needed to meet the a priori definition of success. The proportion of patients with 25% or more EWL at 52 weeks was 58.6% in the AspireAssist group and 22% in the lifestyle counseling group ($p<0.001$). Bulimia or binge eating disorder were exclusion criteria and, during the study, there was no evidence that patients developed bulimia or that devices were overused (i.e., used >3 times a day). Most of the adverse events (83.8%) in the AspireAssist group were associated with placement of a percutaneous endoscopic gastric tube. All 5 serious adverse events occurred in the AspireAssist group (mild peritonitis, severe abdominal pain and 1 case of product malfunction). Product malfunction was related to malfunction of the A-tube, typically occurring within the first week of implantation and seen in 90% of adverse events seen with the AspireAssist. Durability of a treatment effect beyond 1 year was not reported.

Thompson et al. (2019) published 4-year outcomes from the PATHWAY trial. (108) AT patients were permitted to continue the study beyond 1 year up to a maximum of 5 years provided they maintained at least 10% TWL from baseline at each year end. Out of 82 AT patients who completed year 1, 58 continued in the next phase, 43 completed year 2, 22 completed year 3, and 15 completed year 4 in the trial. Of 58 AT participants continuing in the study, 43 withdrew before completion of year 4, with 25/43 meeting their weight loss goal or losing >10% of their baseline weight. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal. Out of 60 patients treated in the lifestyle therapy control group, only 31 completed the full initial study year. Two serious adverse events were reported in years 2 to 4. One patient developed a secondary fistula superior to the A-tube fistula, which resolved

following A-tube removal. The second patient experienced an A-tube malfunction, which was replaced. A total of 57 adverse events, including the 2 serious adverse events, were recorded. The adverse events with the greatest frequency were peristomal irritation (12 events), persistent fistulas (12 events), and peristomal granulation tissue (8 events). A total of 27 A-tubes required replacement over the 4 years of the study. Reasons for replacement include tube defects (~50%) and tube leaks (~30%). According to the study survival analysis, one can expect 50% of A-tubes to be replaced within approximately 3.5 years postgastrostomy. No clinically significant metabolic disorders were observed. No evidence for the development of any eating disorders was noted. Study results are summarized in Table 15. Study relevance, design, and conduct limitations are summarized in Tables 16 and 17.

Table 15. Results of PATHWAY Trial

		>25% EWL[1]	**% TWL**	**ΔHbA1c[2]**	**IWquality of life Total Score [2, 3]**
Thompson et al. (2017); PATHWAY (107)	**Year 1, n**	**% [95% CI]**	**% (SD) [95% CI]**	**% (SD)**	**Mean (SD)**
AT	mITT: 111 PP: 82	mITT:56.8 [49.0 to 64.5] PP:68.3 [NR]	mITT:12.1 (9.6) [NR] PP: 14.2 (9.8) [12.1 to 16.4]	mITT: -0.36 (0.45) PP: NR	mITT: 6.2 (13.4) PP: NR
LT	mITT: 60 PP: 31	mITT: 22.0 [15.3 to 28.1] PP:25.8 [NR]	mITT: 3.6 (6.0) [NR] PP: 4.9 (7.0) [NR]	mITT: -0.22 (0.27) PP: NR	mITT: 3.3 (10.0) PP: NR
Mean Difference [95% CI]		NR	8.6 [6.2 to 10.9][2]	-1.4 [-0.28 to 0.0][2]	2.9 (SD: 12.5)[2]
P-Value		mITT:<0.001 PP: <0.001	NR	P=0.05[2]	P=0.03[4]

Thompson et al. (2019); PATHWAY (108)	**AT[5]**	**>25% EWL[1]**	**% TWL**
		% (SD)	**% (SD) [95% CI]**
Year 1	82	68.3 (NR)	14.2 (9.8) [12.1 to 16.4]
Year 2	43	72.1 (NR)	15.3 (8.8) [12.6 to 18.0]
Year 3	22	63.6 (NR)	16.6 (10.5) [12.0 to 21.3]
Year 4	15	73.3 (NR)	18.7 (11.7) [12.2 to 25.2]

AT: aspiration therapy; CI: confidence interval; EWL: excess weight loss; HbA1c: hemoglobin A1c; IWquality of life: Impact of Weight of Quality of Life survey; LT: lifestyle therapy; mITT:

modified intent-to-treat; NR: not reported; PATHWAY: Pivotal Aspiration Therapy with Adjusted Lifestyle; PP: per protocol; SD: standard deviation; TWL: total weight loss.
[1] Primary outcome measure.
[2] Based on the modified intent-to-treat analysis.
[3] Improvement in quality-of-life measures is reflected by increasing IWquality of life scores.
[4] Treatment differences in individual IWquality of life component scores did not reach statistical significance.
[5] Based on the per-protocol analysis.

Table 16. Study Relevance

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Thompson et al. (2017; 2019); PATHWAY (107, 108)	4. The majority of enrolled patients were white, non-Hispanic.		2: No active comparator for years 2 to 4.		

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
PATHWAY: Pivotal Aspiration Therapy with Adjusted Lifestyle.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 17. Study Design and Conduct Limitations

Study	Allo-cation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Thompson et al. (2017; 2019); PATHWAY (107, 108)		2: Blinding to outcome assessment unclear. 3: Blinding and identity of		1: High loss to follow-up or missing data. High loss to pre- and post-enrollment withdrawals.	1: Study not powered beyond 1 y of follow-up. Study	2: Not all sensitivity analyses are statistically significant for primary

		outcome assessors unclear.		2: Multiple strategies utilized for handling of missing data. 5: Inappropriate exclusion of patients with TWL <10% during years 2-4 from analysis. 6: Modified intent to treat analysis not carried through.	Under-powered for completers at 1 y. 3: Rationale for clinically important difference not provided.	effective-ness outcome (at least 50% of participants achieving at least 25% EWL); unclear if analysis is appropriate for multiple observa-tions per patient or extent of missing data.

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

EWL: excess weight loss; PATHWAY: Pivotal Aspiration Therapy with Adjusted Lifestyle; TWL: total weight loss.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. No intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Case Series

In addition to the RCT, a 2016 case series by Noren and Forssell evaluated AspireAssist use by 25 obese patients. (109) Patients had 1 year of aspiration therapy and also participated in a

cognitive-behavioral therapy weight loss program for the initial 3 months. Patients were instructed to aspirate 3 times a day after meals. Twenty (80%) patients completed the 1-year intervention period. Mean baseline weight was 107.4 kg. In a per protocol analysis, the mean EWL was 54.5% at 12 months. Data on 15 (60%) patients were available at 24 months; mean EWL was 61.5%.

Section Summary: Aspiration Therapy Device for Adults with Class III Obesity

The evidence consists of an RCT with 4 years of follow-up and a small case series with up to 2 years of follow-up. The RCT found significantly greater weight loss (measured several ways) with aspiration therapy compared with lifestyle therapy at 1 year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the PATHWAY study noted a potentially high degree of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on AT remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, safety, and nutrition.

Embolization of Gastric Arteries as a Treatment of Obesity

Shoar et al. (2016) performed a systematic review to evaluate the existing data in the literature for bariatric gastric artery manipulation to highlight the importance of this potential concept as a therapeutic modality. (167) Nine studies including 6 animal experiments and 3 human studies with a total of 25 patients were reviewed. Only particle embolization was used in human subjects, while animal subjects underwent chemical embolization. One human study and 5 animal studies described decreased ghrelin concentration. Significant weight change following gastric artery manipulation was noted in 3 animal experiments and 2 human studies. No serious adverse events that required surgical or interventional management were reported. Conclusions reached by the reviewers included that data regarding the potential role of gastric artery manipulation in decreasing the ghrelin and potential weight loss is scarce.

Vagus Nerve Blocking Therapy For Obesity

Clinical Context and Therapy Purpose

The purpose of vagal nerve blocking therapy for the treatment of obesity is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity who have been unsuccessful with lifestyle management for weight reduction.

Interventions
The therapy being considered is vagal nerve blocking therapy for the treatment of obesity. Vagus nerve blocking therapy involves the intermittent blocking of signals to the intra-abdominal vagus nerve, with the intent of disrupting hunger sensations and inducing feelings of satiety. Individuals with obesity who receive vagal nerve blocking therapy would require follow-up for 6-12 months to ascertain weight loss success and early device complications. Follow-up of maintenance of weight loss or obesity-associated conditions are life-long.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are weight reduction and maintenance of weight reduction, disease status changes such as the development of medical complications of obesity, and treatment-related morbidity.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials
The published literature on vagus nerve blocking for obesity consists of 2 RCTs, both of which were industry-sponsored, multicenter, double-blind, and sham-controlled. (168, 169) Although both trials included a sham treatment group, protocols differed. In the 2012 Vagal Blocking for Obesity Control (EMPOWER) trial, all participants had devices implanted and leads placed. (168) However, external controllers were programmed differently such that if the controllers were worn for 10 hours a day, the total charge delivered was 3.9 coulombs (C) to patients in the treatment group and a negligible amount (0.0014 C), to the sham group. In the 2014 trial to Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge), all participants had devices implanted, but no leads were placed in the sham group. (169)

The primary efficacy outcomes were not met in either RCT. The difference in mean percent EWL was the sole primary efficacy outcome in the Vagal Blocking for Obesity Control (EMPOWER) study and a coprimary outcome in the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) study. This outcome was evaluated in both trials using a superiority margin of 10% (i.e., the efficacy

objective would be met only if there was >10% difference between groups in EWL). The U.S. Food and Drug Administration (FDA) documents have indicated that the unattained 10% margin was considered to indicate a clinically meaningful difference in weight loss between active and sham treatment groups. (170)

For the ReCharge trial, however, in addition to the primary efficacy analysis, the authors conducted a post hoc analysis that evaluated the difference in EWL between groups using a 2-sided *t*-test with no superiority margin. In this post hoc analysis, the difference between groups (8.5% EWL; 95% CI, 3.1% to 13.9%) was statistically significant. (The difference between groups in percent EWL in the Vagal Blocking for Obesity Control (EMPOWER) study was 1%.)

The outcome used in these studies was percent EWL, and modest changes in this outcome may translate to a relatively small amount of weight loss relative to total weight for patients with morbid obesity. Mean initial body weight in the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial was 113 kilograms (249 pounds) in the active treatment group and 116 kilograms (255 pounds) in the sham group. Mean excess body weight was 44 kilograms (97 pounds) in the treatment group and 45 kilograms (99 pounds) in the sham group. Thus, a difference of 10% EWL, used in the primary analyses, represents a difference of only about 5 kilograms (10 pounds) in absolute weight loss and a 4% difference in absolute body weight.

The Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) study had a second primary outcome, which would have been met if at least 55% patients in the active treatment group had achieved at least 20% EWL and at least 45% had achieved at least 25% EWL. This outcome was not achieved; the data showed that 52% of patients in the active treatment group achieved at least 20% EWL and 38% achieved at least 25% EWL. In the Vagal Blocking for Obesity Control (EMPOWER) study, groups did not differ significantly on the secondary outcome measure (percent of patients achieving at least 25% EWL).

In post hoc subgroup analysis of the Vagal Blocking for Obesity Control (EMPOWER) trial, longer duration of device use per day was associated with a larger percent EWL. However, this improvement occurred in the sham group as well as the active treatment group. For example, percent EWL among patients who used the device for less than 6 hours a day was 5% in the active treatment group and 6% in the sham group, whereas percent EWL among patients who used the device for at least 12 hours a day was 30% and 22%, respectively. This finding suggests a substantial placebo effect associated with device use.

Both trials met their primary safety outcomes, which related to serious adverse events. However, there were frequent nonserious adverse events. Most were of mild or moderate severity. The authors of the Vagal Blocking for Obesity Control (EMPOWER) trial did not report individual adverse events.

Additional information on the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial design and findings has been reported in FDA documents. (170) The trial was designed to evaluate primary end points at 12 months and to follow patients to 5 years postimplant. Patients were blinded until 12 months and unblinding began once all patients had completed the 12-month follow-up. After the 12-month follow-up, sham patients had the option to cross over into the active treatment group. At 18 months, follow-up data (n=159) were reported for 117 (72%) patients initially assigned to the active treatment group and 42 (55%) assigned to the sham treatment group. The number of patients in the sham group who crossed over to active treatment and the timing of unblinding were not reported. At 18 months, the mean percent EWL was 25.3% in the active treatment group and 11.7% in the sham group; the mean between-group difference was 13.5% (95% CI, 5.7% to 21.3%). In this analysis, the treatment group maintained the weight loss they achieved at 12 months, and the control group gained weight. Nearly half of the patients initially randomized to the sham group were not included in the 18-month analysis, which limits ability to draw conclusions about these data. In addition, the 18-month analysis could have been biased by unblinding, which occurred after all patients completed the 12-month follow-up. In the 12-month sham intervention phase of the trial, patients in both groups experienced decreased hunger, increased cognitive restraint, and decreased food intake. It is likely that unblinding could have had an impact on these factors. The FDA documents also reported longer term safety data. Analyses of data up to 48 months from the Vagal Blocking for Obesity Control (EMPOWER) trial and 18-month data from the ReCharge trial did not identify any deaths or unanticipated serious adverse events. There were 13 surgical explants through 12 months (5 in active treatment group, 8 in sham group) and an additional 16 explantations between 12 and 18 months. Reasons for explant included patient decision, pain, and need for magnetic resonance imaging.

Eighteen-month follow-up data from the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial were published by Shikora et al. (2015). (171) They reported on a larger proportion of the patient population than that discussed in the FDA documents: in addition to the 159 (67%) of 239 randomized patients who completed the 18-month follow-up, the 2015 analysis included 30 patients who missed the 18-month analysis but had a visit at 16 or 17 months. The additional patients included 11 from the active treatment group and 19 from the sham group, comprising 188 patients (79% of those originally randomized). At 18 months, the mean percent EWL noted was 23.5% (95% CI, 20.8% to 26.3%) in the active treatment group and 10.2% (95% CI, 6.0% to 14.4%) in the sham group. The mean between-group difference in percent EWL was 13.4% (95% CI, 8.4% to 18.4%). The authors also evaluated the potential impact of blinding on outcomes and found no statistically significant effect; their findings were similar to the analysis restricted to patients who remained blinded at 18 months. The percentages of EWL at 18 months in this 2015 analysis of ReCharge trial data were also similar to those previously reported in FDA documents, although this sample size was larger, reducing potential bias from missing data. However, because this post hoc analysis incorporated 16- and 17-month data in addition to 18-month data, the authors considered these results preliminary or hypothesis-generating.

Twenty-four-month outcomes from Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) were published by Apovian et al. (2017). (172) The investigators noted that the sham arm was no longer a valid comparator at 24 months due to crossovers, dropouts, and patient unblinded at 12 months. There was no prespecified statistical analysis plan for assessments after the 12-month primary outcome assessment, including those in this 2017 article. A total of 103 (43%) patients of 239 randomized patients completed the 24-month follow-up. Their mean EWL was 21% (95% CI, 16% to 26%) and mean total weight loss was 8% (95% CI, 6% to 10%). No serious treatment-related adverse events were reported in the 18- to 24-month time period. The analysis lacked a blinded comparison group, and, like the 18-month data, was post hoc.

Section Summary: Vagus Nerve Blocking Therapy for Obesity

Two sham-controlled RCTs have been published. The primary efficacy outcome (at least a 10% difference between groups) was not met for either trial. In the first trial Vagal Blocking for Obesity Control (EMPOWER), the observed difference in EWL between groups at 12 months was 1%. In the more recent trial (Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity - ReCharge), the observed difference in EWL between groups at 12 months was 8.5%; a post hoc analysis found this difference statistically significant, but the magnitude of change may not be viewed as clinically significant according to investigators' original trial design decisions. Additional analyses of data from Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) found a difference in EWL at 18 months of approximately 13% in 79% of initially randomized patients and a mean EWL of 21% at 24 months in 43% of initially randomized patients. However, analyses beyond 12 months were post hoc, considered preliminary, and need to be replicated in other appropriately designed RCTs. In addition, the 18- and 24-month data have potential biases, including missing data and unblinding. Moreover, the 18-month analysis combined data from different follow-up visits and the 24- month analysis lacked a control group. The 2 RCTs found that vagus nerve blocking was reasonably safe in terms of serious adverse events during follow-up, although a substantial number of mild and moderate adverse events were reported.

Revision Bariatric Surgery for Adults with Class III Obesity Who Failed Bariatric Surgery

Clinical Context and Therapy Purpose

The purpose of revision bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in adults with class III obesity and who failed bariatric surgery.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adults with class III obesity and failed bariatric surgery.

Interventions
The therapy being considered is revision bariatric surgery.

Comparators
Comparators of interest include standard medical care. Treatment for adults with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating revision bariatric surgery as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Matar et al. (2021) published a systematic review of 556 patients (n=17 studies) who underwent RYGB for SG-related complications, including GERD (30.4% cases) and insufficient weight loss and weight regain (52% of cases). (110) The mean BMI at the time of conversion ranged from 33.3 to 48.3 kg/m^2. The pooled baseline BMI at conversion was 38.5 kg/m^2 (95% CI, 36.49 to 40.6), at 6 months was down to 28.6 kg/m^2 (95% CI, 16.1 to 41.0), and after 1 year was up to 32.1 kg/m^2 (95% CI, 25.50 to 38.7). The pooled mean %TWL after completion of treatment was 25.2% (95% CI, 12.8 to 37.5) at 6 months and 22.8% (95% CI, 13.5 to 32.1) at 1 year. There was a 16.4% complication rate at 30 days, which decreased to 11.4% after 30 days. At 1-year post RYGB, the rate of resolution for common comorbidities was as follows: GERD, 79.7% (95% CI, 59.6 to 91.3); T2D, 57.7% (95% CI, 36.9 to 76.1); hypertension, 49.4% (95% CI, 25.8 to 73.3).

Parmar et al. (2020) published a systematic review of 1075 patients (n=17 studies) who underwent one anastomosis/mini gastric bypass (OABG-MGB) as a revisional bariatric procedure after failure of a primary LAGB and SG. (111) No RCTs were available on this topic and no meta-analyses were performed as part of this systematic review. The most commonly reported reason for revisional surgery was poor response (81%) followed by gastric band failure (35.9%), GERD (13.9%), intolerance (12.8%), staple line disruption (16.5%), pouch dilatation (17.9%), and stomal stenosis (10.3%). Results revealed that after the revisional OABG-MGB, the mean percent EWL was 50.8% at 6 months, 65.2% at 1 year, 68.5% at 2 years, and 71.6% at 5 years. Resolution of comorbidities after OAGB-MGB was significant with 80.5% of patients with T2D, 63.7% of patients with hypertension, and 79.4% of patients with GERD reporting resolution. The overall readmission rate following OAGB-MGB was 4.73%, the mortality rate was 0.3%, and the leak rate was 1.54%. Although the authors concluded that OAGB-MGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

Brethauer et al. (2014) conducted a systematic review of reoperations after primary bariatric surgery for the American Society for Metabolic and Bariatric Surgery that included 175 studies, most of which were single-center retrospective reviews. (112) The review is primarily descriptive, but made the following conclusions:
"The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise."

<u>Nonrandomized Studies</u>
Petrucciani et al. (2021) published a retrospective analysis of 215 patients who underwent revisional OAGB with a biliopancreatic limb of 150 cm after failing LAGB at a single center between 2010 and 2016. (113) The indication for surgery was weight loss failure in 30.7% of cases and long-term complications in the remaining cases. The mean BMI at the time of OAGB was 42 kg/m^2. At 2 years after OAGB, 9.7% of patients were lost to follow-up, BMI was down to 28 ± 5.5 kg/m^2, %EWL was 88.2 ± 23.9, and %TWL was 38.7 ± 9.3. At 5 years after OAGB, 16.6% of patients were lost to follow-up, BMI was slightly up to 29.2 ± 5.8 kg/m^2, %EWL was 82.4 ± 25, and %TWL was 36.1 ± 10. Overall postoperative morbidity was 13.5% with a 5.9% rate of postoperative abscess with or without staple line leak. Treatment-resistant GERD occurred in 21.3% of patients; conversion to RYGB was required in 4.2% of cases.

Almalki et al. (2018) published a retrospective analysis of patients diagnosed with failed restrictive procedure who underwent revision bariatric surgery. (114) One hundred sixteen patients between 2001 and 2015 had revision RY gastric bypass (R-RYGB; n=35) or revision single anastomosis- (mini-) gastric bypass (R-SAGB; n=81); the primary indications for revisional

procedures were weight regain (50.9%), inadequate weight loss (31%), and intolerance (18.1%). Major complications occurred in 12 (10%) patients without significant difference between groups (R-SAGB, n=9; R-RYGB, n=3). At 1 year after revision surgery, the R-SAGB group (76.8% EWL) showed better weight loss than R-RYGB (32.9% EWL; p=0.001). In the 37.1% of patients available for follow-up at 5 years, R-SAGB had significantly lower hemoglobin levels than R-RYGB (8.2 ± 3.2 g/dl versus 12.8 ± 0.5 g/dl; p=0.03). The study was limited by its retrospective nature, relatively short follow-up time, and lack of consideration of data related to patient compliance.

Sudan et al. (2015) reported on safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database. (115) The Bariatric Outcomes Longitudinal Database was a large, multi-institutional bariatric surgery–specific database to which data were submitted from 2007 through 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence program. Surgeries were classified as primary or reoperative bariatric. Reoperations were further divided into corrective surgeries (when complications or incomplete treatment effect of a previous bariatric operation was addressed, but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation, or a reversal restored original anatomy.) Of 449,473 bariatric operations in the database, 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3%) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective and 8,750 (30.5%) were conversions. The primary bariatric operations were RYGB (n=204,705 [49.1%]), LAGB (n=153,142 [36.5%]), SG (n=42,178 [10%]), and BPD-DS (n=4,260 [1%]), with the rest classified as miscellaneous. LAGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to RYGB). Compared with primary operations, mean hospital length of stay was longer for corrections (2.04 days versus 1.8 days, p<0.001) and for conversions (2.86 days versus 1.8 days, p<0.001). Mean percent EWL at 1 year was 43.5% after primary operation, 39.3% after conversions, and 35.9% after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions (0.31%) than for primary surgeries (0.17%; p<0.001), with no statistically significant difference for corrections (0.24%) compared with primary surgeries (0.17%; p=NS). One-year serious adverse event rates were higher for conversions (3.61%) than for primary operations (1.87%; p<0.001), with no statistically significant difference for corrections (1.9%) compared with primary operations (1.87%; p=NS). The authors concluded that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

Endoscopic Revision Procedures

While bariatric surgery revision or correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices also being evaluated for endoscopic treatment of GERD. The published data on use of these devices for treatment of regained weight is limited. Published case series have reported results using a number of devices and procedures (including sclerosing injections) as treatment for this condition. The largest series (2007) found involved 28 patients treated with a sclerosing agent (sodium morrhuate). (116) Reported trials that used one of the suturing devices had fewer than

10 patients. For example, Herron et al. (2008) reported on a feasibility study in animals. (117) Thompson et al. (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who regained weight and had dilated gastrojejunal anastomoses after RYGB. (118) No comparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss.

The StomaphyX device, which has been used in this approach, was cleared by FDA through the 510(k) process. It was determined be equivalent to the EndoCinch system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. In 2014, Eid et al. reported results from a single-center RCT that compared the StomaphyX device with a sham procedure for revisions in patients with prior weight loss after RYGB at least 2 years earlier. (119) Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphyX patients. The primary 12-month efficacy end point (reduction in pre-RYGB excess weight by ≥15%, excess BMI loss, and BMI <35 kg/m^2) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group ($p<0.01$).

A 2009 survey of American Society for Metabolic and Bariatric Surgery members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. (62) The surgeons were "willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures." The durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven. A 2013 systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by the American Society for Metabolic and Bariatric Surgery concluded: "The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available." (120)

Cohen et al. (2019) conducted a systematic review evaluating the safety and efficacy of endoscopic gastroplasty for medically uncontrolled obesity. (121) Nine observational studies and a single RCT were identified by the authors. Follow-up duration in the majority of studies was limited to 6 to 12 months with several studies reporting high rates of loss to follow-up. Percent total body weight loss ranged from -15.1% to 19.5%. Reduction in BMI ranged from -1.69 to -7.5 kg/m^2. Serious adverse events ranged from 2% to 10%. The quality of the current evidence was graded very low to moderate, with limited long-term data on weight loss durability and procedure safety.

<u>Section Summary: Revision Bariatric Surgery for Adults with Class III Obesity Who Failed Bariatric Surgery</u>

For surgical revision of bariatric surgery after failed treatment, evidence from systematic reviews and nonrandomized studies suggests that revisions are associated with improvements

in weight similar to those seen in primary surgery. However, the published scientific literature on use of endoscopic devices and procedures in patients who regain weight after bariatric surgery is very limited.

Bariatric Surgery in Class III Obese Adolescent Children

Considerations for Bariatric Surgery in Adolescents

Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 kg/m^2 with comorbidities to a BMI of 50 kg/m^2. Most guidelines use weight-based criteria that parallel those for adults.

In addition to the weight-based criteria, there is greater emphasis on issues of developmental maturity, psychosocial status, and informed consent for adolescent patients. All guidelines mention these issues, but recommendations are not uniform. The following are examples from the U.S. guidelines published since 2013 that address issues of maturity and psychosocial status.

Endocrine Society (160)

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

Bariatric Procedure Guidelines

The choice of procedure in adolescents may also differ from adults, but there is a lack consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (173):

- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices used for laparoscopic adjustable gastric banding do not have FDA-approval in the United States for individuals younger than age 18 years.
- Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that biliopancreatic diversion not be done in adolescents.

In 2018, the American Society for Metabolic and Bariatric Surgery published an updated guideline on pediatric metabolic and bariatric surgery. (158) With regard to choice of procedure, the guideline stated:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents."

Clinical Context and Therapy Purpose

The purpose of gastric bypass, LAGB, or SG is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in patients who are adolescent children with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are adolescent children with obesity. While guidelines for bariatric surgery in adolescents are not uniform, most use weight-based criteria that parallel those for adults.

Interventions

The therapy being considered is gastric bypass, LAGB, or SG.

Comparators

Comparators of interest include standard medical care. Treatment for adolescent children with class III obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating gastric bypass, LAGB, or SG as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 6 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Bariatric Surgery Techniques

Systematic Reviews

Qi et al. (2017) published a systematic review and meta-analysis on the use of bariatric surgery for the treatment of adolescents with obesity (Table 18). (122) In a literature search conducted through July 2017, 49 studies were identified for inclusion. Study quality was assessed using the Newcastle-Ottawa Scale. Age of patients ranged from 14 to 20 years. BMI ranged from 34 to 63 kg/m^2. Overall results showed significant improvements in BMI as well as glycemic and lipid control with various bariatric surgery techniques. RYGP showed the largest improvements compared with other procedures, with LAGB and SG also showing improvements in this population.

In a 2013 systematic review of 23 studies, Black et al. (2013) concluded that the available literature demonstrated a high rate of significant short-term weight loss after bariatric surgery (Table 19). (123) The literature search was conducted through January 2013. Quality assessment of the included studies was not discussed. Ages of patients at the time of surgery ranged from 5 to 23 years. A meta-analysis showed significant reductions in BMI. Meta-analyses were not conducted on the resolution of comorbidities due to heterogeneity in reporting. However, most cases of hypertension, OSA, T2D, and dyslipidemia were reported to have resolved at 1-year follow-up. Reviewers noted that complication and comorbidity rates were not well-defined.

Treadwell et al. (2008) conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents (Table 19). (124) Their analysis included English-language articles on currently performed procedures when data were separated by procedure and there was a minimum 1-year follow-up for weight and BMI. Studies must have reported outcomes data for 3 or more patients ages 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on between 11 and 68 patients who were 21 years or younger. Eight studies of LAGB (mean BMI, 45.8 kg/m^2; median age range, 15.6-20 years); 6 studies on RYGB (mean BMI, 51.8 kg/m^2; median age range, 16-17.6 years); 5 studies of other procedures (mean BMI, 48.8 kg/m^2; median age range, 15.7-21 years) were included.

Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB (Table 19). Comorbidity resolution was sparsely reported, but surgery appeared to resolve some medical conditions, including diabetes and hypertension; 2 studies of LAGB showed large rates of diabetes resolution but low patient enrollment, and only 1 study of RYGB reporting relevant data. No in-hospital or postoperative deaths were reported in any LAGB study. The most frequently reported complications for LAGB were band slippage and micronutrient deficiency with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. More severe complications were reported for RYGB, such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. No in-hospital deaths were reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 others died of causes not likely to have been directly related to the bariatric surgeries. No LAGB studies reported data on the impact of surgery on growth and development. One study of RYGB reported pre- and postoperative heights and concluded that there was no

evidence of growth retardation at an average follow-up of 6 years, but it could not be determined from the data whether expected growth was achieved.

Table 18. Systematic Review Characteristics for Bariatric Surgery for Adolescents with Obesity

Study	Dates	Studies	Participants	Design	Duration
Qi et al. (2017) (122)	Jul 2017	49	RYGP: 1216 LAGB: 1028 LSG: 665 Other: 98	1 RCT 22 prospective 26 retrospective	12 to 120 months
Black et al. (2013) (123)	Jan 2013	23	RYGP: 256 LAGB: 271 LSG: 90 Other: 20	1 controlled 22 uncontrolled	6 to 120 months
Treadwell et al. (2008) (124)	Dec 2007	18	RYGB: 131 LAGB: 352 Other: 158	1 prospective 17 retrospective	0 to 22 years

LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; RCT: randomized controlled trial; RYGP: Roux-en-Y gastric bypass.

Table 19. Systematic Review Results for Bariatric Surgery for Adolescents with Obesity

Study	BMI Reduction Mean Difference (95% CI)	Fasting Blood Insulin, mIU/L Mean Difference (95% CI)	Total Cholesterol, mg/dL Mean Difference (95% CI)
Qi et al. (2017) (122)			
RYGP	18.5 (16.4 to 20.7)	24.8 (10.0 to 30.7)	29.4 (18.1 to 40.7)
LAGB	12.1 (11.0 to 13.3)	20.5 (16.4 to 24.6)	2.2 (-10.0 to 14.4)
LSG	16.0 (13.2 to 20.7)	18.4 (11.4 to 25.3)	13.6 (2.9 to 24.2)
Other	23.2 (15.6 to 30.7)	28.3 (5.7 to 50.9)	49.5 (29.9 to 69.2)
Black et al. (2013) (123)			
RYGP	17.2 (14.3 to 20.1)	NR	NR
LAGB	10.5 (9.1 to 11.8)	NR	NR
LSG	14.5 (11.7 to 17.3)	NR	NR
Other	NR	NR	NR
Treadwell et al. (2008) (124)			
RYGP	(17.8 to 22.3) [a]	NR	NR
LAGB	(10.6 to 13.7) [a]		

BMI: body mass index; CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass.
[a] No point estimate provided, only 95% CIs given.

Observational Studies

Dumont et al. (2018) published a retrospective study of obese adolescents who underwent LAGB. (125) Between 2006 and 2015, 97 consecutive teenagers (average age at surgery 17.2 ± 0.7 years; mean BMI of 44.9 ± 6.1 kg/m^2) who had achieved full growth and sexual maturity and had previously failed a medical nutritional and dietary management program for at least 1 year were enrolled in the study. After a mean follow-up time of 56.0 ± 22.0 months, mean total weight loss was 20.0 ± 16.6% and mean excess weight loss was 46.6 ± 39.5%. Nineteen patients underwent band removal (mean 43.0 ± 28.0 months). No limitations to the study were reported.

One of the larger observational studies included in the systematic reviews was by Inge et al. (2014), who reported results from the Teen-Longitudinal Assessment of Bariatric Surgery study, a prospective, multicenter observational study of bariatric surgery in patients ages 19 or younger. (126) The study enrolled 242 patients, with a mean age of 17.1 years and median BMI of 50.5 kg/m^2 (IQR, 45.2 to 58.2 kg/m^2) at the time of surgery. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by OSA (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). Gastric bypass, LAGB, and vertical SG were performed in 66.5%, 5.8%, and 27.7% of patients, respectively. Within 30 days of surgery, 20 major complications occurred in 19 (7.9%) patients, most of which were peri-operative. The cohort is being followed to assess longer term outcomes.

Gastric Bypass

Comparative Studies

Olbers et al. (2017) published results from the Adolescent Morbid Obesity Surgery (AMOS) study. (127) AMOS is a prospective, nonrandomized study of patients ages 13 to 18 years with severe obesity. Enrolled patients underwent RYGB (n=81) and were compared with 80 matched adolescent controls undergoing conservative treatment and 81 matched adult controls undergoing RYGB. The primary outcome was change in BMI after 5 years. Adolescents undergoing RYGB had a mean age of 16.5 years and mean BMI of 45.5 kg/m^2. At 5-year follow-up, adolescents receiving RYGB experienced a mean reduction in BMI of 13.1 kg/m^2 (95% CI, 11.8 to 14.5 kg/m^2). Adolescents receiving conservative treatment experienced a mean increase in BMI of 3.3 kg/m^2 (95% CI, 1.1 to 4.8 kg/m^2). Adult controls receiving RYGB experienced a reduction in BMI similar to the adolescents undergoing RYGB, 12.3 kg/m^2 (95% CI, 10.9 to 13.7 kg/m^2). Adolescents undergoing RYGB also experienced significant improvements in glucose, insulin, cholesterol, and blood pressure levels compared with adolescents in the control group.

Laparoscopic Adjustable Gastric Banding

Systematic Reviews

Willcox and Brennan (2014) conducted a systematic review focusing on studies reporting biopsychosocial outcomes following LAGB in adolescents with obesity. (128) The literature search, conducted through May 2013, identified 11 studies for inclusion. Significant weight loss was reported in all studies. Resolution of comorbidities was also reported, though the evidence was poor quality due to a limited discussion of comorbidity assessment criteria. Reporting of psychosocial outcomes was considered limited, with reviewers concluding that further

research is needed to better understand the behavioral, emotional, and social factors experienced by adolescents undergoing LAGB.

Randomized Controlled Trials

In the only RCT identified in the systematic reviews, O'Brien et al. (2010) reported on 50 adolescents between the ages of 14 and 18 years with a BMI 35 kg/m^2 or higher who received either a lifestyle intervention or LAGB. (2) Follow-up was 2 years. Twenty-four of 25 patients in the gastric banding group and 18 of 25 in the lifestyle group completed the study. Twenty-one (84%) in the gastric banding group and 3 (12%) in the lifestyle group lost more than 50% of excess weight. Overall, mean weight loss in the gastric banding group was 34.6 kg (95% CI, 30.2 to 39.0 kg), representing an EWL of 78.8% (95% CI, 66.6% to 91.0%). Mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1 to 8.1 kg), representing an EWL of 13.2% (95% CI, 2.6% to 21.0%). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 (33%) surgeries were required in 7 patients for revisional procedures, either for proximal pouch dilatation or tubing injury during follow-up.

Case Series

There are many case series of bariatric surgery in adolescents, and they have generally reported weight loss in the same range seen for adults. For example, Nadler et al. (2008) reported on 73 patients ages 13 to 17 years who had undergone LAGB since 2001 at the authors' institution. (129) Mean preoperative BMI was 48 kg/m^2. EWL at 6 months, 1 year, and 2 years postoperatively was 35%, 57%, and 61%, respectively. Six patients developed band slippage, and 3 developed symptomatic hiatal hernias. Nutritional complications included asymptomatic iron deficiency in 13 patients, asymptomatic vitamin D deficiency in 4 patients, and mild subjective hair loss in 14. In the 21 patients who entered the authors' FDA-approved study and had reached 1-year follow-up, 51 comorbid conditions were identified, 35 of which completely resolved, 9 were improved, 5 were unchanged, and 2 were aggravated after 1 year.

<u>Sleeve Gastrectomy</u>

Manco et al. (2017) published results from contemporaneous cohorts of adolescent patients with a BMI of 35 kg/m^2 or more and nonalcoholic steatohepatitis who chose between 3 treatment options. (130) Twenty patients chose to undergo LSG, 20 patients opted to ingest intragastric weight loss devices (IGWLD, either the BioEnterics Intragastric Balloon System or Obalon Gastric Balloon) plus lifestyle interventions, and 53 patients chose lifestyle interventions alone. All patients in the LSG and IGWLD groups completed the study; 22 of the 53 in the lifestyle intervention group completed the study. After 1-year follow-up: patients undergoing LSG lost 21% body weight; patients treated with IGWLD lost 3% body weight, and patients receiving lifestyle interventions only gained 2% body weight. Nonalcoholic steatohepatitis reverted in 100% of patients receiving LSG and in 24% receiving IGWLD. Patients receiving lifestyle interventions alone did not improve significantly.

Alqahtani et al. (2021) conducted a prospective, noncomparative, cohort study analyzing durability of weight loss and comorbidity resolution, growth velocity, and adverse events associated with LSG in children and adolescents with severe obesity over 10 years. (131)

Children and adolescents with class II or III obesity underwent LSG between 2008 and 2021. Overall, 2504 children and adolescents were included, with a mean age ± standard deviation (SD) 15.7 ± 3.7 years (range, 5 to 21 years) at the time of operation. In the 15- to 18-year age group specifically, there were 1517 children enrolled (61%). Mean ± SD baseline BMI was 44.8 ± 12.6 kg/m^2, with a BMI z-score of 3.0 ± 0.5, representing 165% above the 95th percentile for age and sex, on average. In the overall cohort in the short- (1 to 3 years, n=2051), medium- (4 to 6 years, n=1268), and long-term (7 to 10 years, n=632) follow-up, mean %EWL was 82.3% ± 20.5%, 76.3% ± 29.1%, and 71.1%± 26.9%, respectively. At baseline, 263 patients (10.5%) were diagnosed with T2D, 227 (9.1%) were diagnosed with dyslipidemia, and 377 (15.1%) had hypertension. At long-term follow-up, complete comorbidity remission was observed in 74% of T2D cases, 59% of dyslipidemia cases, and 64% of hypertension cases. Mean height z-score change at short-, medium-, and long-term follow-up was 0.1 ± 0.5, 0.1 ± 1.2, and 0.0 ± 0.8, respectively, representing no significant change in growth velocity at each follow-up stage (p=.95, p=.21, and p=.40, respectively). There were 27(1%) reported adverse events within the first 90 days after operation, including 2 patients with a staple line leak, 22 patients with nausea and vomiting, and 3 patients with signs of metabolic neuropathy, with no procedure-related mortality. None of those patients with adverse events had long-standing sequelae or disability.

Section Summary: Bariatric Surgery in Class III Obese Adolescent Children

Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

Several systematic reviews and meta-analyses have been conducted on observational studies evaluating the use of bariatric surgery for the treatment of adolescents with obesity. There is an overlap of studies among the systematic reviews. The majority of evidence assesses the use of gastric bypass, SG, or LAGB. Two nonrandomized comparative studies were published after the systematic reviews. One compared RYGB with conservative treatment and with adults undergoing RYGB, and 1 compared LSG with gastric balloons and lifestyle interventions. The evidence on bariatric surgery in adolescents indicates that the percent EWL and change in BMI are approximately the same as that in adults. There are greater concerns for developmental maturity, psychosocial status, and informed consent in adolescents.

Guideline recommendations for bariatric surgery in adolescents lack uniformity but generally correspond to the clinical selection criteria for adults and supplement these clinical selection criteria with greater attention to issues of maturity and psychosocial status.

Bariatric Surgery in Class III Obese Preadolescent Children

Clinical Context and Therapy Purpose

The purpose of bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in patients who are preadolescent children with class III obesity.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are preadolescent children with class III obesity.

Interventions
The therapy being considered is bariatric surgery.

Comparators
Comparators of interest include standard medical care. Treatment for preadolescent children with class III obesity includes low carbohydrate dieting and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating bariatric surgery as a treatment for class III obesity has varying lengths of follow-up, ranging from 1 to 5 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Alqahtani et al. (2021), described above, included children as young as 5 years of age in their prospective, noncomparative cohort study analyzing durability of weight loss and comorbidity resolution, growth velocity, and adverse events associated with LSG in children and adolescents with severe obesity over 10 years. (131) In the 5- to 14-year age group, 801 (32%) children were included. The mean percent of 95th percentile at baseline for children in this age group was 177% ± 38%. The %EWL after LSG in children aged 5 to 14 years was not significantly different from the adolescent children (>14 years) as results were consistent across age groups. Additionally, the height z-score change did not differ in this age group, indicating no impact on change over 10 years of follow-up.

In 2013, Black et al. (described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents. (123)

Section Summary: Bariatric Surgery in Class III Obese Preadolescent Children

There are few published data, and no studies were identified that focused on bariatric surgery solely in preadolescent children. A recently published (Alqahtani et al. [2021]) prospective noncomparative cohort study demonstrated substantial, long-lasting (follow-up of 10 years) weight loss and comorbidity resolution without safety concerns after LSG in children as young as 5 years of age. In the study of children and adolescents, 801/2504 (32%) children included were ages 5 to 14 years at the time of surgery. Additional comparative studies are needed to permit conclusions about the net health benefit of bariatric surgery in preadolescent children with class III obesity.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery for Adults with Class III Obesity and a Preoperative Diagnosis of Hiatal Hernia

Clinical Context and Therapy Purpose

The purpose of hiatal hernia repair with bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in individuals with class III obesity and a preoperative diagnosis of hiatal hernia.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with class III obesity and a preoperative diagnosis of hiatal hernia.

Interventions

The therapy being considered is hiatal hernia repair with bariatric surgery.

Comparators

Comparators of interest include standard medical care. Treatment for patients with class III obesity and a preoperative diagnosis of hiatal hernia includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating hiatal hernia repair with bariatric surgery as a treatment for class III obesity and a preoperative diagnosis of hiatal hernia has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to

assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Hiatal hernia is associated with obesity, and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of a hiatal hernia has been associated with complications after LAGB. (132) Although other studies have reported no differences in perioperative complications after LAGB in patients with GERD and/or a hiatal hernia or those without GERD and/or hiatal hernia. (133) Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management of hiatal hernia, recommending that, during RYGB, SG, and the placement of LAGBs, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate). (134) There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia.

Systematic Reviews

Chen et al. (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus SG in obese patients (N=937). (135) Results demonstrated that patients who underwent hiatal hernia repair during SG had significant reductions in BMI (MD, -11.42 kg/m^2, 95% CI, -12.8 to -10.03), and the risk of GERD symptoms (OR, 0.20; 95% CI, 0.10 to 0.41) and esophagitis (OR, 0.12; 95% CI, 0.05 to 0.26). Hiatal hernia repair during SG was superior to SG alone for GERD remission (OR, 2.97; 95% CI, 1.78 to 4.95), but not de novo GERD (OR, 0.61; 95% CI, 0.24 to 1.53). The pooled recurrence rate for hiatal hernia after hiatal hernia repair plus SG was 11% (95% CI, 4 to 19).

Cohort Studies

Gulkarov et al. (2008) reported results of a prospective cohort study comparing outcomes for patients who underwent LAGB with or without concurrent hiatal hernia repair (n=1298 with LAGB alone; n=520 with concurrent hiatal hernia repair). (136) The authors reported that, initially, hiatal hernias were diagnosed based on preoperative esophagram and upper

endoscopy, but this was discontinued after these studies were shown to have poor predictive value for small-to-medium size hernias; subsequent patients were diagnosed at the time of surgery. It was not specified how many patients were diagnosed with each method or how many of those had symptoms before gastric banding. Fewer patients who underwent concurrent hiatal hernia repair required reoperation for a complication (3.5% vs 7.9% in the LAGB alone group; p<0.001). Hiatal hernia repair added an average of 14 minutes to surgical time. Weight loss outcomes did not differ significantly between groups.

Santonicola et al. (2014) evaluated the effects of LSG with or without hiatal hernia repair on GERD in obese patients. (137) The study included 78 patients who underwent SG with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia who underwent SG only. The prevalence of typical GERD symptoms did not improve from baseline to follow-up in patients who underwent concomitant hiatal hernia repair (38.4% presurgery vs 30.8% postsurgery, p=0.3). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% presurgery vs 19.6% postsurgery, p=0.003).

Reynoso et al. (2011) reported outcomes after primary and revisional LAGB in patients with hiatal hernia treated at a single hospital system. (138) Of 1637 patients with hiatal hernia undergoing primary gastric banding, 190 (11.6%) underwent concurrent hiatal hernia repair; of 181 patients undergoing revision gastric banding, 15 (8.3%) underwent concurrent hiatal hernia repair. For primary procedures, there were no significant differences in mortality, morbidity, length of stay, and 30-day readmission rates for patients who underwent LAGB with and without hiatal hernia repair. However, this compares patients with hiatal hernia undergoing repair to patients without hiatal hernia. The more relevant comparison would be comparing repair to no repair in patients who have hiatal hernia.

Ardestani et al. (2014) analyzed data from the Bariatric Outcomes Longitudinal Database registry to compare outcomes for patients with and without hiatal hernia repair at the time of LAGB. (139) Of 41,611 patients who had LAGB from 2007 to 2010, 8120 (19.5%) had concomitant hiatal hernia repair. Those with hiatal hernia repair were more likely to have GERD preoperatively (49% vs 40% in the non–hiatal hernia repair group; p<0.001). Perioperative outcomes were similar between groups. Of those with GERD preoperatively, rates of improvement in GERD symptoms did not differ significantly at 1-year postprocedure (53% for hiatal hernia repair vs 52% for non–hiatal hernia repair; p=0.4). Although the hiatal hernia repair added minimal time (mean, 4 minutes) to surgery, the authors concluded that many repairs would have involved small hernias with limited clinical effect.

In general, studies have reported that the addition of hiatal hernia repair at the time of bariatric surgery is safe and feasible. In a small case series of 21 patients, Frezza et al. (2008) described the feasibility of crural repair at the time of LAGB for patients with hiatal hernia. (140) Al-Haddad et al. (2014) used data from the U.S. Nationwide Inpatient Sample to evaluate the surgical risk associated with hiatal hernia repair at the time of bariatric surgery. (141) For laparoscopic RYGB, there were 206,559 and 9060 patients who underwent the procedure alone

or with concomitant hiatal hernia repair, respectively. For LAGB, 52,901 and 9893 patients, respectively, underwent the procedure alone or with hiatal hernia repair. The authors reported no evidence of increased risk of perioperative adverse events associated with the concomitant hiatal hernia repair. However, patients who underwent a concomitant hiatal hernia repair were less likely to have prolonged length of stay, with an average treatment effect on the treated of hiatal hernia repair of -0.124 (95% CI, -0.15 to -0.088) for prolonged length of stay for patients who underwent RYGB and an average treatment effect of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for prolonged length of stay for patients who underwent LAGB.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery for Adults with Class III Obesity and a Preoperative Diagnosis of Hiatal Hernia

Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. The evidence related to whether hiatal hernia repair improves outcomes after bariatric surgery is limited, particularly for hiatal hernias that are incidentally diagnosed at the time of surgery. For patients with a preoperative diagnosis of hiatal hernia, symptoms related to the hernia, and indications for surgical repair, it is reasonable to undertake this procedure at the time of bariatric surgery. For other patients, it is uncertain whether repair of a hiatal hernia at the time of bariatric surgery improves outcomes. A systematic review found that hiatal hernia repair during SG was superior to SG alone for GERD remission, but not de novo GERD.

Liver Biopsy in Conjunction with Bariatric Surgery

In 2014, Reha et al. performed a retrospective review to determine the prevalence of Nonalcoholic steatohepatitis (NASH), a common finding in obese population. (174) Morbidly obese patients who underwent weight reduction surgery had a liver biopsy performed at the time of surgery. Patients were excluded if they had a history of hepatitis infection or previous alcohol dependency. Results reported included: one hundred thirteen patients were analyzed; sixty-one patients had systemic hypertension (54%) and 35 patients had diabetes (31%). The prevalence of NASH in this study population was 35 per cent (40 of 113). An additional 59 patients (52%) had simple steatosis without NASH. Only 14 patients had normal liver histology. The authors noted that patient age, body mass index, hypertension, diabetes, hypercholesterolemia, and abnormal alanine aminotransferase did not predict NASH. Abnormal aspartate aminotransferase (AST) was the only predictive factor for NASH.

Spengler et al. (2015) notes that it is estimated that NASH occurs in 20% of patients with nonalcoholic fatty liver disease (NAFLD), and that approximately 30-40% of patients with NASH will develop fibrosis. (175) The authors note that NAFLD is most commonly recognized through abnormal liver chemistries or incidental ultrasound findings and should be considered in the differential of any patient with elevated transaminases. The author further notes: Liver biopsy is invasive, expensive and not without risk. Liver biopsy should be considered in all patients with persistently elevated aminotransferases in whom the diagnosis remains uncertain.

In 2013, Mechanick et al. noted in the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic & Bariatric Surgery's (ASMBS) Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and

Nonsurgical Support of the Bariatric Surgery Patient that "Consideration can be made for liver biopsy at the time of surgery to document steatohepatitis and/or cirrhosis that may otherwise be unknown due to normal appearance and/or liver function tests (Grade D)" (176) (Grade D recommendation is made in the absence of a two-thirds consensus being reached).

Section Summary: Liver Biopsy in Conjunction with Bariatric Surgery

Liver biopsy at the time of bariatric surgery has been proposed as a method of providing an accurate diagnosis of obesity-associated liver conditions. Spengler has noted that NAFLD is commonly recognized through abnormal liver chemistries. The AACE, TOS, and ASMBS Clinical Practice Guidelines provide a grade D recommendation for liver biopsy at the time of surgery. For individuals who have signs or symptoms of liver disease (e.g., history and physical, biochemical, and serological findings), liver biopsy at the time of bariatric surgery may be considered medically necessary.

Removal of the Gallbladder at the Time of an Approved Gastric Bypass Surgical Procedure

O'Brien and Dixon (2003) noted gallstones are more common in the obese population and may be formed during rapid weight loss. They further noted that after a Roux-en-Y gastric bypass surgery, 40% of patients form stones in the post-operative period. (177) Sneineh et al. (2020) noted that there was significant difference between the type of the bariatric procedure and the incidence of symptomatic cholelithiasis after the operation (178) Because of the high incidence of gallbladder disease even with negative pre-operative findings in morbidly obese patients, routine cholecystectomy at the time of weight loss surgery may be considered medically necessary.

Summary of Evidence

Adults With Class III Obesity

For individuals who are adults with class III obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass. There is less weight loss with LAGB than with gastric bypass, but LAGB is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies (evaluating SG alone and comparing SG with gastric bypass), as well as systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG compared with gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive biliopancreatic diversion (BPD) with duodenal switch (DS), the evidence includes nonrandomized comparative studies, observational studies and a systematic review. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Non-randomized comparative studies found significantly higher weight loss after BPD with duodenal switch compared with gastric bypass at 1 year. A large case series found sustained weight loss after 7 years. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive BPD without DS, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Concerns have been raised about complications associated with BPD without DS, especially long- term nutritional and vitamin deficiencies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive 2-stage bariatric surgery procedures, the evidence includes a small RCT, observational studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months post-surgery. Case series have shown relatively high complication rates in 2-stage procedures,

and patients are at risk of complications in both stages. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive laparoscopic gastric plication, the evidence includes an RCT, an observational study, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2021 systematic review demonstrated that laparoscopic SG is superior to laparoscopic greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One additional RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive single anastomosis duodeno-ileal bypass with SG (SADI-S), the evidence includes a systematic review of observational studies and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of 12 observational studies concluded that SADI-S was associated with promising weight loss and comorbidity resolution. A comparative chart review found that patients without diabetes experienced significantly better weight loss and lipid profiles with SADI-S than with RYGB and patients who had diabetes experienced significantly higher rates of remission with SADI-S than with RYGB. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of SADI-S. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive duodenojejunal sleeve, the evidence includes RCTs, systematic reviews and an observational study. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of duodenojejunal sleeves included 5 RCTs and found significantly greater short-term weight loss (12-24 weeks) with the sleeves compared with medical therapy. There was no significant difference in symptoms associated with diabetes. All RCTs were small and judged by systematic reviewers to be at high-risk of bias. High-quality comparative studies are needed to permit conclusions on the safety and efficacy of the procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive intragastric balloon (IGB) devices, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures,

quality of life, and treatment-related mortality and morbidity. RCTs on the 2 IGB devices approved by the U.S. Food and Drug Administration have found significantly better weight loss with IGB compared with sham treatment or lifestyle therapy alone after 6 months (maximum length of device use). Some adverse events were reported, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how 6 months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive an aspiration therapy device, the evidence includes an RCT and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at 1 year. Forty of 58 patients (69%) achieved at least 10% total weight loss at 4 years or at time of study withdrawal; however, only 15/111 initial aspiration therapy patients completed the study through 4 years. In addition to a high degree of missing data, the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study noted a potentially large number of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years post-gastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. One small case series reported on 15 patients at 2 years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism, safety, nutrition, and long-term durability of treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with obesity who receive vagus nerve blocking therapy, the evidence includes 2 sham-controlled randomized trials. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. The primary efficacy outcome (at least a 10% difference between groups at 12 months) was not met for either trial. In the first trial, Vagal Blocking for Obesity Control (EMPOWER), the observed difference in excess weight loss between groups at 12 months was 1%. In the more recent trial to Evaluate the Safety and Efficacy of vBloc Therapy delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge), the observed difference in excess weight loss between groups at 12 months was 8.5%; a post hoc analysis found this difference statistically significant, but the magnitude of change may not be viewed as clinically significant according to investigators' original trial design decisions. Post hoc analyses of longer-term data have been published and are subject to various biases, including missing data and unblinding at 12 months. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Revision Bariatric Surgery

For individuals who are adults with class III obesity and failed bariatric surgery who receive revision bariatric surgery, the evidence includes systematic reviews, case series and registry data. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adolescent Children With Class III Obesity

For individuals who are adolescent children with class III obesity who receive gastric bypass or LAGB, or SG, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB, or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents is similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m^2. Also, greater consideration should be placed on patient development stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Preadolescent Children With Class III Obesity

For individuals who are preadolescent children with class III obesity who receive bariatric surgery, there are no studies focused solely on this population. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old. A recent (2021) cohort study included 801 children ages 5 to 14 years in their total cohort of children and adolescents, and excess weight loss and comorbidity resolution were substantial and long-lasting without safety concerns across all age groups. However, comparative studies are still lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Hiatal Hernia Repair with Bariatric Surgery

For individuals with morbid obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes a systematic review, cohort studies and case series. Relevant outcomes are overall survival, change in disease status,

functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review found that hiatal hernia repair during SG was superior to SG alone for gastroesophageal reflux disease (GERD) remission, but not de novo GERD. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Association of Clinical Endocrinologists, et al.

In 2020, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology jointly published a comprehensive diabetes type 2 management algorithm. (142) Updates were made in 2022 and recommendations for bariatric surgery are presented in Table 20. (143).

Table 20. Recommendations for Bariatric Surgery in Diabetes

Recommendation	GOE	BEL
Persons with a BMI 35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, NAFLD/NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure	C	3
Persons with BMI 30 to 34.9 kg/m^2 and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure	B	2

BEL: best evidence level; BMI: body mass index; GOE: grade of evidence; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; OSA: obstructive sleep apnea; T2D: type 2 diabetes.

In 2016, the AACE and the American College of Endocrinology jointly published comprehensive clinical guidelines on the medical care of patients with obesity. (144) The guidelines addressed 9 broad clinical questions with 123 recommendations. With regard to bariatric surgery, the following recommendations were added (Table 21).

Table 21. Recommendations for Bariatric Surgery Added in 2016

No.	Recommendation	GOE	BEL
35	"Patients with obesity (BMI ≥30 kg/m^2) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for	B	1[a]

	bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion."		
121	"Patients with a BMI of ≥35 kg/m^2 and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or non-alcoholic 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 BMI of 30 to 34.9 kg/m^2 with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit. • BMI ≥35 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk. • BMI ≥30 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk. • BMI ≥30 kg/m^2 and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk."	A B C	1 2 3
122	"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"	D	
62	"Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett's esophagus." "Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux."	Int Strong	Int Strong

BEL: best evidence level; BMI: body mass index; CVD: cardiovascular disease; GOE: grade of evidence; Int: intermediate; No: Number

[a] Downgraded due to study limitations.

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists. (145) Recommendations on the following questions are summarized below.

- "Which patients should be offered bariatric surgery?"
  - "Patients with a BMI≥40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure."

- "Patients with a BMI≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D [type 2 diabetes], high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
- "Patients with the following comorbidities and BMI≥35 kg/m^2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; GERD [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
- "Patients with BMI of 30 to 34.9 kg/m^2 with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
- "The BMI criterion for bariatric procedures should be adjusted for ethnicity (e.g., 18.5 to 22.9 kg/m^2 is normal range, 23 to 24.9 kg/m^2 overweight, and ≥25 kg/m^2 obesity for Asians)."
- "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related related complications cannot be obtained using only structured lifestyle change with medical therapy."

- "Which bariatric surgical procedure should be offered?"
  - "Selecting a bariatric procedure should be based on individualized goals of therapy (e.g., weight loss target and/or improvement in specific obesity-related complications), available local-regional expertise (obesity specialists, bariatric surgeon, and institution), patient preferences, personalized risk stratification, and other nuances as they become apparent. Notwithstanding technical surgical reasons, laparoscopic bariatric procedures should be preferred over open bariatric procedures due to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding, sleeve gastrectomy, RYGB, and LBPD/DS [laparoscopic biliopancreatic diversion/duodenal switch], or related procedures should be considered as primary bariatric and metabolic procedures performed in patients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD [biliopancreatic diversion], BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy."

<u>American College of Cardiology, et al.</u>

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published joint guidelines on the management of obesity and overweight in adults. (146) The guidelines made the following recommendations related to bariatric surgery:

- "Advise adults with a BMI ≥40kg/m^2 or BMI ≥35 kg/m^2 with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI Grade A (Strong); AHA/ACC COR [class of recommendation]: IIa; AHA/ACC LOE [level of evidence]: A"
- "For individuals with a BMI <35 kg/m^2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation)"

American Society for Metabolic and Bariatric Surgery (ASMBS)

In 2016, ASMBS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES]). (147) The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

- There is level 1 data from RCTs [randomized controlled trials] on the "efficacy [and] safety of intragastric balloon therapy for obesity … [and] lower-level evidence [suggesting] that weight loss can be maintained … for some finite time into the future."
- It is difficult to separate the effect from the intragastric "balloon alone from those of supervised diet and lifestyle changes…." This has been addressed in recent FDA [U.S. Food and Drug Administration] pivotal trials. "In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team…."
- "…serious complications are rare. Early postoperative tolerance challenges … can be managed with pharmacotherapy in the majority of patients…."

In 2017, the ASMBS published a position statement on sleeve gastrectomy. (148) This updated statement provided the following conclusions:

- "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 comorbidities, improved quality of life, and low complication and mortality rates for obesity treatment.".
- "In terms of initial early weight loss and improvement of most weight-related comorbid conditions, SG and RYGB appear similar. The effect of SG on GERD, however, is less clear, because GERD improvement is less predictable and GERD may worsen or develop de novo."
- The ASMBS recognizes SG as an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned staged approach."

Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature.

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery. (149) The guideline contained the following conclusions and summary recommendations:

- "There is a significant link between obesity and hernia formation both after abdominal surgery and de novo. There is also evidence that abdominal wall hernia can more commonly present with obstruction or strangulation in patients with obesity."
- "There is a higher risk for complications and recurrence after hernia repair in patients with obesity."
- "In patients with severe obesity and ventral hernia, and both being amenable to laparoscopic repair, combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection. There is a relative lack of evidence, however, about the use of synthetic mesh in this setting."
- "In patients with severe obesity and abdominal wall hernia that is not amenable to laparoscopic repair, a staged approach is recommended. Weight loss prior to hernia repair is likely to improve hernia repair outcomes. Metabolic/bariatric surgery appears to provide far more significant and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia."

In 2020, ASMBS published an updated statement on single-anastomosis duodenal switch (SADI-S) "in response to numerous inquiries made...by patients, physicians, society members, hospitals, and others regarding [this procedure] as a treatment for obesity and metabolic diseases." (150) The following recommendations were endorsed regarding SADI-S for the primary treatment of obesity or metabolic disease:

- "SADI-S, a modification of classic Roux-en-Y duodenal switch, is an appropriate metabolic bariatric surgical procedure."
- "Publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged, particularly with published details on sleeve gastrectomy size and common channel length."
- "There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for duodenal switch patients."

In 2022, ASMBS, along with the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), updated their guideline on indications for metabolic and bariatric surgery. (151) Historically, class III obesity was the threshold for bariatric surgery; however, ASMBS now recommends metabolic and bariatric surgery in individuals with a BMI greater than or equal to 35 kg/m^2, regardless of the presence, absence, or severity of comorbidities. Studies referenced by the guideline to support this recommendation generally demonstrated weight loss and remission in both T2D and hypertension in the bariatric surgery groups compared to the nonsurgical groups. However, there were no subgroup analyses performed on individuals

without metabolic disorders, so itis difficult to determine if this benefit extends to all patient populations with BMI greater than or equal to 35 kg/m^2, regardless of the presence, absence, or severity of comorbidities. Additionally, only 1 systematic review referenced by the guidelines included RCTs, and heterogeneity of these RCTs was considered high; all other trials referenced were nonrandomized.

The ASMBS/IFSO guideline also states that metabolic and bariatric surgery can be considered for individuals with metabolic disease and class I obesity, defined as BMI of 30 to 34.9 kg/m^2, who do not achieve substantial or durable weight loss or comorbidity improvement with nonsurgical methods. Additionally, they state that BMI thresholds should be adjusted in the Asian population, as the prevalence of diabetes and cardiovascular disease is higher at a lower BMI than in the non-Asian population. Thus, a BMI greater than or equal to 25 kg/m^2 suggests clinical obesity, and individuals with BMI greater than or equal to 27.5 kg/m^2 should be offered bariatric surgery.

Importantly, these recommendation from the 2022 ASMBS/IFSO guideline do not appear to be informed by a separately conducted systematic review, include strength of evidence ratings, or include a description of management of conflict of interest.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

In 2013, SAGES issued evidence-based guidelines for the management of hiatal hernia, which included a recommendation about repair of hiatal hernias incidentally detected at the time of bariatric surgery. (134) These guidelines stated: “During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired” (moderate quality evidence, weak recommendation).

International Federation for the Surgery of Obesity and Metabolic Disorders

In 2019, members of societies affiliated with the International Federation for the Surgery of Obesity and Metabolic Disorders established an expert consensus statement on revisional bariatric surgery (RBS). (152) Consensus agreement was established for the following recommendation statements:

- "RYGB is an acceptable RBS option after gastric banding."
- "OAGB is an acceptable RBS option after gastric banding."
- "SADI-S is an acceptable RBS option after gastric banding."[a]
- "RBS after gastric banding can be carried out in either 1 or 2-stage."
- "OAGB is an acceptable RBS option after SG."
- "BPD-DS is an acceptable RBS option after SG."
- "SADI-S is an acceptable RBS option after SG."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after RYGB."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after OAGB."[a]

BPD-DS: bilio-pancreatic diversion duodenal switch; OAGB: one gastric bypass; RBS: revisional bariatric surgery; RYGB: Roux-en-Y gastric bypass; SADI: single anastomosis duodeno-ileal bypass with sleeve gastrectomy; SG: sleeve gastrectomy.
[a] Consensus achieved in second round of voting.

In 2020, members of societies affiliated with the International Federation for the Surgery of Obesity and Metabolic Disorders established a position statement on Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS). (153) The following recommendations were made based on available data:

- "SADI-S/OADS offers substantial weight loss that is maintained into the medium term."
- "SADI-S/OADS provides an improvement in metabolic health that is maintained into the medium term."
- "Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure and patients undergoing this procedure need to be aware of this and counseled to stay in long-term multidisciplinary care."
- "Surgeons performing the SADI-/OADS, as well as other bariatric/metabolic procedures, are encouraged to participate in a national or international registry so that data may be more effectively identified."
- "IFSO supports the SADI-S/OADS as a recognized bariatric/metabolic procedure, but highly encourages RCT's in the near future."

<u>Guidelines for Children and Adolescents</u>

Childerhose et al. (2017) conducted a systematic review of adolescent bariatric surgery recommendation documents published in the United States and provided recommendations based on their review. (154) The literature search was conducted from 1999 through 2013 and identified 16 recommendations for inclusion: 10 clinical practice guidelines, 4 position statements, and 2 consensus statements. Fifteen of the 16 publications recommended bariatric surgery for adolescents. The main reasons for recommending bariatric surgery for adolescents included: 1) surgery is effective in producing short- and long-term weight loss; 2) surgery is appropriate when the patient does not respond to behavioral or medical interventions; 3) surgery is appropriate when serious comorbidities threaten the health of the patient; and 4) surgery can improve long-term health and/or emotional problems. Body mass index thresholds ranged from 35 kg/m^2 or more to 50 kg/m^2 or more, with lower thresholds usually requiring the presence of at least 1 serious comorbidity. The minimum age was specified in 10 publications, with most using physiologic maturity (Tanner stage IV and/or 95% of adult height based on bone age, corresponding to ≥13 years for females and to ≥15 years for males) rather than years.

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) published a report outlining the current evidence regarding adolescent bariatric surgery that provided recommendations for practitioners and policy makers. (155) Within this report, AAP listed indications for adolescent metabolic and bariatric surgery that reflected 2018 ASMBS recommendations. Additionally, the AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse,

concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2023, the AAP published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity. (156) There commendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is below:

"Pediatricians and other PHCPs [pediatric health care providers] should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

They list indications for adolescent metabolic and bariatric surgery (Table 22) that align with the 2019 indications.

Table 22. Indications for Adolescent Metabolic and Bariatric Surgery

Weight Criteria	Comorbid Conditions
Class 2 obesity; BMI ≥35, or 120% of the 95th percentile for age and sex, whichever is lower Class 3 obesity; BMI ≥40, or 140% of the 95th percentile for age and sex, whichever is lower	Clinically significant disease, including OSA (AHI >5), T2D, IIH, NASH, Blount disease, SCFE, GERD, and hypertension Not required but commonly present

AHI: apnea-hypopnea index; BMI: body mass index; GERD: gastroesophageal reflux disease; IIH: idiopathic intracranial hypertension; NASH: nonalcoholic steatohepatitis; OSA: obstructive sleep apnea; SCFE: slipped capital femoral epiphysis; T2D: type 2 diabetes.

American Society for Metabolic and Bariatric Surgery (ASMBS)
In 2012, ASMBS best practice guidelines found that current evidence was insufficient to discriminate between specific bariatric procedures, but allowed that there is an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population. (157) Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:
Strong indications:

- Type 2 diabetes mellitus,
- Moderate or severe obstructive sleep apnea (apnea-hypopnea index >15),
- Nonalcoholic steatohepatitis,
- Pseudotumor cerebri.

Less strong indications:

- Cardiovascular disease,
- Metabolic syndrome.

The guidelines stated that depression and eating disorders should not be considered exclusion criteria for bariatric surgery. The guidelines also noted that depression should be monitored following the procedure and that eating disorders should be treated and the patient stabilized prior to the procedure.

In 2018, ASBMS published an update to the 2012 guideline. (158) Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: 1) BMI cut offs of 35 kg/m^2 or 120% of the 95th percentile with a comorbidity, or 2) BMI >40 kg/m^2 or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI <45 kg/m^2) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."
- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children, these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."
- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI >120% of

the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."
- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."

In 2022, the ASMBS updated their guideline on indications for metabolic and bariatric surgery. (151) They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as 5 years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that syndromic obesity, developmental delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents.

Endocrine Society
The Endocrine Society published recommendations on the prevention and treatment of pediatric obesity in 2008. (159) In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology. (160) These guidelines recommended the following:
“We suggest that bariatric surgery be considered only under the following conditions:
- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI > 40 kg/m^2 or has BMI above 35 kg/m^2 and significant, extreme comorbidities.
- Extreme obesity and comorbidities persist, despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- 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.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents (and for those planning to become pregnant within 2 yr 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, untreated psychiatric disorder.”

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 23.

Table 23. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01172899	The BASIC Trial. Morbid Obesity in Children and Adolescents: a Prospective Randomised Trial of Conservative Treatment Versus Surgery	60	Dec 2022 (active, not recruiting)
NCT02390973[a]	Surgery Versus Best Medical Management for the Long Term Remission of Type 2 Diabetes and Related Diseases (REMISSION)	408	Mar 2024 (recruiting)
NCT04174768	The Effect of Bariatric Surgery on Glucose Metabolism and Kidney Function	50	Nov 2021 (unknown)
NCT03891056	Metabolic Surgery for Patients with Type 2 DM and Grade 1 Obesity with Bad Metabolic Control (MSO1CT)	40	Jan 2022 (recruiting)
NCT02310178	Obesity Cohort: Medical Follow-Up of Severe or Morbid Obese Patients Undergoing Bariatric Surgery	750	May 2022 (recruiting)
NCT02328599	A Prospective Consortium Evaluating the Long-term Follow-up of Patients With Type 2 Diabetes Enrolled In a Randomized Controlled Trial Comparing Bariatric Surgery Versus Medical Management (ARMMS-T2D)	302	Jun 2024 (enrolling by invitation)
NCT04583683	Effects of Very Low Calorie Diet vs Metabolic Surgery on Weight Loss and Obesity Comorbidities: a Randomized Controlled Trial	218	Sep 2022 (active, not recruiting)
NCT03610256	Prospective Multicentric Randomized Trial Comparing the Efficacy and Safety of single anastomosis - Duodeno Ileal Bypass With Sleeve Gastrectomy (SADI-S) Versus Roux-en-Y Gastric Bypass (RYGB) (SADISLEEVE)	382	Oct 2023 (recruiting)
NCT03517072	Determinants of the Long-Term Success of Bariatric Surgery	1000	Jan 2023 (unknown)
NCT03472157	Prospective Multicentric, Open Label, Randomized Clinical Trial of Superiority, With Two Arms, Comparing Bariatric Surgery to the Recommended Medical Treatment for NASH (NASHSURG)	100	Mar 2023 (recruiting)
NCT04506190	A Prospective Multicenter Study to Evaluate the Perioperative Outcomes of Laparoscopic	100	Mar 2023

	and Robotic-Assisted Revisional Bariatric Surgery		(active, not recruiting)
NCT04128995	Surgical or Medical Treatment for Pediatric Type 2 Diabetes	100	Sep 2025 (recruiting)
NCT03236142	The Single, 300 cm Loop, Duodenal Switch (SIPS) Results in Less Nutritional Deficiencies Than the Standard Duodenal Switch (DS) Operation: A Multicenter, Randomized Controlled Trial	110	Jan 2025 (recruiting)
NCT02692469	Laparoscopic single anastomosis- Duodenal-Jejunal Bypass With Sleeve Gastrectomy vs Laparoscopic Duodenal Switch as a Primary Bariatric Procedure. 5 Year Patient Follow	140	Apr 2026 (not yet recruiting)
NCT04165694	Single Anastomosis Duodenal Ileal Bypass (SADI) as a Second Stage for Sleeve Gastrectomy Weight Loss Failure	54	Dec 2030 (active, not recruiting)
Unpublished			
NCT02881684[a]	Weight Reduction by Aspiration Therapy in Asian Patients with Morbid Obesity	15	Dec 2018 (unknown)
NCT02142257	Gastric Bypass Procedure and AspireAssist Aspiration Therapy System for the Treatment of Morbid Obesity, Observational Study over 5 Years	100	May 2020 (unknown)
NCT03493620	Multicenter Randomized Prospective Study With Sham Group to Evaluate the Efficacy and Results of Endoscopic Gastroplasty Using Overstitch in Patients With Class I and II Obesity	60	Aug 2020 (unknown)
NCT03102697	Optimization and Follow-Up of the Consecutive Use of Two Intragastric Balloons (Heliosphere Bag®) in the Treatment of Obesity: A Prospective Clinical Study	30	Dec 2020 (completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	00797, 43236, 43290, 43291, 43632, 43633, 43644, 43645, 43659, 43770, 43771, 43772, 43773, 43774, 43775, 43842, 43843, 43845, 43846, 43847, 43848, 43886, 43887, 43888, 43999, 47379, 64999, 0813T, [Deleted 1/2023: 0312T, 0313T, 0314T, 0314T, 0315T, 0316T, 0317T]
HCPCS Codes	C1767, C9784, C9785, S2083

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2025	Reviewed. No changes.
05/15/2024	Document updated with literature review. The following changes were made to Coverage: 1) Replaced “morbid obesity” terminology with specific obesity classification(s); 2) Changed statement on gastric bypass, as a primary procedure from “experimental, investigational and/or unproven” to “not medically necessary” with additional revision(s); and 3)Changed “Surgery for weight gain/failure to lose weight” to “Subsequent surgery for weight gain/failure to lose weight” in Repeat/Revisions section with additional

	revision(s). Added references: 1, 131, 143, 146, 151, and 156; some references updated and others removed.
01/01/2023	Document updated with literature review. The following change was made to Coverage: Added "Vagus nerve blocking (e.g., Maestro)" to list of experimental, investigational, and/or unproven bariatric procedures, which was previously addressed on SUR701.039. Added references 192-197.
12/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Revised the wording for diagnosis of morbid obesity, for a BMI equal to or greater than 35 kg/meters^2 with at least one (1) of the following clinically significant obesity-related diseases changed to the following: BMI equal to or greater than 35 kg/meters^2 with at least one (1) of the following clinically significant obesity-related diseases or complications that are not well controlled with medical management: 2) Added NOTE 2: Individual consideration of other factors such as race/ethnicity may be given to adult patients with type 2 diabetes and a BMI 32.5 to 35 kg/m2 requesting bariatric surgery; 3) Added the following to the Repeat/Revisions section: When the indication for a revision is a weight gain OR a failure of the patient to lose a desired amount of weight due to patient non-compliance, then the patient must re-qualify for the subsequent procedure and meet all of the initial preoperative criteria; 4) Revised experimental, investigational and/or unproven statement for patients with a BMI less than 35 kg/m^2 to "Bariatric surgery is considered not medically necessary for patients not meeting the above criteria"; 5) Removed the following NOTE: Successful weight-loss is defined as weight loss equal to or greater than 50 percent of excess body weight; 6) Removed from the Repeat/Revisions section: Coverage statement addressing New bariatric surgery following a previous different bariatric procedure. The following references were added: 10-12, 36-38, 41, 43, 47, 54, 65, 87, 97, 109, 112, 153, 168, 176, and 191: others were removed.
01/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Removed: Contraindications for surgical treatment of obesity, 2) Clarified criteria by adding the word obstructive to the following criteria: Obstructive sleep apnea. The following references were added: 1, 4-5, 8-9, 17, 20-21, 41-43, 47, 49, 52-60, 65-67, 72, 75, 86, 93-94, 96-97, 104-105, 111, 113, 115, 122, 129-130, 134, 143, 146, 148, 151, 161, 163, 165-168, 173, and 182-183; other references were updated.
01/01/2021	Reviewed. No changes.
02/01/2019	Document updated with literature review. The following changes were made to Coverage: 1) Added embolization of gastric arteries as a treatment of obesity to the group of bariatric procedures that are considered experimental, investigational and/or unproven as a treatment of morbid obesity, 2) Added sub header for procedures performed simultaneously with bariatric surgery, with additional criteria addressing repair of hiatal hernia and liver biopsy, and 3) Added sub header under the Miscellaneous

	Procedure Coverage Statements dividing sections into Complications and Repeat/Revisions, with modifications to criteria under both sections 4) As a primary procedure was added as clarification of various types of bariatric surgeries being considered experimental, investigational and/or unproven for the treatment of any condition other than morbid obesity, 5) Willingness to comply with was added to the following statement: Documentation from the surgeon attesting that the patient has been educated in and understands the post-operative regimen, which should include willingness to comply with ALL the following components. Added references 131-137.
03/01/2018	Document updated with literature review. Coverage in the Patient Selection Criteria has had the following added to Osteoarthritis: "in weight bearing joints". Coverage for adolescent individuals has been added and bariatric surgery may be considered eligible for benefit coverage when criteria are met. Specific Coverage for adult and adolescents have been delineated. Any devices used for bariatric surgery must be used in accordance with the FDA-approved indications. The following coverage statement for preadolescent children has been added: Bariatric surgery is considered experimental, investigational and/or unproven for the treatment of morbid obesity in preadolescent children. The following NOTE: has been added to the Coverage section for clarification: NOTE: A bariatric procedure that has to be aborted (i.e., no bariatric procedure is completed), but is then performed at a later date, is not considered a staged procedure. The patient must meet benefit coverage, contractual eligibility and coverage criteria at the time the bariatric procedure is completed.
03/15/2017	Document updated with literature review. The following changes were made to Coverage:1) The words include, but are not limited to, have been added to the following sentence: The following bariatric procedures considered experimental, investigational and/or unproven as a treatment of morbid obesity. 2) The following has been added to the experimental, investigational and/or unproven procedure list: Single anastomosis duodenoileal bypass with sleeve gastrectomy and AspireAssist® device. 3) The following statements have been added to the MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS section: Reoperation related to previous bariatric surgery may be considered medically necessary for complications such as stricture, obstruction, or erosion except when the members benefit plan excludes coverage of such complications, and Removal of an adjustable gastric band may be considered medically necessary for complications not resolved by band deflation, including but not limited to obstruction, erosion, aspiration pneumonia, GERD, night cough, Barrett's esophagus, persistent vomiting, or persistent pain except when the members benefit plan excludes coverage of such complications. 4) Or when the member's benefit plan does not allow for coverage, has been added to the following coverage statement: New bariatric surgery following a previous different bariatric procedure: A Roux-en-Y procedure following a previously approved vertical banded

	gastroplasty or laparoscopic adjustable banded gastroplasty is not eligible for coverage for patients who have been substantially noncompliant with a prescribed nutrition and exercise program following the original procedure or when the member's benefit plan does not allow for coverage. 5) Examples have been changed in the technical failure statement in the MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS section. Previously examples were: break down of gastric pouch, slippage, breakage or erosion of gastric band, bowel obstruction, staple line failure, etc.
09/01/2015	Document updated with literature review. The following procedures were added to the Coverage section as experimental, investigational and/or unproven: Insertion of a gastric balloon, endoscopic gastroplasty, or use of an endoscopically placed duodenojejunal sleeve as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches) and Laparoscopic gastric plication. The following Coverage statements were added: Repair of a hiatal hernia at the time of bariatric surgery may be considered medically necessary for patients who have a preoperatively-diagnosed symptomatic hiatal hernia. Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair, is considered not medically necessary.
02/01/2015	CPT/HCPCS code(s) updated.
06/15/2014	Coverage revised. Section 2: Documentation from the Requesting surgical program: changed from "Patient has completed an evaluation by a licensed professional counselor, psychologist or psychiatrist within the 12 months preceding the request for surgery" to: "Patient has completed an evaluation by a masters level or higher behavioral healthcare provider acting within the scope of their licensure under applicable state law, within the 12 months preceding the request for surgery".
03/01/2014	Document updated with literature review. The following coverage changes have been made: 1) under the "PATIENT SELECTION CRITERIA FOR COVERAGE" for a BMI equal to or greater than 35kg/meters^2 the requirements have changed from: at least two (2) of the following comorbid conditions related to obesity that have not responded to maximum medical management and that are generally expected to be reversed or improved by bariatric treatment; to: at least one (1) of the following clinically significant obesity-related diseases or complications that are not controlled by best practice medical management. The following has been added to the coverage section: 2) Bariatric surgery is considered experimental, investigational and/or unproven for patients with a BMI less than 35 kg/m2. 3) Gastric bypass using a Roux-en-Y anastomosis, adjustable gastric banding, sleeve gastrectomy or biliopancreatic bypass (Scopinaro procedure) with duodenal switch are considered experimental, investigational and/or unproven for the treatment of any condition other than morbid obesity,

	including but not limited to metabolic syndrome, gastroesophageal reflux disease and sleep apnea. 4) Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time) has been added to the list of procedures considered experimental, investigational and/or unproven as a treatment of morbid obesity. The following has been removed from the coverage section: 5) Bariatric surgery is considered experimental, investigational and unproven as a cure for type-2 diabetes mellitus. 6) References to "for morbid obesity that has not responded to the required conservative measures" have been removed from the coverage section.
02/01/2012	Document updated with literature review. The patient selection requirement for a pre-surgical weight loss program for at least six (6) months, occurring within the twenty-four (24) months prior to the proposed surgery has been replaced with "Documentation from the surgeon attesting that the patient has been educated in and understands the post-operative regimen".
03/15/2011	Document updated with literature review. The following changes were made: Vertical banded gastroplasty is considered not medically necessary; added NOTES and TOGA procedures as examples of procedures considered experimental, investigational and unproven as a treatment of morbid obesity: added Transoral ROSE procedure (Restorative Obesity Surgery) as an example of a procedure considered experimental, investigational and unproven for treating weight gain after bariatric surgery; original procedure must have been under the current benefit plan for a repeat/revision to be considered; non-surgical weight loss management has been changed to six months.
07/01/2010	Document updated with literature review. The following change was made: Open or laparoscopic sleeve gastrectomy may be conditionally medically necessary.
09/15/2009	Policy updated with literature review, to include changes in required weight loss criteria, comorbid conditions, and bariatric surgery used for treatment of Type 2 Diabetes mellitus. Additional coverage position added for biliopancreatic bypass with duodenal switch. Policy title change from Surgery for Morbid Obesity to Bariatric Surgery.
06/01/2009	Coverage revised
11/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
07/01/2007	CPT/HCPCS code(s) updated
12/01/2006	Revised/updated entire document
09/01/2006	Coverage revised
07/01/2006	Coverage revised. New CPT/HCPCS code(s) added
01/01/2006	New CPT/HCPCS code(s) added
01/18/2005	Coverage revised
11/01/2004	Coverage revised/ New CPT/HCPCS code(s) added

10/06/2004	Coverage revised
04/09/2004	Revised/updated entire document
08/15/2003	Revised/updated entire document
05/01/1999	Revised/updated entire document
06/01/1998	Revised/updated entire document
05/01/1996	Revised/updated entire document
01/01/1993	Revised/updated entire document
09/01/1990	New medical document