

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Bariatric and Metabolic Surgery
Policy Number	7.01.29
Category	Technology Assessment
Original Effective Date	10/18/01
Committee Approval Date	03/21/02, 02/20/03, 10/15/03, 11/18/04, 08/18/05, 04/20/06, 11/16/06, 11/15/07, 12/18/08, 01/21/10, 12/16/10, 10/20/11, 12/20/12, 11/21/13, 12/18/14, 11/19/15, 10/20/16, 04/20/17, 03/15/18, 08/16/18, 05/16/19, 10/17/19, 09/17/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24
Current Effective Date	05/16/24
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the surgical treatment of obesity by open or laparoscopic Roux-en-Y gastric bypass, duodenal switch procedure (biliopancreatic diversion), laparoscopic adjustable gastric banding (LAGB), and sleeve gastrectomy have been medically proven to improve health outcomes and, therefore, are considered **medically appropriate** for patients who meet **ALL** of the following criteria:

A. The patient has a body mass index (BMI) of **ONE** of the following:

Adult

- Class 3 obesity (BMI 40 kg/m² or greater),
- Class 2 obesity (BMI 35 to 39.9 kg/m²) and at least one (1) obesity-related comorbidity (e.g., cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, or weight-bearing joint arthropathy), **or**
- Class 1 obesity (BMI 30 to 34.9 kg/m²) and type 2 diabetes (T2D) with documentation of inadequate glycemic control despite optimized lifestyle and medical management.

Adolescent

- Class 3 obesity (BMI greater than or equal to 40 kg/m², or BMI greater than or equal to 140% of the 95th percentile, whichever is lower based on age and sex), **or**
- Class 2 obesity (BMI 35 to 39.9 kg/m², or BMI between 120% to 139.9% of the 95th percentile, whichever is lower based on age and sex), and at least one (1) obesity-related comorbidity (e.g.,

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 2 of 19

cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, type 2 diabetes, or weight-bearing joint arthropathy);

- B. Documentation of efforts to achieve weight loss/metabolic improvements, including **ALL** the following:
 - 1. Pre-surgical lifestyle and medical management optimization efforts including the type of the weight-loss/nutritional program(s), applicable medication(s), length of participation, and results achieved (e.g., weight loss, lowered hemoglobin A1C). Documentation can be provided by the bariatric surgeon, primary care provider, registered dietician, or nutritionist;
 - 2. Pre-surgical nutritional evaluation conducted by a registered dietician is mandatory and documentation must be included; **and**
 - 3. Documentation that the patient will participate in a post-operative weight management program that promotes long-term success through nutritional management (including assessment for malabsorption), physical activity, and behavioral health support;
 - C. Medical clearance attestation for bariatric surgery from the primary care provider or bariatric surgeon;
 - D. Behavioral health clearance for bariatric surgery is documented by **ONE** of the following:
 - 1. The bariatric surgeon or primary care provider documents the absence of any psychiatric or psychosocial comorbidities; **or**
 - 2. A licensed behavioral health provider familiar with the implications of weight loss surgery is required for patients with **ANY** of the following:
 - a. history of alcohol or substance use disorder with six (6) months or less of abstinence; **or**
 - b. psychosocial, psychological, or psychiatric concerns identified by any member of the bariatric pre-operative evaluation team, including but not limited to the patient's primary care, bariatric surgeon, or Registered Dietician.
- II. Based upon our criteria and assessment of the peer-reviewed literature, the following procedures for the primary surgical treatment of obesity have not been medically proven to improve health outcomes and, therefore, are considered **investigational**:
- A. Aspiration therapy (e.g., AspireAssist device);
 - B. Laparoscopic gastric plication (also known as laparoscopic greater curvature plication);
 - C. Mini-gastric bypass (also known as loop or one anastomosis gastric bypass);
 - D. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) / Stomach-intestine pylorus-sparing surgery (SIPS);
 - E. Intra-gastric space occupying mechanisms (e.g., intra-gastric balloon or expanding material/capsules);
 - F. Endoscopic/endoluminal procedures or devices (e.g. transoral gastroplasty [also known as vertical sutured gastroplasty, endoluminal vertical gastroplasty, TOGA System]; restorative obesity surgery, endoluminal [ROSE]); StomaphyX device; closure devices [e.g., EndoCinch, Apollo Overstitch, and TransPyloric Shuttle Device]; gastrointestinal liners [duodenal-jejunal bypass liner (e.g., EndoBarrier)]; and Endoscopic sleeve gastroplasty;
 - G. Transoral outlet reduction [TORe]).
- III. Based upon our criteria and assessment of the peer-reviewed literature, bariatric surgery as a treatment for patients with a BMI less than or equal to 29.9 kg/m², with or without type 2 diabetes mellitus, has not been medically proven to be effective and, therefore, is considered **investigational**.

Reoperation

- IV. The adjustment of a previously placed laparoscopic adjustable gastric band (LAGB), beyond the global, 90-day limit, is considered **medically appropriate** to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following the initial medically necessary adjustable gastric banding procedure. Adjustment of LAGB is performed via accessing the subcutaneous port, with or without imaging).
- V. Surgical revisions are considered **medically necessary** for complications, such as malabsorption/malnutrition, obstruction, staple disruption, severe gastroesophageal reflux disease refractory to medical treatment, or stricture following the primary procedure. (*Refer to Policy Guidelines*)

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 3 of 19

- VI. A revision or removal of a LAGB is considered **medically appropriate** for a documented complication(s) or technical failure(s) (e.g., band slippage, band erosion, infection, esophageal dilation, dysphagia, heartburn/reflux, displaced band, port dislocation band intolerance [e.g., pain or vomiting], and port and/or catheter leakage).
- VII. A revision or conversion to another medically appropriate procedure because of unsatisfactory weight loss or metabolic improvements due to technical failure of the primary bariatric procedure (*Refer to Policy Guidelines*) is considered **medically appropriate** if there is documentation of **BOTH** of the following:
- A. Primary procedure was initially successful in inducing weight loss;
 - B. Patient remained compliant with the prescribed post-operative nutrition and exercise program for at least six (6) months.
- VIII. Repeat surgery for morbid obesity is considered **not medically necessary** for patients who have either failed to lose weight or who have regained weight due to non-adherence with the prescribed post-operative nutrition and exercise program following the primary surgery.
- IX. Placement of a second adjustable gastric band (AGB) is considered **investigational**, as there is no published literature to support the efficacy of a second AGB after failure of the first procedure to produce weight loss.
- X. Based upon our criteria and assessment of the peer-reviewed literature, revision surgery with an endoscopic/endoluminal procedure (e.g., transoral outlet reduction [TORe]) has not been medically proven to be effective and, therefore, is considered **investigational**.

Concomitant Procedures

- XI. Based upon our criteria and assessment of the peer-reviewed literature, performing a routine liver biopsy at the time of the bariatric surgery is considered **not medically necessary** in the absence of documented signs or symptoms of liver disease (e.g., abnormal liver function tests of unknown etiology, knowledge of a specific diagnosis that will likely alter the treatment plan, known liver disease where prognostic information about fibrosis may guide subsequent treatment, the presence of a mass or lesions, or focal or diffuse abnormalities seen on imaging studies of unknown etiology).
- XII. Based upon our criteria and assessment of the peer-reviewed literature, prophylactic removal of a normal and asymptomatic gallbladder at the time of bariatric surgery is considered **not medically necessary**, unless cholelithiasis is present, or the patient will undergo biliopancreatic diversion with or without duodenal switch based on a higher incidence of biliary complications.

Refer to Corporate Medical Policy #3.01.02 Psychological Testing

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

Refer to Corporate Medical Policy #7.01.11 Cosmetic and Reconstructive Procedures

Refer to Corporate Medical Policy #7.01.53 Abdominoplasty and Panniculectomy (for criteria related to surgical removal of redundant/excessive skin as a result of bariatric surgery)

Refer to Corporate Medical Policy #7.01.64 Gastric Electrical Stimulation

Refer to Corporate Medical Policy #11.01.01 Medical/Non-Surgical Weight Management Programs and Services

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

- I. Patients considering surgery must participate in an integrated pre- and post-surgery program consisting of dietary therapy, physical activity, and behavioral and social support programs. Post-surgically, patients must be involved in a formal program for at least one year. These multidisciplinary programs support people through the long-term commitment of weight loss (e.g., lifestyle changes and psychosocial impacts).

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 4 of 19

- II. Body mass index (BMI) is a measure used to screen for excess body adiposity (body fat) and is calculated by dividing a person's weight in kilograms (kg) by the square of height in meters (m²).
- III. BMI thresholds may be adjusted for ethnicity (e.g., Asian population) on a case-by-case basis. Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m² (Eisenberg et al., 2022). Mechanick et al. (2020) report that BMI for identifying excess adiposity and risks of cardiometabolic disease are lower for some ethnicities and should be considered during screening and diagnosis.
- IV. The American Society of Metabolic and Bariatric Surgery (ASMBS) reiterates the 1991 National Institute of Health (NIH) Consensus statement that a multidisciplinary team should evaluate patients to optimize surgical outcomes including:
 - A. Comprehensively evaluating patients seeking metabolic and bariatric surgery through assessment of medical history, physical examination, laboratory testing (e.g., *H. pylori*, kidney function, liver profile, thyroid stimulating hormone), psychosocial history (e.g., functioning, substance use, maladaptive eating patterns), lifestyle/nutritional evaluation (e.g., sleep hygiene, smoking, healthy eating index) (Carter et al., 2021; Mechanick et al., 2019).
 - B. Management of modifiable risk factors prior to elective surgery, with the goal of reducing the risk of perioperative complications and improving outcomes, by making proactive referrals to specialists to mitigate identified risks and to coordinate pre- and post-surgical care (Sogg et al., 2021).
 - C. Pre-surgical evaluation process to optimize surgical outcomes and implement interventions that can address disordered eating, severe uncontrolled mental illness, or active substance abuse (Eisenberg et al., 2022).
- V. Adult classification of obesity by BMI (NHLBI, 1998)
 - Class 1 obesity: BMI 30 to 34.9 kg/m²
 - Class 2 obesity: BMI 35 to 39.9 kg/m²
 - Class 3 extreme obesity: BMI 40 kg/m² or greater
- VI. Child and adolescent BMI interpretation is age- and sex-specific with weight category and classification of (Hampl et al., 2023):
 - Class 2 obesity: BMI 35 to 39.9 kg/m² or BMI between 120% to 139.9% of the 95th percentile
 - Class 3 obesity: BMI greater than or equal to 40 kg/m² or BMI greater than or equal to 140% of the 95th percentile
- VII. Some post-bariatric surgery patients regain lost weight or never lose sufficient weight. Other patients may develop unacceptable post-operative symptoms (e.g., de novo gastroesophageal reflux disease (GERD) that does not respond to medical therapies). A revision due to medical complications does not require six (6) months of demonstrated compliance; otherwise, patients must demonstrate compliance for at least six (6) months before a revision will be considered for failure to lose adequate weight and/or weight regain.
 - A. Non-patient controllable factors which can lead to pouch dilation include but are not limited to variations in technique in the initial pouch creation (e.g., size and the anatomic configuration [lesser curvature based pouch creation vs a horizontally oriented pouch incorporating the gastric fundus] or distal subacute stricture or narrowing can lead to proximal gastric pouch dilation). These failures may warrant reversal surgery or revision surgery (e.g., conversion to Roux-en-Y).
 - B. Failures due to patient noncompliance reflect poor patient selection and do not warrant revision procedures. A clue to this is gastric pouch dilation in a patient not adhering to the recommended eating protocols. These patients are likely to fail again.
- VIII. The behavioral health evaluation should be performed by a licensed behavioral health provider familiar with the implications of weight reduction surgery. A current licensed behavioral health provider familiar with the implications of weight reduction surgery who is providing ongoing care for the patient may also provide this evaluation. The use of routine psychological testing as a screening tool or as part of the psychological evaluation prior to bariatric surgery is considered not medically necessary (*Refer to Corporate Medical Policy #3.01.02 Psychological Testing*).

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 5 of 19

- IX. Adolescents, due to their special needs, should be referred to a Center of Excellence or other facilities specializing in bariatric surgery procedures for the adolescent population. This will allow for greater consideration to be given to psychosocial and informed consent issues.
- X. Coverage is limited to physicians who have been properly trained in performing a bariatric procedure at facilities with the diagnostic and support services necessary for the care of morbidly obese patients.
- XI. Any device used for bariatric surgery must be used in accordance with the approved indications of the United States Food and Drug Administration (FDA).
- XII. An expected outcome of successful bariatric surgery is redundant/excessive skin.

DESCRIPTION

Obesity is a complex, multifactorial, chronic condition that substantially raises an individual's risk of weight-related complications and morbidity caused by or exacerbated by excess adiposity. Complications include but are not limited to asthma, nonalcoholic fatty liver disease, hypertension, dyslipidemia, pre-diabetes, type 2 diabetes, metabolic syndrome, coronary artery disease, stroke, gallbladder disease, osteoarthritis, obstructive sleep apnea, respiratory problems, and a variety of certain types of cancers (e.g., colorectal cancer).

Clinically severe obesity includes class 3 obesity (formerly referred to as morbid obesity) and class 2 obesity with associated comorbid conditions (NHLBI, 1998). The NHLBI outlines the following relationship between overweight/obesity BMI and disease risk, which is noted to vary among individuals and different populations:

Obesity Classification	Body Mass Index (kg/m²)	Disease Risk*
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	High
Class 2 obesity	35-39.9	Very High
Class 3 extreme obesity	>40	Extremely High

*Disease risk for type 2 diabetes, hypertension, and cardiovascular disease.

The first line of treatment for obesity is dietary and lifestyle changes, including intensive lifestyle intervention (ILI). Under medical supervision ILI programs include multiple comprehensive behavioral management activities that focus on increasing healthful food consumption, participating in physical activity for enjoyment and self-care reasons, and improving overall self-esteem and self-concept. Strong evidence suggests that multidomain ILI reduces cardiovascular risk factors among persons with type 2 diabetes (Huckfeldt et al., 2023). Although this strategy may be effective in some patients, not all individuals can reduce and control weight through diet and activity/exercise/movement. When conservative measures fail, some patients consider surgical approaches.

Bariatric surgery, also referred to as metabolic or bariatric surgery (MBS), has proven results as a weight loss option for people with class II or III obesity who fail to lose weight with conservative measures. Long-term evidence demonstrates significant and durable clinical improvement, and in some cases remission, of co-morbidities (e.g., type 2 diabetes). Bariatric or metabolic surgery work by changing the anatomy and size of the stomach to reduce/restrict food intake, as well as modifying the digestion process to improve fat metabolism. Some procedures can also affect the production of intestinal hormones, which can influence appetite and metabolic improvements.

Bariatric and metabolic surgery for people with Class 1 obesity and T2D is increasingly being performed as a treatment option based on published findings of the resolution (cure) or improvement of T2D after bariatric surgery, and observations that glycemic control may improve immediately after surgery before a significant amount of weight is lost. The various surgical procedures have different effects on weight loss, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides (e.g., glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY) are secreted in response to contact with unabsorbed nutrients and by vagally

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 6 of 19

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 insulintropic 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 is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

Procedures/Interventions

Bariatric surgery can be divided into two categories: gastric restrictive procedures and malabsorptive procedures. Gastric restrictive procedures mechanically typically limit volume of food intake prior to achieving satiety; malabsorptive procedures interfere with the absorption of ingested nutrients. Examples of gastric restrictive procedures include legacy procedures such as vertical and horizontal banded gastroplasty and adjustable gastric banding. Laparoscopic sleeve gastrectomy is generally considered a predominately restrictive procedure but has the distinction of also stimulating hindgut derived GI hormones. Predominantly malabsorptive procedures also incorporate a component of restriction and include operations such as biliopancreatic diversion, biliopancreatic diversion with duodenal switch malabsorptive procedures include biliopancreatic bypass, and long-limb gastric bypass. The Roux-en-Y gastric bypass is a combination of a gastric restrictive and malabsorptive procedure.

The original gastric bypass surgeries were based on the observation that post gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal). 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.” Dumping syndrome can cause absolute or relative postprandial reactive hypoglycemia. Autonomic dumping syndrome cannot be mitigated with dietary or medical intervention and may require reversal of gastric bypass. 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. Gastric bypass may be performed with either an open or laparoscopic technique.

Sleeve gastrectomy (SG) 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 [DS]). 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. Weight loss following SG may improve a patient’s overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., BPD).

Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure), 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. 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.

Biliopancreatic diversion with duodenal switch was introduced in 2005 as a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a SG 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

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 7 of 19

dumping syndrome and decrease the incidence of ulcers at the duodeno-ileal by providing a more physiologic transfer of stomach contents to the duodenum. The SG also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment is similar to that of the BPD.

Adjustable gastric banding 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. Complications include slippage of the external band or band erosion through the gastric wall.

Gastric plication (GP) is a restrictive bariatric procedure similar to endoscopic gastrectomy (ESG) but performed laparoscopically without resection of stomach tissue. The stomach is folded and sutured reduce the stomach volume.

Aspiration therapy as a treatment for obesity involves the percutaneous endoscopic placement of a gastrostomy tube system to aspirate (drain) a portion of the stomach contents after every meal. This restrictive procedure induces weight loss by removing a portion of the ingested caloric intake and is dependent of the patient's compliance.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) (also known as stomach-intestine pylorus-sparing surgery (SIPS) has a restrictive component when reducing the greater curvature of the stomach, but especially a malabsorptive component, as the common channel is also reduced. The objective of this surgical technique is to lessen the intestinal loop where nutrients are absorbed. The procedure is based on biliopancreatic diversion, in which a sleeve gastrectomy is followed by an end-to-side duodeno-ileal diversion. The preservation of the pylorus makes possible the reconstruction in one loop. A proposed benefit of the procedure is that it does not cause abrupt rise and fall of blood glucose, thus preserving the pyloric valve. Also, by not bypassing as much intestine, it may reduce the complications of short bowel syndrome.

Intragastric balloons (e.g., Orbera, Obalon, Spatz3), have been proposed as a temporary, non-surgical obesity treatment for short-term weight loss in patients who have had unsatisfactory results with their diet and exercise programs. The intragastric balloon has also been proposed for weight loss in the super-obese patient prior to a permanent, invasive surgical procedure. The saline-filled intra-gastric balloon, placed endoscopically, is intended to reduce gastric capacity, creating satiety, and reducing food intake.

TransPyloric Shuttle (BAROnova Inc. Goleta, CA) is an endoscopically inserted device that delays gastric emptying by intermittently obstructing the pylorus, which may enable an overall reduction in caloric intake and weight loss by helping the subject feel full sooner (early satiation) and/or feel full longer (prolonged satiety/reduced hunger). The device is a solid coiled cord of silicone and cannot be deflated.

Vertical banded gastroplasty (VBG) 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. This bariatric procedure creates a small pouch by vertically stapling and horizontally banding the upper stomach. Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site.

Transoral gastroplasty (TG), also known as vertical sutured gastroplasty or endoluminal vertical, is a procedure that consists of a set of endoscopically guided staples used to create a restrictive pouch along the lesser curvature of the stomach. The TOGA system (Satiety, Inc) was developed specifically for this procedure.

EndoCinch endoscopic suturing device was initially developed for endoscopic treatment of gastroesophageal reflux disease (GERD). EndoCinch, is a partial-thickness endoscopic suturing system that deploys a continuous and cross-linked fashion from the proximal fundus to the distal body. Once the suture is fixed, distention of the stomach is significantly limited, thus providing a method of restricting food intake. The RESTORE Suturing System (Bard/Davol, Warwick, RI) is an updated version.

The Apollo OverStitch (Apollo Endosurgery) device allows for full-thickness endoscopic suturing, compared to the superficial-thickness suturing provided by other devices. They are being investigated as the primary bariatric surgery and

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 8 of 19

as a revisional procedure to treat weight gain (e.g., large gastric pouch, large gastric stoma/dilated gastrojejunal anastomosis).

Transoral outlet reduction (TORe) is a procedure that reduces the gastric outlet opening (the opening between the gastric pouch and the small intestine) in people who have regained weight after gastric bypass surgery. Overtime, the gastric outlet can enlarge, allowing food to move into the small intestine faster and increasing hunger. Endoscopically, sutures are placed to tighten the gastric outlet opening to slow down the emptying of food from the stomach, leaving the patient to feel full longer.

Duodenal-jejunal bypass liner, also known as EndoBarrier (GI Dynamics Inc., Boston MA), is a barrier sleeve used to prevent the absorption of luminal contents in the small intestine. The fluoropolymer sleeve is inserted endoscopically and fixated to the duodenal bulb and extends 80 cm into the small bowel, usually terminating in the proximal jejunum.

Reversal or Revisional Surgery

Post-bariatric surgery patients who regain lost weight, do not lose sufficient weight, or develop unacceptable post-operative symptoms due to structural complications may warrant reversal or revision surgery. Reversal or revision of bariatric procedures is usually not warranted in patients whose failure is due to noncompliance (e.g., gastric pouch dilation from 20cc to greater than 100cc in a patient who is not adhering to the recommended eating protocols).

Revisional surgery for complications, such as those related to malabsorption resulting in hypoglycemia, malnutrition, or weight loss of 20% below ideal body weight may be warranted. Complications associated with laparoscopic adjustable gastric banding are well-documented in published literature. Examples of complications that may warrant revision, removal or conversion to another procedure include, but are not limited to, band slippage, band erosion, infection, esophageal dilation, dysphagia, and heartburn/reflux. Technical failures of LAGB include, but are not limited to, a displaced band, port dislocation, too tight a band (creating food passage problems), band intolerance (e.g., pain, reflux, vomiting), and port and/or catheter leakage.

RATIONALE

The hallmark piece of literature supporting the safety and effectiveness of bariatric surgery was published in 1991 by the National Institutes of Health (NIH) Consensus Statement. In 2022 the American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement based on the current available scientific information on metabolic and bariatric surgery and its indications (Eisenberg et al., 2022).

Bariatric surgery as treatment for class 2 and 3 obesity is supported by sufficient data published in medical literature demonstrating the safety and efficacy of specific bariatric procedures including: open or laparoscopic Roux-en-Y gastric bypass procedures (Himpens et al., 2012, Wadden et al., 2019, Cui et al., 2021, Angrisani et al., 2021), sleeve gastrectomy (Leyba et al. 2011, Himpens et al. 2010, D'Hondt et al. 2011, Chouillard et al. 2011, Wölnerhansen et al., 2021, Vitiello et al., 2023), adjustable gastric band (Dixon et al., 2008, Himpens et al, 2011) or the biliopancreatic diversion with duodenal switch (Prachand et al., 2006, Strain et al., 2007, Skogar et al., 2017).

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. Beginning in 1987 the prospective controlled trial of surgically induced weight loss, reported findings of the 2,010 people who chose surgery, and 2,037 people who chose conservative care for at least 10 (Sjöström et al., 2007). This trial demonstrated that surgery resulted in substantial weight loss, improved co-morbid conditions, and improved quality of life after surgery.

Bariatric surgery as treatment for class 1 obesity and type 2 diabetes is supported by the systematic reviews of RCTs and observational studies that have found certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in adults with obesity, including those with a BMI between 30 and 34.9 kg/m². The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Meta-analysis (DeLuca et al., 2023, Wu et al., 2016, Rao et al., 2015) and systematic reviews (Yan et al., 2016; Muller-Stich et al., 2015) have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure.

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 9 of 19

Most randomized clinical trial (RCTs) in this population have 1 to 5 years of follow-up data; however, longer-term (>5 years) data is beginning to be published. The 5-year outcomes of the randomized controlled STAMPEDE trial reported medical therapy with RYGB or sleeve gastrectomy were shown to be superior to medical therapy alone in the long-term treatment of T2D among patients with T2D and a BMI between 27 to 43 (Schauer et al., 2017).

Courcoulas et al. (2024) reported long-term follow-up of participants in the Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) project at the primary end point of 7 years, and up to 12 years, after randomization. During follow-up, 25% of participants randomized to undergo medical/lifestyle management underwent bariatric surgery. Based on follow-up the authors concluded that participants originally randomized to undergo bariatric surgery had superior glycemic control with less diabetes medication use and higher rates of diabetes remission, compared with medical/lifestyle intervention. From the 305 eligible participants, 262 participants (86%) enrolled in long-term follow-up were used for this pooled analysis. The median follow-up was 11 years. At 7 years, HbA1c decreased by 0.2% (95% confidence interval [CI], -0.5% to 0.2%) from a baseline of 8.2% in the medical/lifestyle group and by 1.6% (95% CI, -1.8% to -1.3%), from a baseline of 8.7%, in the bariatric surgery group. The between-group difference was -1.4% (95% CI, -1.8% to -1.0%; $p < 0.001$) at 7 years and -1.1% (95% CI, -1.7% to -0.5%; $p = 0.002$) at 12 years. Fewer anti-diabetes medications were used in the bariatric surgery group. Diabetes remission was greater after bariatric surgery (6.2% in the medical/lifestyle group vs. 18.2% in the bariatric surgery group; $p = 0.02$) at 7 years and at 12 years (0.0% in the medical/lifestyle group vs. 12.7% in the bariatric surgery group; $p < 0.001$).

Kirwan et al. (2022) published ARMMS-T2D project data from the 3-year follow-up which is noted as the largest cohort of randomized patients followed to date. Results demonstrated that metabolic/bariatric surgery is more effective and durable than medical/lifestyle intervention in remission of type 2 diabetes, including among individuals with class I obesity, for whom surgery is not widely used.

Bariatric surgery as treatment for a BMI less than 35 kg/m² who do not have T2D has limited evidence for. 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.

Intragastric balloon devices (IGB) (e.g., ORBERA Intragastric Balloon, Obalon Balloon System, ReShape Integrated Dual Balloon System) are gastric space occupying devices being investigated for the treatment of obesity. Published findings are insufficient and further studies are needed to demonstrate the long-term effects of utilizing intragastric balloon as a weight loss strategy (Ponce et al., 2015, Bazerbach et al., 2018)

Transoral gastroplasty (TG), for the treatment of obesity, has limited published literature and the data is insufficient to provide conclusions on its safety and efficacy. Well-designed studies with long-term follow-up are needed, to measure the durability of the observed weight loss. In particular, the stability of the gastric sutures' procedure remains unproven, given the lack of long-term data.

Mini-gastric bypass (also called loop gastric by-pass) lacks sufficient published in the medical literature to draw conclusions about the safety and effectiveness of the procedure.

Gastric plication research preliminarily supports that the procedure has acceptable complication rates and weight loss outcomes in the short-term (e.g., Fried et al., 2012; Skrekas et al., 2011; Kourkoulos et al., 2012; Talebpour et al., 2012); however, additional well-designed comparative studies with established bariatric procedures are needed, to determine its overall safety, efficacy, and impact on health outcomes.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy has not been researched by randomized controlled trials (RCTs) or other well-designed studies. Some case series have reported on weight loss and other clinical outcomes up to five years post-surgery. One larger series was published in 2015 (Sanchez-Pernaute et al.) and reported on 97 patients with obesity and T2D. The authors reported that control of diabetes, defined as an HbA1c less than 6.0%, was achieved by between 70% and 84% of patients at different time points. Remission rates were higher for patients on oral therapy than for those on insulin and were higher in patients with a shorter duration of diabetes. Currently, data is insufficient to provide conclusions on SADI-S safety and efficacy.

Transoral outlet reduction (TORe) is being evaluated as an endoscopic revisional surgery in patients with weight regain following their primary bariatric procedure (e.g., gastric bypass). Although preliminary results showing promising

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 10 of 19

feasibility, safety, and short-term efficacy being demonstrated in case series (Jirapino et al., 2013; Thompson et al., 2013; Kumar et al., 2014), longer-term durability of the procedure still needs to be proven in larger studies.

Stomach intestine pylorus sparing surgery (SIPS) lacks sufficient literature to determine the long-term outcomes of in the treatment of obesity.

Routine Liver Biopsy in Conjunction with Bariatric Surgery– Literature and Professional Societies

Medical literature does not support routine liver biopsy as a standard practice during bariatric surgery. Its impact on patient health outcomes has not been well-established, and there is insufficient clinical evidence to support routine liver biopsy in patients undergoing bariatric surgery.

American guidelines also do not endorse routine liver biopsies with abdominal surgeries.

In 2023, the American Association for the Study of Liver Diseases (AASLD) published a practice guideline on the clinical assessment and management of nonalcoholic fatty liver disease, citing NAFLD is closely linked to and often precedes the development of metabolic abnormalities such as insulin resistance, dyslipidemia, central obesity, and hypertension (Rinella et al., 2023). Statements within the guidance include:

- Liver biopsy should be considered when there is diagnostic uncertainty, competing or concomitant possible diagnoses (e.g., autoimmune hepatitis, iron overload); or when there is persistent elevation (>6 month) in liver chemistries.
- General population-based screening for NAFLD is not advised.
- High-risk individuals (e.g., with T2DM, medically complicated obesity, family history of cirrhosis, or more than mild alcohol consumption) should be screened for advanced fibrosis.
- Patients with NAFLD who are overweight or obese should be prescribed a diet that leads to a caloric deficit. When possible, diets with limited carbohydrates and saturated fat and enriched with high fiber and unsaturated fats (e.g., Mediterranean diet) should be encouraged due to their additional cardiovascular benefits.
- Patients with NAFLD should be strongly encouraged to increase their activity level to the extent possible. Individualized prescriptive exercise recommendations may increase sustainability and have benefits independent of weight loss.
- Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves NAFLD or NASH in the majority of patients without cirrhosis and reduces mortality from CVD and malignancy.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery – Literature and Professional Societies

Chen et al. (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus sleeve gastrectomy (SG) in obese patients (N=937). Results demonstrated that patients who underwent hiatal hernia repair during SG had significant reductions in BMI, and the risk of GERD symptoms and esophagitis. Hiatal hernia repair during SG was superior to SG alone for GERD remission, but not de novo GERD.

There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia (Ardestani et al., 2014; Santonicola et al., 2014; Gulkarov et al., 2008).

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery concluding that combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection (Menzo et al., 2018).

The 2013 Society of American Gastrointestinal and Endoscopic Surgeons evidence-based guidelines on the management of a hiatal hernia, recommended repair of hiatal hernias incidentally detected at the time of bariatric surgery (Kohn et al., 2013).

Professional Societies/Organizations

Adults

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 11 of 19

The 2024 American Diabetes Association Standards of Medical Care in Diabetes sets forth recommendations for the treatment diabetes, including Section 8, which discusses metabolic surgery (ADAPPC, 2024). Citing that a substantial body of evidence has demonstrated that metabolic surgery has beneficial effects on type 2 diabetes irrespective of pre-surgical BMI, including achieving superior glycemic management, reduction of cardiovascular risk and obesity, the ADAPPC recommends:

- Consider metabolic surgery as a weight and glycemic management approach in people with diabetes with BMI ≥ 30.0 kg/m² (or ≥ 27.5 kg/m² in Asian American individuals) who are otherwise good surgical candidates (grade A.)
- People being considered for metabolic surgery should be evaluated for comorbid psychological conditions and social and situational circumstances that have the potential to interfere with surgery outcomes (grade B).
- In people who undergo metabolic surgery, routinely screen for psychosocial and behavioral health changes, and refer to a qualified behavioral health professional as needed (grade C).
- Metabolic surgery should be performed in high-volume centers with interprofessional teams knowledgeable about and experienced in managing obesity, diabetes, and gastrointestinal surgery (grade E).

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications (Eisenberg et al., 2022). The understanding of obesity and MBS has significantly grown based on a large body of clinical experience and research. Long-term data, published in the decades following the 1991 NIH Consensus Statement, consistently demonstrates the safety, efficacy, and durability of MBS in the treatment of clinically severe obesity.

With significant improvement of metabolic disease, decreases in overall mortality, and superior weight loss outcomes compared with nonoperative treatment, the joint statement indicates:

- MBS is recommended for individuals with BMI >35 kg/m², regardless of presence, absence, or severity of comorbidities.
- MBS is recommended in patients with T2D and BMI >30 kg/m².
- MBS should be considered in individuals with BMI of 30 - 34.9 kg/m² who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m². Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Children and adolescents with BMI $>120\%$ of the 95th percentile and a major co-morbidity, or a BMI $>140\%$ of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.
- MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.

The 2022 ASMBS Position Statement on the Impact Of Metabolic and Bariatric Surgery on Nonalcoholic Steatohepatitis concluded that metabolic and bariatric surgery has a positive impact on nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) either with or without fibrosis (Mazzini, et al. 2022). Although randomized controlled trials are needed to determine whether MBS should be considered as a frontline therapy for NAFLD and NASH, metabolic and bariatric surgery should be considered for patients with severe obesity.

Children and Adolescents

In 2023, the American Academy of Pediatrics (AAP) published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity. (Hampf et al., 2023). The recommendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is: "Pediatricians and other pediatric health care providers should offer referral for adolescents 13 years and older with severe obesity (BMI $\geq 120\%$ of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery center)."

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 12 of 19

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications, stating MBS is safe and produces durable weight loss and improvement in comorbid conditions (Eisenberg et al., 2022).

In 2019, the AAP published a report outlining the current evidence regarding adolescent bariatric surgery for adolescent metabolic and bariatric surgery that reflected the 2018 American Society for Metabolic and Bariatric Surgery (ASMBS) recommendations (Armstrong et al., 2019). The AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2018, the American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee updated its evidence-based guidelines published in 2012 (Pratt et al., 2018). Based on an increased body of evidence the committee stated that metabolic and bariatric surgery (MBS) with vertical sleeve gastrectomy (VSG) and RYGB can be considered both safe and effective treatments for adolescents with a BMI of 35 kg/m² or 120% of the 95th percentile with a co-morbidity or BMI ≥40 kg/m² or 140% of the 95th percentile without a comorbidity (whichever is lower). With limited data the committee indicated that adjustable gastric banding and biliopancreatic diversion with or without duodenal switch is less desirable and should be reserved for adults in most cases. Endoscopic bariatric therapies (e.g., intragastric balloons, vagal stimulation, gastric aspiration) are not currently FDA for under 18 years of age. Studies on the long-term durability and physiologic consequences are needed.

Regulatory Body - U.S. Food and Drug Administration (FDA)

The following devices currently do not have FDA approval for use: EndoBarrier Gastrointestinal Liner (GI Dynamics, Lexington, MA), TOGA system (Satiety Inc., Palo Alto, CA),

The LAP-BAND Adjustable Gastric Banding System (BioEnterics Corp, Carpinteria, CA) received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for use in weight reduction for severely obese adults with a BMI of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or for those who weigh 100 lbs. or more over their estimated ideal weight in June 2001. The FDA granted expanded approval for use in adult patients with a BMI of 30-35 kg/m² in the presence of at least one weight-related comorbidity in February 2011. The adjustable gastric band is not currently FDA-approved for use in patients under 18 years of age.

The REALIZE Adjustable Gastric Band (Ethicon Endo-Surgery, Cincinnati, OH) received FDA premarket approval (PMA) for use in weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m², or a BMI of at least 35 kg/m² with one or more co-morbid conditions in September 2007.

The AspireAssist device (Aspire Bariatrics, King of Prussia, PA) received FDA premarket approval (PMA) to assist in weight reduction of obese patients in June 2016. It is indicated for use in adults aged 22 or older with a BMI of 35.0-55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring.

The TransPyloric Shuttle (BAROnova, San Carlos, CA) received FDA premarket approval (PMA) for weight reduction in adult patients with obesity with a Body Mass Index (BMI) of 35.0-40.0 kg/m² or a BMI of 30.0 to 34.9 kg/m² with one or more obesity-related comorbid conditions and is intended to be used in conjunction with a diet and behavior modification program in 2019,

The Obalon Intragastric Balloon System (ReShape Lifesciences, San Clemente, CA) received FDA premarket approval (PMA) for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40 kg/m²) who have failed to lose weight through diet and exercise in September 2016. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.

The ReShape Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA) received FDA premarket approval (PMA) as a temporary implant designed to facilitate weight loss by occupying space in the stomach in July 2015. The device is also intended to facilitate weight loss in obese adult patients with a BMI of 30-40 kg/m² who have been unsuccessful in losing weight through diet and exercise. Patients must have one or more obesity-related conditions, such

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 13 of 19

as diabetes, high blood pressure, or high cholesterol. Both approved devices are considered temporary and should be removed after six months.

The ORBERA IntraGastric Balloon (Apollo Endosurgery, Inc.) received FDA approval for patients with a BMI of 30-40, to assist those patients in losing and maintaining weight in August 2015. Obalon Therapeutics received FDA approval for the Obalon Balloon System in September 2016.

The StomaphyX device (EndoGastric Solutions, Redmond, WA) was cleared by FDA through the 510(k) process in 2007, and the Apollo OverStitch Suture System received FDA approval in 2008. Both are approved for endoluminal trans-oral tissue approximation and ligation in the GI tract.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN)*

CPT Codes

Code	Description
0813T (E/I)	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon (<i>Effective 01/01/24</i>)
43290 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	revision of adjustable gastric restrictive device component only
43772	removal of adjustable gastric restrictive device component only
43773	removal and replacement of adjustable gastric restrictive device component only
43774	removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	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	with small intestine reconstruction to limit absorption

Medical Policy: BARIATRIC AND METABOLIC SURGERY**Policy Number: 7.01.29****Page: 14 of 19**

Code	Description
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	removal of subcutaneous port component only
43888	removal and replacement of subcutaneous port component only
47000 (*NMN)	Biopsy of liver, needle; percutaneous (*NMN when billed with an ICD-10 code listed below)
47100 (*NMN)	Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (List separately in addition to code for primary procedure) (*NMN when billed with an ICD-10 code listed below)
47379 (*NMN)	Unlisted laparoscopic procedure, liver (*NMN when billed with an ICD-10 code listed below)

*Copyright © 2024 American Medical Association, Chicago, IL***HCPCS Codes**

Code	Description
C9784 (E/I)	Gastric restrictive procedure, endoscopic sleeve gastropasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785 (E/I)	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD10 Codes

Code	Description
E66.01	Morbid (severe) obesity due to excess calories
E66.2	Morbid (severe) obesity with alveolar hypoventilation
K91.0-K91.32	Postprocedural complications and disorders of digestive system, code range
K95.01-K95.09	Complications of gastric band procedure (code range)
K95.81-K95.89	Complications of other bariatric procedure (code range)
Z68.35-Z68.45	Body mass index (BMI), 35.0-70 or greater, adult (code range)

REFERENCES

*Abbatini F, et al. Type 2 diabetes in obese patients with body mass index of 30-35 kg/m²; sleeve gastrectomy versus medical treatment. Surg Obes Relat Dis 2012 Jun;8(3):20-4.

Agarwal L, et al. Bariatric surgery in non-alcoholic fatty liver disease (NAFLD): Impact assessment using paired liver biopsy and fibroscan. Obesity Surgery 2021;(31):617-626.

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 15 of 19

Alderman EM and Bruenner C. Unique needs of the adolescent. Pediatrics 2019 Dec;144(6):e20193150.

*Ali M, et al. American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons. Surg Obes Relat Dis 2016 Mar;12(3):462-467.

*Ali M, et al. American Society for Metabolic and Bariatric Surgery updated position statement on sleeve gastrectomy as a bariatric procedure. Surg Obes Relat Dis 2017 Oct;13(10):1652-1657. PMID: 29054173

*American Diabetes Association Professional Practice Committee. 8. Obesity and weight management for the prevention and treatment of type 2 diabetes: Standards of Care in Diabetes—2024. Diabetes Care 2024;47(Suppl. 1):S145–S157 [https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention] accessed 04/12/24.

*American Diabetes Association. Standards of care in diabetes-2024. Diabetes Care 2024 Jan;47(Suppl_1):S1-S4. [https://diabetesjournals.org/care/issue/47/Supplement_1] accessed 04/12/24.

*Angrisani L, et al. Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial. Surg Obes Relat Dis 2007 Mar-Apr;3(2):127-32.

*Angrisani L, et al. Long-term results of laparoscopic Roux-en-Y gastric bypass for morbid obesity: 105 patients with minimum follow-up of 15 years. Surg Obes Relat Dis 2021 Apr;17(4):727-739. Epub 2020 Dec 01.

*Ardestani A and Tavakkoli A. Hiatal hernia repair and gastroesophageal reflux disease in gastric banding patients: analysis of a national database. Surg Obes Relat Dis 2014 May-Jun;10(3):438-443. PMID 24680760

*Armstrong SC, et al. AAP section on obesity, section on surgery. Pediatric metabolic and bariatric surgery: evidence, barriers and best practices. Pediatrics 2019;144(6):E20193223.

Batista Dantas AC, et al. One-anastomosis gastric bypass versus roux-en-y gastric bypass as revisional surgery after sleeve gastrectomy: a systematic review and meta-analysis. Obesity Surgery 2022 Dec;32(12):4082-4088.

Bazerbacki F, et al. Endoscopic revision of gastrojejunal anastomosis for the treatment of dumping syndrome in patients with Roux-en-Y gastric bypass: a systematic review and meta-analysis. Surg Endos 2022 Jun;36(6):4099-4107.

*Bazerbach F, et al. Fluid-filled versus gas-filled intragastric balloons as obesity interventions: a network meta-analysis of randomized trials. Obes Surg 2018 Sep;28(9):2617-2625. PMID: 29663250

Benson-Davies S, et al. American Society of Metabolic and Bariatric Surgery consensus statement on laparoscopic adjustable gastric band management. Surg Obes Relat Dis 2022 Sept;18(9):1120-1133.

Chen W, et al. Effect of concomitant laparoscopic sleeve gastrectomy and hiatal hernia repair on gastroesophageal reflux disease in patients with obesity: a systematic review and meta-analysis. Obes Surg 2021 Sep;31(9):3905-3918. PMID 34254259

Carter J, et al. ASMBS position statement on preoperative patient optimization before metabolic and bariatric surgery. Surg Obes Relat Dis 2021 Dec;17(12):1956-1976. PMID: 34629296

*Chen W, et al. Effect of concomitant laparoscopic sleeve gastrectomy and hiatal hernia repair on gastroesophageal reflux disease in patients with obesity: a systematic review and meta-analysis. Obes Surg 2021 Sep;31(9):3905-3918. PMID 34254259

*Chouillard EK, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for morbid obesity: case-control study. Surg Obes Relat Dis 2011 Jul-Aug;7(4):500-5.

Clapp, B, et al. Safety of liver biopsy at the time of bariatric surgery: an analysis of the MBSAQIP database. Surg Endosc 2022 Jan;36(1):413-421.

*Courcoulas AP, et al. Bariatric surgery vs lifestyle intervention for diabetes treatment: 5-year outcomes from a randomized trial. J Clin Endocrinol Metab 2020 Mar 01;105(3):866-76. PMID 31917447.

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 16 of 19

*Courcoulas AP, et al. Long-term outcomes of medical management vs bariatric surgery in type 2 diabetes. JAMA 2024;331(8):654–664

Cuda S, et al. Special considerations for the adolescent with obesity: an Obesity Medicine Association (OMA) clinical practice statement (CPS). Obes Pillars 2023 Dec 07;9:100096.

*Cui BB, et al. Long-term outcomes of Roux-en-Y gastric bypass versus medical therapy for patients with type 2 diabetes: a meta-analysis of randomized controlled trials. Surg Obes Relat Dis 2021 Jul; 17(7):1334-1343. PMID 33863632

De Luca M, et al. Metabolic bariatric surgery as a therapeutic option for patients with type 2 diabetes: a meta-analysis and network meta-analysis of randomized controlled trials. Diabetes Obes Metab 2023;25(8):362-2373.

*D'Hondt M, et al. Laparoscopic sleeve gastrectomy as a single-stage procedure for the treatment of morbid obesity and the resulting quality of life, resolution of comorbidities, food tolerance, and 6-year weight loss. Surg Endosc 2011 Aug;25(8):2498-504.

Di Lorenzo N, et al. Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP. Surg Endosc 2020 Jun;34(6):2332-2358.

*Dixon JB, et al. Adjustable gastric banding, and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA 2008 Jan 23;299(3):316-323.

*Eisenberg D, et al., 2022 American Society Of Metabolic And Bariatric Surgery (ASMBS) and International Federation For The Surgery Of Obesity And Metabolic Disorders (IFSO) indications for metabolic and bariatric surgery. Obesity Surgery 2022 Oct 20;18(12):1345-1356.

*Fakhry TK, et al. Bariatric surgery improves nonalcoholic fatty liver disease: a contemporary systematic review and meta-analysis. Surg Obes Relat Dis 2019 Mar;15(3):502-511.

*Fayad L, et al. A real-world, insurance-based algorithm using the two-fold running suture technique for transoral outlet reduction for weight regain and dumping syndrome after Roux-En-Y gastric bypass. Obes Surg 2019;29(7):2225-2232. PMID: 30937874

*Fried M, et al. Laparoscopic greater curvature plication (LGCP) for treatment of morbid obesity in a series of 244 patients. Obes Surg 2012 Aug;22(8):1298-307.

Ghiassi S, et al. American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass. Surg Obes Relat Dis 2024;20(4):319-335.

Goyal H, et al. Endobariatric procedures for obesity: clinical indications and available options. Ther Adv Gastrointest Endosc 2021 Jan-Dec;14:1-17.

*Gulkarov I et al. Hiatal hernia repair at the initial laparoscopic adjustable gastric band operation reduces the need for reoperation. Surg Endosc 2008 Apr;22(4):1035-1041. PMID 18080712

*Hampl SE, et al. From the American Academy of Pediatrics. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. Pediatrics 2023 Jan;151(2):e2022060640.

*Hedberg J, et al. Superior weight loss and lower HbA1c 3 years after duodenal switch compared with Roux-en-Y gastric bypass-- a randomized controlled trial. Surg Obes Relat Dis 2012 May-Jun;8(3):338-43.

*Himpens J, et al. Long-term outcomes of laparoscopic adjustable gastric banding. Arch Surg 2011;146(7):802-807.

*Himpens J, et al. Long-term results of laparoscopic sleeve gastrectomy for obesity. Ann Surg 2010 Aug;252(2):319-24.

*Himpens J, et al. Long-term results of laparoscopic Roux-en-Y gastric bypass: evaluation after 9 years. Obes Surg 2012 Oct;22(10):1586-93.

*Huckfeldt PJ, et al. Association of intensive lifestyle intervention for type 2 diabetes with labor market outcomes. JAMA Inter Med 2023;183(10):1071-1079.

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 17 of 19

*Jensen MD, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and The Obesity Society. J Am Coll Cardiol 2014 Jul 1;63(25 Pt B):2985-3023. Epub 2013 Nov 12. PMID: 24239920

Jirapinyo P, et al. Effect of endoscopic bariatric and metabolic therapies on nonalcoholic fatty liver disease: a systematic review and meta-analysis. Clin Gastroenterol Hepatol 2022 Mar;20(3):511-524.e1.

*Jirapinyo P, et al. Evaluation of an endoscopic suturing device for transoral outlet reduction in patients with weight regain following Roux-en-Y gastric bypass. Endoscopy 2013 Jul;45(7):532-6.

Kiesswetter E, et al., Bariatric surgery in adults with obesity and diabetes mellitus: a network meta-analysis (Protocol). Cochrane Database of Systematic Reviews 2024, Issue 1. Art. No.: CD015622.

Kim JY and Chung H. Endoscopic intervention for anastomotic leakage after gastrectomy. J Gastric Cancer 2024;24(1):108-121.

Kiser HM, et al. Associations between psychological evaluation outcomes, psychiatric diagnoses, and outcomes through 12 months after bariatric surgery. Surg Obes Relat Dis 2023 Jun;19(6):594-603. Epub 2022 Dec 10. PMID: 36610864.

*Kohn GP, et al. Guidelines for the management of hiatal hernia. Surg Endosc 2013 Dec 2013;27(12):4409-4428. PMID 24018762

*Kourkoulos M, et al. Laparoscopic gastric plication for the treatment of morbid obesity: a review. Minim Invasive Surg 2012;2012:696348.

*Kumar N, et al. Comparison of a superficial suturing device with a full thickness suturing device for transoral outlet reduction. Gastrointest Endoscopy 2014 Jun;79(6):984-9.

Lembo E, et al. Prevalence and predictors of non-alcoholic steatohepatitis in subjects with morbid obesity and with or without type 2 diabetes. Diabetes & Metabolism 2022 Sep;48(5):101363.

*Leyba JL, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the treatment of morbid obesity. A prospective study of 117 patients. Obes Surg 2011 Feb;21(2):212-6.

Leyva-Alvizo A, et al.; ASMBS Foregut Committee. Systematic review of management of gallbladder disease in patients undergoing minimally invasive bariatric surgery. Surg Obes Relat Dis 2020 Jan;16(1):159-164. Epub 2019 Oct 31.

*Mazzini GS, et al. ASMBS position statement on the impact of metabolic and bariatric surgery on nonalcoholic steatohepatitis. Surg Obes Relat Dis 2022 Mar;18(3):314-325.

*Mechanick JJ, et al. Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures - 2019 update: cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic & Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. Surg Obes Relat Dis 2020 Feb;16(2):175-247. PMID: 31917200.

*Menzo EL, et al. American Society for Metabolic and Bariatric Surgery and American Hernia Society consensus guideline on bariatric surgery and hernia surgery. Surg Obes Relat Dis 2018 Sep;14(9):1221-1323. PMID:30154033

*National Heart, Lung, and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The Evidence Report. NIH Pub. No. 98-4083. 1998 Sep [https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf] accessed 04/13/24.

National Institute for Health Care Excellence (NICE). Endoscopic sleeve gastroplasty for obesity. Interventional procedure [IPG783]. 2024 Feb 22 [https://www.nice.org.uk/guidance/ipg783] accessed 03/26/24.

*National Institute for Health and Care Excellence (NICE). Implantation of a duodenal-jejunal bypass sleeve for managing obesity. Interventional procedure [IPG 471] 2013 Nov 27 [https://www.nice.org.uk/guidance/ipg471] accessed 03/26/24.

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 18 of 19

National Institute for Health and Care Excellence (NICE). Laparoscopic gastric plication for the treatment of severe obesity. Interventional procedure [IPG432]. 2012 Feb 27 [<https://www.nice.org.uk/guidance/ipg783>] accessed 03/26/24.

National Institute for Health and Care Excellence (NICE). Obesity: identification, assessment, and management. Clinical guideline [CG189]. Published 2014 Nov 24. Last updated 2023 Jul 26 [<https://www.nice.org.uk/guidance/cg189>] accessed 03/26/24.

*National Institute for Health and Care Excellence (NICE). Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Interventional procedure [IPG 569]. 2016 Nov [<https://www.nice.org.uk/guidance/ipg569/chapter/1-Recommendations>] accessed 03/26/24.

National Institute of Health Consensus Development Conference Panel. Gastrointestinal surgery for severe obesity: Consensus Development Conference statement. Ann Intern Med 1991;115:956-961.

Navarini D, et al. Predictive factors of gastroesophageal reflux disease in bariatric surgery: a controlled trial comparing sleeve gastrectomy with gastric bypass. Obes Surg 2020;30:1360–1367.

Netanel C, et al. The impact of bariatric surgery on nonalcoholic fatty liver disease as measured using non-invasive tests. Am J Surg 2020 Nov 25:S0002-9610(20)30767-4.

*Ogle S, et al. Outcomes of bariatric surgery in older versus younger adolescents. Pediatrics 2021;147(3).

Olmi S, et al. Modified laparoscopic sleeve gastrectomy with Rossetti anti-reflux fundoplication: results after 220 procedures with 24-month follow-up. Surg Obes Relat Dis 2020 Sep;16(9):1202-1211.

Parikh M, et al. American Society for Metabolic and Bariatric Surgery review of the literature on one-anastomosis gastric bypass. Surg Obes Relat Dis 2018 Aug;14(8):1088-1092.

*Ponce J, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis 2015 Jul-Aug;11(4):874-81. Epub 2014 Dec 16.

*Prachand VN, et al., Duodenal switch provides superior weight loss in the super-obese (BMI > or =50kg/m²) compared with gastric bypass. Ann Surg 2006 Oct;244(4):611-619. PMID 16998370

*Pratt JSA, et al. ASMBS pediatric metabolic and bariatric surgery guidelines, 2018. Surg Obes Relat Dis 2018;14(7):882–901.

*Rinella ME, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology 2023 May 01;77(5):1797-1835.

*Rothstein RI, et al. Randomized Double-blind Sham-controlled Trial of a Novel Silicone-filled Endoscopically Placed Device for Weight Loss. Tech Innov Gastrointest Endos 2024;26(1):21-29.

*Santonicola A, et al. The effect of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on gastroesophageal reflux disease in obese patients. Surg Obes Relat Dis 204 Mar-Apr;10(2):250-255. PMID 24355324

Sarma S and Palcu P. Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: a systematic review and meta-analysis. Obesity (Silver Spring). 2022;30(11):2111-2121.

*Schauer PR, et al. STAMPEDE investigators bariatric surgery versus intensive medical therapy for diabetes – 5-year outcomes. N Engl J Med 2017;376(7):641–651.

Simonson DC, et al. Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D): study rationale, design, and methods. Diabetes Obes Metab 2022;24(7):1206-1215.

*Sjöström L, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med 2007 Aug 23;357(8):741-52.

*Skogar ML et al., duodenal switch is superior to gastric bypass in patients with super obesity when evaluated with the bariatric analysis and reporting outcome system (BAROS). Obes Surg 2017 Sep; 27(9):2308-2316. PMID 28439748

Medical Policy: BARIATRIC AND METABOLIC SURGERY

Policy Number: 7.01.29

Page: 19 of 19

- *Skrekas G, et al. Laparoscopic gastric greater curvature plication: results and complications in a series of 135 patients. Obes Surg 2011 Nov;21(11):1657-63.
- *Sogg S, et al. ASMBS Guidelines/Statements. Recommendations for the presurgical psychosocial evaluation of bariatric surgery patients. Surg Obes Relat Dis 2016 May;12(4):731-749. Epub 2016 Feb 12
- *Strain GW, et al. Comparison of effects of gastric bypass and biliopancreatic diversion with duodenal switch on weight loss and body composition 1-2 years after surgery. Surg Obes Relat Dis 2007 Jan- Feb 2007;3(1):31-36. PMID 17116424
- *Styne DM, et al. Pediatric obesity – assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. J Clin Endocrinol & Metab 2017 Mar;102(3):709-757.
- *Sucandy I, et al. Risk of biliary events after selective cholecystectomy during biliopancreatic diversion with duodenal switch. Obes Surg 2016 Mar;26(3):531-7.
- *Talebpoor M, et al. Twelve-year experience of laparoscopic gastric plication in morbid obesity: development of the technique and patient outcomes. Ann Surg Innov Res 2012;Aug 22;6(1):7.
- Tan YZ, et al. Impact of pre-bariatric surgery weight loss on post-bariatric surgery weight loss and can it predict post-surgical weight loss. Surgery for Obesity and Related Disease 2019 Oct;15(4):S180.
- *Telem DA, et al. Updated panel report: best practices for the surgical treatment of obesity. Practice guideline. 2018 Oct;32(10):4158-4164. [<https://www.sages.org/publications/guidelines/updated-panel-report-best-practices-for-the-surgical-treatment-of-obesity/>] accessed 03/26/24.
- *Thompson CC, et al. Endoscopic suturing for transoral outlet reduction increases weight loss after Roux-en-Y gastric bypass surgery. Gastroenterology 2013 Jul;145(1):129-37.
- Verrastro O, et al. Bariatric–metabolic surgery versus lifestyle intervention plus best medical care in non-alcoholic steatohepatitis (BRAVES): a multicentre, open-label, randomised trial. Lancet 2023;401:1786-1797.
- *Vitiello A, et al. Long-term results of laparoscopic sleeve gastrectomy: a review of studies reporting 10+ years outcomes. Obes Surg 2023 Sep 25;33:3565-3570.
- Wattacheril JJ, et al. AGA Clinical Practice Update on the Role of Noninvasive Biomarkers in the Evaluation and Management of Nonalcoholic Fatty Liver Disease: Expert Review. Gastroenterol 2023;165:1080-1088.
- *Wölnerhanssen BK, et al, Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy: 5-year outcomes of merged data from two randomized clinical trials (SLEEVEPASS and SM-BOSS). Br J Surg 2021 Jan 27;108(1):49-57. PMID 33640917

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) (100.1) for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity. Please refer to the following NCD website for Medicare Members:

[<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=57&ncdver=5&=>] accessed 04/17/24.

There is also a Local Coverage Article (A52447) from the National Government Services contractor related to sleeve gastrectomy. Please refer to the following web site: [<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52447&ver=29>] accessed 04/17/24.