

## MEDICAL POLICY – 7.01.516

# Bariatric Surgery

BCBSA Ref. Policy: 7.01.47

Effective Date: **July 1, 2024\***  
Last Revised: June 24, 2024  
Replaces: 7.01.47

\*This policy has been revised.  
Click here to view the changes  
effective October 3, 2025.

### RELATED MEDICAL POLICIES:

- 2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
- 7.01.522 Gastric Electrical Stimulation
- 7.01.523 Panniculectomy and Excision of Redundant Skin

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[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)  
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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## Introduction

Bariatrics is the branch of medicine dealing with the causes and treatment of obesity. Clinically severe obesity (also known as morbid obesity) is when a person is excessively overweight. Obesity itself is a health hazard as it impacts the heart, lungs, muscles, and bones of the body. In addition, obesity is a known risk factor to develop type 2 diabetes, heart disease and high blood pressure. Many individuals are able to lose weight by changing their diet and increasing their exercise. The challenge for most people is keeping off the weight they have lost. For some people surgery may be needed. Bariatric surgery is often referred to as weight loss surgery or obesity surgery. Surgical approaches to support long-term weight loss have been developed over the past 20 years. For some individuals surgery works very well, although even after surgery people may need to significantly change their eating habits. Surgery is not without risk, however. There are several different types of weight loss surgery that are done on the stomach, intestine, or both. They generally fall into two main categories: surgeries that restrict the amount of food that may be eaten, and surgeries that restrict the body's ability to absorb calories and nutrients. Not all plans cover obesity surgery. When plans have a benefit for obesity surgery, then this policy describes what information is needed by the health plan to determine if the surgery may be covered.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

**Note:** Bariatric (weight loss) surgery should be performed by a surgeon with specialized training and experience in the bariatric surgery procedure used, and in an institution (facility or hospital) that includes a comprehensive bariatric surgery program. Any device used for bariatric surgery must be FDA approved for that purpose and used according to the labeled indications.

Indication	Coverage Criteria
<b>Contract limitations</b>	<p><b>Some health plan contracts do not have benefits to cover surgical treatment of morbid obesity, complications, or after-effects associated with weight loss surgery. Refer to member contract language for benefit determination on weight loss surgery.</b></p>
<b>Covered bariatric (weight loss) surgeries</b>	<p><b>The following bariatric (weight loss) surgery procedures may be considered medically necessary for the treatment of class III obesity*, class II obesity with one obesity related co-morbid condition, or T2** diabetes with class I obesity in adults who have failed weight loss by conservative measures:</b></p> <ul style="list-style-type: none"> <li>• Biliopancreatic bypass (i.e., the Scopinaro procedure) with duodenal switch (open [43845] or laparoscopic [43659])</li> <li>• Gastric bypass using a Roux-en-Y anastomosis (open or laparoscopic) (43644, 43645, 43846***)</li> <li>• Laparoscopic adjustable gastric banding (e.g., LAP-BAND, REALIZE) (43770)</li> <li>• Sleeve gastrectomy (43775)</li> </ul>



Indication	Coverage Criteria
	<p><b>*Note: Class III obesity is defined by the CDC as a BMI of 40 kg/m<sup>2</sup> or greater (see <a href="#">Related Information</a>)</b></p> <p><b>**Note: T2DM-Type II diabetes mellitus (see <a href="#">Related Information</a>)</b></p> <p><b>***Note: CPT 43846 is for short limb (150 cm or less) Roux-en-Y gastroenterostomy. See <a href="#">Investigational</a> Coverage Criteria for long-limb gastric bypass procedure (i.e., &gt; 150 cm)</b></p>
<p><b>Individual selection criteria for adults with class II or III obesity (Must meet all 3 criteria)</b></p>	<p><b>Bariatric (weight loss) surgery may be considered medically necessary for the treatment of class II or III obesity in adults who have failed weight loss by conservative measures when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Class III obesity (a body mass index (BMI) <math>\geq</math> 40) kg/m<sup>2</sup></li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Class II obesity (a BMI of <math>\geq</math>35 kg/m<sup>2</sup> or more) with at least <b>ONE</b> of the following obesity related comorbid conditions: <ul style="list-style-type: none"> <li>○ Established Coronary Heart Disease, such as: <ul style="list-style-type: none"> <li>▪ History of angina pectoris (stable or unstable)</li> <li>▪ History of angioplasty</li> <li>▪ History of coronary artery surgery</li> <li>▪ History of myocardial infarction</li> </ul> </li> <li>○ Other Atherosclerotic Disease, such as: <ul style="list-style-type: none"> <li>▪ Abdominal aortic aneurysm</li> <li>▪ Hypertension that is uncontrolled or resistant to treatment (medically refractory) despite optimal medical management (attempted medical management must have included at least 2 medications of different classes).</li> <li>▪ Peripheral arterial disease</li> <li>▪ Symptomatic carotid artery disease</li> </ul> </li> <li>○ Type 2 Diabetes, uncontrolled (individual has inadequate glycemic control [i.e., HbA1c* level is <math>\geq</math> 7]), despite lifestyle changes and use of antidiabetic medications</li> <li>○ Moderate to severe obstructive sleep apnea (OSA), as documented by a sleep study (polysomnography),** that</li> </ul> </li> </ul>



Indication	Coverage Criteria
	<p>has failed*** an adequate trial of CPAP/BIPAP or oral appliance.</p> <p><b>* Note:</b> HbA1c-Hemoglobin A1C</p> <p><b>**Note:</b> OSA severity categories: normal: AHI &lt; 5 events/h, mild: AHI 5 to ≤15 events/h, moderate: AHI 15 to ≤ 30 events/h, and severe: AHI &gt; 30 events/h</p> <p><b>***Note:</b> CPAP/BIPAP or oral appliance failure is defined as residual AHI≥15 or inability to tolerate CPAP/BIPAP ≥ 4hours per night for ≥ 5 nights per week</p> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Participation in a physician administered weight reduction program lasting at least three continuous months (over a 90-day period of time) within the 12-month period before surgery is considered. <ul style="list-style-type: none"> <li>○ Evidence of active participation documented in the medical record includes: <ul style="list-style-type: none"> <li>▪ Weight</li> <li>▪ Current dietary program (e.g., MediFast, OptiFast)</li> <li>▪ Physical activity (e.g., exercise/work-out program)</li> </ul> </li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Documentation of participation in a structured weight reduction program such as Weight Watchers or Jenny Craig is an acceptable alternative if done in conjunction with physician supervision</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Mental health evaluation and clearance by a licensed mental health provider* to rule out any mental health disorders that would be a contraindication to bariatric surgery, rule out inability to provide informed consent, and rule out inability to comply with pre- and post-surgical requirements</li> </ul> <p><b>*Note:</b> A summary letter from the requesting bariatric surgeon alone is not sufficient for this documentation.</p>



Indication	Coverage Criteria
<p><b>Individual selection criteria for adults with T2 diabetes and class I obesity</b></p>	<p><b>Bariatric (weight loss) surgery may be considered medically necessary for the treatment of adults with T2 diabetes and class I obesity (a BMI <math>\geq</math> 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>) who have failed weight loss by conservative measures when ALL of the following criteria are met</b></p> <ul style="list-style-type: none"> <li>Individual has inadequate glycemic control (i.e., HbA1c* level is <math>\geq</math> 7) despite lifestyle changes and use of antidiabetic medications</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Participation in a physician administered weight reduction program lasting at least three continuous months (over a 90-day period of time) within the 12-month period before surgery is considered (e.g., MediFast, OptiFast)</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>Documentation of participation in a structured weight reduction program such as Weight Watchers or Jenny Craig is an acceptable alternative if done in conjunction with physician supervision</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Mental health evaluation and clearance by a licensed mental health provider to rule out any mental health disorders that would be a contraindication to bariatric surgery, rule out inability to provide informed consent, and rule out inability to comply with pre- and post-surgical requirements</li> </ul> <p><b>Note:</b> A physician's summary letter alone is not sufficient documentation.</p> <p><b>*Note:</b> HbA1c-Hemoglobin A1C</p>
<p><b>Individual selection criteria for adolescents less than 18 years of age</b></p>	<p><b>Bariatric (weight loss) surgery may be considered medically necessary for the treatment of class III obesity in adolescents who have failed weight loss by conservative measures when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>The health plan contract allows bariatric surgery for those younger than 18 years of age (refer to member contract</li> </ul>



Indication	Coverage Criteria
	<p>language for benefit determination on treatment of obesity for adolescents)</p> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>The adolescent meets the same individual selection criteria as an adult with class II or III obesity noted above</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>The facility has experienced staff to support adolescents including psychosocial and informed consent issues for bariatric surgery</li> </ul> <p><b>Note:</b> Devices used for laparoscopic adjustable gastric banding do not have FDA approval in the United States for individuals younger than age 18 years.</p>
<p><b>Revision bariatric surgery to correct complications</b></p>	<p><b>Revision bariatric (weight loss) surgery (such as replacement and/or removal of an adjustable gastric band, surgical repair or reversal, or conversion to another covered bariatric surgical procedure) may be considered medically necessary to address perioperative or late complications from the primary bariatric procedure including, but not limited to:</b></p> <ul style="list-style-type: none"> <li>Band erosion, slippage, leakage, herniation, or intractable nausea/vomiting that cannot be corrected with manipulation or adjustment</li> <li>Non-absorption resulting in hypoglycemia or malnutrition</li> <li>Obstruction</li> <li>Staple-line failure (e.g., gastrogastic fistula)</li> <li>Stricture</li> <li>Treatment of symptomatic gastroesophageal reflux disease (GERD) meeting the following criteria: <ul style="list-style-type: none"> <li>Reflux is documented by abnormal 24-hour pH monitoring or endoscopic findings of esophagitis performed after a sleeve gastrectomy, and</li> <li>Symptoms persist despite optimal medical therapy (i.e., 8 weeks of daily proton pump inhibitor [PPI] therapy)</li> </ul> </li> <li>Ulceration</li> <li>Weight loss of 20% or more below ideal body weight</li> </ul>



Indication	Coverage Criteria
	<p><b>AND</b></p> <ul style="list-style-type: none"> <li>Coverage for bariatric surgery is available under the individual's current health benefit plan</li> </ul>
<p><b>Revision of failed procedure due to dilation of the gastric pouch</b></p>	<p><b>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.</b></p>
<p><b>Reoperation bariatric surgery for inadequate weight loss</b></p>	<p><b>Reoperation of a previous bariatric surgical procedure due to inadequate weight loss, in the absence of a technical failure or major complication, may be considered medically necessary, when ALL of the following criteria are met:</b></p> <p><b>All criteria listed above for the initial procedure must be met again;</b></p> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Previous surgery for morbid obesity was at least 2 years prior to the repeat procedure</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>There is documentation of compliance with the previously prescribed postoperative nutrition and exercise program</li> </ul> <p><b>AND</b></p> <p><b>Coverage for bariatric surgery is available under the individual's current health benefit plan</b></p>
<p><b>Cholecystectomy</b></p>	<p><b>Routine cholecystectomy (gallbladder removal) may be considered medically necessary when performed at the time of bariatric surgery.</b></p>
<p><b>Hiatal hernia repair</b></p>	<p><b>Repair of a hiatal hernia at the time of bariatric surgery may be considered medically necessary for individuals who have a preoperative diagnosis of hiatal hernia with clinical indications for surgical repair.</b></p>



Indication	Coverage Criteria
	Repair of a hiatal hernia performed at the time of bariatric surgery in the absence of preoperative clinical indications for surgical repair is considered not medically necessary
Routine liver biopsy	Routine liver biopsy during obesity surgery is considered not medically necessary in the absence of preoperative signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver).
Bariatric surgery for a BMI less than 35 kg/m <sup>2</sup>	Bariatric (weight loss) surgery is considered not medically necessary for individuals with a BMI less than 35 kg/m <sup>2</sup> who do not have T2 diabetes and for all individuals with a BMI < 30 kg/m <sup>2</sup> .
Bariatric type surgery to treat conditions other than morbid obesity	Gastric bypass as a primary procedure using laparoscopic adjustable gastric banding, gastric bypass using a Roux-en-Y anastomosis, sleeve gastrectomy, or biliopancreatic bypass with duodenal switch for the treatment of gastroesophageal reflux disease (GERD), or gastroparesis in individuals not meeting the medical necessity criteria for obesity classifications noted above is considered investigational.
Vertical-banded gastroplasty (43842)	Vertical banded gastroplasty (VBG) (stomach stapling) is considered not medically necessary as a treatment for class III obesity due to high rates of complications, revisions, and reoperations.

Indication	Investigational
<p>Non-covered bariatric (weight loss) surgery procedures</p> <p>(These listed procedures may not have specific codes assigned and could be billed using any of the following unlisted procedure codes: 43659, 43999, 44238, or 44799)</p>	<p>The following bariatric (weight loss) surgery procedures are considered investigational for the treatment of class III obesity:</p> <ul style="list-style-type: none"> <li>• Biliopancreatic diversion or bypass without duodenal switch</li> <li>• Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)</li> <li>• Laparoscopic gastric plication (aka laparoscopic greater curvature plication [LGCP]) (43843)</li> <li>• Long-limb gastric bypass procedure (i.e., &gt;150 cm) (43847)</li> </ul>



Indication	Investigational
	<ul style="list-style-type: none"> <li>• Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) (aka single anastomosis duodenal switch or stomach intestinal pylorus sparing surgery [SIPS])</li> <li>• Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)</li> <li>• Vagus nerve blocking (e.g., the VBLOC device or Maestro)</li> <li>• Endoscopic procedures (aka endoluminal, endosurgical) as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy a large gastric stoma or large gastric pouches) including, but not limited to, any of the following: <ul style="list-style-type: none"> <li>○ Endoscopic sleeve gastropasty (ESG; Accordion procedure) (aka transoral gastropasty, TOGA)</li> <li>○ Insertion of the StomaphyX device or any other closure device (e.g., Apollo OverStitch, EndoCinch System)</li> <li>○ Intragastic balloons (e.g., Orbera, ReShape, Obalon, Spatz3 (0813T), TransPyloric Shuttle [TPS])</li> <li>○ Natural orifice transluminal endoscopic surgery (NOTES)</li> <li>○ Restorative obesity surgery, endoluminal (ROSE)</li> <li>○ Stomach aspiration therapy (drainage tube device) (e.g., AspireAssist)</li> <li>○ Transoral outlet reduction endoscopy (TORe procedure)</li> <li>○ Use of an endoscopically placed duodenal-jejunal sleeve (aka gastrointestinal liners, endoscopic gastrointestinal bypass device) (e.g., EndoBarrier)</li> </ul> </li> </ul>

Documentation Requirements
<p><b>The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of ALL of the following criteria:</b></p> <ul style="list-style-type: none"> <li>• A body mass index (BMI) <math>\geq 40 \text{ kg/m}^2</math>, or BMI <math>\geq 35 \text{ kg/m}^2</math> with at least ONE (1) of the following obesity related comorbid conditions: <ul style="list-style-type: none"> <li>○ Established coronary heart disease</li> <li>○ Other atherosclerotic disease</li> </ul> </li> </ul>



## Documentation Requirements

- Type 2 diabetes uncontrolled by medications
- Obstructive sleep apnea, as documented by a sleep study, that that has failed\* an adequate trial of CPAP/BIPAP or oral appliance.

### OR

- T2 diabetes and class I obesity (a BMI  $\geq 30$  kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>) and inadequate glycemic control despite optimal lifestyle and medical therapy (e.g., Hb A1C level is  $\geq 7$ )

### AND

- Completion of a physician administered weight-loss program that:
  - Lasted for at least three (3) months in a row (a 90-day period of time)
  - Took place within 12 months before the proposed weight loss surgery
  - Demonstrates in the medical record that the member actively took part in the program, as well as include member's weight, the current dietary program (MediFast, OptiFast) and exercise/work-out program.

### OR

- Documents participation in a structured weight loss program such as Weight Watchers or Jenny Craig and that this program was supervised by the healthcare provider
- Mental health evaluation and clearance by a licensed mental health provider to rule out any mental health disorders that would be a contraindication to bariatric surgery, rule out inability to provide informed consent, and rule out inability to comply with presurgical and postsurgical requirements.

**Note:** A letter by a healthcare provider is not enough to meet these criteria.

### AND

- The requested bariatric surgical procedure is considered a medically necessary procedure for the age of the individual.

## Coding

### Code

### Description

CPT



Code	Description
0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon (e.g., Spatz3)
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43659	Unlisted laparoscopy procedure, stomach
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption



Code	Description
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach
44238	Unlisted laparoscopy procedure, intestine (except rectum)
44799	Unlisted procedure, small intestine
HCPCS	
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

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## Related Information

### CDC Classification of Obesity

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

- Class I: BMI of 30 to < 35 kg/m<sup>2</sup>
- Class II: BMI of 35 to < 40 kg/m<sup>2</sup>
- Class III: BMI of 40 kg/m<sup>2</sup> or higher (class III obesity is sometimes categorized as “severe” obesity).<sup>1</sup>



## CDC T2 Diabetes Diagnosis Test Results Criteria

- Hemoglobin A1C (HbA1c) test-6.5 % or above, or
- Fasting blood sugar (FBS) test-126 mg/dl or above, or  
Glucose tolerance test-200 mg/dl or above

## Body Mass Index Calculation

BMI is calculated by dividing an individual's weight (in kilograms) by height (in meters) squared.

- To convert pounds to kilograms, multiply pounds by 0.45
- To convert inches to meters, multiply inches by 0.0254
- Click [here](#) for BMI calculation.

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

## Individual Selection Criteria

Class III obesity, formerly known as morbid obesity, is defined as a body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup> or a BMI of 35 kg/m<sup>2</sup> or more with at least one clinically significant obesity-related disease such as diabetes, obstructive sleep apnea (OSA), coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management. 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.

Individuals 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.

Individuals 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 individuals 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 individual.

Individuals 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.

## **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 individuals. All guidelines mention these issues, but recommendations are not uniform for addressing them (see Practice Guidelines and Position Statements).

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 A, Lobstein T, Knai C. Review of current guidelines on adolescent bariatric surgery. Clin Obes. Feb 2011;1(1):3-11. PMID 25586970):

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

## Hiatal Hernia Repair Guidelines

In 2018, the American Society for Metabolic and Bariatric Surgery (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 individuals with obesity."
- "There is a higher risk for complications and recurrence after hernia repair in individuals with obesity."
- "In individuals 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 individuals 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 individuals 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 individual's age and co-morbidities" (moderate quality evidence, weak recommendation).

## Evidence Review

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### Description

Bariatric surgery is a treatment for obesity in individuals 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.

### Background

#### Bariatric Surgery

Bariatric surgery is performed to treat obesity and obesity-related comorbid conditions.

The first treatment of obesity is dietary and lifestyle changes. Although this strategy may be effective in some individuals, only a few individuals with obesity can reduce and control weight through diet and exercise. Most individuals find it difficult to comply with these lifestyle



modifications on a long-term basis. When conservative measures fail, some individuals may consider surgical approaches.

## **Types of Bariatric Surgery Procedures**

### **Open Gastric Bypass**

The original gastric bypass surgeries were based on the observation that postgastrectomy individuals tended to lose weight. The current procedure (CPT 43846) involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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

### **Laparoscopic Gastric Bypass**

CPT code 43644 was introduced in 2005 and described the same procedure as open gastric bypass (CPT code 43846) but performed laparoscopically.



## Laparoscopic Adjustable Gastric Banding

Adjustable gastric banding (CPT code 43770) involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two banding devices are approved by the US Food and Drug Administration (FDA) for marketing in the United States. The first to receive FDA approval was the LAP-BAND (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). The labeled indications for this device are as follows:

- The LAP-BAND system is indicated for use in weight reduction for severely obese individuals with a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lb or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult individuals who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Individuals who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.
- In 2011, the FDA-labelled indications for the LAP-BAND were expanded to include individuals with a BMI from 30 to 34 kg/m<sup>2</sup> with at least 1 obesity-related comorbid condition.

The second adjustable gastric banding device approved by the FDA through the premarket approval process is the REALIZE model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are:

- The [REALIZE] device is indicated for weight reduction for morbidly obese individuals and is indicated for individuals with a Body Mass Index of at least 40 kg/m<sup>2</sup>, or a BMI of at least 35 kg/m<sup>2</sup> with one or more comorbid conditions. The Band is indicated for use only in morbidly obese adult individuals who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.



## **Open or Laparoscopic Sleeve Gastrectomy**

A sleeve gastrectomy (CPT code 43775) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through the stomach into intestines) seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high-risk individuals. Weight loss following sleeve gastrectomy may improve an individual's overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., biliopancreatic diversion).

## **Open or Laparoscopic Biliopancreatic Diversion**

The biliopancreatic diversion procedure (BPD) (also known as the Scopinaro procedure; CPT code 43847) developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:

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



malabsorption. The length of the common segment will influence the degree of malabsorption.

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

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

### **Open or Laparoscopic Biliopancreatic Diversion With Duodenal Switch**

CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the BPD, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the BPD, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

### **Vertical-Banded Gastroplasty**

Vertical-banded gastroplasty (VBG; CPT code 43842) was formerly one of the most common gastric restrictive procedures performed in the United States but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. In order to create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of the stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded



gastroplasty may be performed using an open or laparoscopic approach. It is largely not performed in the US 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 May 8, 2024).

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

Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures (CPT code 43847), which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways (e.g., resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

### **Laparoscopic Malabsorptive Procedure**

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



## Laparoscopic Gastric Plication

Laparoscopic gastric plication is a bariatric procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. To achieve gastric restriction the procedure requires 2 main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach. CPT code 43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty is commonly used for this procedure.

## Summary of Evidence

### Adults With Class III Obesity

For individuals who are adults (18 years or older) with class III obesity (body mass index [BMI]  $\geq 40\text{kg/m}^2$ ) 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 (i.e., Scopinaro procedure) with duodenal switch, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. 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 II Obesity

For individuals who are adults (18 years or older) with class II obesity (BMI  $\geq 35$  to  $39.9\text{kg/m}^2$ ) 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 (i.e., Scopinaro procedure) with duodenal



switch, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. 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 I obesity (BMI  $\geq 30$  to 34.9 kg/m<sup>2</sup>) and T2D 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 (i.e., 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/m<sup>2</sup>. 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/m<sup>2</sup> Who Do Not Have Type 2 Diabetes**

For individuals with a BMI <35 kg/m<sup>2</sup> 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. Systematic 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 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/m<sup>2</sup>. Also, greater consideration should be placed on the individual's developmental stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the individual 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 overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review found that hiatal hernia repair during SG was superior to SG alone for 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.



## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT02390973<sup>a</sup></a>	Surgery Versus Best Medical Management for the Long Term Remission of Type 2 Diabetes and Related Diseases (REMISSION)	408	Mar 2024
<a href="#">NCT02328599</a>	A Prospective Consortium Evaluating the Long-term Follow-up of Patients With Type 2 Diabetes Enrolled In a Randomized Controlled Trial Comparing Bariatric Surgery Versus Medical Management (ARMMS-T2D)	302	Jun 2031
<a href="#">NCT03610256</a>	Prospective Multicentric Randomized Trial Comparing the Efficacy and Safety of Single-anastomosis Duodeno Ileal Bypass With Sleeve Gastrectomy (SADI-S) Versus Roux-en-Y Gastric Bypass (RYGB) (SADISLEEVE)	382	Dec 2031
<a href="#">NCT03517072</a>	Determinants of the Long-Term Success of Bariatric Surgery	1000	Jan 2024
<a href="#">NCT03472157</a>	Prospective Multicentric, Open Label, Randomized Clinical Trial of Superiority, With Two Arms, Comparing Bariatric Surgery to the Recommended Medical Treatment for NASH (NASHSURG)	100	Mar 2026
<a href="#">NCT04506190</a>	A Prospective Multicenter Study to Evaluate the Perioperative Outcomes of Laparoscopic and Robotic-Assisted Revisional Bariatric Surgery	100	Sep 2024
<a href="#">NCT04128995</a>	Surgical or Medical Treatment for Pediatric Type 2 Diabetes	100	Sept 2025
<a href="#">NCT03236142</a>	The Single, 300 cm Loop, Duodenal Switch (SIPS) Results in Less Nutritional Deficiencies Than the Standard Duodenal Switch (DS) Operation: A Multicenter, Randomized Controlled Trial	110	Jan 2025



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02692469	Laparoscopic Single Anastomosis Duodenal-jejunal Bypass with Sleeve Gastrectomy vs Laparoscopic Duodenal Switch as a Primary Bariatric Procedure. 5 Year Patient Follow	140	Apr 2026
NCT04165694	Single Anastomosis Duodenal Ileal Bypass (SADI) as a Second Stage for Sleeve Gastrectomy Weight Loss Failure	54	Dec 2030
NCT01172899	The BASIC Trial. Morbid Obesity in Children and Adolescents: a Prospective Randomised Trial of Conservative Treatment Versus Surgery	60	Dec 2022 (unknown status)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.<sup>1</sup> 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 presented 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/m <sup>2</sup> without coexisting medical problems and for whom the procedure would not be associated with excessive risk should be eligible for bariatric surgery	A	1
9.2 When should bariatric surgery be used to treat obesity and weight-related complications?	R121. Patients with a BMI of ≥35 kg/m <sup>2</sup> 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/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		



Key Question	Recommendation	Evidence Grade	Best Evidence Level
	studied and lack of long-term data demonstrating net benefit.		
	BMI $\geq 35$ kg/m <sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk	A	1
	BMI $\geq 30$ kg/m <sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk	B	2
	BMI $\geq 30$ kg/m <sup>2</sup> and therapeutic target of glycemic control in T2DM and improved biochemical markers of CVD risk	C	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 recommendation for bariatric surgery or be ameliorated by weight loss resulting from the procedure	A	1

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 individuals were published by the AACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and the American Society of Anesthesiologists.<sup>131</sup> Recommendations on the following questions are summarized below.

"Which patients should be offered bariatric surgery?"

- "Patients with a BMI  $\geq 40$  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, 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; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."
- "Patients with BMI of 30-34.9 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 (e.g., 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, and laparoscopic biliopancreatic diversion with duodenal switch (LBPD/DS), 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, BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy.”

## Individuals with Type 2 Diabetes Mellitus

In 2022, The AACE published updated guidelines for the comprehensive care of individuals with diabetes mellitus.<sup>132</sup> 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	Evidence Grade	Best Evidence Level
10.9	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
10.10	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.

## 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.<sup>133</sup>

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 <sup>1</sup>
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 $\geq 30$ kg/m <sup>2</sup> and type 2 diabetes mellitus.	Weak



Recommendation Number	Recommendation Statement	Strength of Evidence <sup>1</sup>
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 $\geq 40$ kg/m <sup>2</sup> or those with body mass index $\geq 35$ kg/m <sup>2</sup> 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 $\geq 30$ kg/m <sup>2</sup> ) 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

<sup>1</sup>The 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 undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

## 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 hiatal hernia, which included a recommendation about the repair of hiatal hernias incidentally detected at the time of bariatric surgery.<sup>129</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).



## 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>134</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>135</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>136</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  $\geq$  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 $\geq$ 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>137</sup> 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.<sup>138</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 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, 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>139</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>140</sup> In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.<sup>141</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.”

## Medicare National Coverage

In 2006, the Centers for Medicare & Medicaid Services published a National Coverage Determination on bariatric surgery.<sup>142</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) >35 kg/m<sup>2</sup>, have at least one comorbidity 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:

- Open vertical banded gastroplasty;



- Laparoscopic vertical banded gastroplasty;
- Open sleeve gastrectomy;
- Laparoscopic sleeve gastrectomy; and
- Open adjustable gastric banding."<sup>142</sup>

## 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 6** shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

**Table 6. 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 yo, 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, 30-40 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.



Device	Manufacturer	PMA Date	Labeled Indications
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 (e.g., supervised diet, exercise, behavior modification programs).
REALIZE Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m <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 (e.g., supervised diet, exercise, behavior modification programs).

BMI: body mass index; FDA: US 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 two 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 US) and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of five 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; seven of these deaths were in patients in the US

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."



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## History

Date	Comments
05/05/97	Add to Surgery Section - New Policy
09/21/00	Replace Policy - Policy updated to include expanded discussion of biliopancreatic bypass and gastric banding. Policy statement unchanged.
06/19/02	Replace Policy - Policy revised to include mini-gastric bypass.
04/09/02	Replace Policy - Policy revised to include further information on laparoscopic banding. Policy statement unchanged.
02/11/03	Replace Policy - Policy revised to include LAP-BAND Gastric Restrictive Procedure as medically necessary. Policy replaces CP.MP.BC.7.01.47.
10/16/03	Replace Policy - Policy revised; additional rationale language and references added.
01/13/04	Replace Policy - Scheduled review; HCPC code updated.
02/10/04	Replace Policy - Policy reviewed; language clarification in description and policy guidelines.
09/01/04	Replace Policy - Policy renumbered from PR.7.01.116. No changes to dates.
01/11/05	Replace Policy - Scheduled review; policy statement revised to add medically necessary and investigative procedures. Rationale and references updated.
07/18/05	Replace Policy - Disclaimer added to Description section only. No other changes.
01/10/06	Replace Policy - Policy reviewed with literature search; policy statement unchanged. Title changed for clarification (old title: Surgery for Morbid Obesity).
03/29/06	Codes Updated - No other changes.
05/26/06	Codes Updated; Scope and Disclaimer Updated - No other changes.
06/30/06	Coded updated - No other changes.



Date	Comments
10/10/06	Replace Policy - Policy updated with literature search; references added; policy statement expanded to indicate liver biopsy during morbid obesity surgery as not medically necessary.
11/14/06	Replace Policy - Clinical criteria regarding liver biopsy added to policy guidelines section; no other changes.
11/13/07	Replace Policy - Policy updated with literature search. Policy statement updated for clarification of conservative measures; to include Bariatric surgery in adolescents is considered investigational with criteria listed. Added "Reoperation" section with a note to see separate policy on surgery for abdominoplasty and panniculectomy skin. Policy description and guidelines were updated to support this change. References added.
01/15/08	Description Updated - To include "REALIZE Adjustable Gastric Band" as an FDA approved device. No other changes.
07/08/08	Replace Policy - Policy updated with literature search. Policy statement updated to include bariatric patients under the age of 18 is considered investigational. "Prophylactic Cholecystectomy" was also added as a not medically necessary indication. References added.
10/14/08	Replace Policy - Policy updated with literature search. Policy statement updated to add "Biliopancreatic bypass with duodenal switch (CPT 43845) is considered medically necessary in the treatment of morbid obesity that has not responded to conservative measures such as supervised diet, exercise and behavior modification programs" under the Malabsorptive Procedures heading. References added.
01/13/09	Replace Policy - Policy updated with literature search; no change to the policy statement. Policy guidelines updated.
06/09/09	Code Update - Code 44.99 added.
10/13/09	Cross Reference Update - No other changes.
11/10/09	Replace Policy - Policy updated with literature search; no change to the policy statement. Rationale extensively updated on the sleeve gastrectomy procedure. Guidelines revised to eliminate the requirement of "at least once per month" medical visits during physician-supervised weight reduction program.
02/09/10	Code Update - New 2010 codes added.
05/11/10	Cross Reference Update - No other changes.
11/09/10	Replace Policy - Policy updated with literature search. Policy statement updated to clarify that member needs to meet selection criteria in Guidelines before being considered for a medically necessary procedure. Bariatric surgery is considered not medically necessary for those members not meeting selection criteria. Endoscopic procedures, previously only addressed for weight gain after bariatric surgery, are now also considered investigational as a primary procedure. Rationale updated and references added.



Date	Comments
05/10/11	Replace Policy - Policy updated with literature search and references added. Sleeve gastrectomy, previously considered investigational, may now be considered medically necessary.
05/22/12	Replace policy. References added: 81- 83.No change in policy statements. Codes 44.38 and 44.39 added.
01/10/13	Coding update. CPT code 0155T removed from the policy; it was deleted effective 1/1/12.
03/15/13	Update title to Related Policy 7.01.523.
12/09/13	Policy extensively updated (now mirrors 7.01.47 which was not adopted). Title changed. Vertical banded gastroplasty previously considered medically necessary now considered not medically necessary. Added investigational policy statement for two stage procedures. Adolescent bariatric surgery previously considered investigational, now considered medically necessary. Prophylactic cholecystectomy policy statement removed. Codes updated; appendix removed.
05/08/14	Update Related Policies. Add 2.01.73.
12/08/14	Annual Review. Laparoscopic gastric plication was added to the list of investigational procedures and the policy statement on bariatric surgery in patients with BMI<35 changed from investigational to not medically necessary. Policy statements added related to the repair of preoperatively-diagnosed and incidentally identified hiatal hernias. Policy 7.01.73 added to Related Policies list. Indications for hiatal hernia repair added to the Policy Guidelines. Regulatory Status information added. References 13, 16-23, 29, 37-39, 69-78, 85, 87, 89, 93, 96, 101- 102, 104, 106-114, 116-118 added. ICD-9 and ICD-10 procedure codes removed from the policy; these are not utilized in adjudication of this policy.
04/20/15	Update Related Policies. Edit title to 8.01.502.
09/01/15	Update Related Policies. Add 7.01.150.
11/10/15	Annual Review. Policy updated with literature search; no change to the policy statement. Reference added.
05/01/16	Annual Review, approved April 12, 2016. Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) added to the list of investigational procedures. Added statement that bariatric surgery is considered investigational to treat patients that do not meet morbid obesity criteria for conditions that include but are not limited to diabetes and gastroesophageal reflux disease (GERD). Removed respiratory disturbance index (RDI) and "laboratory" sleep study (polysomnography) from sleep apnea criteria. Added related policy 2.01.503. Policy updated with a literature review; references added.
09/01/16	Interim Review, approved August 9, 2016. In the Policy Guidelines section clarified the statement that a decision for a sleep study in the home or facility setting, when indicated, is based on the criteria located in policy 2.01.503. Policy statements unchanged.



Date	Comments
03/01/17	Annual Review, approved February 14, 2017. Policy moved into new format. Policy updated with literature search through November 2016. Rationale section consolidated into summary statements. Cholecystectomy as medically necessary added to policy statements, other policy statements unchanged.
12/01/17	Interim Review, approved November 9, 2017. Evidence Review section updated; reorganized. Practice Guidelines updated with AACE recommendations; Revision surgery language clarified. Reoperation surgery language added to indicate initial medical necessity criteria must be met again for weight loss failure not previously addressed. Clarified criteria language regarding physician supervised weight reduction requirements. Clarified language in defining signs/symptoms of liver disease. Added aspiration therapy device to investigational endoscopic procedures list. Added vagus nerve block to list of investigational procedures with link to separate policy. Added reference 130. Removed CPT code S2083.
01/30/18	Minor update, an example of an investigational gastric balloon (Orbera) was added to the policy.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; references 11, 36, 38, 47, 50, 62, 69-70, 73, 79, 112, 116, 119, and 139 added. Policy statements unchanged.
01/01/19	Interim Review, approved December 19, 2018. Minor clarifications were added to some policy statements Policy intent not changed.
05/01/19	Annual Review, approved April 9, 2019. Policy updated with literature review through January 2019. Several References added. Expanded medical necessity criteria for revision and reoperation bariatric surgical procedures.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through November, 2019; references added. Policy statements unchanged.
05/01/21	Annual Review, approved April 13, 2021. Policy updated with literature review through December 17, 2020; references added. Policy criteria for physician administered weight loss program changed from six months participation to 3 months in the past 12 months; otherwise policy statements unchanged. Added CPT codes 0312T, 0313T, 0314T, 0315T, 0316T and 0317T. Update Related Policies, removed policy 7.01.150 as it was archived.
08/01/21	Interim Review, approved July 22, 2021. Modified language used and intent of mental health evaluation requirement.



Date	Comments
10/01/21	Interim Review, approved September 2, 2021. Clarified OSA as a comorbidity under patient selection of BMI of 35 kg/m <sup>2</sup> is for those whose OSA is uncontrolled by medical management (e.g., CPAP or oral appliance).
05/01/22	Annual Review, approved April 25, 2022. Policy updated with literature review through December 16, 2021; references added. Minor edits and formatting changes for clarity; otherwise policy statements unchanged and intent unchanged.
08/01/22	Interim Review, approved July 12, 2022. Clarified obstructive sleep apnea comorbidity criteria by adding definition of CPAP and oral appliance failure. Added transoral outlet reduction, endoscopic (TORe) procedure and restorative obesity surgery, endoluminal (ROSE) procedure to list of endoscopic procedures that are considered investigational.
11/01/22	Interim Review, approved October 10, 2022. Minor edits and formatting changes for greater clarity only. Policy statements unchanged. Policy intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/18/22	Minor update. Added the term BIPAP where CPAP is noted in the policy criteria statements.
01/01/23	Coding update. Removed CPT codes 0312T, 0313T, 0314T, 0315T, 0316T, and 0317T from the policy statement section as the codes are termed effective 01/01/23. Added term date to CPT codes 0312T, 0313T, 0314T, 0315T, 0316T, and 0317T in the coding section. Added new CPT codes 43290 and 43291. Added unlisted code details to the Non-covered bariatric (weight loss) surgery procedures section. Added unlisted CPT codes 43659, 43999, 44238, and 44799 to the coding table.
05/01/23	Annual Review, approved April 11, 2023. Policy updated with literature review through January 3, 2023; references added. Added, medically necessary policy statement for individuals who are T2 diabetic and have class I obesity. Additional minor editorial refinements made to policy statements with intent unchanged. Several guidelines updated and added.
07/01/23	Coding update. Added new HCPCS codes C9784 and C9785.
08/01/23	Interim Review, approved July 11, 2023. Added medically necessary indication of treatment of symptomatic gastroesophageal reflux disease (GERD) under revision surgery when criteria are met. Added examples of intragastric balloons (Spatz3, TransPyloric Shuttle) considered investigational; other minor edits made for clarity; policy intent unchanged.
01/01/24	Interim Review, approved December 26, 2023. Modified obesity related comorbid conditions of hypertension and type II diabetes listed under Class II obesity criteria for greater clarity. Added new CPT code 0813T.
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through March 7, 2024; references added.. Policy statements revised to align with current obesity classification terminology. Minor editorial refinements made to policy statements for clarity only; otherwise policy statements unchanged.



**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

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