

FEP Medical Policy Manual

FEP 7.01.47 Bariatric Surgery

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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 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, adolescents, and preadolescent children with obesity.

POLICY STATEMENT

Bariatric Surgery in Adults With Class 3 Obesity (BMI ≥40 kg/m²)

The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 3 obesity (BMI ≥40.0 kg/m²) in adults (ages 18 and older) who have failed weight loss by conservative measures:

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

Bariatric Surgery in Adults With Class 2 Obesity (BMI ≥35 to 39.9 kg/m²)

The following bariatric surgery procedures may be considered **medically necessary** for the treatment of class 2 obesity in individuals with at least 1 obesity-related comorbid condition (see Policy Guidelines) who have failed weight loss by conservative measures:

- · Open or laparoscopic gastric bypass using a Roux-en-Y,
- · Laparoscopic adjustable gastric banding,
- Open or laparoscopic 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. (see Policy Guidelines for bariatric surgery selection criteria).

Bariatric Surgery in Individuals With Class 1 Obesity (BMI ≥30 to 34.9 kg/m²) and Type 2 Diabetes

For individuals with Class 1 obesity (BMI ≥30 to 34.9 kg/m²) and type 2 diabetes, the following bariatric surgery procedures may be considered **medically necessary** in adults who have failed weight loss by conservative measures:

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

Bariatric surgery is considered investigational for individuals with Class 1 obesity who do not have type 2 diabetes.

Bariatric surgery is considered **investigational** for individuals with a BMI less than 30 kg/m².

The following bariatric surgery procedures are considered investigational for the treatment of obesity: s:

- 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.

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.

Revision surgery to address severe gastroesophageal reflux disease refractory to medical treatment is considered medically necessary.

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 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**.

Endoscopic Procedures

The following endoscopic procedures are **investigational** 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,
- Intragastric balloons, and
- · Aspiration therapy device.

POLICY GUIDELINES

Bariatric Surgery Selection Criteria

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/m² 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/m². 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.

Weight-Related Complications

Clinical Practice Guidelines list the following conditions weight-related complications, defined as conditions caused by or exacerbated by excess adiposity:¹,

- Asthma
- · Cardiovascular disease
- Certain types of cancer (eg, colorectal cancer)
- Type 2 diabetes
- Dyslipidemia
- Gastroesophageal reflux disease (GERD)
- Hypertension
- Infertility
- · Male hypogonadism
- Mental health (depression)
- Metabolic syndrome
- Nonalcoholic fatty liver disease (nonalcoholic fatty liver and nonalcoholic steatohepatitis)
- · Obstructive sleep apnea
- Osteoarthritis
- · Polycystic ovarian syndrome
- Prediabetes
- Stroke
- · Urinary stress incontinence

Recommendations specify that bariatric surgery may be considered in individuals with a body mass index (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, GERD, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life. ¹ Guidelines do not explicitly define thresholds for determining the clinical significance of obesity-related conditions that would qualify individuals for bariatric surgery, however.

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/m² with comorbidities to a BMI of 50 kg/m². 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 Selection for Adolescents

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 laparoscopic adjustable gastric band (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 [Roux-en-Y gastric bypass] 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 TM 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	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/m² 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/m²) 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/m² or a BMI of at least 30 kg/m² 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/m², or a BMI of at least 35 kg/m² 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 3 Obesity

For individuals who are adults (18 years or older) with class 3 obesity (body mass index [BMI] ≥40kg/m²) who are treated with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic biliopancreatic bypass/diversion (ie, Scopinaro procedure) with duodenal switch, 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. Evidence from nonrandomized comparative studies, case series, and meta-analyses of 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) found that bariatric surgery was associated with improvements in mortality, type 2 diabetes (T2D), cardiovascular risk factors, and quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with Class 2 Obesity

For individuals who are adults (18 years or older) with class 2 obesity (BMI ≥35 to 39.9 kg/m²) who are treated with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic biliopancreatic bypass/diversion (ie, Scopinaro procedure) with duodenal switch, 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. Evidence from nonrandomized comparative studies, case series, and meta-analyses of 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) found that bariatric surgery was associated with improvements in mortality, T2D, cardiovascular risk factors, and quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with Class 1 Obesity and Type 2 Diabetes

For individuals who have Class 1 obesity (BMI ≥30 to 34.9 kg/m²) and T2Ded with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic biliopancreatic bypass/diversion (ie, Scopinaro procedure) with duodenal switch, 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 adults with obesity, 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 laparoscopic adjustable gastric banding, laparoscopic sleeve gastrectomy, and biliopancreatic bypass/diversion. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c (HbA1c) levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with a Body Mass Index <35 kg/m² Who Do Not Have Type 2 Diabetes

For individuals with a BMI <35 kg/m² who do not have T2D who receive bariatric surgery, 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. 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.

Revision Bariatric Surgery

For individuals who are adults 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. SSystematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including gastroesophageal reflux disease. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. A large retrospective analysis found a serious complication rate of 7.2% for conversion to Roux-en-Y gastric bypass (RYGB) in 13,432 individuals and no difference in 30-day mortality compared to primary RYGB. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adolescents with Obesity

For individuals who are adolescent children with obesity who are treated with bariatric surgery using open or laparoscopic gastric bypass, laparoscopic adjustable gastric banding, or open or laparoscopic sleeve gastrectomy, 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 laparoscopic adjustable gastric banding or sleeve gastrectomy, 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/m². 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.

Preadolescent Children with Obesity

For individuals who are preadolescent children with 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 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 sleeve gastrectomy was superior to sleeve gastrectomy alone for gastroesophageal reflux disease remission, but not de novo. 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 and American College of Endocrinology

In 2016, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published comprehensive clinical guidelines on the medical care of individuals with obesity. The guidelines addressed 9 broad clinical questions with 123 recommendations. The recommendations specific to bariatric surgery are shown in Table 13. The guidelines noted that a de novo evidence-based review of questions pertaining to bariatric surgery was not undertaken. Instead, the 2013 guidelines from AACE, the Obesity Society, and the American Society for Metabolic & Bariatric Surgery were reviewed and determined to be adequate. Key recommendations from those guidelines were included in the 2016 document and are shown in Table 2.

Table 2. Recommendations on Bariatric Surgery Included in the American Association of Clinical Endocrinologists and the American College of Endocrinology Guidelines for Medical Care of Patients with Obesity (2016)

Key Question	Recommendation	Evidence Grade	Best Evidence Level
9.1 Is bariatric surgery effective to treat obesity and weight-related complications?	R120. Patients with a BMI of >40 kg/m2 without coexisting medical problems and for whom the procedure would not be associated with excessive risk should be eligible for bariatric surgery		1
9.2 When should bariatric surgery be used to treat obesity and weight-related complications?	R121. Patients with a BMI of ≥35 kg/m² and 1 or more severe obesity-related complications, including T2D, 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 QOL may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m² with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.		
	BMI ≥35 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk	А	1
	BMI ≥30 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk	В	2
	BMI ≥30 kg/m² and therapeutic target of glycemic control in T2DM and improved biochemical markers of CVD risk	С	3
	R122. Independent of BMI criteria, there is insufficient evidence to recommend a bariatric surgical procedure specifically for glycemic control, lipid lowering, or CVD risk reduction alone	D	NA
	R123. All patients should undergo pre-operative evaluation for weight-related complications and causes of obesity, with special attention directed to factors that may affect a	А	1

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recommendation for bariatric surgery or be ameliorated by weight loss resulting from the		J
procedure		

BMI: body mass index; CVD: cardiovascular disease; NA: not applicable; QOL: quality of life; T2D: type 2 diabetes.

American Academy of Clinical Endocrinologists, ACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists

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. 131, Recommendations on the following questions are summarized below.

- "Which patients should be offered bariatric surgery?"
 - "Patients with a BMI [body mass index] ≥40 kg/m² without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure."
 - o "Patients with a BMI ≥35 kg/m² 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 [obstructive sleep apnea], osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
 - "Patients with the following comorbidities and BMI≥35 kg/m² may also be considered for a bariatric procedure, though the strength of
 evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk;
 idiopathic intracranial hypertension; [gastroesophageal reflux disease]; severe venous stasis disease; impaired mobility due to obesity,
 and considerably impaired quality of life."
 - "Patients with BMI of 30 to 34.9 kg/m² 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/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 [Roux-en-y gastric bypass], and LBPD/DS [laproscopic 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."

Individuals with Type 2 Diabetes Mellitus

In 2022, The AACE published updated guidelines for the comprehensive care of individuals with diabetes mellitus. 132, Recommendations related to bariatric procedures are shown in Table 3.

Table 3. Recommendations on Bariatric Surgery Included in the American Association of Clinical Endocrinology Guidelines on Care of Persons with Diabetes Mellitus (2022)

Recommendation Number	Recommendation		Best Evidence Level
10.9	Persons with a BMI ≥35 kg/m² 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	С	3
10.10	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	В	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.

Veterans Affairs/Department of Defense

In 2020, the Department of Veterans Affairs/Department of Defense (VA/DoD) published a clinical practice guideline for the management of adult overweight and obesity. 133, Recommendations on bariatric surgery are shown in Table 4

Table 4. Recommendations on Bariatric Surgery Included in VA/DoD Obesity Treatment Guidelines (2020)

Recommendation Number	Recommendation Statement	Strength of Evidence ¹
12	We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥30 kg/m2 and type 2 diabetes mellitus.	Weak
13	We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a body mass index ≥40 kg/m2 or those with body mass index ≥35 kg/m2 with obesity-associated condition(s).	Weak
14	There is insufficient evidence to recommend for or against metabolic/bariatric surgery to patients over age 65.	Neither for nor against
15	There is insufficient evidence to recommend for or against percutaneous gastrostomy devices for weight loss in patients with obesity.	Neither for nor against
16	We suggest offering intragastric balloons in conjunction with a comprehensive lifestyle intervention to patients with obesity (body mass index ≥30 kg/m²) who prioritize short-term (up to six months) weight loss.	Weak
17	There is insufficient evidence to recommend for or against intragastric balloons for long-term weight loss to support chronic weight management or maintenance.	Neither for nor against

¹The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh

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. These guidelines stated:

undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

"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).

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. ^{134,} 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 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. 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. ¹³⁶, 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 5) that align with the 2019 indications.

Table 5. 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	Clinically significant disease, including, but not limited to, OSA (AHI >5), T2D, IIH, NASH, Blount disease, SCFE, depressed health-related quality of life, and hypertension
Class 3 obesity; BMI ≥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; 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.^{137,} Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

Strong indications: T2D, 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. 138, 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 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 or 120% 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 (at a 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, , 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. 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. ¹⁴⁰, In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology. ¹⁴¹, These guidelines recommended the following:

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

• The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.

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

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

In 2006, the Centers for Medicare & Medicaid Services published a National Coverage Determination on bariatric surgery. 142, 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) ≥35, have at least 1 co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity."

The decision memo also states, "The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary; therefore, the following are non-covered for all Medicare beneficiaries:

- 1. open vertical banded gastroplasty;
- 2. laparoscopic vertical banded gastroplasty;
- 3. open sleeve gastrectomy;
- 4. laparoscopic sleeve gastrectomy; and
- 5. open adjustable gastric banding." 142,

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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.
June 2024	Replace policy	Policy updated with literature review through March 7, 2024; references added. Evidence review extensively pruned for clarity. Policy statements and evidence review indications revised to align with current obesity classification terminology and clinical practice guidelines. New medically necessary statement added for bariatric surgery in adults with class 2 obesity and at least 1 obesity-related comorbid condition. Medically necessary statement on revision surgery clarified to include GERD as an indication for revision surgery.