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# Title: Bariatric Surgery (Gastric Surgery for Morbid Obesity)

## Description/Background

**BARIATRIC SURGERY**

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

Per the Centers for Disease Control and Prevention (CDC), obesity is also frequently classified into the categories of Class 1: BMI of 30 to < 35 kg/m$^2$; Class 2: BMI of 35 to< 40 kg/m$^2$; and Class 3: BMI of 40 kg/m$^2$ or higher. Class 3 obesity is sometimes categorized as “severe” obesity. [1]

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 (1GLP-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. GLP-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. GIP acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

**Guidelines on how to calculate BMI**
The BMI calculation (BMI=weight/height$^2$) is made utilizing kilograms for the patient's weight and meters for height.

Note: To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to meters, multiply inches by 0.0254.

There are a number of online sites that will assist in calculating the patient's BMI by inserting the patient's statistics into the appropriate boxes. One such site is http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

**Types of Bariatric Surgery Procedures**

The following list summarizes the different restrictive and malabsorptive procedures used in bariatric surgery.

- **Open Gastric Bypass (gastric restrictive procedure with gastric bypass, with short-limb Roux-en-Y gastroenterostomy) (CPT code 43846)**
  The original gastric bypass surgeries were based on the observation that post-gastrectomy 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 anastomosis). 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 "sweet eaters." Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there may be more metabolic complications compared with other gastric restrictive procedures, including iron deficiency anemia, vitamin 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 a laparoscopic technique.

  **Note**: In 2005, the CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared to 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 (CPT code 43644)**
  This code essentially describes the same procedure as open gastric bypass but performed laparoscopically.

- **Sleeve Gastrectomy (CPT code 43775)**
  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 with duodenal switch). 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) that is 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 two-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, such as biliopancreatic diversion.

- **Biliopancreatic Diversion with Duodenal Switch (CPT code 43845)**
  CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is a variation of the biliopancreatic bypass described above. 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 biliopancreatic bypass, 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 duodenoileal anastomosis 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 biliopancreatic bypass i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

- **Biliopancreatic Diversion (also known as the Scopinaro procedure) (CPT code 43847)**
  Biliopancreatic diversion (BPD) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the 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," which connects the duodenum, jejunum and remaining ileum to the common distal segment.
  - A 50 to 100 cm "common tract," 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 (i.e., 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, a patient typically will undergo an associated cholecystectomy.

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

- **Adjustable Gastric Banding (CPT code 43770)**
Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is 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 such devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S. The first such device that received FDA approval was the LAP-BAND (original applicant, Allergan Inc., BioEnterics, Carpinteria, CA; sold to Apollo Endosurgery Inc., Austin, TX, in 2013). 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 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. 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-labeled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 with at least one obesity-related comorbid condition.

  A second adjustable gastric banding device was approved by the FDA through the Premarket Approval (PMA) process in September 2007, the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are as listed below:

  “The [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m2, or a BMI of at least 35 kg/m2 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.”

- **Mini Gastric Bypass (no specific CPT code)**

In this variant of the gastric bypass, using a laparoscopic approach, the stomach is segmented as in 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. The unique aspect of this procedure is not based on its laparoscopic approach, but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

- **Endoluminal (also called endosurgical, endoscopic, or natural orifice) bariatric procedures (no specific CPT code)**
  With these procedures, access to the relevant anatomical structures is gained endoscopically through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce the 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 duodenal-jejunal sleeve and gastric balloon.

- **Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S) (no specific CPT code)**
  The SADI-S is a type of type of bariatric surgery with a single anastomosis. It has a restrictive component when reducing the greater curvature of the stomach, but specially a malabsorptive component, as the common channel is also reduced. The objective of this surgical technique is to lessen the intestinal loop where nutrients are absorbed.

- **Stomach Intestinal Pylorus-Sparing Surgery (SIPS) (No specific CPT code)**
  SIPS is a type of weight-loss surgery. It was developed in 2013 by two U.S. surgeons. The SIPS is a modified version of the duodenal switch surgery. The SIPS involves the creation of a 300-cm common channel with a single-anastomosis duodenal enterostomy.

- **Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847)**
  Recently, 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, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially 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. Note that CPT code for gastric bypass explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

- **Laparoscopic Malabsorptive Procedure (CPT code 43645)**

Code 43645 was introduced in 2005 to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.

- **Laparoscopic Gastric Plication (no specific CPT code)**
  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 two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.

### 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 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” is based on 1983 Metropolitan Life Insurance Company height-weight tables for “medium frame”.

These 2 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 variations 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 morbidly obese |
| Decrease in 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 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 | No. 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 |

BMI: body mass index; 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 VBG due to pouch ligation.

**Long-Term Complications (Metabolic Adverse Events, Nutritional Deficiencies)**
Metabolic adverse events 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 diabetes, cardiovascular risk factors (i.e., increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

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## Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Several gastric bands for use in bariatric surgery have received FDA-approval through the premarket approval process and are summarized in Table 2 (FDA Product Code: LTI):

**Table 2: FDA-Approved Bariatric Surgery Devices**

| Device | Manufacturer | PMA Date | Labeled Indications |
|---|---|---|---|
| ObalonTM intragastric balloon system | Obalon Therapeutics, Inc. | Sept 2016 | For use in obese adults (BMI, 30 to 40 kg/m2) 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 BME of 35.0 to 55.0 kg/m$^2$ and no contraindications to the procedure who have failed to achieve and maintain 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. |
| 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 conditions, 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) |
| LAP-BAND® Adjustable Gastric Banding System | Apollo Endosurgery | 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 comorbid conditions 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; 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. A second set of adverse 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 US) 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."

## Medical Policy Statement

The safety and effectiveness of laparoscopic and open gastric restrictive procedures including but not limited to Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch, and adjustable gastric band have been established. They may be considered useful therapeutic options when specified criteria are met.

## Inclusionary and Exclusionary Guidelines

**Inclusions:**

Surgical procedures are considered established treatment options if **all** of the following criteria are met:

- The individual has:
  - a BMI >40 **OR**
  - a BMI of >35 with **one** or more co-morbid conditions including, but not limited to:
    - Degenerative joint disease (including degenerative disc disease)
    - Hypertension
    - Hyperlipidemia, coronary artery disease
    - Presence of other atherosclerotic diseases
    - Sleep apnea
    - Congestive heart failure

    **OR**
  - a BMI > 30 with type 2 diabetes
- All individuals 18 to 60 years of age with conditions above.
- Individuals above 60 years of age may be considered if it is documented in the medical record that the individual's physiologic age and co-morbid condition(s) result in a positive risk/benefit ratio.
- Criteria for bariatric surgery for individuals younger than 18 years of age are similar: 1) BMI ≥40 kg/m2 (or 140% of the 95th percentile for age and sex, whichever is lower); 2) BMI ≥35 kg/m2 (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant comorbidities; and should include documentation that the primary care physician has addressed the risk of surgery on future growth, the patient's maturity level and the patient's ability to understand the procedure and comply with postoperative instructions, as well as the adequacy of family support.
- The individual has undergone multidisciplinary evaluation by an established bariatric treatment program to include medical, nutritional and mental health evaluations to determine ultimate candidacy for bariatric surgery. Such an evaluation should include an assessment of the patient's likely ability and willingness to cooperate effectively with a rigorous post-operative program. This should include documentation of past participation in a non-surgical weight loss program. Documentation of a non-surgical weight loss program is waived for super morbidly obese individuals who have a BMI ≥50.
- The non-surgical program participation and multi-disciplinary evaluation must have occurred within 4 years of the date of surgery.
- A psychological evaluation must be performed as a pre-surgical assessment by a contracted mental health professional in order to establish the patient's emotional stability, ability to comprehend the risk of surgery and to give informed consent, and ability to cope with expected post-surgical lifestyle changes and limitations. Such psychological consultations may include one unit total of psychological testing for purposes of personality assessment (e.g., the MMPI-2 or adolescent version, the MMPI-A).
- In cases where a revision of the original procedure is planned because of failure due to anatomic or technical reasons (e.g., obstruction, staple dehiscence, etc.), or excessive weight loss of 20% or more *below* ideal body weight, the revision is determined to be medically appropriate without consideration of the initial preoperative criteria. The medical records should include documentation of:
  - The date and type of the previous procedure
  - The factor(s) that precipitated the failure and/or the nature of the complications from the previous procedure that mandate (necessitate) the takedown
- If the indication for the revision is a weight gain OR a failure of the patient to lose a desired amount of weight DUE TO PATIENT NON-ADHERENCE, then the patient must re-qualify for the subsequent procedure and meet all of the initial preoperative criteria.

**Exclusions:**

The following surgical procedures are considered experimental/investigational because their safety and/or effectiveness have not been proven:

- Loop gastric bypass gastroplasty using a Billroth II type of anastomosis, also known as mini gastric bypass
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., >150 cm)
- Stomach stapling (Vertical banded gastroplasty)
- Endoscopic/endoluminal procedures (including but not limited to insertion of the StomaphyX™ device, use of the Overstitch device, insertion of a gastric balloon, endoscopic gastroplasty, intragastric balloons, aspiration therapy device 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).
- Any bariatric surgery for individuals with type 2 diabetes who have a BMI of less than 30.
- Laparoscopic gastric plication
- Vagus nerve blocking (see separate policy, "Vagus Nerve Blocking for Morbid Obesity."
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)
- Stomach intestine pylorus sparing surgery (SIPS)
- Bariatric surgery for pre-adolescents
- Natural Orifice Transluminal Endoscopic Surgery (NOTES™)
- Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time).

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### *Established codes:*

| | | | | | |
|---|---|---|---|---|---|
| 43644 | 43645 | 43770 | 43771 | 43772 | 43773 |
| 43774 | 43775 | 43843 | 43845 | 43846 | 43847 |
| 43848 | 43886 | 43887 | 43888 | 43999 | 44130 |
| 96130 | 96131 | 96136 | 96137 | 96138 | 96139 |
| S2083 | | | | | |

### *Other codes (investigational, not medically necessary, etc.):*

| | | | | |
|---|---|---|---|---|
| 43999* | 96146 | 43290 | 43291 | 43842 |

**When used to indicate any of the following procedures:*

- *Loop gastric bypass gastroplasty - also known as mini-gastric bypass*
- *Stomach stapling*
- *SADI-S*
- *SIPS*
- *Endoscopic procedures to treat weight gain after bariatric surgery*
- *Natural Orifice Transluminal Endoscopic Surgery (NOTES™)*

## Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

The following overview section is a summary of the key literature to date.

**Overview: Bariatric Surgery In Adults With Class III Obesity**

There is a vast amount of literature published over the last few decades on bariatric surgery for adults with morbid 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 (AEs). 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. There are some comparative trials, including randomized and nonrandomized designs, which compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedure. The emphasis for this literature review will be on comparative trials that compare bariatric surgery to nonsurgical therapy or that compare different types of bariatric surgery procedures. RCTs 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

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 evidence review 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 was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/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 were self-selected into treatment, and there were baseline differences between groups, primarily reflecting weight that is more excess and a higher incidence of co-morbidities in the surgery group. There were a total of 2,010 people who chose surgery and 2,037 individuals who 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 individual surgeon chose the surgical procedure offered. Most of the procedures were vertical-banded gastroplasty (VBG) (over 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. The patients are followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

There have been many publications from this trial reporting on methods, weight loss, and clinical outcomes.[3-6] The following general conclusions can be drawn from the SOS study:

- Weight loss is greater with bariatric surgery compared to conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight, compared to a weight gain of 1.6% in the conservative treatment group.
- There is definite improvement in glucose control for diabetics and a reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors, e.g. hypertension and lipidemia is also positive, but less marked than that seen for diabetes
- Mortality is reduced by 29% after a mean follow-up of 10.9 years
- Quality of life shows improvement in the 2-10 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 (LABS) Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding with follow-up through 3 years post procedure.[7] The study enrolled 2458 subjects, with median BMI 45.9 (interquartile range [IQR], 41.7-51.5). For their first bariatric surgical procedure, 1738 participants underwent Roux-en-Y gastric bypass, 610 laparoscopic adjustable gastric banding, 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 adjustable gastric banding patients with available data at 3 years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years post-surgery, 67.5% and 28.5% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in

0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the Roux-en-Y gastric bypass patients and 17.5% (95% CI, 13.8% to 21.9%) of laparoscopic adjustable gastric banding patients.

### National Patient-Centered clinical Research Network (PCORnet) - Bariatric Study

The PCORnet Bariatric Study is a large retrospective, comparative study of 65,093 patients aged 20-79 years who underwent Roux-en-Y gastric bypass (RYGB) (n= 32,208), laparoscopic adjustable gastric banding (LAGB) (n=29,693), or sleeve gastrectomy (SG)(n=3192) with follow-up through five years postprocedure.[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 AGB is associated with the lowest amount of weight loss as observed in a large and diverse patient cohort.

**Table 3. PCORnet Bariatric Study Results**

| | Mean TWL, % (95% CI) | | | MAE, % (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 been published on the efficacy of bariatric surgery compared with conservative therapy or compared different types of bariatric surgery techniques, some of which are older and/or do not include 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 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 identifying 45 RCTs for inclusion on RYGB (2 studies vs. control), SG (3 studies vs. control), LAGB (5 studies vs. control), and BPD with duodenal switch (BPD-DS; 3 studies vs. RYGB). Based on 33 trials,

superior efficacy for %EWL compared to standard-of-care was seen for BPDDS (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 % 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 (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 3-5 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 vs. SG; 2 RYGB vs. LAGB; 1 SG vs. 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, 1-5). A meta-analysis for the outcome of BMI reduction showed that there was no difference between SG and RYGB (6 trials): 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 compared with 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, with 1798 participants, with sample sizes from 15 to 250. All 7 RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at 1- to 2-year follow-up. However, the authors note that AE rates and reoperation rates were poorly reported across trials, and long-term follow-up (beyond 1-2 years) is 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 BMI of 30 or more.[17] A total of 11 studies with 796 patients were included. Overall, patients after bariatric surgery lost more body weight than patients after nonsurgical treatment (mean difference, -26 kg; 95% CI, -31 to -21; p<0.001). Remission of type 2 diabetes mellitus (T2DM) was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of remission with T2DM, 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 of 261 (8%) patients required reoperations (5/124 after adjustable gastric banding, 4/69 after Roux-en-Y gastric bypass, 1/49 after sleeve gastrectomy, 1/19 after BPD). Similar to the Colquitt et al meta-analysis, no studies reported longer-term follow-up (beyond 2 years) and heterogeneity between studies was 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] The authors included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean pre-surgery BMI was 45.62, and among the studies that provided information about obesity-related comorbidities, 26.2% of patients had T2DM, 47.39% had hypertension, 27.97% had dyslipidemia, 7.15% had cardiovascular disease, and 25.30% had sleep apnea. 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, compared with 10% for observational studies (10% [95% CI, 7% to 13%]). At 1-year follow-up, mean change in BMI was -13.53 (95% CI, -15.51 to -11.55) in RCTs and -11.79 (95% CI, -13.89 to -9.69) in observational studies. Decreases in BMI were generally sustained over 2 to 4 years of follow-up among the studies with longer term follow-up. Puzziferri et al (2014) conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies (N=7971patients). [19] At follow-up, which ranged from 2 to 5 years post-procedure, the mean sample size-weighted percentage of 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 rely primarily on the results of observational studies and include the outcomes of hypertension, T2DM, 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=2198) 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 18national 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 to0.83; 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 review.

#### Populations
The relevant population of interest are individuals who are adults with morbid obesity. Morbid obesity is defined as a body mass index (BMI) 40 kg/$m^2$ or more or a BMI 35 kg/$m^2$ or more with at least 1 clinically significant obesity-related disease such as diabetes, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

#### 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 anastomosis); 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, 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 at the anastomotic, and metabolic complications, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia.

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

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

Yan et al. (2016) published a systematic review of RCTs comparing gastric bypass and medical treatment in obese patients (i.e., BMI $\geq$30 kg/m$^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).

A 2005 TEC Assessment focused on laparoscopic gastric bypass, which intends to reproduce the open procedure via minimally invasive techniques. [44] This technically complex surgery requires a dedicated team and a relatively high degree of skill and experience in laparoscopic technique. This Assessment reviewed 7 comparative trials of the open gastric bypass and laparoscopic gastric bypass, including 3 RCTs. Also, 18 large clinical series of laparoscopic gastric bypass were included. The Assessment concluded that weight loss at 1 year was similar for laparoscopic and open gastric bypass approaches. Longer follow-up periods were less well-reported but appeared to be similar for both approaches. While comparisons of complication rates were less certain, some patterns were evident and consistent across the data examined. The profile of adverse events differed between the 2 approaches, with each having advantages and disadvantages. Laparoscopic gastric bypass offered a less invasive procedure associated with decreased hospital stay and earlier return to usual activities. Mortality might be lower with the laparoscopic approach, although both procedures had mortality rates less than 1%. Postoperative wound infections and incisional hernias were also less frequent with laparoscopic gastric bypass. However, anastomotic problems, gastrointestinal tract bleeding, and bowel obstruction appeared to be higher with the laparoscopic approach, though not markedly higher. Given these data, the overall benefit-risk profile for these 2 approaches appeared to be similar.

**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.[45] 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 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.[46] 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/m2. 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 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. TEC Assessments and other systematic reviews found that gastric bypass improved health outcomes, including weight loss and remission of T2D. A TEC Assessment also found similar weight loss with open and laparoscopic gastric bypass.

## Laparoscopic Adjustable Gastric Banding for Adults with Class III Obesity

### Clinical Context and Therapy Purpose
The purpose of laparoscopic adjustable gastric banding 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 review.

### Populations
The relevant population of interest are individuals who are adults with morbid obesity.

### Interventions
The therapy being considered is laparoscopic adjustable gastric banding.

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

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

The existing literature evaluating laparoscopic adjustable gastric banding as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 2 years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, one-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5-10 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:

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

**Systematic Reviews**
A 2006 TEC Assessment updated the evidence on LAGB, and compared outcomes to those of gastric bypass.[47] This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the two procedures to allow the optimal choice to be made based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at 1 year is less for LAGB compared with GBY. The percentage of excess weight lost (EWL) at 1 year is in the range of approximately 40%, compared to 60% or higher for GBY. At time points longer than 1 year, some of the comparative studies report that the difference in weight loss between LAGB and GBY lessens, but others do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss between the procedures begins to lessen after 1 to 2 years of follow-up. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

These studies also confirm that short-term (perioperative) complications are very low with LAGB and lower than with either open or laparoscopic GBY. Death is extremely rare, and

serious perioperative complications probably occur at rates of less than 1%. The reported rates of long-term AEs vary considerably. In the comparative trials, re-operations are reported in approximately 25% of patients, while in the single-arm studies, the composite rate for re-operations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the range of rates for band slippage is 1–36%, and the range for port access problems is 2–20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. A recent publication by Ibrahim et al (2017) reviewed 25,042 Medicare beneficiaries who underwent a laparoscopic gastric band surgery; 18.5% (n=4636) patients underwent one or more reoperation(s). Reoperation was prompted by the need for band removal (41.8%), band and port replacement (28.6%), and other requirements.[48] The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ratio for LAGB.

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the benefits, as defined by the amount of weight loss, will also be less for LAGB. The patterns of long-term complications also differ between the two 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 systematic review by Chakravarty et al. (2012) [49] comparing LAGB with other bariatric surgery procedures drew conclusions similar to the TEC Assessment. Reviewers 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 gastrectromy [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).[50] Between 2009 and 2013, 652 patients with a mean BMI of 45.4 kg/m$^2$ were treated at 17 participating centers in the US and Canada. At 5 years, the explant rate was 8.74% (95% CI: 6.6–10.9%). 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, is associated with fewer serious adverse events.

## SLEEVE GASTRECTOMY FOR ADULTS WITH CLASS III OBESITY

### Clinical Context and Therapy Purpose

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

The following **PICO** was used to select literature to inform this review.

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

**Interventions**
The therapy being considered is sleeve gastrectomy, 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 overall survival, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating sleeve gastrectomy as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 5 years. While studies described below all reported at least one 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 5-10 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:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. 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 biliopancreatic diversion with duodenal switch. It has also been proposed as the first step in a 2-stage procedure, with gastric bypass or biliopancreatic diversion as the second stage.

Numerous recent systematic reviews have compared SG and RYGB with regard to effects on weight, comorbidities, andcomplications.[51-56]

Lee et al (2021) performed a meta-analysis evaluating long-term (5 years) outcomes of laparoscopic RYGB versus SG (Table 4).[57] A total of 33 studies (N=2475) 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 (Table4).[51] 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 18studies (N=2917) that compared weight loss and comorbidity resolution between laparoscopic SG and RYGB (Table 4).[52] 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 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).[53] 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.[54] 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.[159]

Osland et al (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB (see Table 4).[59] The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (total 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 (see 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.[60] 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/m2 (range: -6.3 to -15.7 kg/m2) and RYGB: -12.6 kg/m2 (range: -9.5 to -15.4 kg/m2) 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 2016 systematic review by Juodeikis and Brimas (2017) summarized evidence on long-term results after SG (see Table 4).[61] Reviewers included 1 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, gastroesophageal reflux disease (GERD), and degenerative joint diseases also improved in most patients (see 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 (total N=18,766 patients) comparing SG with LRYGB for morbid obesity, Zhang et al. (2015) reported no significant difference in percent EWL from 0.5 to 1.5 year follow-ups (see Tables 4 and 5).[62] However, after 1.5 years, Roux-en-Y bypass 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 Roux-en-Y bypass (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

In 2013, Trastulli et al conducted a systematic review of randomized trials that compared SG with other bariatric procedures (see Table 4).[63] Summary statistics were provided; meta-analyses were not conducted (see Table 5). The authors reported mean complication rates with SG of 12.1% (range, 10%-13.2%) compared with 20.9% with LAGB (range, 10%-26.4%). Percent EWL ranged from 49% to 81% with SG compared with 62.1% to 94.4% with LAGB.

In 2009, Brethauer et al reviewed 36 studies (n=2570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers (see Table 4).[64] Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (n=1,749) on SG as primary procedure. Mean percentage of excess weight loss (% EWL) was reported in 24 studies (n=1,662) and was 55.4% overall (range, 33–85%). Mean postoperative BMI was reported in 26 studies (n=1940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with greater 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 reporting detailed complication data (n=2,570). 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 and 3 in the primary procedure group).

**Table 4. Systematic Review Characteristics for Sleeve Gastrectomy**

| Study | Dates | Studies | Participants | Design | Duration |
|---|---|---|---|---|---|
| Lee et al (2021) [57] | Through Jan 2019 | 33 | SG=1252; RYGB=1223 | RCTs | 1 to 5 y |
| Gu et al. (2020)[51] | Through Jan 2019 | 28 | SG=4597; RYGB=4441 | 7 RCTs; 6 prospective; 15 retrospective | 3 to 7 y |
| Han et al. (2020)[52] | Through Jan 2020 | 18 | 2917 | 9 RCTs; 9 nonrandomized studies of interventions | 1 to 82.2 mo |

| | | | | | |
|---|---|---|---|---|---|
| Sharples et al. (2020)[53] | Through Dec 2018 | 5 | 729 | RCTs | 5 y |
| Shenoy et al. (2020)[54] | 1991 to 2019 | 9 | SG=683; RYGB=1557 | RCTs; observational studies | Minimum follow-up: 1 y |
| Osland et al. (2017)[59] | 2000 to Nov 2017 | 9 | SG=437; RYGB=428 | RCTs | 3 mo to 5 y |
| Juodeikis et al. (2017)[61] | Through May 2016 | 20 | 1626 | 1 RCT; 19 retrospective | 5 to 11 y |
| Zhang et al. (2015)[62] | Through Oct 2013 | 21 | 18,766 | 8 RCTs; 13 nonrandomized comparative | 1 to 5 y |
| Trastulli et al. (2013)[63] | Through Nov 2012 | 15 | 1191 | RCTs | 6 mo to 3 y |
| Brethauer et al. (2009)[64] | 1996 to 2009 | 36 | 2570 | 2 RCTs; 1 cohort; 33 case series | 3 mo to 5 y |

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

**Table 5. Systematic Review Results for Sleeve Gastrectomy**

| Study | Percent EWL (95% CI) | Comorbidities (95% CI) |
|---|---|---|
| Lee et al (2021)[57] | Mean difference SG vs RYGB:<br>1 y (16 trials): -1.25 kg/m2 (-2.01 to -0.49)<br>3 y (5 trials): -1.71 kg/m2 (-2.68 to -0.74)<br>5 y (4 trials): -1.46 kg/m2 (-3.15 to 0.23) | Remission, SG vs RYGB:<br>T2D (1 y): RR, 0.86 (0.71 to 1.04)<br>T2D (3 y): RR, 0.88 (0.72 to 1.07)<br>T2D (5 y): RR, 0.79 (0.57 to 1.10)<br>Hypertension (5 y): RR, 0.86 (0.68 to 1.10)<br>Dyslipidemia (5 y): RR, 0.68 (0.46 to 1.23) |
| Gu et al (2020)[51] | Weighted mean difference, RYGB and SG:<br>3 y (13 trials): -4.37 (-8.10 to -0.64)<br>5 y (9 trials): -2.20 (-3.83 to -0.57) | Remission, RYGB and SG:<br>Type 2 diabetes (3 y): OR, 0.68 (0.48 to 0.95)<br>Type 2 diabetes (5 y): OR, 0.63 (0.41 to 0.96)<br>Hypertension (5 y): OR, 0.51 (0.38 to 0.68)<br>Dyslipidemia (5 y): OR, 0.3 (0.19 to 0.48) |
| Han et al (2020)[52] | Mean difference, RYGB and SG: RCTs: -0.16 (-0.52 to 0.19) | Resolution, RYGB and SG:<br>Type 2 diabetes: RR, 1.07 (0.89 to 1.28)<br>Dyslipidemia: RR, 1.36 (1.17 to 1.59)<br>Hypertension: RR, 1.23 (1.04 to 1.45)<br>GERD symptoms: RR, 0.16 (0.06 to 0.44) |
| Sharples et al (2020)[53] | 5 y:<br>RYGB: 65.7%<br>SG: 57.3% | RYGB vs. SG at 5 y:<br>Type 2 diabetes resolution: 37.4% vs. 27.5%<br>Diabetes improvement: 77.5% vs. 74%<br>Hypertension resolution: 60.1% vs. 48.4%<br>Hypertension improvement: 86.4% vs. 76.6%<br>Dyslipidemia resolution: 68.6% vs. 55.2%<br>GERD remission: 60.4% vs. 25% |
| Shenoy et al (2020)[54] | Mean difference, RYGB and SG:<br>-7.79 (-23.96 to 8.38) | Resolution, RYGB and SG:<br>Type 2 diabetes (5 studies): OR, 1.02 (0.63 to 1.66)<br>Hypertension (4 studies): OR, 0.57 (0.35 to 0.93)<br>Obstructive sleep apnea (2 studies): OR, 1.14 (0.55 to 2.34) |
| Osland et al (2017)[59] | Mean difference, SG and RYGB: 6 mo (3 trials): 0.5 (-5.0 to 6.0) | NR |

| | | |
|---|---|---|
| | 12 mo (2 trials): 7.6 (-0.1 to 15.3) | |
| Juodeikis et al (2017)[61] | Mean rates for SG: 5 y (17 trials): 58.4%<br>7 y (2 trials): 56.6%<br>11 y (1 trial): 62.5% | Remission/improvement:<br>Type 2 diabetes: 77.8%<br>Hypertension: 68.0%<br>Dyslipidemia: 65.9%<br>Sleep apnea: 75.8% |
| Zhang et al (2015)[62] | Mean difference, RYGB and SG: 6 mo (9 studies): 0.2 (-2.5 to 2.9)<br>12 mo (15 studies): 2.9 (-0.2 to 6.0)<br>4 y (3 studies): 2.7 (0.2 to 5.2) | Mean difference resolution, RYGB and SG:<br>Type 2 diabetes (10 studies): 3.3 (2.0 to 5.5)<br>Hypertension (10 studies): 1.3 (0.7 to 2.4)<br>Dyslipidemia (5 studies): 1.1 (0.3 to 1.3)<br>Sleep apnea (7 studies): 1.5 (0.8 to 2.6) |
| Trastulli et al (2013)[63] | Mean by procedure:<br>SG: 49% to 81%<br>LGB: 62% to 94%<br>LAGB: 29% to 48% | Type 2 diabetes:<br>SG, 67% to 100%<br>LGB, 80% to 100% |
| Brethauer et al (2009)[64] | Mean rate overall for SG: 55% (range, 33% to 85%) | Remission/improvement:<br>Type 2 diabetes: >70%<br>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.

## Randomized Controlled Trials

Hofsø et al (2019) published the results of a single-center, triple-blind RCT comparing the efficacy of Roux-en-Y gastric bypass (RYGB) (n=54) vs. sleeve gastrectomy (SG) (n=55) on diabetes remission and ß-cell function in patients with obesity and T2D.[65] Inclusion criteria included previously verified BMI ≥35 kg/m$^2$ and current BMI ≥33.0 kg/m$^2$, hemoglobin A1c (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 sleeve gastrectomy group (risk difference 27%; 95% CI, 10 to 44; relative risk [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 two 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 (SG) or Roux-en-Y gastric bypass (RYGB).[66] 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 (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 laparoscopic sleeve gastrectomy (SG; n=121) or Roux-en-Y gastric bypass (RYGB; n=119).[67] Five-year estimated mean percentage excess weight

loss was 49% (95% CI: 45–52%) for sleeve gastrectomy and 57% (95% CI: 53–61%) for gastric bypass. For SG and RYGB, respectively, rates of remission of type 2 diabetes 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-yr morbidity rate was 19% for SG and 26% for RYGB (p=0.19), and there was no significant difference in QOL 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 sleeve gastrectomy 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. [68] 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 laparoscopic sleeve gastrectomy with gastric bypass was published in 2012.[69] The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to sleeve gastrectomy. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the sleeve gastrectomy group (p=0.29). Minor complications were more common in the gastric bypass group compared to sleeve gastrectomy (17.1% versus 7.4%, p=0.02), as was combined major and minor complications (26.5% versus 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.[70] 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 and laparoscopic isolated SG in 80 patients and reported 3 year follow-up.[71] Median baseline BMI was 37 kg/m$^2$ (range, 30-47) in the LAGB groups and 39 kg/m$^2$ (range, 30-53) 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) after 1 year and 18 kg/m$^2$ (range, 0-39) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m$^2$ (range, 0-45) and 27.5 kg/m$^2$ (range, 0-48) 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 authors 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 WITH DS) WITH CLASS III OBESITY

### Clinical Context and Therapy Purpose
The purpose of biliopancreatic diversion with duodenal switch 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 review.

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

### Interventions
The therapy being considered is biliopancreatic diversion with duodenal switch. 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 morbid obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

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

The existing literature evaluating biliopancreatic diversion with duodenal switch as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 15 years. While studies described below all reported at least one 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 5-10 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:

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

**Systematic Review**

In an evidence-based review of literature, Farrell et al (2009) summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at the mean of 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies, aggregate n=896 patients), 67% for RYGB (7 studies, n=1,627), and 42% for AGB (11 studies, n=4,456 patients).[72] At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies, aggregate n=174 patients), 58% for RYGB (3 studies, n=176 patients), and 55% for AGB (5 studies, n=640 patients). The authors note that "given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another."

**Non-randomized Comparative Studies**

Skogar et al (2017) published results from a retrospective mail survey of patients undergoing BPD/DS (n=113) or RYGB (n=98) (see Table 6).[73] Reduction in BMI was statistically larger in patients receiving BPD/DS compared with patients receiving RYGB (see Table 7). Both groups experienced significant reductions in diabetes and sleep apnea. 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 either RYGB (n=50) or BPD (n=22) (see Table 6). Choice of surgery was per surgeon and/or patient, and the patient populations differed in age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 23.3 for BPD compared to 16.5 for RYGB ($p<0.001$).[74]

Prachand et al published the largest comparative series of 350 super-obese patients with BMI greater than 50 who underwent either RYGB (n=152) or Scopinaro BD combined with the DeMeester duodenal switch (DS-BPD) (n=198) (see Table 5).[75] In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The DS-BPD patients differed from RYGB patients on weight and BMI; mean weight in pounds was 368.2 $\pm$ 52.3 (range, 267.4–596.5) in DS-BPD patients versus 346.3 $\pm$ 55.2 (range, 239.8–504.9) in the RYGB group, and mean BMI was 58.8 $\pm$ 6.7 (range, 50–96) in DS-BPD patients versus 56.4 $\pm$ 6.8 (range, 49.5–84.2) in the RYGB group. At 1 year, data were reported for 143 DS-BPD patients and 81 RYGB patients (see Table 7). The EWL was greater for BPD versus RYGB (64.1% vs. 55.9%, respectively; $p<0.01$), and the reduction in BMI was also greater for BPD versus RYGB

(23.6 vs. 19.4, respectively; p<0.001). Complications and data on resolution of comorbidities were not reported in this study.

**Table 6. Nonrandomized Comparative Study Characteristics for BPD/DS**

| Author | Country | Dates | Participants | Follow-up |
|---|---|---|---|---|
| Skogar et al (2017)[73] | Sweden | 2003-2012 | • BPD/DS: 113<br>• RYGB: 98 | 4 y |
| Strain et al (2007)[74] | United States | 2002-2005 | • BPD/DS: 22<br>• RYGB: 50 | • BPD/DS: 19 mo<br>• RYGB: 15 mo |
| Prachand et al (2006)[75] | United States | 2002-2005 | • BPD/DS: 198<br>• RYGB: 152 | 3 y |

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

**Table 7. Nonrandomized Comparative Study Results for BPD/DS**

| Study | Mean Reduction in BMI (SD) | | | Percent Achieving ≥50% EBWL | | |
|---|---|---|---|---|---|---|
| | Presurgery, kg/m$^2$ | Post-surgery, kg/m$^2$ | P[a] | 1 Year | 2 Years | 3 Years |
| Skogar et al (2017)[73] | | | | | | |
| BPD/DS | 56 (6.7) | 31 (5.5) | | | NR | |
| RYGB | 52 (4.0) | 36 (7.1) | <0.01 | | NR | |
| Strain et al (2007)[74] | | | | | | |
| BPD/DS | 54 (11.9) | 30 (6.1) | | | NR | |
| RYGB | 48 (6.3) | 31 (5.0) | <0.001 | | NR | |
| | **Change in BMI** | | | | | |
| Prachand et al (2006)[75] | | | | | | |
| BPD/DS | 59 (6.7) | 27.8 | | 83.9 | 89.2 | 84.2 |
| RYGB | 56 (6.8) | 18.9 | <0.01 | 70.4[b] | 79.3 | 59.3[b] |

BMI: body mass index; BPD/DS: biliopancreatic diversion with duodenal switch; EBWL; excess body weight loss; RYGB: Roux-en-Y gastric bypass
[a] Between groups, difference in change
[b] p<0.05

## Case Series

In 2017, Strain et al reported on the nutrient status of 190 patients receiving BPD/DS after 9 years of follow-up.[76] At baseline, the patients had a mean age of 43 years and mean BMI of 53 kg/m2. 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 DS in 1423 patients from 1992–2005.[77] Follow-up evaluation was 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 equal to or less than 50 obtained BMI less than 35, and 83% of patients with BMI greater than 50 achieved a BMI of less than 40. Diabetes medication was discontinued in 92% and decreased in others. The use of continuous positive airway pressure (CPAP) was discontinued in 92% of patients, and the prevalence of cardiac risk index greater than 5 was 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%. 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.

## BPD WITHOUT DUODENAL SWITCH FOR ADULTS WITH A CLASS III OBESITY

### Clinical Context and Therapy Purpose
The purpose of biliopancreatic diversion without duodenal switch 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 review.

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

### Interventions
The therapy being considered is biliopancreatic diversion without duodenal switch.

### 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, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating biliopancreatic diversion without duodenal switch as a treatment for morbid obesity has varying lengths of follow up, ranging to 9 years. While studies described below all reported at least one 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 5-10 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:

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

## Review of Evidence

### Systematic Review

The available evidence on BPD-DS was reviewed in the 2006 TEC Assessment, and BPB outcomes, with or without DS, were compared with those of gastric bypass.[47] One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 year were in the same range as for gastric bypass. While these data were not sufficient to distinguish small differences in weight loss between the 2 procedures, they did not support the hypothesis that BPB resulted in greater weight loss than open gastric bypass.

### 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 BPB. Slater et al (2004) focused specifically on vitamin and calcium deficiencies following BPB.[78] They 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 BPB.[79] They 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%. In addition, this study reported high rates of iron deficiency (11%-47%) and anemia (11%-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 BPB that included Roux-en-Y gastrectomy in place of SG.[80] 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 BPB have been published, but high-quality trials that directly comparing outcomes of this procedure with gastric bypass are lacking. The largest experience with BPD (N= 1217 patients) was reported by Scopinaro et al. (1996), who developed the procedure.[81] With follow-up of up to 9 years, the authors reported a durable excess weight loss of 75%, suggesting that weight loss is greater with this procedure compared to gastric restrictive procedures. In addition, the vast majority of patients reported disappearance or improvement of such complications as obstructive sleep apnea, hypertension, hypercholesteremia, and diabetes. The authors considered protein malnutrition to be the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity, and presumably, eating habits of the patients, 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 are encouraged to maintain an oral calcium intake of 2 g/day, with monthly vitamin D supplementation.

**Section Summary: BPD Without Duodenal Switch for Adults with Class III Obesity**
A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPB without duodenal switch 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

Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the U.S. An example of these results are a large case series with long-term follow-up by MacLean et al, who reported on 201 patients undergoing VBG who were followed up for a minimum of 2 years.[82] 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.

## TWO-STAGE BARIATRIC SURGERY PROCEDURES FOR ADULTS WITH CLASS III OBESITY

### Clinical Context and Therapy Purpose

The purpose of two-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 review.

### Patients

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

### Interventions

The therapy being considered is two-stage bariatric surgery. Bariatric surgeries that are 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 with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a sleeve gastrectomy, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a biliopancreatic diversion (e.g., BPD), is performed.

### Comparators

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

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

The existing literature evaluating two-stage bariatric surgery as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 5 year. While studies described below all reported at least one 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:

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

**Review of Evidence**

**Randomized Controlled Trial**
Coffin et al (2017) published results on the use of intragastric balloons prior to a LGBP on patients with super obesity.[83] Patients with BMI greater than 45 kg/m$^2$ were randomized to an intragastric balloon (IGB, n=55) or standard medical care (n=60) during the 6 months prior to a planned LGBP 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 compared with patients receiving standard care: IGB (2.8 kg/m$^2$; range 1.7-6.2 kg/m$^2$) vs. standard care (0.4 kg/m$^2$; range 0.3-2.2 kg/m$^2$). Weight loss during months 6 through 12, after the LGBP procedure, was greater in the patients who received standard of care prior to the procedure. Duration of hospitalization after LGBP and quality of life did not differ between the groups.

**Case Series**
A majority of the evidence on 2-stage procedures consists of case-series of patients undergoing SG as the initial procedure. Many of these case series do not report on the second-stage surgery. A minority of patients undergoing the first stage actually proceed to the second-stage surgery. Cottam et al (2006) reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first phase of a planned 2-stage procedure.[84] The incidence of major perioperative complications for laparoscopic SG was 13%. After one year, the mean EWL was 46%. A total of 36 patients (29%) 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.[85] After 1-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 patients

(44% of total) 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 undergoing a stage I SG followed by a BPD in 27 patients.[86] For the first stage of the operation, 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, major complications occurred in 29.6% including bleeding, duodenoileal 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 that a 2-stage bariatric surgery procedure improves outcomes for 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 such that a second procedure is no longer indicated. In addition, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is possible 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 review.

### Populations

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

### Interventions

The therapy being considered is 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. 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 overall survival, 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 one 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 5-10 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:

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

**Systematic Reviews**

Li et al (2021) reported on a systematic review of 18 studies (N=1329) comparing outcomes after laparoscopic SG versus laparoscopic greater curvature gastric plication.[87] 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 a systematic review of studies reporting outcomes after laparoscopic gastric plication (see Table 7).[88] The study included 14 publications, including 1 nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports. The mean preoperative BMI ranged from 31.2 to 44.5 kg/m$^2$. The mean percent EWL after the procedure was reported in 9 studies (N=1407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from 6 to 24 months (see Table 8). 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 and greater curvature plication and reported improved weight loss with greater curvature plication (percent EWL of 53.7% vs. 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no mortality was 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 preformation. Surgical techniques were not standardized.

In a systematic review, Abdelbaki et al (2012) summarized outcomes from seven 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 was mild. Twenty patients (6.5 %) were readmitted, of whom 14 (4.6 %) patients required reoperation, most commonly for gastric obstruction (8/14 [57%]). Tables 8 and 9 discuss characteristics and results, respectively.

**Table 8. Systematic Review Characteristics for Laparoscopic Gastric Plication**

| Study | Dates | Studies | Participants | Design | Duration |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Li et al (2021)[87] | Dec 2020 | 18 | 1329 | • 6 retrospective cohort; 7 prospective cohort; 5 RCTs | 1 mo to 3 y |
| Ji et al (2014)[88] | Jun 2013 | 14 | 1450 | • 1 matched cohort<br>• 10 case series<br>• 3 case reports | 6 mo. to 10 y |
| Abdelbaki et al (2012)[90] | NR | 7 | 307 | • 5 case series<br>• 2 case reports | 3 y |

NR: not reported; RCT: randomized controlled trial.

**Table 9. Systematic Review Results for Laparoscopic Gastric Plication**

| Study | % Excessive Weight Loss | Complication Rate (Range), % | Conclusions |
|---|---|---|---|
| Li et al (2021)[87] | MD (95% CI) between SG and gastric plication:<br>6 mo: 5.37 (1.59 to 9.16)<br>12 mo: 13.23 (9.93 to 16.54)<br>24 mo: 19.62 (1.15 to 38.08)<br>36 mo: 24.63 (-1.94 to 51.21) | OR (95% CI)between SG and gastric plication:<br>Bleeding: 1.37 (0.61to 3.09)<br>Stenosis: 0.57 (0.23to 1.38)<br>Leak: 1.58 (0.61 to4.15)<br>Mortality: 1.39 (0.09to 22.55) | 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. |
| Ji et al (2014)[88] | 31.8-74.4% | 3.7 (0-15.4) | Favorable short-term efficacy and safety profile; long-term follow-up and prospective trials needed. |
| Abdelbaki et al (2012)[90] | 6 no: 51-54<br>12 mo: 53-67 | 8 (7-15.3) | Prospective randomized trials vs. gastric plication with established bariatric procedures needed. |

## Randomized Controlled Trials

Sullivan et al. (2017) published results from the ESSENTIAL trial, a randomized sham-controlled trial evaluating the efficacy and safety of endoscopic gastric plication (see Table 9).[91] Patients (N=332) were randomized 2:1 to receive active or sham procedure. All patients were provided low-intensity life-style therapy. The primary end point was total body weight loss (TBWL) at 12-month follow-up. The mean difference 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 change in weight from baseline, percent excessive weight loss, BMI, and improvement in diabetes (see Table 10). No significant differences were detected in improvements in hyperlipidemia or hypertension between the treatment groups.

**Table 10. RCT Characteristics for Laparoscopic Gastric Plication**

| Author | Countries | Sites | Dates | Participants | Active | Comparator |
|---|---|---|---|---|---|---|
| Sullivan et al (2017)[91] | U.S. | 11 | 2013-2014 | • Patients 22-60 y<br>• BMI $\geq$30 kg/m$^2$ and $\geq$1 obesity-related comorbidity or BMI $\geq$35 kg/m$^2$ and with or without obesity-related comorbidity<br>  • Race (active, sham): | Endoscopic gastric plication (n=221) | Sham procedure (n=111) |

| | |
|---|---|
| | • White: 71%, 64.8%<br>• Indian: 0%, 0.9%<br>• Black: 28.1%, 31.5%<br>• Mixed: 0.9%, 2.8%<br><br>• Ethnicity (active, sham)<br>• Not Hispanic/Latino: 93.7%, 92.8%<br>• Hispanic/Latino: 6.3%, 7.2% |

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

**Table 11. 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; RCT: randomized controlled trial; 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 12 and 13.

**Table 12. 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 patients. | 4. Low-intensity lifestyle therapy used with procedure. | 2. Low-intensity 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 13. Study Design and Conduct Limitations**

| Study | Allocation[a] | Blinding[b] | Selective Reporting[c] | Data Completeness[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

Pattanshetti et al. (2013) published results of a study that described the evolution of a laparoscopic adjustable gastric banded plication procedure, a hybrid procedure involving both adjustable gastric banding and greater curvature plication that was developed by the authors.[93] Eighty patients were included, with mean BMI 38.05 (±4.73) kg/m$^2$. At 6, 12, 18, and 24 months, mean percent EWL was 42.6%, 56.4%, 57.6%, and 65.8%, respectively. Five postoperative complications developed that 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 to 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.

## SINGLE ANASTOMOSIS DUODENOILEAL BYPASS WITH SLEEVE GASTRECTOMY (SADI-S) FOR ADULTS WITH CLASS III OBESITY

### Clinical Context and Therapy Purpose

The purpose of single anastomosis duodenoileal bypass with sleeve gastrectomy 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 review.

### Populations

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

### Interventions

The therapy being considered is single anastomosis duodenoileal bypass.

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

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

The existing literature evaluating single anastomosis duodenoileal bypass as a treatment for class III obesity has varying lengths of follow up, ranging from 3 to 5 years. While studies described below all reported at least one 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 5-10 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:

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

**Review of Evidence**
No controlled trials of SADI-S were identified. Some case series have been published that report on weight loss and other clinical outcomes up to 5 years post-surgery.

**Systematic Review**
Shoar et al. (2018) 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.[94] 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/m2. 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, and87.5% 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.[95] 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), biliopancreatic diversion/duodenal switch (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 excess weight loss; systolic blood pressure; total, HDL and LDL cholesterol; and insulin. Significant differences were not found in diastolic blood pressure or fasting glucose. Among the patients with type 2 diabetes, remission rates according to 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 experienced significantly lower total cholesterol and triglyceride levels compared with those undergoing RYGB after 3 years of follow-up.

**Case Series**

One of the larger series was published in 2015 by Sanchez-Pernaute et al and reported on 97 patients with obesity and type 2 DM.[96] The authors reported that control of DM, defined as $HgA_{1c}$ <6.0%, was achieved in between 70% and 84% of patients at the 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 DM.

**Section Summary: Single Anastomosis Duodenoileal 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.

## STOMACH INTESTINE PYLORUS SPARING SURGERY (SIPS) 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 review.

### Populations

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

### Interventions

The therapy being considered is the SIPS procedure.

Patients who are adults with morbid obesity are actively managed by nutritionists and primary care providers in an outpatient clinical setting and bariatric surgeons for the provision of surgical intervention.

### 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, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating SIPS as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 2 years. Longer follow-up to 5-10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions and appearance of long-term complications.
Neichoy et al (2018) performed a retrospective analysis on data from 225 patients who underwent a primary SIPS procedure by 2 surgeons at a single center.[97] Two hundred twenty-five patients were identified for analysis. The mean preoperative body mass index (BMI) was 52.4 ± 9.1 kg/m$^2$. Forty-eight patients were beyond 2 years after surgery, with data available for 30 patients (62.5% follow-up). Three patients were lost to follow-up. At 2 years, the patients had an average change in BMI of 26.6 U (kg/m$^2$) with an average of 88.7% of excess weight loss. Three deaths were related to the surgery. The most common short-term complication was a leak (2.2%), whereas the most common long-term complication was diarrhea (2.2%).

Mitzman et al. (2016) also collected data from patients who underwent the SIPS procedure for analysis. Regression analyses were performed for all follow-up weight loss data.[98] One hundred twenty-three patients were available. One hundred two patients were beyond 1 year postoperative, with data available for 64 (62%followed up). The mean body mass index (BMI) was 49.4 kg/m$^2$. Two patients had diarrhea (1.6 %), four had abdominal hematoma (3.2 %), and one had a stricture (0.8 %) in the gastric sleeve. Two patients (1.6 %) were readmitted within 30 days. One patient (0.8 %) was re-operated due to an early postoperative ulcer. At 1 year, patients had an average change in BMI of 19 units (kg/m$^2$), which was compared to an average of 38 % of total weight loss or 72 % of excess weight loss. The authors concluded that the SIPS procedure had effective weight loss results.

### Section Summary: Stomach Intestinal Pylorus Sparing Surgery (SIPS) for Adults with Class III Obesity
No published controlled trials have evaluated the SIPS procedure. Two retrospective analyses showed effective weight loss results. Morbidity appears to be comparable to other stapling reconstructive procedures; however, future analyses are required to determine if the SIPS procedure reduces the risk of future small bowel obstructions or micronutrient deficiencies.

## DUODENOJEJUNAL SLEEVE FOR ADULTS WITH MORBID OBESITY 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 review.

**Populations**
The relevant population of interest are 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 morbid obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

**Outcomes**
The general outcomes of interest are overall survival, 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 one 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 5-10 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:

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

**Review of Evidence**

**Systematic Review**
The EndoBarrier (GI Dynamics, Lexington, MA) 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.[99] 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 $HgbA_{1c}$ 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, which included 77 patients with BMI greater than 30 $kg/m^2$.[100] 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 compared to medical therapy (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/$m^2$, $p=0.06$). The $HgA_{1c}$ 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 was not significantly different (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/m2. [101] 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 (12-24 weeks) with duodenojejunal sleeves compared with medical therapy. There was no significant difference in symptom reduction associated with diabetes. All RCTs had small sample sizes and were judged by the systematic reviewers to be at high risk of bias.

## INTRAGASTRIC BALLOON DEVICES FOR ADULTS WITH CLASS III OBESITY

**Clinical Context and Therapy Purpose**
The purpose of intragastric balloon devices (IGB) 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 review.

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

**Interventions**
The therapy being considered is intragastric balloon devices. Intragastric balloons are placed in the stomach via endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2017, 3 gastric balloon devices have FDA approval; All are 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 balloon.

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

**Outcomes**

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

The existing literature evaluating intragastric balloon devices as a treatment for class III obesity has varying lengths of follow up, ranging from 5 to 10 years. While studies described below all reported at least one 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 5-10 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:

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

**Review of Evidence**

**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.[102-105]

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.[105] 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/m2, 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 recent RCTs, published between 2006 and 2016.[106] Additional inclusion criteria were: sham, lifestyle modification, or pharmacologic agent as 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 four of the RCTs contributing to the meta-analysis. The meta-analysis included 777 patients and showed a significant improvement in % 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 % TBWL with IGB is lower than expected with RYGB (reported 27%) or with the most efficacious pharmacologic agent (reported 9%).

Saber et al. (2017) identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention.[102] 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.

Courcoulas et al. (2017) published a multicenter, pivotal RCT evaluating the Obera IGB in the United States (as noted, the device has been used in other countries).[107] 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, they included 1 case of gastric outlet obstruction and 1 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 gastric balloon (now called the Obera device) was published by Genco et al in 2006.[108] 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, they 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, they 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.[109] 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 these 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. 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, one warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016-2017 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 MORBID OBESITY FOR ADULTS WITH CLASS III OBESITY

**Clinical Context and Therapy Purpose**
The purpose of the aspiration therapy 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 review.

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

**Interventions**
The therapy being considered is the aspiration therapy 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 overall survival, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating aspiration therapy device as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 2 years. While studies described below all reported at least one 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:

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

**Review of Evidence**

**Randomized Controlled Trials**
Aspiration therapy 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 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).[110] 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 (≈90%) 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.[111] Aspiration therapy (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 (LT) control group, only 31 completed the full initial study year. Two serious adverse events were reported in years 2-4. 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 post-gastrostomy. No clinically significant metabolic disorders were observed. No evidence for the development of any eating disorders was noted. Study results are summarized in Table 14. Study relevance, design, and conduct limitations are summarized in Tables 15-16.

**Table 14. Results of PATHWAY Trial**

| | | >25% EWL[1] | % TWL | ΔHbA1c[2] | IWQOL Total Score[2,3] |
|---|---|---|---|---|---|
| **Thompson et al (2017); PATHWAY[110]** | **Year 1, n** | **% [95% CI]** | **% (SD) [95% CI]** | **% SD** | **Mean (SD)** |
| AT | mITT: 111<br>PP: 82 | mITT: 56.8 [49.0 to 64.5] | mITT: 12.1 (9.6) [NR]<br>PP: 14.2 (9.8) [12.1 to 16.4] | mITT: -0.36 (0.45)<br>PP: NR | mITT: 6.2 (13.4)<br>PP: NR |
| LT | mITT: 60<br>PP: 31 | mITT: 22.0 [15.3 to 28.1]<br>PP: 25.8 [NR] | mITT: 3.6 (6.0) [NR]<br>PP: 4.9 (7.0) [NR] | mITT: -0.22 (0.27)<br>PP: NR | mITT: 3.3 (10.0)<br>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 | NR | P=0.052 | P=0.034 |
| **Thompson et al (2019); PATHWAY[111]** | **AT[5]** | **>25% EWL1<br>% (SD)** | | **% TWL<br>% (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 body weight loss; HbA1c: hemoglobin A1c; IWQOL: Impact of Weight of Quality of Life survey; LT: lifestyle therapy; mITT: modified intent-to-treat; NR: not reported; PP: per protocol; SD: standard deviation; TWL: total body 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 IWQOL scores.
4 Treatment differences in individual IWQOL component scores did not reach statistical significance.

5 Based on the per-protocol analysis.

**Table 15. Relevance Limitations**

| Study; Trial | Population[a] | Intervention[b] | Comparator[c] | Outcomes[d] | Follow-Up[e] |
|---|---|---|---|---|---|
| **Thompson et al (2017); (2019); PATHWAY** [110,111] | | | 2.No active comparator for years 2-4 | | |

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[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 16. Study Design and Conduct Limitations**

| Study | Allocation[a] | Blinding[b] | Selective Reporting[c] | Data Completeness[d] | Power[e] | Statistical[f] |
|---|---|---|---|---|---|---|
| Thompson et al (2019); PATHWAY [110,111] | | 2.Blinding to outcome assessment unclear. 3.Blinding and identity of outcome assessors unclear. | | 1.High loss to follow-up or missing data. High loss to pre- and post-enrollment withdrawals. 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 carrier through | 1. 1: Study not powered beyond 1 year of follow-up. Study underpowered for completers at 1 year. 3: Rationale for clinically important difference not provided. | 2: Not all sensitivity analyses are statistically significant for primary effectiveness outcome (at least 50% of participants achieving at least 25% EWL); unclear if analysis is appropriate for Multiple observations per patient or extent of missing data. |

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[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.[112] 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 1 RCT with 4-year 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 aspiration therapy 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 Post-gastrostomy 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 aspiration therapy 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.

## REVISION BARIATRIC SURGERY FOR ADULTS WITH CLASS III OBEISTY 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 review.

### Populations

The relevant population of interest are 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 overall survival, 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 morbid obesity has varying lengths of follow up, ranging from 1 to 3 years. While studies described below all reported at least one 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 5-10 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:

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

**Review of Evidence**

**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).113, The mean BMI at the time of conversion ranged from 33.3 to 48.3 kg/m2. The pooled baseline BMI at conversion was 38.5 kg/m2 (95% CI, 36.49 to 40.6), at 6 months was down to 28.6 kg/m2 (95% CI, 16.1 to 41.0), and after 1 year was up to 32.1 kg/m2 (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/minigastric bypass (OABG-MGB) as a revisional bariatric procedure after failure of a primary LAGB and SG.[114] 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% at2 years, and 71.6% at 5 years. Resolution of comorbidities after OAGB-MGB was significant with 80.5% of patients withT2D, 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 for the American Society for Metabolic and Bariatric Surgery that included 175 studies, most of which were single-center retrospective reviews.[115] The review is primarily descriptive, but the authors make 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."

**Nonrandomized Studies**

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.[116] 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/m2. At 2 years after OAGB, 9.7% of patients were lost to follow-up, BMI was down to 28 ± 5.5 kg/m2, %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/m2, %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.[117] 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-RSAGB; 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 vs 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 safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.[118] The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (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.) There were a total of 449,473 bariatric operations in the database of which 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 operations and 8750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1%), AGB (N=153,142, 36.5%), SG (N=42,178, 10%), and BPD±DS (N=4,260, 1%), with the rest classified as miscellaneous. AGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Roux-en-Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs. 1.8±4.9, p<0.001) and for conversions (2.86±4.58 vs. 1.8±4.9, p<0.001). The mean percent EBWL 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 compared with primary operations (0.31% vs. 0.17%, p<0.001), but not for corrections compared with primary operations (0.24% vs. 0.17%, p=*NS*). One-year serious adverse event (SAE) rates were higher for conversions compared with primary operations (3.61% vs. 1.87%, p<0.001), but not for corrections compared with primary operations (1.9% vs. 1.87%, p=*NS*). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

**Endoscopic Revision Procedures**

While bariatric surgery revision/correction can be conducted using standard operative approaches, novel endoscopic procedures are being publicized as an option for these patients. Some of these procedures use devices that are also being evaluated for endoscopic treatment of GERD. The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate).[119] 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.[120] Thompson et al. (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who had weight regain and dilated gastrojejunal anastomoses after RYGB.[121] 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 of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after RYGBP at least 2 years earlier.[122] 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 after preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphyX patients. The primary efficacy end point (reduction in pre-Roux-en-Y gastric bypass excess weight by ≥15%, excess BMI loss, and BMI <35, at 12 months post procedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1 of 29 (3.4%) of the sham control group (p<0.01).

An unusual complication of the commonly performed bariatric procedure of gastric bypass (with use of a Roux-en-Y configuration) is the development of a gastrogastric fistula (between the remaining proximal and distal gastric remnants). Endoscopic suturing represents a highly versatile minimally invasive endoscopic surgical technique for closure of the fistula. Although several other platforms have been previously described, the Apollo Overstitch and Overstitch SX (Apollo Endosurgery Inc, Austin, TX) are FDA approved currently available for use in the management of gastrointestinal perforations, leaks, and fistulas. The device allows physicians to place full thickness sutures (of a gastrogastric fistula). The devices allow physicians to endoscopically place full thickness fistula closure stitches. Small studies have demonstrated permanent closure of small (initial size <10mm) and recurrence of fistulas with initial size greater than 20 mm., necessitating reoperation.

The overstitch device has additionally been used for endoscopic closure of duodenal diverticula.

There are no current long-term, double blind studies of the efficacy of the use of the overstitch device for gastrogastric fistula closure or for the use of the overstitch device for the endoscopic closure of duodenal diverticula. Pending results of long-term studies, the procedure is currently considered investigational.

A 2009 survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons indicates different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures.[64] 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 ASMBS 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."[123]

Cohen et al (2019) conducted a systematic review evaluating the safety and efficacy of endoscopic gastroplasty (EG) for medically uncontrolled obesity.[124] Nine observational studies and a single RCT were identified by the authors. Follow-up duration in the majority of studies was limited to 6-12 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/m2. 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.

**Section Summary: Revision Bariatric Surgery for Adults with Class III Obesity Who Failed Bariatric Surgery**

For surgical revision of bariatric surgery after failed treatment, evidence from 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 AS A TREATMENT FOR TYPE 2 DIABETES (T2DM) FOR ADULTS WITH DIABETES WHO DO NOT HAVE CLASS III OBESITY

**Clinical Context and Therapy Purpose**
The purpose of gastric bypass, sleeve gastrectomy, biliopancreatic diversion, and adjustable gastric banding is to provide treatment options that are alternatives to or improvements on existing therapies, such as standard medical care, in patients who are diabetic and do not have class III obesity.
The following **PICO** was used to select literature to inform this review.

**Populations**
The relevant population of interest are individuals who are diabetic and who do not have class III obesity.

**Interventions**
The therapy being considered is gastric bypass, sleeve gastrectomy, biliopancreatic diversion, and adjustable gastric banding. Current indications for bariatric surgery view poorly or uncontrolled diabetes as a comorbidity whose presence supports the need for surgery in patients with a BMI of less than 35 kg/m2.

**Comparators**
Comparators of interest include standard medical care. Treatment for patients who are diabetic include blood sugar regulation and insulin therapy.

**Outcomes**
The general outcomes of interest are overall survival, 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, sleeve gastrectomy, biliopancreatic diversion, and adjustable gastric banding as a treatment for diabetes has varying lengths of follow up, ranging from 1 to 5 years.

While studies described below all reported at least one 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 5-10 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:

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

## Review of Evidence

### Type 2 Diabetes (T2D) and Body Mass Index Less Than 35 kg/m$^2$

### Systemic Reviews

Wu et al. (2016) published a meta-analysis of studies comparing bariatric surgery and nonsurgical interventions for patients with T2D.[125] Eight RCTs with 619 patients were included. RCTs addressed RYGBP (6 studies), LAGB (3 studies), LSG (1 study), and BPD (1 study). Mean BMI across studies was 29 kg/m$^2$ or higher; in 6 of 8 studies, mean BMI was 35 kg/m$^2$ or higher. One study had 5-year follow-up and the others had 1 to 3 years of follow-up. The study with 5-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m$^2$.[126] All 8 studies reported remission of T2D as an efficacy end point. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR=5.76; 95% CI, 3.15 to 10.55; p<0.001). Another diabetes-related outcome (mean reduction in $HgbA_{1c}$ levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD = -1.29; 95% CI, -1.70 to -0.87). In addition, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD = -5.80; 95% CI, -6.95 to -4.64; p<0.001).

Since publication of the Wu meta-analysis, 5-year follow-up has been reported for the Schauer et al RCT, which is shown in Table 15. When the Wu et al meta-analysis was published, only 3 year findings of the Schauer study were available. The study included patients with T2D who had a BMI of 27-43 kg/m$^2$. The RCTs evaluating bariatric surgery in patients with T2D, including the 5-year follow-up of the Schauer study, are summarized in Table 15.

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m$^2$.[127] Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified. Follow-up was between 1 and 3 years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR=14.1; 95% CI, 6.7 to 29.9; p<0.001). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD = -5.5 kg/m$^2$; 95% CI, -6.7 to -4.3 kg/m$^2$, p<0.001), a lower $HgbA_{1c}$ level (MD = -1.4%; 95% CI, -1.9% to -0.9%; p<0.001), lower rates of hypertension (OR=0.25; 95% CI, 0.12 to 0.50; p<0.001), and lower rates of dyslipidemia (OR=0.21; 95% CI, 0.10 to 0.44; p<0.001).

Also, Rao et al. (2015) published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m$^2$ or less who underwent RYGBP.[128] Nine articles were included (N=343 patients). After 12 months, patients with T2D had a significant decrease in BMI (weighted mean difference [WMD], -7.42; 95% CI, -8.87 to -5.97; p<0.001) and improvements in $HgbA_{1c}$ levels (WMD = -2.76; 95% CI, -3.41 to -2.11; p<0.000). Reviewers reported that longer term follow-up would be needed.

Previously, a 2012 TEC Assessment evaluated bariatric surgery in diabetic patients with a BMI less than 35 kg/m$^2$.[129] The evidence consisted mainly of case series. The Assessment identified only observational studies. Based on the data, the assessment concluded that gastric bypass met TEC criteria as a treatment for diabetes in patients with a BMI less than 35 kg/m$^2$ but that other procedures did not meet the TEC criteria for this indication:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with a BMI less than 35 kg/m$^2$. There was only 1 randomized trial

comparing 2 bariatric procedures. Therefore, studies were categorized by procedure type and presented as case series, regardless of the underlying study type.

- Nine studies reported diabetes remission rates and other outcomes in subjects undergoing gastric bypass. Diabetes remission rates varied between 48% and 100% at follow-up times of 1 year and beyond. One study was a randomized clinical trial of gastric bypass versus SG; in it, diabetes remission associated with gastric bypass was 93% versus 47% for SG at 1 year.
- Two studies reported outcomes of SG. Diabetes remission rates were 55% and 47% at 1 year.
- One study reported outcomes of ileal interposition. The diabetes remission rate at a mean follow-up time of 39.1 months was 78.3%.
- Two studies reported outcomes of gastric banding. The outcomes reported were not considered to be rigorous, because the only measure of diabetes outcome was withdrawal of diabetes medication. Reported remission rates were 27.5% and 50% at variable follow-up times.
- One study of BPD reported a remission rate of 67% for subjects with a BMI between 30 and 35 kg/m$^2$ and 27% for subjects with a BMI between 25 and 30 kg/m$^2$ at 12-month follow-up.
- One study reported outcomes of duodenojejunal exclusion. Subjects in this study had more severe diabetes than subjects enrolled in other studies; 100% were on insulin treatment and the duration of diabetes was between 5 and 15 years. The diabetes remission rate was 17% at 6 months.

Summaries of various systematic reviews and meta-analyses on the use of bariatric or metabolic surgery in patients with a BMI <35 kg/m$^2$ are available, and report efficacy in achieving weight loss, glycemic control, T2D remission, and mitigation of various cardiovascular disease factors through 1-5 years of follow-up.[113,114] However, current studies are limited by heterogeneity in applied surgical intervention and threshold definitions for T2D remission. Longer-term (>5 years) RCTs evaluating the use of metabolic surgery in lower-BMI patients for the treatment of type 2 diabetes are pending (NCT02328599).

Observational studies evaluating patients undergoing bariatric surgery in patients with T2D with follow-up to 3 or more years are shown in Table 17.

**Table 17. RCTs[a] Comparing Bariatric Surgery in Patients With T2D to Control**

| Study (Country) | N | BMI Range, kg/m$^2$ | Patients With BMI ≤35 kg/m$^2$ | Length of FU, years | Definition of Diabetes Remission | Diabetes Remission Rate, n/N (%) | | P-Value |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Surgery (LAGB) | Control (DWM) | |
| Simonson et al (2019) [132] (US) | 40 | 30 to 45 | 39% LAGB; 36% DWM | 3 | FPS <126 mg/dL AND HbA1c <6.5% | 13% | 5% | 0.601 |
| | | | | | | Surgery (LAGB) | Control (ILI/A1C-R) | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Dixon et al (2008) [50] (US) | 60 | 30 to 40 | 22% | 2 | % achieving FBS <126mg/dL HbA1c <6.2% (off meds) | 22/30 (93%) | | 4/30 (13%) | <0.001 |
| | | | | | | Surgery (RYGB) | | Control (HILI/A1C-R) | |
| Ikramuddin et al (2015)[133] (U.S.) | 120 | 30 to 40 | 59% | 2 | % achieving all 3 ADA goals: HbA1c <7.0% LDL <2.59 mmol/L SBP <130 mm Hg | 26/60 (43%) | | 8/59 (14%) | <0.001 |
| | | | | | | Surgery (RYGB) | Control 1 (GCP/A1C-R) | Control 2 (GCP/A1C-S) | |
| Liang et al (2013)[134] (China) | 108 | >28[g] | | 1 | T2D remission[b] | 28/31 (90%) | 0% | 0% | <0.05 |
| | | | | | | Surgery (RYGB) | Surgery (LAGB) | Control (HILI/A1C-S) | |
| Courcoulas et al (2015)[135] (U.S.) | 61 | 30 to 40 | 43% | 3 | Partial: HbA1c <6.5% Full: HbA1c <5.7% (off meds) | 8/20 (40%) Full: 3/20 (15%) | 6/21 (29%) Full: 1/21 (5%) | 0% | 0.004 |
| Courcoluas et al (2020) [136] (U.S.) | | | | 5 | Partial: HbA1c <6.5% Full: HbA1c <5.7% (off meds) | 6/20 (30%) Full: 1/20 (5%) | 4/21 (19%) Full: 0 | 0% | 0.0208 |
| | | | | | | Completers | | | |
| | | | | | | Surgery (RYGB) | Surgery (LSG) | Control (ILI/A1C-S) | |
| Schauer et al (2017) [137] (U.S.) | 150 | 27 to 43 | 37% | 5[h] | % HbA1c <6.0% ( meds) | 14/49 (29%) | 11/49 (23%) | 2/38 (5%) | 0.01[c]/0.03[d] |
| | | | | | | Intention-to-Treat | | | |
| | | | | | | 26.4% | 20.4% | 7.3% | 0.08[e]/0.17[f] |
| | | | | | | Surgery (RYGB) | Surgery (BPD) | Control (GCP/A1C-S) | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Mingrone et al (2015)[126] (Italy) | 60 | 35+ | 0% | 5 | %HbA1c ≤6.5% (% meds ×1 y) | 8/19 (42%) | 13/19 (68%) | 0% | <0.001 |
| | | | | | | Surgery (LAGB) | | Control (ILI/A1C-R) | |
| Wentworth et al (2014)[138] (Australia) | 51 | 25 to 30 | 100% | 2 | <125 mg/dL or 200 mg/dL 2-h OGTT (off meds x2 d) | 12/23 (52%) | | 2/25 (8%) | 0.001 |
| | | | | | | Surgery (RYGB) | | Control (HILI/A1C-S) | |
| Halperin et al (2014)[139] (U.S.) | 43 | 30 to 42 | 30% | 1 | % HbA1c <6.5% | 11/19 (58%) | | 3/19 (16%) | 0.03 |

ADA: American Diabetes Association; A1C-R: HbA1c reasonable goal of <7%; A1C-S: HbA1c stringent goal of <6.5%; BMI: body mass index; BPD: biliopancreatic diversion; DWM: diabetes and weight management; FBS: fasting blood sugar; FU: follow-up; GCP: good clinical practice; HbA1c: hemoglobin A1c; HILI:
highly intensive lifestyle intervention; ILI: intensive lifestyle intervention; LAGB; laparoscopic adjustable gastric banding;
LDL: low-density lipoprotein; LSG: laparoscopic sleeve gastrectomy; OGTT: Oral Glucose Tolerance Test; RYGB: Roux-en-Y gastric bypass; SBP: systolic blood pressure; T2D: type 2 diabetes.

[a] All RCTs in this table are in the Wu et al (2016) meta-analysis; 7 of the 8 (except Mingrone et al) are in the Muller-Stich et al (2015) meta-analysis; the Rao et al (2015) meta-analysis and the TEC Assessment did not include RCTs.
No additional RCTs comparing bariatric surgery with nonsurgical treatment in patients who had T2D were identified.

[b] Used as a secondary outcome. Primary outcome was change in left ventricular mass index.

[c] Unadjusted (RYGB vs. control).

[d] Unadjusted (LSG vs. control).

[e] RYGB vs. control.

[f] LSG vs. control.

[g] WHO Asia-Pacific Obesity Classification.

[h] Through February 2017.

**Table 18: Observational Studies on Bariatric Surgery in Patients with T2D with Follow-up ≥3 years**

| Study (Country) | N | BMI Range, kg/m$^2$ | Pts with BMI ≤35 kg/m$^2$ | Length of FU | Interv | Mean $HgA_{1c}$ | | Mean BMI, kg/m$^2$ | | Diabetes Remission Rate |
|---|---|---|---|---|---|---|---|---|---|---|
| **Group I** | | | | | | **Base** | **FU** | **Base** | **FU** | |
| Scopinaro et al (2014)[81] (Italy) | 20*; 27** | 30-34.9 | 100% | 3 year | RYGB | 9.5% | 7.0%[a] | 32.9 | 26.0[a] | 5/20 (25%) |
| | | | | | Control | 9.3% | 7.7%[a] | 33.0 | 32.6 | |
| Lanzarini et al (2013)[140] (Chile) | 31 | 30-35 | 100% | 30 mo[c] | RYGB | 7.9% | 5.5%[a] | 33.1 | 24.7[a] | 29/31 (94%) |
| Boza et al (2011)[141] (Chile) | 30 | <35 | 100% | 2 years | RYGB | 8.1% | ≈6.2%[a,b] | 33.5 | 23.9[a] | 12 mo: 25/30 (83.3%)<br>2 y: 13/20 (65%) |
| DePaula et al (2012)[142] (Brazil) | 202 | <35 | 100% | 39 mo[c] | SG | 8.7% | 6.1%[a] | 29.7 | 23.5[a] | 171/198 (86.4%) |
| **Group II** | | | | | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Lee et al (2008)[143] (Taiwan) | 544 | 32-77 | NR | 3 years | Bypass | 6.2% | 4.8% | 41.3 | 28.0 | NR |
| | 116 | | NR | | LAGB | 5.9% | 5.2% | 41.9 | 32.7 | |

Group I is defined as poor control optimal medical management (may include insulin). Group II is defined as adequate control with medication (may include insulin).
Base: baseline; BMI: body mass index; Bypass: mini-gastric bypass; FU: follow-up; $HgbA_{1c}$: hemoglobin A1c; Interv: intervention; LAGB; laparoscopic adjustable gastric banding; NR: not reported; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.
*Treated
**Matched diabetic controls
[a] p<0.05 (follow-up vs. baseline)
[b] Estimated from figure
[c] Mean

**Section Summary: Bariatric Surgery as a Treatment for Type 2 Diabetes for Adults with Diabetes Who Do Not Have Class III Obesity**

Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/m2. The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 5 years of follow-up data.

## BARIATRIC SURGERY IN NONDIABETIC PATIENTS WITH A BMI LESS THAN 35 KG/M$^2$

### Clinical Context and Therapy Purpose

The purpose of any bariatric surgery procedure is to provide a treatment option that is an alternative to or improvement on existing therapies, such as standard medical care, in patients who are not diabetic and do not have class III obesity.

The following **PICO** was used to select literature to inform this review.

### Populations

The relevant population of interest are individuals who are not diabetic and do not have class III obesity.

### Interventions

The therapy being considered is any bariatric surgery procedure.

### Comparators

Comparators of interest include standard medical care for nondiabetic patients.

### Outcomes

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

The existing literature evaluating any bariatric surgery procedure has varying lengths of follow up, ranging from 1 to 3 years. While studies described below all reported at least one 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 5-10 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:

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

**Review of Evidence**

**Systematic Reviews**

A 2012 TEC Assessment evaluated laparoscopic gastric banding in individuals without diabetes who had a BMI less than 35 kg/m$^2$.[144] This Assessment was prompted by FDA approval of LAP-BAND for this indication in 2011. The TEC Assessment concluded that LAGB did not meet TEC criteria in these patients and made the following summary statements:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There is only 1 small RCT, which has methodologic limitations, 1 nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB is greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities can be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB were uncertain, and this uncertainty has been one of the main reasons why it is difficult to determine whether the benefit of LAGB outweighs the risk for this population. While the short-term safety of LAGB has been well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

**Section Summary: Bariatric Surgery in Nondiabetic Patients With a BMI Less Than 35 kg/m$^2$**

There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

## BARIATRIC SURGERY IN CLASS III OBESE ADOLESCENT CHILDREN

**Clinical Context and Therapy Purpose**
The purpose of gastric bypass, laparoscopic adjustable gastric banding, or sleeve gastrectomy 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 review.

**Populations**
The relevant population of interest are individuals who are adolescent children with class III 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, laparoscopic adjustable gastric banding, or sleeve gastrectomy.

**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 overall survival, 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, laparoscopic adjustable gastric banding, or sleeve gastrectomy as a treatment for morbid obesity has varying lengths of follow up, ranging from 1 to 6 years. While studies described below all reported at least one 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 5-10 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:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. 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 effects of bariatric surgery for the treatment of adolescents with obesity (see Table 17).[145] 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, and glycemic and lipid control with bariatric surgery techniques. RYGP showed the largest improvements compared with other procedures.

In a systematic review of 23 studies, Black et al (2013) concluded that the available literature demonstrates a high rate of significant short-term weight loss after bariatric surgery (see Table 17).[146] Quality assessment of the included studies was not discussed. Ages of patients at time of surgery ranged from 5 to 23 years. A meta-analysis showed significant reductions in BMI (Table 14). Meta-analysis were not conducted on resolution of comorbidities due to heterogeneity in reporting. However, the majority of cases of hypertension, sleep apnea, type 2 diabetes, and dyslipidemia were reported to have resolved at 1 year follow-up. The authors note 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 (see Table 17).[147] 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 outcome data for 3 or more patients aged 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on from 11 to 68 patients who were 21 years or younger. Eight studies of LAGB (mean BMI 45.8, median age range, 15.6–20 years); 6 studies on RYGB (mean BMI 51.8, median age range 16–17.6 years); 5 studies of other procedures (mean BMI 48.8, 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 (see Table 17). 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 death was 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 death was reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 more died of causes that were 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 19. Systematic Review Characteristics for Bariatric Surgery for Adolescents with Obesity**

| Study (Year) | Dates | Studies | Participants | Design | Duration |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Qi et al (2017)[145] | Jul 2017 | 49 | • RYGP: 1216<br>• LABG: 1028<br>• LSG: 665<br>• Other: 98 | • 1 RCT<br>• 22 prospective<br>• 26 retrospective | 12-120 mo |
| Black et al (2013)[146] | Jan 2013 | 23 | • RYGP: 256<br>• LAGB: 271<br>• LSG: 90<br>• Other: 20 | • 1 controlled<br>• 22 uncontrolled | 6-120 mo |
| Treadwell et al (2008)[147] | Dec 2007 | 18 | • RYGB: 131<br>• LAGB: 352<br>• Other: 158 | • 1 prospective<br>• 17 retrospective | NR |

LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass

**Table 20. Systematic Review Results for Bariatric Surgery for Adolescents with Obesity**

| Study (Year) | 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)[145] | | | |
| 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)[146] | | | |
| 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)[147] | | | |
| 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 Study

Dumont et al (2018) published a retrospective study of obese adolescents who underwent LAGB.[148] 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 reporting results from the Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study, a prospective, multicenter observational study of bariatric surgery in patients aged 19 or younger.[149] The study enrolled 242 participants, with mean age of 17.1 and median BMI 50.5 (IQR, 45.2-58.2) at the time of operation. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by sleep apnea (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). RYGBP, adjustable gastric banding, and vertical SG were performed in 66.5%, 5.8%, and 27.7%, respectively. Within 30 days of

surgery, 20 major complications occurred in 19 patients (7.9%), most of which were perioperative complications. The cohort will be followed to assess longer-term outcomes.

### Gastric Bypass

#### Comparative Studies

Olbers et al (2017) published results from the Adolescent Morbid Obesity Surgery study.[150] Adolescent Morbid Obesity Surgery 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 Review

Willcox et al (2014) conducted a systematic review focusing on studies reporting biopsychosocial outcomes following LAGB in adolescents with obesity.[151] The literature search, conducted through May 2013, identified 11 studies for inclusion. Significant weight loss was reported in all of the studies. Resolution of comorbidities was also reported, though the evidence was poor quality due to limited discussion of comorbidity assessment criteria. Reporting of psychosocial outcomes was considered limited, with the authors concluding that further research is needed to better understand the behavioral, emotional, and social factors experienced by adolescents undergoing LAGB.

#### Randomized Controlled Trial

One RCT of LAGB has been published. O'Brien et al (2010) reported on a prospective, randomized trial from Australia of 50 adolescents between the ages of 14 and 18 years with BMI greater than 35 who received either a lifestyle intervention or gastric banding and were followed up for 2 years.[2] 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, the mean changes in the gastric-banding group were a weight loss of 34.6 kg (95% confidence interval [CI]: 30.2-39.0), representing an excess weight loss of 78.8% (95% CI: 66.6-91.0%). The mean losses in the lifestyle group were 3.0 kg (95% CI: 2.1-8.1), representing EWL of 13.2% (95% CI: 2.6%-21.0). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 operations (33%) 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 these generally report weight loss that is in the same range seen for adult patients. For example, Nadler et al (2008) reported on 73 patients aged 13 to 17 years who have undergone LAGB since 2001 at the authors' institution.[152] Mean preoperative BMI was 48. The EWL at 6 months, 1 year, and 2 years postoperatively was 35% $\pm$ 16%, 57% $\pm$ 23%, and 61% $\pm$ 27%, 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.

**Sleeve Gastrectomy**

Manco et al (2017) published results from contemporaneous cohorts of adolescent patients with BMI of 35 kg/m$^2$ or more and nonalcoholic steatohepatitis who chose between 3 treatment options.[153] Twenty patients chose to undergo laparoscopic SG, 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 laparoscopic SG 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 laparoscopic SG 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 laparoscopic SG 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. [154] Children and adolescents with class II or III obesity underwent LSG between2008 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 II Obese Adolescent Children**

**Gastric Bypass, Laparoscopic Adjustable Gastric Banding, and 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 one compared laparoscopic SG 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.

**Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy**

There is less evidence for the use of bariatric techniques other than gastric bypass, LAGB, and SG. Sample sizes are small for these other techniques and meta-analyses have shown wide confidence intervals in the estimates.

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 review.

### Populations

The relevant population of interest are 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 overall survival, 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 morbid obesity has varying lengths of follow up, ranging from 1 to 5 years. While studies described below all reported at least one 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 5-10 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:

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

**Review of Evidence**
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.[154] In the 5- to 14-yearage 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.

Black et al. (2013; described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents.[146]

**Section Summary: Bariatric Surgery in Morbidly 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 patients with class III obesity and a preoperative diagnosis of hiatal hernia

The following **PICO** was used to select literature to inform this review.

**Populations**
The relevant population of interest are 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 overall survival, 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 morbid 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 one 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 5-10 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:

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

**Review of Evidence**
Hiatal hernia is associated with obesity and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of hiatal hernia has been associated with complications after laparoscopic adjustable gastric banding.[155] Although other studies report no differences in perioperative complications after laparoscopic adjustable gastric banding in patients with GERD and/or hiatal hernia and those without GERD and/or hiatal hernia.[156] 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 that recommends that, during operations for RYGBP, SG, and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate).[4] There is limited evidence about whether the repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery, consisting primarily of cohort studies comparing outcomes for patients with hiatal hernia who underwent repair during bariatric surgery to patients without 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).[158] Results demonstrated that patients who underwent hiatal hernia repair during SG had significant reductions in BMI (MD, -11.42 kg/m2, 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 laparoscopic adjustable gastric banding with or without concurrent hiatal hernia repair (N=1298 with adjustable gastric banding alone; N=520 with concurrent hiatal hernia repair).[159] The authors report 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 operation. It is not specified how many patients were diagnosed with each method, and 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 adjustable gastric banding alone group; p<0.001). Hiatal hernia repair added an average of 14 minutes to operative time. Weight loss outcomes did not differ significantly between the groups.

Santonicola et al (2014) evaluated the effects of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on GERD in obese patients.[160] The study included 78 patients who underwent sleeve gastrectomy with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia identified 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% post-surgery, p=0.3). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% pre-surgery vs. 19.6% post-surgery, p=0.003).

Reynoso et al (2011) reported outcomes after primary and revisional laparoscopic adjustable gastric banding in patients with hiatal hernia treated at a single hospital system.[161] 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 adjustable gastric banding with and without hiatal hernia repair. However, it appears that this comparison is for patients without hiatal hernia compared with patients with hiatal hernia who also underwent hiatal hernia repair.

Ardestani et al (2014) analyzed data from the Bariatric Outcomes Longitudinal Database to compare outcomes for patients with and without hiatal hernia repair at the time of laparoscopic adjustable gastric banding.[162] Of 41,611 patients who underwent laparoscopic adjustable gastric banding 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 1 year post procedure (53% in the hiatal hernia repair group vs. 52% in the non-hiatal hernia repair group; p=0.4). Although the hiatal hernia repair added minimal time (mean, 4 minutes) to surgery, the authors conclude that many repairs may involve small hernias with limited clinical effect.

In general, studies report 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 laparoscopic adjustable gastric banding for patients with hiatal hernia.[163] 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.[164] For laparoscopic RYGBP, there were 206,559 and 9060 patients who underwent the procedure alone or with concomitant hiatal hernia repair, respectively. For laparoscopic AGB, there were 52,901 and 9893 patients who underwent the procedure alone or with hiatal hernia repair, respectively. 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 (PLOS), with an average treatment effect of hiatal hernia repair of -0.124 (95% CI, -0.15 to -0.088) for PLOS for patients who underwent Roux-en-Y gastric bypass and an average treatment effect of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for PLOS for patients who underwent laparoscopic adjustable gastric banding.

**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. However, 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. No studies were identified that compared outcomes after bariatric surgery with or without hiatal hernia repair in a population of patients with known hiatal hernia. 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 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.

## 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, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. 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 compared with gastric bypass, LAGB procedure 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, 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 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 AEs. 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, 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 duodenal switch, 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. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without duodenal switch or gastric bypass. However, there are concerns about complications associated with BPD without duodenal switch, 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. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, 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 and 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 plus gastric bypass with 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, 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. 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 OS, 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 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 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 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). There are some adverse events, 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 1 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% TWL 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 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 and 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.

**Revision Bariatric Surgery**
For individuals with class III obesity who experience complications from bariatric surgery who receive revision bariatric surgery, the evidence includes 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. 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.

**Adults With type 2 diabetes (T2D)**
For individuals who are T2D and do not have class III obesity who receive gastric bypass, sleeve gastrectomy, biliopancreatic diversion, or adjustable gastric banding, the evidence includes RCTs, nonrandomized comparative 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. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/$m^2$. The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in $HgbA_{1c}$ levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most of the RCTs in this population have 1 to 3 years of follow-up; with a few having 5-year follow-up data. There are clinical concerns about durability and long-term outcomes at 5 to 10 years as well as potential variation in observed outcomes in community practice versus clinical trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

**Nondiabetic and Nonobese Adults**

For individuals who are not diabetic and do not have class III obesity who receive any bariatric surgery procedure, the evidence includes RCTs, nonrandomized comparative 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 limited evidence for bariatric surgery in patients who are not diabetic and do not have class III obesity. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Adolescent Children With Class III Obesity Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy**

For individuals who are adolescent children with class III obesity who receive gastric bypass or 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 studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB, 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 $kg/m^2$. In addition, 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.

**Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy**

For individuals who are adolescent children with class III obesity who receive bariatric surgery other than gastric bypass, or LAGB, or SG, the evidence includes systematic reviews and a cohort study. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Studies using bariatric surgery other than gastric bypass, LAGB, or SG, have small sample sizes. Results from a meta-analysis including patients using other procedures have shown significant improvements in BMI reduction, fasting blood insulin, and total cholesterol, although the estimates have wide confidence intervals, limiting interpretation. The evidence is insufficient 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 morbid obesity who receive bariatric surgery, the evidence includes no studies focused 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.

### Hiatal Hernia Repair with Bariatric Surgery

For individuals with class III obesity and a preoperative diagnosis of hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes 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. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of hiatal hernia was 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.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 20.

**Table 20. Summary of Key Trials**

| NCT No. | 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 (active, not 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 and Robotic-Assisted Revisional Bariatric Surgery | 100 | Mar 2023 (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 (completed) |
| 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

## SUPPLEMENTAL INFORMATION

### Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2008 Input

In response to the request for input from physician specialty societies and academic medical centers, BCBSA received information from the American Gastroenterological Association (AGA) and 2 academic medical centers regarding use of the REALIZE band while the policy was under review in 2008. All 3 responses supported use of the REALIZE band as another surgical option for patients, as adopted into the policy in February 2008.

In response to the request for input from physician specialty societies and academic medical centers, BCBSA received information from 2 academic medical centers regarding the use of the new endoscopic placement of devices to remedy weight gain that occurs after bariatric surgery while the policy was under review in 2008. Input from both centers agreed that this approach is considered investigational, as adopted in the policy in February 2008.

### PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be

given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Association of Clinical Endocrinologists et al

In 2020, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm.[165] Updates were made in 2022 and recommendations for bariatric surgery are presented in Table 21. [166]

**Table 21. 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, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity.[167] The guidelines addressed 9 broad clinical questions with 123 recommendations. With regard to bariatric surgery for these guidelines, the following recommendations were added (Table 22)

**Table 22. 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 bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion. | B | 1[a] |
| 121 | "Patients with a BMI of ≥35 kg/m2 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 nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with 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." | A | 1 |
| | • BMI >30 kg/m$^2$ and therapeutic target of weight control and improved biochemical markers of CVD risk. | B | 2 |
| | • BMI >30 kg/m$^2$ and therapeutic target of glycemic control in type 2 diabetes and improved biochemical marker of CVD risk." | C | 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." | Int | Int |

| | | |
|---|---|---|
| “Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux.” | Strong | Strong |

BEL: best evidence level; BMI: body mass index; CVD: cardiovascular disease; GOE: grade of evidence; In: intermediate.
[a] Downgraded due to evidence gaps.

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by AACE, the Obesity Society, and American Society for Metabolic and Bariatric Surgery (ASMBS) Obesity Medicine Association, and American Society of Anesthesiologists.[168] 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, high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure.”
- "Patients with the following comorbidities and BMI≥35 kg/m2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; GERD; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
- “Patients with BMI of 30-34.9 kg/m$^2$ 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/m2 is normal range, 23 to 24.9 kg/m2 overweight, and ≥25 kg/m2 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 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, or related procedures should be considered as primary bariatric and metabolic procedures performed inpatients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD, 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."

**American College of Cardiology et al**

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published guidelines on the management of obesity and overweight in adults.[169] The guidelines make the following recommendations related to bariatric surgery:

- For 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, advise 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 class of recommendation: IIa; AHA/ACC 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 & Bariatric Surgery (ASBMS)**

In 2016, ASBMS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES].[170] 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 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 pivotal trials. “In general, multidisciplinary team…”
- “…serious complications are rare. Early postoperative tolerance challenges…can be managed with pharmacotherapy in the majority of patients…”

In 2017**,** ASMBS published a position on sleeve gastrectomy.[171] 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 herniasurgery.[172] 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 inpatients 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."[173] 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. [174] 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 it is 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 includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery.[157] These guidelines state, “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 (IFSO) established an expert consensus statement on revisional bariatric surgery (RBS).[175] 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 anastomosis 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 IFSO established a position statement on Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS). [176] 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."

**Guidelines for Children and Adolescents**

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.[177] 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/m2 or more to 50 kg/m2 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. [178] 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. [179] The recommendations 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 95thpercentile 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 23) that align with the 2019 indications.

**Table 23. 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<br>Class 3 obesity; BMI ≥40, or 140% of the 95th percentile for age and sex, whichever is lower | Clinically significant disease, including, but not limited to, OS<br>Blount disease, SCFE, GERD, depressed health-related qua<br>Not required but commonly present |

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

**American Society for Metabolic and Bariatric Surgery**

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.[180] 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 that eating disorders should be treated, and the patient stabilized prior to the procedure.

In 2018, ASBMS published an update to the 2012 guideline.[181] 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/m2 or120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m2 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 (ata BMI <45 kg/m2) 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.[174] 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 supported2018 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 for the following for prevention and treatment of pediatric obesity in 2008.[182] In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.[183] 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 above 40kg/$m^2$ or has BMI above 35 kg/$m^2$ and significant, severe 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 medical center employing 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 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, or untreated psychiatric disorder."

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

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## Government Regulations
## National:

**NCD 100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity**
Effective December 17, 2013:
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&KeyWord=bariatric&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=100.1&ncd_version=3&basket=ncd%25253A100%25252E1%25253A3%25253ABariatric+Surgery+for+Treatment+of+Morbid+Obesity&bc=gAAAABAAAAAAAA%3d%3d&

**Nationally Covered Indications**[184]
Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

Effective for dates of service on and *after* February 21, 2006, these procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006). **Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified.**

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determines that Type 2 diabetes mellitus is co-morbidity for purposes of this NCD.

**Nationally Non-Covered Indications**
Treatments for obesity alone remain non-covered.
Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).

The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:

- **Open** adjustable gastric banding;
- **Open** sleeve gastrectomy;
- Laparoscopic sleeve gastrectomy (**prior to June 27, 2012**);
- Open and laparoscopic vertical banded gastroplasty;
- Intestinal bypass surgery; and,
- Gastric balloon for treatment of obesity.

Effective for services performed on and after June 27, 2012, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied:

a. The beneficiary has a body-mass index (BMI) ≥ 35 kg/$m^2$,
b. The beneficiary has at least one co-morbidity related to obesity, and,
c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-covered, for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs.

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for coverage on a case-by-case basis or pursuant to a local coverage determination. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

## Local:

There is no current WPS LCD on this topic.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

Gastric Electrical Stimulation
Vagus Nerve Blocking for Morbid Obesity

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2023, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 5/22/02 | 5/22/02 | 5/22/02 | Joint medical policy established |
| 9/11/02 | 9/11/02 | 9/11/02 | New procedure added |
| 11/20/02 | 11/20/02 | 12/05/02 | Criteria updated |
| 2/9/04 | 2/9/04 | 3/1/04 | Criteria updated maintenance review |
| 5/5/04 | 5/5/04 | 6/1/04 | Coding update S2085 which was effective 01/01/04 but was already payable with PC 43659 until 12/31/03 |
| 6/15/05 | 6/15/05 | 6/10/05 | Maintenance review, coding update |
| 10/24/05 | 10/24/05 | 10/24/05 | New codes added for effective 1/1/06 |
| 7/1/06 | 5/5/06 | 6/28/06 | Routine maintenance |
| 7/1/07 | N/A | 6/24/07 | Routine maintenance |
| **1/1/08 – BCBSM 9/1/07 - BCN** | 10/16/07 | 11/12/07 | Maintenance review new procedure added |
| 11/1/08 | 8/19/08 | 10/30/08 | Maintenance review new procedure added |
| 7/1/09 | 4/21/09 | 4/20/09 | Maintenance review |
| 11/1/10 | 8/17/10 | 10/13/10 | Re-presented at committee with addition of sleeve gastrectomy as established as a standard, stand-alone gastric surgical weight reduction procedure. Added CPT code for sleeve gastrectomy (43775). |
| 5/1/12 | 2/21/12 | 2/21/12 | Revised BCN benefit page. Title changed from “Gastric Surgery for Morbid Obesity” to “Bariatric Surgery (Gastric Surgery for Morbid Obesity). |
| 5/1/13 | 2/19/13 | 2/19/13 | Updated NCD and LCD to include coverage for sleeve gastrectomy for Medicare members. Updated policy to include discussion on bariatric surgery for adolescents. Updated references. |

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| 1/1/14 | 10/15/13 | 10/25/13 | Clarified language regarding repeat bariatric surgery: non-compliance vs. complications. Updated references and rationale. Added new Medicare decision memo information. |
| 5/14/14 | N/A | N/A | Deleted vertical banded gastroplasty, 43842, as an exclusionary criterion. It was originally added in error. |
| 5/1/15 | 2/17/15 | 2/27/15 | Routine maintenance. Added information regarding endoluminal bariatric procedures as experimental/investigational. Added references. No change in policy status. |
| 7/1/16 | 4/19/16 | 4/19/16 | Routine maintenance. Added single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) to the exclusions. Added word “trials” under SADI-S description, pg. 24. |
| 3/1/17 | 12/13/16 | 12/13/16 | Routine policy maintenance. |
| 1/1/18 | | | • Updated literature review focused on surgery in patients with type 2 diabetes and lower BMI February 9, 2017<br>• multiple references added (33, 36, 38, 65, 67, 68, 71, 74 and 75)<br>• Intragastric balloon, aspiration therapy and bariatric surgery in preadolescents added to exclusions |
| 7/1/18 | 4/17/18 | 4/17/18 | • Updated rationale section, added the following references: 11, 36, 38, 47, 50, 62, 69-70, 73, 79, 112, 116, 119, 139-141. Added the SIPS procedure to the policy as E/I. No change in policy status. |
| 7/1/19 | 4/16/19 | | Routine policy maintenance, updated rationale, added references 38, 44, 45, 89, and 119. Deleted expired codes 96101-96103 and replaced with codes 96130-96139, code 96146 is E/I. |

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| 7/1/20 | 4/14/20 | | Routine policy maintenance, updated rationale, added references 15, 40, 50, 97, 107 and 148. No change in policy status. |
| 7/1/21 | 4/20/21 | | Routine policy maintenance, added references 36, 154-170, added Natural orifice Transluminal Endoscopic Surgery (Notes ™) under exclusion. No change in policy status.<br>Updated the policy to say 4 years for both BCBSM and BCN as per the JUMP's recommendation and eliminated the 6 months waiting period statements. The below is the updated language added to the policy.<br>○ The patient has undergone multidisciplinary evaluation by an established bariatric treatment program to include medical, nutritional and mental health evaluations to determine ultimate candidacy for bariatric surgery. Such an evaluation should include an assessment of the patient's likely ability and willingness to cooperate effectively with a rigorous post-operative program. This should include documentation of past participation in a non-surgical weight loss program.<br>○ The non-surgical program participation and multi-disciplinary evaluation must have occurred within 4 years of the date of surgery.<br><br>Eliminated all but one paragraph in the rationale on VBG, enough to say it has been abandoned. Removed the 43842 from covered/EST to Excluded.<br>Added in the Am. Acad. Peds criteria to inclusions because although they are virtually identical to adult criteria they include the % above expected |

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| | | | on the growth chart as an alternative to BMI. |
| 7/1/22 | 4/19/22 | | • Routine policy maintenance<br>• References added and updated.<br>• No change in policy status<br>• Added for clarification purposes under Inclusion: Documentation of a non-surgical weight loss program is waived for super morbidly obese individuals who have a BMI ≥50. This was removed inadvertently last year when the decision to remove the six full consecutive months documentation. |
| 7/1/23 | 4/26/23 | | • Routine policy maintenance<br>• References added and updated.<br>• Added Overstitch device under Exclusions and under section Endoscopic Revision Procedures –<br>o Endoscopic/endoluminal procedures (including but not limited to insertion of the StomaphyX™ device, use of the Overstitch device, 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).<br>• This policy will replace the IMP policy " Use of Overstitch Device for endoscopic gastrogastric |

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| | | | fistula closure and for endoscopic closure of duodenal diverticula”<br>• Added codes 43290 Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon and 43291 Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s) under E/I per code update. JUMP policy already has Intragastric balloons under Exclusions and policy evidence already support Intragastric balloons as E/I.<br>• New this review from BCBSA – BCBSA adopted the CDC’s classification of obesity. Updated morbid obesity to class III obesity as per BCBSA.<br>o Per the Centers for Disease Control and Prevention (CDC), obesity is also frequently classified into the categories of Class 1: BMI of 30 to < 35 kg/m2; Class 2: BMI of 35 to< 40 kg/m2; and Class 3: BMI of 40 kg/m2 or higher. Class 3 obesity is sometimes categorized as “severe” obesity.<br>• Vendor: N/A<br>• Added Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time) under exclusion to align with BCBSA, There is already a PICO section to support this procedure as an exclusion in the policy.<br>• Updated under Exclusions **from** Any bariatric surgery for patients with type 2 diabetes who have a BMI of less than 35 **to** Any bariatric surgery for individuals |

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| | | | with type 2 diabetes who have a BMI of less than 30.<br><br>Post JUMP changes:<br>• Added “with duodenal switch” to the Medical Policy Statement (MPS).<br>• Removed type 2 diabetes from under: a BMI of >35 with one or more co-morbid conditions including, but not limited to under Inclusions.<br>• Added a BMI > 30 with type 2 diabetes under Inclusions.<br>• Moved intragastric balloons and aspiration therapy device from being separate bullets to under the Endoscopic/endoluminal procedures bullet under Exclusions.<br>• Rearranged Types of Bariatric Surgery Procedures section with the most common types of bariatric surgery first: Roux-en-Y gastric bypass, sleeve gastrectomy, and Biliopancreatic diversion with duodenal switch.<br>• Rearranged MPS reordering the options to match their above order, to read:<br>The safety and effectiveness of laparoscopic and open gastric restrictive procedures including but not limited to Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch, and adjustable gastric band have been established. They may be considered useful therapeutic options when specified criteria are met. (ky) |

Next Review Date: 2nd Qtr. 2024

**Pre-Consolidation Medical Policy History**

| Original Policy Date | Comments |
|---|---|
| BCN: 10/1/97 | Revised: 5/8/01, 11/1/01 |
| BCBSM: N/A | Revised: N/A |

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: BARIATRIC SURGERY

## I. Coverage Determination:

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| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Covered, see certificate for applicable deductibles and co-payments.<br><br>**Note: Gastric surgery is not a covered benefit under SRO Tier 2** |
| **Self-funded Groups:**<br>**U-M Premier Care**<br>**Grad Care** | Refer to the weight reduction section of the certificate for deductibles and copayments. |
| **BCNA (Medicare Advantage)** | See government section |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.