



# FEP Medical Policy Manual

## FEP 7.01.47 Bariatric Surgery

**Annual Effective Policy Date: January 1, 2024**

**Original Policy Date: December 2023**

### **Related Policies:**

2.01.38 - Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

7.01.73 - Gastric Electrical Stimulation

## Bariatric Surgery

### Description

#### Description

Bariatric surgery is a treatment for class III obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these techniques have heterogeneous mechanisms of action, the result is a smaller gastric pouch that leads to restricted eating. However, these surgeries may lead to malabsorption of nutrients or eventually to metabolic changes.

### OBJECTIVE

The objective of this evidence review is to evaluate whether various bariatric surgery procedures improve the net health outcome in adults who are obese, in adolescents and preadolescents who are obese, and in those with type 2 diabetes who are obese.

## POLICY STATEMENT

### Bariatric Surgery in Adults With Class III Obesity

The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class III obesity (see Policy Guidelines section for bariatric surgery selection criteria) in adults who have failed weight loss by conservative measures:

- Open gastric bypass using a Roux-en-Y,
- Laparoscopic gastric bypass using a Roux-en-Y,
- Laparoscopic adjustable gastric banding,
- Sleeve gastrectomy (SG), and
- Open or laparoscopic biliopancreatic bypass/diversion (ie, Scopinaro procedure) with duodenal switch (DS).

Bariatric surgery should be performed in appropriately selected individuals, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery.

The following bariatric surgery procedures are considered **investigational** for the treatment of class III obesity in adults who have failed weight loss by conservative measures:

- Vertical-banded gastroplasty,
- Gastric bypass using a Billroth II type of (mini-gastric bypass),
- Biliopancreatic diversion (BPD) without DS,
- Long-limb gastric bypass procedure (ie, >150 cm),
- Two-stage bariatric surgery procedures (eg, SG as initial procedure followed by BPD at a later time),
- Laparoscopic gastric plication, and
- Single anastomosis duodeno-ileal bypass with SG.

The following endoscopic procedures are **not medically necessary** as a primary bariatric procedure or as a revision procedure (ie, to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches):

- Insertion of the StomaphyX™ device,
- Endoscopic gastroplasty,
- Use of an endoscopically placed duodenojejunal sleeve,
- Intra-gastric balloons, and
- Aspiration therapy device.

### Bariatric Surgery in Individuals With Type 2 Diabetes and With a BMI > 30 kg/m<sup>2</sup>

For individuals with type 2 diabetes and with a BMI > 30 kg/m<sup>2</sup>, the following bariatric surgery procedures may be considered **medically necessary** in adults who have failed weight loss by conservative measures:

- Biliopancreatic diversion with DS,
- Laparoscopic adjustable gastric banding,
- Roux-en-Y gastric bypass, and
- Sleeve gastrectomy.

## Bariatric Surgery in Individuals With a Body Mass Index Less Than 35 kg/m<sup>2</sup>

Bariatric surgery is considered **investigational** for individuals with a body mass index less than 35 kg/m<sup>2</sup> who do not have diabetes and for all individuals with a BMI < 30 kg/m<sup>2</sup>.

### Revision Bariatric Surgery

Revision surgery to address perioperative or late complications of a bariatric procedure is considered **medically necessary**. These include but are not limited to, staple line failure, obstruction, stricture, nonabsorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, and band slippage that cannot be corrected with manipulation or adjustment (see Policy Guidelines section).

Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) is considered **medically necessary** if the initial procedure was successful in inducing weight loss prior to pouch dilation, and the individual has been compliant with a prescribed nutrition and exercise program.

### Bariatric Surgery in Adolescents

Bariatric surgery in adolescents may be considered **medically necessary** according to similar weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues (see Policy Guidelines section). In addition, any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration approved indications.

### Bariatric Surgery in Preadolescent Children

Bariatric surgery is considered **investigational** for the treatment of class III obesity in preadolescent children.

### Concomitant Hiatal Hernia Repair With Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery may be considered **medically necessary** for individuals who have a preoperatively diagnosed hiatal hernia with indications for surgical repair (see Policy Guidelines section).

Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not have indications for surgical repair is considered **investigational**.

## POLICY GUIDELINES

### Bariatric Surgery Selection Criteria

Class III obesity, formerly known as morbid obesity, is defined as a body mass index (BMI) 40 kg/m<sup>2</sup> or more. Individuals with class III obesity (BMI 35 kg/m<sup>2</sup> to <40 kg/m<sup>2</sup>) with at least 1 clinically significant, high-risk obesity-related disease such as type 2 diabetes (T2D), obstructive sleep apnea, coronary artery disease, or hypertension, or an obesity-induced physical problem that interferes with lifestyle, have historically been considered candidates for bariatric surgery. However, no evidence-based guidance has been identified that explicitly defines thresholds for determining the clinical significance of obesity-related disease that would qualify individuals for bariatric surgery.

Additionally, a 2022 joint statement by the American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) recommends metabolic and bariatric surgery in individuals with a BMI greater than or equal to 35 kg/m<sup>2</sup>, regardless of the presence, absence, or severity of comorbidities. This recommendation is based on nonrandomized, single-arm, single-center clinical studies described in detail in the Rationale section and briefly in the Background section; these include Gloy et al (2013), Puzziferri et al (2014), and the Swedish Obese Subjects (SOS) (Sjostrom et al 1999, Sjostrom et al 2004, Sjostrom et al 2007, Sjostrom et al 2012) trials. However, as these studies did not separately evaluate outcomes in individuals without comorbidities, evidence of the net health outcome in individuals without comorbidities is inconclusive.

While there are limited evidence on which to assess the long-term impacts of bariatric surgery for patients younger than age 18 years, severely obese (class III obesity, BMI  $\geq 40$  kg/m<sup>2</sup> or 140% of the 95th percentile for age and sex, whichever is lower) adolescents with commonly present though not required comorbidities, or who have a BMI of 35 kg/m<sup>2</sup> or greater (class II obesity or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant disease (including, but not limited to, T2D, idiopathic intracranial hypertension, nonalcoholic steatohepatitis, Blount disease, slipped capital femoral epiphysis, gastroesophageal reflux disease, obstructive sleep apnea [apnea-hypopnea index  $>5$ ], cardiovascular disease risks [HTN, hyperlipidemia, insulin resistance], depressed health-related quality of life) may be considered for bariatric surgery according to the American Academy of Pediatrics (Armstrong et al, 2019 and Hampl et al, 2023). U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND System indicates it is intended for severely obese adults. (The clinical study submitted to FDA for approval of the LAP-BAND was restricted to adults ages 18 to 55 years.)

Patients should have documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure. As a result, some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. However, there is a lack of evidence on the optimal timing, intensity, and duration of nonsurgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Patients with a BMI of 50 kg/m<sup>2</sup> or more need a bariatric procedure to achieve greater weight loss. Thus, the use of adjustable gastric banding, which results in less weight loss, should be most useful as a procedure for patients with a BMI less than 50 kg/m<sup>2</sup>. Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient. Patients who undergo adjustable gastric banding and fail to achieve adequate weight loss must show evidence of postoperative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.

## Bariatric Procedure Considerations

Of note, vertical-banded gastroplasty (VBG) is a purely restrictive procedure that is largely not performed in the U.S. and has been replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50% (Balsiger et al, 2000, PMID11307094; Miller et al, 2007, PMID17116427). Vertical-banded gastroplasty is not included on the list of endorsed procedures by the American Society for Metabolic and Bariatric Surgery (<https://asmbs.org/resources/endorsed-procedures-and-devices>. Accessed January 3, 2023 ).

## Considerations for Bariatric Surgery in Adolescents

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

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

## Endocrine Society

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits (Styne et al, 2017).

## Bariatric Procedure Guidelines

The choice of procedure in adolescents may also differ from adults, but there is a lack of consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (Aikenhead et al, 2011; PMID: 25586970):

- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices used for LAGB do not have FDA approval in the United States for individuals younger than age 18 years.

- Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions (BPD) because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that BPD not be done in adolescents.

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

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

## Hiatal Hernia Repair Guidelines

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

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

The Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines for the management of hiatal hernia (Kohn et al, 2013). The Society noted that the general methodologic quality of available studies is low. Recommendations for indications for repair are as follows:

- "Repair of a type I hernia [sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm] in the absence of reflux disease is not necessary" (moderate-quality evidence, strong recommendation).
- "All symptomatic paraesophageal hiatal hernias should be repaired [high-quality evidence, strong recommendation], particularly those with acute obstructive symptoms or which have undergone volvulus."
- "Routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient's age and co-morbidities" (moderate-quality evidence, weak recommendation).

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

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

Table 1 shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

**Table 1. FDA Approved Bariatric Surgery Devices**

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m <sup>2</sup> ) 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	Jun 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m <sup>2</sup> and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy.
ORBERA intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30 to 40 kg/m <sup>2</sup> ) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
LAP-BAND Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m <sup>2</sup> or a BMI of at least 30 kg/m <sup>2</sup> with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).
REALIZE Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m <sup>2</sup> , or a BMI of at least 35 kg/m <sup>2</sup> 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 (eg, supervised diet, exercise, behavior modification programs).

BMI: body mass index; FDA: U.S. 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. The second set of adverse event reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape (no longer marketed in the U.S.) and ORBERA brands. The adverse events may require premature removal of the balloons.

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

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

## RATIONALE

### Summary of Evidence

#### Adults with Class III Obesity

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

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

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

For individuals who are adults with class III obesity who receive BPD without DS, the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, 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 a DS or gastric bypass. However, concerns have been raised about complications associated with BPD without DS, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, 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, 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. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months postsurgery. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive laparoscopic gastric plication, the evidence includes an RCT, an observational study, and systematic reviews. Relevant outcomes are OS, 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 Roux-en-y gastric bypass (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 a duodenojejunal sleeve, the evidence includes RCTs, systematic reviews, and an observational study. 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 duodenojejunal sleeves included 5 RCTs and found significantly greater short-term weight loss (12 to 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 IGB devices, the evidence includes RCTs, systematic reviews, 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. RCTs assessing the 2 IGB devices approved by the U.S. Food and Drug Administration have found significantly greater weight loss with IGB than with sham treatment or lifestyle therapy alone after 6 months (maximum length of device use). Some adverse events were reported, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long-term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how 6 months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with class III obesity who receive an aspiration therapy (AT) device, the evidence includes an RCT 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. The RCT found significantly greater weight loss with AT than lifestyle therapy at 1 year. Forty of 58 patients (69%) achieved at least 10% total weight loss at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study noted a potentially large number of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy 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 AT remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism, safety, nutrition, and long-term durability of treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Revision Bariatric Surgery

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

## Adults with Type 2 Diabetes

For individuals who have T2D and do not have class III obesity who receive gastric bypass, SG, BPD, or LAGB, the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies 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 body mass index (BMI) between 30 and 34.9 kg/m<sup>2</sup>. The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c 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 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 OS, 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 a 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, or SG, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents are 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<sup>2</sup>. Also, greater consideration should be placed on the patient developmental 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 OS, 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 class III obesity who receive bariatric surgery, there are no studies focused solely on this population. Relevant outcomes are OS, 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 a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes a systematic review, cohort studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review found that hiatal hernia repair during SG was superior to SG alone for gastroesophageal reflux disease (GERD) remission, but not de novo GERD. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### 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 jointly published a comprehensive diabetes type 2 management algorithm.<sup>165</sup> Updates were made in 2022 and recommendations for bariatric surgery are presented in Table 2.<sup>166</sup>

**Table 2. Recommendations for Bariatric Surgery in Diabetes**

Recommendation	GOE	BEL
Persons with a BMI $\geq 35$ kg/m <sup>2</sup> 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 <sup>2</sup> and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure	B	2

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

In 2016, the AACE and the American College of Endocrinology jointly published comprehensive clinical guidelines on the medical care of patients with obesity.<sup>167</sup> The guidelines addressed 9 broad clinical questions with 123 recommendations. With regard to bariatric surgery, the following recommendations were added (Table 3).

**Table 3. Recommendations for Bariatric Surgery Added in 2016**

No.	Recommendation	GOE	BEL
35	Patients with obesity (BMI $\geq 30$ kg/m <sup>2</sup> ) 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 <sup>a</sup>
121	"Patients with a BMI of $\geq 35$ kg/m <sup>2</sup> 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 <sup>2</sup> 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.  <ul style="list-style-type: none"> <li>BMI <math>\geq 35</math> kg/m<sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk.</li> </ul>	A B C	1 2 3

	<ul style="list-style-type: none"> <li>• BMI <math>\geq 30</math> kg/m<sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk.</li> <li>• BMI <math>\geq 30</math> kg/m<sup>2</sup> and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk.</li> </ul>		
122	"Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone."	D	
62	"Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett's esophagus." "Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux."	Int Strong	Int Strong

BEL: best evidence level; BMI: body mass index; CVD: cardiovascular disease; GOE: grade of evidence; Int: intermediate.

<sup>a</sup> Downgraded due to study limitations.

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists.<sup>168</sup> Recommendations on the following questions are summarized below.

- "Which patients should be offered bariatric surgery?"
  - "Patients with a BMI [body mass index]  $\geq 40$  kg/m<sup>2</sup> 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  $\geq 35$  kg/m<sup>2</sup> and 1 or more severe obesity-related complications remediable by weight loss, including T2D [type 2 diabetes], high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
  - "Patients with the following comorbidities and BMI  $\geq 35$  kg/m<sup>2</sup> may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial hypertension; GERD [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
  - "Patients with BMI of 30 to 34.9 kg/m<sup>2</sup> with T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
  - "The BMI criterion for bariatric procedures should be adjusted for ethnicity (eg, 18.5 to 22.9 kg/m<sup>2</sup> is normal range, 23 to 24.9 kg/m<sup>2</sup> overweight, and  $\geq 25$  kg/m<sup>2</sup> 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 [Roux-en-y gastric bypass], and LBPD/DS [laparoscopic biliopancreatic diversion/duodenal switch], or related procedures should be considered as primary bariatric and metabolic procedures performed in patients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD [biliopancreatic diversion], BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered

for selected patients who are expected to benefit from short-term (ie, 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 joint guidelines on the management of obesity and overweight in adults.<sup>169</sup> The guidelines made the following recommendations related to bariatric surgery:

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

## American Society for Metabolic and Bariatric Surgery

In 2016, the ASMBS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons).<sup>170</sup> The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

There is level 1 data from RCTs [randomized controlled trials] on the "efficacy [and] safety of intragastric balloon therapy for obesity ... [and] lower-level evidence [suggesting] that weight loss can be maintained ... for some finite time into the future."

It is difficult to separate the effect from the intragastric "balloon alone from those of supervised diet and lifestyle changes...." This has been addressed in recent FDA [U.S. Food and Drug Administration] pivotal trials. "In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team...."

"...serious complications are rare. Early postoperative tolerance challenges ... can be managed with pharmacotherapy in the majority of patients...."

In 2017, the ASMBS published a position statement on sleeve gastrectomy.<sup>171</sup> This updated statement provided the following conclusions:

- "Substantial long-term outcome data published in the peer-reviewed literature, including studies comparing outcomes of various surgical procedures, confirm that sleeve gastrectomy [SG] provides significant and durable weight loss, improvements in medical comorbidities, improved quality of life, and low complication and mortality rates for obesity treatment."
- "In terms of initial early weight loss and improvement of most weight-related comorbid conditions, SG and RYGB appear similar. The effect of SG on GERD, however, is less clear, because GERD improvement is less predictable and GERD may worsen or develop de novo."
- The ASMBS recognizes SG as an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned staged approach."

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

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery.<sup>172</sup> The guideline contained the following conclusions and summary recommendations:

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

and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia."

In 2020, ASMBS published an updated statement on single-anastomosis duodenal switch (SADI-S) "in response to numerous inquiries made...by patients, physicians, society members, hospitals, and others regarding [this procedure] as a treatment for obesity and metabolic diseases."<sup>173</sup> 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.<sup>174</sup> 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<sup>2</sup>, 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<sup>2</sup>, 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<sup>2</sup>, 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<sup>2</sup> suggests clinical obesity, and individuals with BMI greater than or equal to 27.5 kg/m<sup>2</sup> 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

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines on the management of a hiatal hernia, which included a recommendation about the repair of hiatal hernias incidentally detected at the time of bariatric surgery.<sup>157</sup> These guidelines stated: "During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired" (moderate quality evidence, weak recommendation).

## International Federation for the Surgery of Obesity and Metabolic Disorders

In 2019, members of societies affiliated with the IFSO established an expert consensus statement on revisional bariatric surgery (RBS).<sup>175</sup> 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."<sup>a</sup>
- "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."<sup>a</sup>

BPD-DS: bilio-pancreatic diversion duodenal switch; OAGB: one gastric bypass; RBS: revisional bariatric surgery; RYGB: Roux-en-Y gastric bypass; SADI: single anastomosis duodeno-ileal bypass with sleeve gastrectomy; SG: sleeve gastrectomy.

<sup>a</sup> 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).<sup>176</sup> 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.<sup>177</sup> The literature search was conducted from 1999 through 2013 and identified 16 recommendations for inclusion: 10 clinical practice guidelines, 4 position statements, and 2 consensus statements. Fifteen of the 16 publications recommended bariatric surgery for adolescents. The main reasons for recommending bariatric surgery for adolescents included: (1) surgery is effective in producing short- and long-term weight loss; (2) surgery is appropriate when the patient does not respond to behavioral or medical interventions; (3) surgery is appropriate when serious comorbidities threaten the health of the patient; and (4) surgery can improve long-term health and/or emotional problems. Body mass index thresholds ranged from 35 kg/m<sup>2</sup> or more to 50 kg/m<sup>2</sup> 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.<sup>178</sup> 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.<sup>179</sup> 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 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

They list indications for adolescent metabolic and bariatric surgery (Table 4) that align with the 2019 indications.

**Table 4. Indications for Adolescent Metabolic and Bariatric Surgery**

Weight Criteria	Comorbid Conditions
Class 2 obesity; BMI $\geq 35$ , or 120% of the 95th percentile for age and sex, whichever is lower	Clinically significant disease, including, but not limited to, OSA (AHI $>5$ ), T2D, IIH, NASH, Blount disease, SCFE, GERD, depressed health-related quality of life, and hypertension
Class 3 obesity; BMI $\geq 40$ , or 140% of the 95th percentile for age and sex, whichever is lower	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, the ASMBS best practice guidelines found that current evidence was insufficient to discriminate among specific bariatric procedures, but allowed that there was an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population.<sup>180</sup> Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

- Strong indications: Type 2 diabetes, Moderate or severe obstructive sleep apnea (apnea-hypopnea index  $>15$ ), Nonalcoholic steatohepatitis, Pseudotumor cerebri.
- Less strong indications: Cardiovascular disease, Metabolic syndrome.

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

In 2018, ASBMS published an update to the 2012 guideline.<sup>181</sup> Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m<sup>2</sup> or 120% of the 95th percentile with a comorbidity, or (2) BMI  $>40$  kg/m<sup>2</sup> or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI  $>40$  to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI  $<45$  kg/m<sup>2</sup>) 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.<sup>174</sup> They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as 5 years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that syndromic obesity, developmental delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents.

## Endocrine Society

In 2008, the Endocrine Society published recommendations on the prevention and treatment of pediatric obesity.<sup>182</sup> In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.<sup>183</sup> These guidelines recommended the following:

"We suggest that bariatric surgery be considered only under the following conditions:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI > 40 kg/m<sup>2</sup> or has BMI above 35 kg/m<sup>2</sup> and significant, extreme comorbidities.
- Extreme obesity and comorbidities persist, despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents (and 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.

## Medicare National Coverage

The Centers for Medicare & Medicaid Services have published a national coverage decision on bariatric surgery.<sup>184</sup> The Centers determined that:

"...the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body mass index (BMI)  $\geq 35$ , have at least 1 co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity."

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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

Date	Action	Description
December 2023	New Policy - language clarity	Policy Statement language edited to provide clarity adding Diabetes Type II, as well adding this language in other relevant text throughout the policy. FEP adopting to align with 2024 member benefits.