

## MEDICAL POLICY – 7.01.516

### Bariatric Surgery

BCBSA Ref. Policy: 7.01.47

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Replaces: 7.01.47

RELATED MEDICAL POLICIES:

7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

7.01.522 Gastric Electrical Stimulation

7.01.523 Panniculectomy and Excision of Redundant Skin

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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 the 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

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>
<p><b>Patient selection criteria for adults (Must meet all 3 criteria)</b></p>	<p><b>Bariatric (weight loss) surgery in an adult may be considered medically necessary when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• A body mass index (BMI) greater than 40 kg/m<sup>2</sup></li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• A BMI of 35 kg/m<sup>2</sup> or more with at least <b>ONE</b> of the following 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) with a blood pressure (BP) greater than 140/90 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 by pharmacotherapy</li> </ul> </li> </ul>



Indication	Coverage Criteria
	<ul style="list-style-type: none"> <li>○ Obstructive sleep apnea as documented by a sleep study (polysomnography).</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 six continuous months within the two year 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 (eg, MediFast, OptiFast)</li> <li>▪ Physical activity (eg, 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 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>• Psychological evaluation and clearance by a licensed mental health provider to rule out psychological disorders, inability to provide informed consent, or 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>Patient selection criteria for adolescents less than 18 years of age</b></p>	<p><b>Bariatric (weight loss) surgery in adolescents may be considered medically necessary 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</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The adolescent meets the same patient selection criteria as an adult</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>



Indication	Coverage Criteria
	<p data-bbox="589 296 1438 369"><b>Refer to member contract language for benefit determination on treatment of obesity for adolescents.</b></p> <p data-bbox="589 426 1438 489"><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 data-bbox="183 531 537 604"><b>Covered bariatric (weight loss) surgeries</b></p>	<p data-bbox="589 531 1425 604"><b>The following bariatric (weight loss) surgery procedures may be considered medically necessary when criteria are met:</b></p> <ul data-bbox="589 621 1390 909" style="list-style-type: none"> <li data-bbox="589 621 1390 695">• Adjustable gastric banding–laparoscopic (eg, LAP-BAND®, REALIZE™)</li> <li data-bbox="589 709 1390 783">• Biliopancreatic bypass (ie, the Scopinaro procedure) with duodenal switch–open or laparoscopic</li> <li data-bbox="589 798 1390 871">• Gastric bypass using a Roux-en-Y anastomosis–open or laparoscopic</li> <li data-bbox="589 886 886 909">• Sleeve gastrectomy</li> </ul>
<p data-bbox="183 930 459 1003"><b>Surgeon and facility requirements</b></p>	<p data-bbox="589 930 1304 961"><b>Bariatric (weight loss) surgery should be performed:</b></p> <ul data-bbox="589 978 1406 1052" style="list-style-type: none"> <li data-bbox="589 978 1406 1052">• By a surgeon with specialized training and experience in the bariatric surgery procedure used</li> </ul> <p data-bbox="589 1066 654 1098"><b>AND</b></p> <ul data-bbox="589 1115 1287 1188" style="list-style-type: none"> <li data-bbox="589 1115 1287 1188">• In an institution (facility or hospital) that includes a comprehensive bariatric surgery program</li> </ul> <p data-bbox="589 1203 654 1234"><b>AND</b></p> <ul data-bbox="589 1251 1455 1325" style="list-style-type: none"> <li data-bbox="589 1251 1455 1325">• Any device used for bariatric surgery must be FDA approved for that purpose and used according to the labeled indications</li> </ul>
<p data-bbox="183 1335 537 1409"><b>Revision bariatric surgery to correct complications</b></p>	<p data-bbox="589 1335 1446 1587"><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 correct complications from the primary bariatric procedure including, but not limited to:</b></p> <ul data-bbox="589 1604 1455 1810" style="list-style-type: none"> <li data-bbox="589 1604 1455 1719">• Band erosion, slippage, leakage, herniation or intractable nausea/vomiting that cannot be corrected with manipulation or adjustment</li> <li data-bbox="589 1734 1382 1766">• Non-absorption resulting in hypoglycemia or malnutrition</li> <li data-bbox="589 1780 789 1810">• Obstruction</li> </ul>



Indication	Coverage Criteria
	<ul style="list-style-type: none"> <li>• Staple-line failure (eg, Gastrogastric fistula)</li> <li>• Stricture</li> <li>• Ulceration</li> <li>• Weight loss of 20% or more below ideal body weight</li> <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 patient 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 (not described above), 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> <ul style="list-style-type: none"> <li>• All criteria listed above for the initial procedure must be met again</li> <li>• Previous surgery for morbid obesity was at least 2 years prior to the repeat procedure</li> <li>• There is documentation of compliance with the previously prescribed postoperative nutrition and exercise program</li> <li>• Coverage for bariatric surgery is available under the individual's current health benefit plan</li> </ul>
<p><b>Cholecystectomy</b></p>	<p><b>Routine cholecystectomy (gallbladder removal) may be considered medically necessary when performed with bariatric surgery.</b></p>
<p><b>Hiatal hernia repair</b></p>	<p><b>Repair of a hiatal hernia during bariatric surgery may be considered medically necessary for a preoperative diagnosis of hiatal hernia with clinical indications for surgical repair.</b></p> <p><b>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</b></p>



Indication	Coverage Criteria
<b>Routine liver biopsy</b>	<b>Routine liver biopsy during obesity surgery is considered not medically necessary in the absence of preoperative signs or symptoms of liver disease (eg, elevated liver enzymes, enlarged liver).</b>
<b>Bariatric surgery for a BMI less than 35 kg/m<sup>2</sup></b>	<b>Bariatric (weight loss) surgery is considered not medically necessary for patients with a BMI less than 35 kg/m<sup>2</sup>.</b>
<b>Bariatric type surgery to treat conditions other than morbid obesity</b>	<b>Adjustable gastric banding, gastric bypass using a Roux-en-Y anastomosis, or sleeve gastrectomy is considered investigational for the primary treatment of any condition other than morbid obesity, including, but not limited to diabetes, gastroesophageal reflux disease (GERD), or gastroparesis</b>
<b>Non-covered bariatric surgeries/procedures</b>	<p><b>Vertical banded gastroplasty (stomach stapling) is considered not medically necessary as a treatment for obesity due to too many long-term complications.</b></p> <p><b>The following weight loss (bariatric) surgery procedures are considered investigational for the treatment of morbid obesity:</b></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])</li> <li>• Long-limb gastric bypass procedure (ie, &gt; 150 cm)</li> <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 (eg, sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)</li> <li>• Vagus nerve blocking (eg, the VBLOC<sup>®</sup> device or Maestro<sup>®</sup>) (see related medical policy <a href="#">7.01.150</a>)</li> <li>• Endoscopic procedures (aka endoluminal, endosurgical, or natural orifice) as a primary bariatric procedure or as a revision</li> </ul>



Indication	Coverage Criteria
	<p>procedure (ie, 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:</p> <ul style="list-style-type: none"> <li>○ Endoscopic gastroplasty</li> <li>○ Intra-gastric balloons (eg, Orbera<sup>®</sup>, ReShape<sup>™</sup>, Obalon<sup>™</sup>)</li> <li>○ Insertion of the StomaphyX<sup>™</sup> device or any other closure device (eg, Apollo OverStitch<sup>™</sup>, EndoCinch<sup>™</sup> System)</li> <li>○ Stomach aspiration drainage tube device (eg, AspireAssist<sup>®</sup>)</li> <li>○ Use of an endoscopically placed duodenal-jejunal sleeve (EndoBarrier)</li> </ul>

**Documentation Requirements**

**The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of ALL THREE (3) criteria:**

1. A body mass index (BMI) greater than 40 kg/m<sup>2</sup>, or BMI of 35 kg/m<sup>2</sup> or more with at least ONE (1) of the following conditions:
  - Established coronary heart disease
  - Other atherosclerotic disease
  - Type 2 diabetes uncontrolled by medications
  - Obstructive sleep apnea as documented by a sleep study
2. Completion of a physician administered weight-loss program that:
  - Lasted for at least six (6) months in a row
  - Took place within two (2) years 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
3. Psychological evaluation and clearance by a licensed mental health provider to rule out psychological disorders, inability to provide informed consent, or inability to comply with presurgical and postsurgical requirements. **Note:** A letter by a healthcare provider is not enough to meet these criteria.



## Coding

Code	Description
<b>CPT</b>	
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
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 (ie, 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
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)



Code	Description
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

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Body Mass Index Calculation

Morbid obesity, also known as clinically severe obesity, is measured using the body mass index (BMI). Severe obesity is weight-based and is defined as a BMI greater than 40 kg/m<sup>2</sup> or a BMI of 35 kg/m<sup>2</sup> or more with obesity-associated health conditions.

BMI is calculated by dividing a patient'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.

### Patient Selection Criteria

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



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

Patients who undergo adjustable gastric banding and fail to achieve adequate weight loss must show evidence of postoperative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.

### **Considerations for Bariatric Surgery in Adolescents**

In addition to the weight-based criteria, there is greater emphasis on issues of developmental maturity, psychosocial status, and informed consent for adolescent patients. All guidelines mention these issues, but recommendations are not uniform for addressing them (see [Guidelines for Children and Adolescents](#) under 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

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

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

## Evidence Review

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### Description

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these techniques have different 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 morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m<sup>2</sup> or a BMI greater than 35 kg/m<sup>2</sup> with



associated complications including, but not limited to, diabetes, hypertension, or obstructive sleep apnea. Morbid obesity results in a very high risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectal, prostate; for women: breast, uterine, ovarian), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 fewer years than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis.

When conservative measures fail, some patients may consider surgical approaches. A 1991 National Institutes of Health Consensus Conference defined surgical candidates as “those patients with a BMI of greater than 40 kg/m<sup>2</sup>, or greater than 35 kg/m<sup>2</sup> in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes.”<sup>1</sup>

Resolution (cure) or improvement of type 2 diabetes after bariatric surgery and observations that glycemic control may improve immediately after surgery, before a significant amount of weight is lost, have promoted interest in a surgical approach to the treatment of type 2 diabetes. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, eg, glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY, are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide YY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

## Types of Bariatric Surgery Procedures

The following summarizes the most common types of bariatric surgery procedures.



## **Open Gastric Bypass**

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (ie, 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 (ie, 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.

## **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 Food and Drug Administration (FDA) for marketing in the United States. The first to receive FDA approval was the LAP-BAND (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). The labeled indications for this device are as follows:

The LAP-BAND® system is indicated for use in weight reduction for severely obese patients with a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lb or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

In 2011, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m<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 patients 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 patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.

## **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 patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (eg, BPD).

### **Biliopancreatic Diversion**

The BPD procedure (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, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein



malnutrition may require treatment with total parenteral nutrition. Also, several case reports have noted liver failure resulting in death or liver transplant.

### **BPD 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, ie, producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

### **Vertical-Banded Gastroplasty**

Vertical-banded gastroplasty (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.

### **Long-Limb Gastric Bypass (ie, >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 (eg, 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.

### **Weight Loss Outcomes**

There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are the percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. EBW is defined as actual weight minus "ideal weight" and "ideal weight" is based on 1983 Metropolitan Life Insurance height-weight tables for medium frame.

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



**Table 1. Weight Loss Outcomes**

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

BMI: body mass index; EBW: excess body weight.

## Durability of Weight Loss

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

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

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (eg, pneumonia, myocardial infarction).



## Reoperation Rate

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

## Long-Term Complications (Metabolic Adverse Events, Nutritional Deficiencies)

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

## Improved Health Outcomes in Terms of Weight-Related Comorbidities

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

## Summary of Evidence

### Adults With Morbid Obesity

For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes. A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. The evidence is



sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

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

For individuals who are adults with morbid obesity who receive BPD without duodenal switch, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without a duodenal switch or gastric bypass. However, concerns have been raised about complications associated



with BPD without duodenal switch, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes a small RCT and observational studies. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. The small RCT compared IGB plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months postsurgery. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes 2 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. A 2014 systematic review identified only a small nonrandomized comparative study comparing laparoscopic gastric plication with other bariatric surgery procedures. Since the systematic review, 2 RCTs have been published, one comparing laparoscopic gastric plication with a sham procedure and another comparing laparoscopic gastric plication with sleeve gastrectomy (SG). Laparoscopic gastric plication was more effective than the sham procedure at 1-year follow-up and equally effective as SG at 2-year follow-up. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), the evidence includes observational studies. Relevant



outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. No controlled trials have evaluated single anastomosis duodenoileal bypass with SG. There are a few case series, the largest of which had fewer than 100 patients. A retrospective chart review of patients receiving gastric bypass, biliopancreatic diversion (BPD), and SADI-S, reported that among patients without diabetes, SADI-S was more effective in weight loss and cholesterol outcomes than gastric bypass. Among patients with diabetes, SADI-S and BDP had higher remission rates than gastric bypass. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of single anastomosis duodenoileal bypass with (SADI-S). The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who are adults with morbid obesity who receive intragastric balloon (IGB) devices, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. RCTs assessing the 2 IGB devices approved by the Food and Drug Administration have found significantly greater weight loss with IGB than with sham treatment or lifestyle therapy alone after 6 months (maximum length of device use). Some adverse events were reported, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how 6 months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes an RCT and case series. Relevant outcomes are overall survival, change in



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

## **Revision Bariatric Surgery**

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

## **Adults With Type 2 Diabetes**

For individuals who are diabetic and not morbidly obese who receive gastric bypass, sleeve gastrectomy, biliopancreatic diversion, or laparoscopic adjustable gastric banding, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than



medical therapy as a treatment for type 2 diabetes in obese patients, including those with a BMI between 30 and 34.9 kg/m<sup>2</sup>. The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c levels levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 3 years of follow-up; 1 RCT that included patients with BMI between 30 and 34.9 kg/m<sup>2</sup> had 5 year follow-up data. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

However, there are clinical concerns about durability and long-term outcomes at 5 to 10 years as well as potential variation in observed outcomes in community practice vs clinical trials. As a result, bariatric surgery for individuals who are diabetic and not morbidly obese is considered not medically necessary.

## **Nondiabetic and Nonobese Adults**

For individuals who are not diabetic and not morbidly obese who receive any bariatric surgery procedure, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. 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 the effects of the technology on health outcomes.

## **Hiatal Hernia Repair with Bariatric Surgery**

For individuals with morbid obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes cohort studies and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of 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.

## **Adolescent Children With Morbid Obesity**

### **Gastric Bypass, Laparoscopic Adjustable Gastric Banding (LAGB), or Sleeve Gastrectomy (SG)**

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

### **Bariatric Surgery Other Than Gastric Bypass, LAGB, or SG**

For individuals who are adolescent children with morbid obesity who receive bariatric surgery other than gastric bypass, or LAGB, or SG, the evidence includes systematic reviews and a cohort study. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Studies using bariatric surgery other than gastric bypass, LAGB, or SG, have small sample sizes. Results from a meta-analysis including patients using other procedures have shown significant improvements in BMI reduction, fasting blood insulin, and total cholesterol, although the estimates have wide confidence intervals, limiting interpretation. The evidence is insufficient to determine the effects of the technology on health outcomes.



## Preadolescent Children With Morbid Obesity

For individuals who are preadolescent children with morbid obesity who receive bariatric surgery, the evidence includes no studies focused on this population. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old, but findings were not reported separately for preadolescent children. Moreover, clinical practice guidelines have recommended against bariatric surgery for preadolescent children. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 2](#).

**Table 2. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT02881684<sup>a</sup></a>	Weight Reduction by Aspiration Therapy in Asian Patients with Morbid Obesity	15	Dec 2018 (recruiting)
<a href="#">NCT02142257</a>	Gastric Bypass Procedure and AspireAssist Aspiration Therapy System for the Treatment of Morbid Obesity, Observational Study over 5 Years	100	May 2020 (ongoing)
<a href="#">NCT03493620</a>	Multicenter Randomized Prospective Study With Sham Group to Evaluate the Efficacy and Results of Endoscopic Gastroplasty Using Overstitch in Patients With Class I and II Obesity	60	Aug 2020 (ongoing)
<a href="#">NCT03102697</a>	Optimization and Follow-Up of the Consecutive Use of Two Intra-gastric Balloons in the Treatment of Obesity	30	Dec 2020 (recruiting)



NCT No.	Trial Name	Planned Enrollment	Completion Date
<a href="#">NCT01172899</a>	The BASIC Trial. Morbid Obesity in Children and Adolescents: a Prospective Randomised Trial of Conservative Treatment Versus Surgery	60	Dec 2020 (recruiting)
<a href="#">NCT03891056</a>	Metabolic Surgery for Patients with Type 2 DM and Grade 1 Obesity with Bad Metabolic Control (MSO1CT)	40	Jan 2022 (recruiting)
<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 2022
<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)	366	Oct 2022
<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 2023 (recruiting)
<a href="#">NCT02792166</a>	Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S): a Prospective Cohort Study	40	Jun 2024 (recruiting)
<a href="#">NCT04128995</a>	Surgical or Medical Treatment for Pediatric Type 2 Diabetes	90	Aug 2024 (recruiting)
<a href="#">NCT02779322</a>	Laparoscopic Roux-en-Y Gastric Bypass Versus Single Anastomosis Gastric Bypass (MGB vs LGBP)	20	Jun 2025 (ongoing)
<a href="#">NCT02692469</a>	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
<a href="#">NCT04165694</a>	Single Anastomosis Duodenal Ileal Bypass (SADI) as a Second Stage for Sleeve Gastrectomy Weight Loss Failure	50	Dec 2030 (recruiting)

NCT: national clinical trial.

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



## Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

In response to the requests, input was received from 1 physician specialty society and 2 academic medical centers on the use of the REALIZE band while the policy was under review in 2008. All 3 responses supported the use of the REALIZE band as a surgical option for patients, as adopted into the policy in 2008.

In response to the requests, input was also received from 2 academic medical centers on the use of the new endoscopic placement of devices to remedy weight gain that occurs after bariatric surgery while the policy was under review in 2008. Input from both centers agreed that this approach is considered investigational, as adopted in the policy in 2008.

## Practice Guidelines and Position Statements

### American Association of Clinical Endocrinologists et al

In 2017, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm.<sup>141</sup> The document stated: "Bariatric surgery should be considered for adult patients with a BMI [body mass index] of 35 kg/m<sup>2</sup> or more and comorbidities, especially if therapeutic goals have not been reached using other modalities."

In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on the medical care of patients with obesity.<sup>142</sup> The guidelines addressed 9 broad clinical questions with 123 recommendations. It was noted that the 2013 guidelines specifically on bariatric surgery (see below) were considered adequate in the current form. With regard to bariatric surgery for these guidelines, the following recommendations were added to those in the 2013 guideline (see [Table 3](#)).



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

No.	Recommendation	GOE	BEL
35	Patients with obesity (BMI $\geq 30$ kg/m <sup>2</sup> ) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion."	B	1 <sup>a</sup>
121	"Patients with a BMI of $\geq 35$ kg/m <sup>2</sup> and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m <sup>2</sup> with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.		
	<ul style="list-style-type: none"> <li>BMI <math>\geq 35</math> kg/m<sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk."</li> </ul>	A	1
	<ul style="list-style-type: none"> <li>BMI <math>\geq 30</math> kg/m<sup>2</sup> and therapeutic target of weight control and improved biochemical markers of CVD risk.</li> </ul>	B	2
	<ul style="list-style-type: none"> <li>BMI <math>\geq 30</math> kg/m<sup>2</sup> and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk.</li> </ul>	C	3
122	"Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone."	D	
62	"Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett's esophagus."	Int	Int
	"Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux."	Strong	Strong

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

<sup>a</sup> Downgraded due to evidence gaps.

In 2013, joint guidelines on support for bariatric surgery patients were published by AACE, the Obesity Society, and American Society for Metabolic and Bariatric Surgery (ASMBS).<sup>135</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 1 of the procedures.”
- “Patients with a BMI  $\geq 35$  kg/m<sup>2</sup> and 1 or more severe obesity-related comorbidities...”
- “Patients with BMI of 30-34.9 kg/m<sup>2</sup> with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.”
- “There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.”

“Which bariatric surgical procedure should be offered?”

- “The best choice for any bariatric procedure (type of procedure and type of approach) depends on the individualized goals of therapy (eg, weight loss and/or metabolic [glycemic] control), available local-regional expertise (surgeon and institution), patient preferences, and personalized risk stratification.... At this time, there is still insufficient evidence to generalize in favor of one bariatric surgical procedure for the severely obese population.”

## American College of Cardiology et al

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

- “Advise adults with a BMI  $\geq 40$  kg/m<sup>2</sup> or BMI  $\geq 35$  kg/m<sup>2</sup> with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI Grade A (Strong); AHA/ACC COR [class of recommendation]: IIa; AHA/ACC LOE [level of evidence]: A”



- “For individuals with a BMI <math><35\text{ kg/m}^2</math>, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation)”

## American Society for Metabolic and Bariatric Surgery

In 2016, the American Society for Metabolic and Bariatric Surgery (ASBMS) published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES]).<sup>144</sup> The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

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

In 2012, the ASMBS published a position statement on sleeve gastrectomy.<sup>145</sup> This updated statement provided the following conclusions:

- “Substantial comparative and long-term data have now been published in the peer-reviewed studies demonstrating durable weight loss, improved medical co-morbidities, long-term patient satisfaction, and improved quality of life after SG [sleeve gastrectomy].
- The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first-stage procedure in high-risk patients as part of a planned staged approach.
- From the current published data, SG has a risk/benefit profile that lies between laparoscopic adjustable gastric banding (LAGB) and the laparoscopic RYGB [Roux-en-Y gastric bypass]. As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this could be managed effectively with reintervention. Informed consent for SG used as a primary



procedure should be consistent with consent provided for other bariatric procedures and should include the risk of long-term weight gain.

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

## **Society of American Gastrointestinal and Endoscopic Surgeons**

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines for the management of hiatal hernia, which included a recommendation about the repair of hiatal hernias incidentally detected at the time of bariatric surgery.<sup>4</sup> These guidelines stated: “During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired” (moderate quality evidence, weak recommendation).

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

In 2019, members of societies affiliated with the International Federation for the Surgery of Obesity and Metabolic Disorders established an expert consensus statement on revisional bariatric surgery (RBS).<sup>146</sup> Consensus agreement was established for the following recommendation statements:

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



- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after OAGB."<sup>a</sup>

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

<sup>a</sup> Consensus achieved in second round of voting.

## 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>147</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 Society for Metabolic and Bariatric Surgery

In 2012, American Society for Metabolic and Bariatric Surgery (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>148</sup> Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

Strong indications:

- Type 2 diabetes mellitus



- Moderate or severe obstructive sleep apnea (apnea-hypopnea index >15)
- Nonalcoholic steatohepatitis
- Pseudotumor cerebri

Less strong indications:

- Cardiovascular disease
- Metabolic syndrome

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

## European Society for Gastroenterology, Hepatology and Nutrition et al

In 2015, a joint position paper published by the European Society for Gastroenterology, Hepatology and Nutrition and the North American Society for Gastroenterology, Hepatology and Nutrition made the following recommendations on indications for bariatric surgery in adolescents<sup>149</sup>:

- "BMI > 40 kg/m<sup>2</sup> with severe comorbidities
  - Type 2 diabetes mellitus
  - Moderate-to-severe sleep apnea
  - Pseudotumor cerebri
  - NASH [nonalcoholic steatohepatitis] with advanced fibrosis (ISHAK score > 1)
- BMI > 50 kg/m<sup>2</sup> with mild comorbidities
  - Hypertension
  - Dyslipidemia
  - Mild obstructive sleep apnea



- Chronic venous insufficiency
- Panniculitis
- Urinary incontinence
- Impairment in activities of daily living
- NASH [nonalcoholic steatohepatitis]
- Gastroesophageal reflux disease
- Severe psychological distress
- Arthropathies related to weight”
- Additional criteria included:
  - “Have attained 95% of adult stature
  - Have failed to attain a healthy weight with previously organized behavioral/medical treatments
  - Demonstrate commitment to psychological evaluation perioperatively
  - Avoid pregnancy for 1 year after surgery...
  - Have decisional capacity and will provide informed assent/consent, as age appropriate”

## Endocrine Society

In 2008, the Endocrine Society published recommendations on the prevention and treatment of pediatric obesity.<sup>1</sup> In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.<sup>150</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 for those planning to become pregnant within 2 yr of surgery) and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder.”

## U.S. Preventive Services Task Force Recommendations

Bariatric surgery is not considered a preventive service.

## Medicare National Coverage

The Centers for Medicare & Medicaid Services have published a national coverage decision on bariatric surgery.<sup>151</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.”



## Regulatory Status

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

**Table 4** shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

**Table 4. FDA-Approved Bariatric Surgery Devices**

Device	Manufacturer	PMA Date	Labeled Indications
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.
ReShape® Integrated Dual Balloon System	ReShape Medical	Jul 2015	For use in obese adults (BMI, 30-40 kg/m <sup>2</sup> ) and ≥1 comorbid conditions who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon delivered transorally and inflated with saline.
LAP-BAND® Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m <sup>2</sup> or a BMI of at least 30 kg/m <sup>2</sup> with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).
REALIZE® Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m <sup>2</sup> , or a BMI of at least 35 kg/m <sup>2</sup> with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults who have failed more



Device	Manufacturer	PMA Date	Labeled Indications
			conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).

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

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intragastric balloons in response to reports of 2 types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. 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 and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices.

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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.



Date	Comments
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.
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



Date	Comments
	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.
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.



Date	Comments
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.
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.



Date	Comments
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.

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**This Notice has Important Information.** This notice may have important information about your application or coverage through LifeWise Health Plan of Washington. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-592-6804 (TTY: 800-842-5357).

### አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ LifeWise Health Plan of Washington ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንን ለመጠበቅና በአስፈላጊ አርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች አርምቫ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና ያለምንም ክፍያ በቋንቋዎ አርዳታ እንዲያገኙ መብት አለዎት። በስልክ ቁጥር 800-592-6804 (TTY: 800-842-5357) ይደውሉ።

### العربية (Arabic):

يحتوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تريد الحصول عليها من خلال LifeWise Health Plan of Washington. LifeWise Health Plan of Washington. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تواريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-592-6804 (TTY: 800-842-5357).

### 中文 (Chinese):

**本通知有重要的訊息。**本通知可能有關於您透過 LifeWise Health Plan of Washington 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-592-6804 (TTY: 800-842-5357)。

### Oromoo (Cushite):

**Beeksisni kun odeeffannoo barbaachisaa qaba.** Beeksisni kun sagantaa yookan karaa LifeWise Health Plan of Washington tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhuma irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-592-6804 (TTY: 800-842-5357) tii bilbilaa.

### Français (French):

**Cet avis a d'importantes informations.** Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de LifeWise Health Plan of Washington. Le présent avis peut contenir des dates clés. Vous devrez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-592-6804 (TTY: 800-842-5357).

### Kreyòl ayisyen (Creole):

**Avi sila a kapab genyen enfòmasyon enpòtan ladann.** Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè LifeWise Health Plan of Washington. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w lan oswa pou yo ka ede w avèk depans yo. Se dwa w pou resevwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-592-6804 (TTY: 800-842-5357).

### Deutsche (German):

**Diese Benachrichtigung enthält wichtige Informationen.** Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch LifeWise Health Plan of Washington. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-592-6804 (TTY: 800-842-5357).

### Hmoob (Hmong):

**Tsaw ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsaw ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam los ntawm LifeWise Health Plan of Washington. Tej zaum muaj cov hnuab tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyoog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-592-6804 (TTY: 800-842-5357).

### Iloko (Ilocano):

**Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion.** Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenno coverage babaen iti LifeWise Health Plan of Washington. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodda a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-592-6804 (TTY: 800-842-5357).

### Italiano (Italian):

**Questo avviso contiene informazioni importanti.** Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso LifeWise Health Plan of Washington. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-592-6804 (TTY: 800-842-5357).

**日本語 (Japanese):**

この通知には重要な情報が含まれています。この通知には、LifeWise Health Plan of Washington の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-592-6804 (TTY: 800-842-5357)までお電話ください。

**한국어 (Korean):**

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 LifeWise Health Plan of Washington 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-592-6804 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄ່າຄ່ອງສະໜັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ LifeWise Health Plan of Washington. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດດວງສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-592-6804 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរ៉ាប់រងរបស់អ្នកកម្រោយ: LifeWise Health Plan of Washington ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កំណត់ថ្លៃជាក់លាក់នានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ នឹងជំនួយនៅក្នុងការសរសេរអ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-592-6804 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿੱਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿੱਚ LifeWise Health Plan of Washington ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਜਵਾਬ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਹਤ ਕਵਰੇਜ ਚਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੇ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-592-6804 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق LifeWise Health Plan of Washington باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-592-6804 (TTY: 800-842-5357) تماس بگیرید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez LifeWise Health Plan of Washington. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-592-6804 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do LifeWise Health Plan of Washington. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-592-6804 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin LifeWise Health Plan of Washington. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența privitoare la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-592-6804 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через LifeWise Health Plan of Washington. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-592-6804 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, LifeWise Health Plan of Washington, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma ona fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-592-6804 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de LifeWise Health Plan of Washington. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-592-6804 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng LifeWise Health Plan of Washington. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng habbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-592-6804 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน LifeWise Health Plan of Washington และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการบางอย่างในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลืออื่นในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-592-6804 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через LifeWise Health Plan of Washington. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-592-6804 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình LifeWise Health Plan of Washington. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-592-6804 (TTY: 800-842-5357).