



Subject:	Bariatric Surgery and Other Treatments for Clinically Severe Obesity		
Guideline #:	CG-SURG-83	Publish Date:	10/31/2018
Status:	New	Last Review Date:	07/26/2018

Description

This document addresses surgical and other treatments for clinically severe obesity. Clinically severe obesity is a result of persistent and uncontrollable weight gain that constitutes a present or potential threat to life. There are a variety of surgical procedures and other treatment modalities intended for the treatment of clinically severe obesity.

Clinical Indications

Medically Necessary:

Gastric bypass and gastric restrictive procedures with a Roux-en-Y procedure up to 150 cm, laparoscopic adjustable gastric banding (for example, the Lap-Band® System or the REALIZE™ Adjustable Gastric Band), vertical banded gastroplasty, biliopancreatic bypass with duodenal switch, and sleeve gastrectomy (open or laparoscopic) are considered **medically necessary** for the treatment of clinically severe obesity for selected adults (18 years and older) who meet **ALL** the following criteria (A, B, and C):

- A. BMI of 40 or greater, or BMI of 35 or greater with an obesity-related co-morbid condition including, but not limited to:
 - 1. diabetes mellitus; or
 - 2. cardiovascular disease; or
 - 3. hypertension; or
 - 4. life threatening cardio-pulmonary problems, (for example, severe obstructive sleep apnea, Pickwickian syndrome, obesity related cardiomyopathy); **and**
- B. The individual must have serially documented active participation in a non-surgical weight reduction regimen for at least 6 continuous months, in the 2 years prior to surgery, to enable both behavioral changes and adequate assessment of anticipated postoperative dietary maintenance. These efforts must be fully appraised and documented by the physician requesting authorization for surgery; **and**
- C. The physician requesting authorization for the surgery must provide documentation of **ALL** of the following (1 through 7):
 - 1. The individual’s psychiatric profile is such that the candidate is able to understand, tolerate and comply with all phases of care and is committed to long-term follow-up requirements; and
 - 2. The candidate’s post-operative expectations have been addressed; and
 - 3. The individual has undergone a preoperative medical consultation and is felt to be an acceptable surgical candidate; and
 - 4. The individual has undergone a preoperative mental health assessment and is felt to be an acceptable candidate; and
 - 5. The individual has received a thorough explanation of the risks, benefits, and uncertainties of the procedure; and
 - 6. The candidate’s treatment plan includes pre- and post-operative dietary evaluations and nutritional counseling; and
 - 7. The candidate’s treatment plan includes counseling regarding exercise, psychological

issues and the availability of supportive resources when needed.

Surgical repair following gastric bypass and gastric restrictive procedures is considered **medically necessary** when there is documentation of a surgical complication related to the original surgery, such as a fistula, obstruction, erosion, disruption/leakage of a suture/staple line, band herniation, or pouch enlargement due to vomiting.

Repeat surgical procedures for revision or conversion to another surgical procedure (that is also considered medically necessary within this document) for inadequate weight loss, (that is, unrelated to a surgical complication of a prior procedure) are considered **medically necessary** when **ALL** the following criteria are met (A, B and C):

- A. The individual meets **ALL** the medical necessity criteria for bariatric surgery (see Criteria A thru C) (**Note:** Meeting the criteria for the initial bariatric surgery does not count toward meeting the criteria again for the repeat surgical procedure for revision or conversion to another surgical procedure.); **and**
- B. 2 years following the original surgery, weight loss is less than 50% of pre-operative excess body weight and weight remains at least 30% over ideal body weight (taken from standard tables for adult weight ranges based on height, body frame, gender and age, an example is available from the National Heart Lung and Blood Institute [NHLBI] at: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm); **and**
- C. If inadequate weight loss or regain of initial weight loss following the initial surgery is determined to be due to noncompliance with the previously prescribed postoperative dietary and exercise programs, documentation is required to confirm that a mental health assessment has determined that behavioral issues that resulted in inadequate weight loss or regain, related to noncompliance with postoperative dietary and lifestyle modifications following the initial surgery, have been adequately addressed to significantly mitigate the risk of an inadequate weight loss outcome from the additional surgery.

Not Medically Necessary:

Stretching of a stomach pouch formed by a previous gastric bypass/restrictive surgery, due to overeating, does not constitute a surgical complication and the revision of this condition is considered **not medically necessary**.

Gastric bypass and gastric restrictive procedures with a Roux-en-Y procedure up to 150 cm, laparoscopic adjustable gastric banding (for example, the Lap-Band® System or the REALIZE™ Adjustable Gastric Band), vertical banded gastroplasty, biliopancreatic bypass with duodenal switch, and sleeve gastrectomy (open or laparoscopic) are considered **not medically necessary** when the criteria are not met.

Gastric bypass, using a Billroth II type of anastomosis (also known as a "mini gastric bypass") is considered **not medically necessary** as a treatment of clinically severe obesity.

Bariatric surgical procedures including, but not limited to, laparoscopic adjustable gastric banding are considered **not medically necessary** for individuals with a BMI below 35 kg/m².

Malabsorptive procedures including, but not limited to, jejunioileal bypass, biliopancreatic bypass without duodenal switch, single anastomosis duodenal switch or very long limb (greater than 150 cm) gastric bypass (other than the biliopancreatic bypass with duodenal switch) are considered **not medically necessary** as a treatment of clinically severe obesity.

Repeat procedures for repair, revision, or conversion to another surgical procedure following a gastric bypass or gastric restrictive procedure are considered **not medically necessary** when the criteria are not met.

All other gastric bypass/restrictive procedures and other treatment modalities not listed above as medically necessary are considered **not medically necessary** including, but not limited to the following:

- Minimally invasive endoluminal gastric restrictive surgical techniques, such as use of the EndoGastric StomaphyX™ endoluminal fastener and delivery system or endoscopic sleeve gastropasty; **or**
- Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding; **or**
- Balloon systems, (such as the ReShape® Integrated Dual Balloon System or the Orbera Intragastric Balloon System); **or**
- Vagus (or vagal) nerve blocking devices, (such as the MAESTRO® Rechargeable System); **or**
- Endoscopically placed percutaneous aspiration tube (such as AspireAssist®).

Further Consideration:

A bariatric surgeon with experience in the pediatric population may request further consideration of a case of an individual under 18 years old with severe morbid obesity and unique circumstances by contacting a Medical Director. *(Further information available in the Rationale section of this document).*

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Gastric bypass and gastric restrictive procedures:

CPT

00797	Anesthesia for intraperitoneal procedures in upper abdomen, including laparoscopy; gastric restrictive procedure for morbid obesity
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)
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

ICD-10 Procedure

0DP60CZ	Removal of extraluminal device from stomach, open approach
0DP64CZ	Removal of extraluminal device from stomach, percutaneous endoscopic approach
0DV60CZ	Restriction of stomach with extraluminal device, open approach
0DV64CZ	Restriction of stomach with extraluminal device, percutaneous endoscopic approach
0DV60ZZ	Restriction of stomach, open approach

0DV64ZZ	Restriction of stomach, percutaneous endoscopic approach
0DW60CZ	Revision of extraluminal device in stomach, open approach
0DW64CZ	Revision of extraluminal device in stomach, percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

Other bypass and excision procedures:

ICD-10 Procedure

The following codes when specified as bariatric procedures:

0D160ZA	Bypass stomach to jejunum, open approach
0D160ZB	Bypass stomach to ileum, open approach
0D164ZA	Bypass stomach to jejunum, percutaneous endoscopic approach
0D164ZB	Bypass stomach to ileum, percutaneous endoscopic approach
0D164Z9	Bypass stomach to duodenum, percutaneous endoscopic approach
0D190ZB	Bypass duodenum to ileum, open approach
0DB60Z3	Excision of stomach, open approach, vertical
0DB64Z3	Excision of stomach, percutaneous endoscopic approach, vertical
0DB68Z3	Excision of stomach, via natural or artificial opening endoscopic, vertical
0DB60ZZ	Excision of stomach, open approach
0DB64ZZ	Excision of stomach, percutaneous endoscopic approach

ICD-10 Diagnosis

E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation (Pickwickian syndrome)
E66.3	Overweight
E66.8	Other obesity
E66.9	Obesity, unspecified
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z68.35-Z68.39	Body mass index (BMI) 35.0-39.9, adult
Z68.41-Z68.45	Body mass index (BMI) 40 or greater, adult
Z68.51-Z68.54	Body mass index (BMI) pediatric (special consideration)
Z98.84	Bariatric surgery status

Note: services are considered not medically necessary for these BMI codes:

Z68.20-Z68.29	Body mass index (BMI) 20.0-29.9, adult
Z68.30-Z68.34	Body mass index (BMI) 30.0-34.9, adult

Other procedures:
Note: the following procedures are considered not medically necessary

CPT

43632	Gastrectomy, partial distal; with gastrojejunostomy (Billroth II) [when specified as bariatric surgery]
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction [when specified as bariatric surgery]

43659	Unlisted laparoscopy procedure, stomach [when specified as gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding, sleeve gastropasty, or mini-gastric bypass procedure]
43999	Unlisted procedure, stomach [when specified as endoluminal gastric restrictive surgery, placement of intragastric balloon device, or aspiration therapy]
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed

ICD-10 Procedure

0D160ZA	Bypass stomach to jejunum, open approach [when specified as Billroth II]
0DV60DZ	Restriction of stomach with intraluminal device, open approach
0DV63DZ	Restriction of stomach with intraluminal device, percutaneous approach
0DV64DZ	Restriction of stomach with intraluminal device, percutaneous endoscopic approach
0DV67DZ	Restriction of stomach with intraluminal device, via natural or artificial opening
0DV68DZ	Restriction of stomach with intraluminal device, via natural or artificial opening endoscopic

0DP60DZ	Removal of intraluminal device from stomach, open approach
0DP63DZ	Removal of intraluminal device from stomach, percutaneous approach
0DP64DZ	Removal of intraluminal device from stomach, percutaneous endoscopic approach
0DP67DZ	Removal of intraluminal device from stomach, via natural or artificial opening
0DP68DZ	Removal of intraluminal device from stomach, via natural or artificial opening endoscopic

ICD-10 Diagnosis

E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation (Pickwickian syndrome)
E66.3	Overweight
E66.8	Other obesity
E66.9	Obesity, unspecified
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z68.20-Z68.29	Body mass index (BMI) 20.0-29.9, adult
Z68.30-Z68.34	Body mass index (BMI) 30.0-34.9, adult
Z68.35-Z68.39	Body mass index (BMI) 35.0-39.9, adult
Z68.41-Z68.45	Body mass index (BMI) 40 or greater, adult
Z68.51-Z68.54	Body mass index (BMI) pediatric (special consideration)

Z98.84

Bariatric surgery status

Discussion/General Information

Background

According to the National Institutes of Health (NIH), an increase of 20 percent or more above an individual's ideal body weight is the point at which excess weight becomes a health risk. Nearly two-thirds of Americans are overweight or obese, with approximately 15 million classified as having clinically severe obesity, in which there is higher risk of one or more obesity-related health conditions that result either in significant physical disability or even death. While medical complications of obesity may occur in moderately obese people, the frequency increases dramatically as weight increases.

The first line treatment of clinically severe obesity is dietary and lifestyle changes, including regular exercise. In order to lose weight, an individual must have a caloric deficit, that is, calories out must be greater than calories in. This can be accomplished by decreasing the calories ingested with some form of dietary restriction and by increasing the calories expended through exercise. All available therapies (dietary, behavioral, pharmacologic, and surgical) help with weight loss by changing the calories ingested, absorbed, or expended.

Surgery for clinically severe obesity (bariatric surgery) falls into two categories: gastric restrictive procedures and malabsorptive procedures. The first category, gastric restrictive procedures, includes procedures in which a small pouch is created in the stomach. Weight loss occurs as the individual feels full sooner, having eaten much less than usual. The second category, malabsorptive procedures, includes procedures that rearrange the connections between the stomach and intestines, causing the food to be poorly digested and incompletely absorbed. Weight loss is due to malabsorption without necessarily requiring dietary modification. The two most commonly performed bariatric procedures in the United States (US) are both done laparoscopically- sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (Kim, 2017). A more recent treatment modality consists of devices which decrease appetite or induce feelings of satiety.

Surgery for the treatment of clinically severe obesity may be appropriate in a select group of individuals. According to the National Institutes of Health (NIH), weight loss surgery should be reserved for individuals suffering from the complications of extreme obesity, for whom conservative medical therapy has failed. Possible surgical candidates are those with severe obesity, defined as a body mass index (BMI) of 40 or greater, or 35 or greater with other medical complications. Such complications include, but are not limited, to the following:

- Type 2 diabetes;
- Heart disease;
- Sleep apnea;

A study conducted by the Agency for Healthcare Research and Quality (AHRQ) is purported to be the most extensive, to date, on postsurgical complications from obesity operations. The AHRQ researchers found that the complication rate among privately insured, nonelderly subjects receiving obesity surgery increased from 21.9%, while they were still hospitalized, to 39.6% by the end of the 180-day study period. Most studies of complications from obesity surgery have been limited to those that occur before hospital discharge or, at the most, up to 30 days post-discharge. This study extends the observation period up to 180 days, (that is, 6 months) after hospital discharge. The five most common complications were dumping syndrome, which includes vomiting, reflux, and diarrhea (nearly 20%); anastomosis complications (that is, complications resulting from the surgical joining of the intestine and stomach), such as leaks or strictures (12%); abdominal hernias (7%); infections (6%); and pneumonia (4%). The overall death rate for the entire 180-day postoperative period studied was low (0.2%). These findings were based on claims for hospital care and outpatient care for 5.6 million enrollees under age 65 in employer-sponsored health plans for 45 large employers in 49 states for the time period of 2001 and 2002. The claims data included information on 2522 bariatric procedures (AHRQ, 2009).

Of note, further information published in May 2009 reported an improvement in complication rates following bariatric surgical procedures. According to this article entitled, “Recent Improvements in Bariatric Surgery Outcomes,” the AHRQ study reported that the average rate of post-surgical and other complications in those who have had obesity surgery declined 21% between 2002 and 2006. They also found that the complication rate among those initially hospitalized for bariatric surgery dropped from approximately 24% to roughly 15%, much of this driven by a reduction in the post-surgical infection rate, which plummeted 58%. Other factors believed to contribute to the improved bariatric outcomes included a mix of within-hospital volume increases, a move to laparoscopic techniques, and an increase in banding without bypass (Encinosa, 2009).

In addition to surgical complications following bariatric procedures, (for example, stricture, erosion, leakage, band slippage, etc.), it has been noted that some individuals do not achieve, or maintain, adequate weight loss post-operatively, despite documented compliance with postoperative nutritional and exercise regimens. In general, it may take up to 2 years to reach maximum weight loss following bariatric surgery. Follow-up bariatric surgery, such as conversion to RYGB, may be proposed when adequate weight loss has not occurred after 1 to 2 years following the initial surgery. There is agreement among some experts in the field that adequate weight loss has been achieved when at least 50% of EWL has been achieved, or when the body weight has reached within 30% of ideal weight ranges (by age, gender, height, etc.). Inadequate weight loss due to noncompliance with the recommended postoperative regimens is not considered to be a failure of the original surgery.

Gastric bypass and gastric restrictive procedures

The evidence in the peer-reviewed medical literature to support the use of gastric bypass with a Roux-en-Y procedure (RYGB) up to 150 cm and/or vertical banded gastroplasty (VBG) for the indication of clinically severe obesity suggests that these procedures are beneficial for this indication in a selected group of individuals. The Swedish Obese Subjects (SOS) intervention trial reported a large reduction in diabetes over a 5.5 year mean follow-up for the surgery group. Peri-operative mortality varies by procedure, surgeon, and center, and occurs at a rate of approximately 1 in 200 procedures. In order to minimize potential morbidity and mortality, individuals who undergo such treatment should meet specific criteria prior to undergoing the procedure. The preoperative workup should include documentation by the treating physician of active participation in a formal weight reduction program for at least 6 months duration, in the 2 years prior to surgery, that includes serial documentation of all weights, as well as dietary and exercise regimens. Conservative weight loss efforts should be fully appraised by the physician requesting surgical authorization, so that preoperative assessment of the individual’s capability for appropriate behavioral changes can be determined. A 6 month preoperative assessment of anticipated postoperative dietary compliance is a prudent indicator of anticipated postoperative successful weight loss which could be maintained over time. As further clarification of what constitutes reasonable documentation of active participation in a preoperative nonsurgical weight loss program, the following is suggested as relevant information to be documented in the medical record for a continuous sequential 6-month period in the 2 years prior to surgery:

- The documented appraisal should describe “what” the individual was actually doing in the program, that is, were they following the diet and exercise recommendations as an active participant for six continuous months in the two years prior to surgery.
- The individual’s weight should be documented at each preop visit including how much weight loss was achieved each month for the documented six month period.
- The documentation should include any specifics about “how” the surgeon and the nutrition team members guided and worked with the individual to encourage compliance and address any individual obstacles to enable positive behavioral changes prior to surgery.

Results of a prospective, nonrandomized, comparative trial reported long-term outcomes of 563 VBG and 554 adjustable gastric banding (AGB) procedures performed by two surgeons. The mean BMI was 46.9 ± 09.9 kg/m⁽²⁾ for those undergoing VBG and 46.7 ± 07.8 kg/m⁽²⁾ for those in the AGB group. VBG was performed by laparotomy and AGB using laparoscopy. The Bariatric Analysis and Reporting Outcome System (BAROS) was used to evaluate postoperative health status and quality of life. The mean duration of follow-up was 92 months (range 60-134), with a

minimum of 5 years. The overall follow-up rate was 92%. The 30-day mortality rate was 0.4% for VBG and 0.2% for AGB. The overall re-intervention rate in the long-term was 49.7% for VBG and 8.6% for AGB (p<0.0001). The reoperation rate was 39.9% for VBG and 7.5% for AGB (p<0.0001). The excess weight loss (EWL) was significantly greater in the VBG group (58%) than in the AGB group (42%) after 12 months (p<0.05). At 92-month follow-up, no significant difference in weight loss was found between the two study groups (59% for VBG and 62% for AGB, p=0.923). The BAROS score was significantly in favor of the AGB group (p<0.0001). The overall resolution rate of co-morbidities was 80% in both groups (Miller, 2007).

A retrospective cohort study of different procedures for morbid obesity was reported for: open VBG (n=125), open Scopinaro biliopancreatic diversion (BPD; n=150), open modified BPD (that is, common limb 75 cm; alimentary limb 225 cm; n=100), and laparoscopic RYGB (LRYGB; n=115). Mean follow-up was 12 years for VBG, 7 years for BPD, and 4 years for LRYGB. An excellent initial weight loss was observed at the end of the second year of follow-up in all techniques, followed by regain of weight observed in the VBG and LRYGB groups. Participants in the BPD groups maintained weight loss results. Mortality was: VBG 1.6%, BPD 1.2%, and LRYGB 0%. Early postoperative complications were: VBG 25%, BPD 20.4%, and LRYGB 20%. Late postoperative morbidity was: protein malnutrition of 11% in Scopinaro BPD, 3% in modified BPD group, and no cases reported either in the VBG group or the LRYGB group; iron deficiency was 20% for VBG, 62% for the Scopinaro BPD, 40% for the modified BPD, and 30.5% for the LRYGB group. Conversion to gastric bypass or to BPD was needed for 14.5% of the VBG group, due to 100% weight regain or vomiting. For those in the Scopinaro BPD group, revision surgery was needed to lengthen the common limb to 100 cm in 3.2% of cases, due to severe protein malnutrition. Revision surgery was also required for 0.8% of the LRYGB subjects, due to 100% weight regain. It was noted that the more complex bariatric procedures increase effectiveness but also increase morbidity and mortality. The authors concluded:

LRYGB is safe and effective for the treatment of morbid obesity. Modified BPD (75-225 cm) can be considered for the treatment of superobesity (BMI greater than 50 kg/m²), and restrictive procedures, such as VBG, should only be performed in well-selected patients, due to high rates of failure in long-term follow-up (Gracia, 2009).

The current evidence does not support the use of the biliopancreatic bypass with duodenal switch (BPD/DS) for individuals who have clinically severe obesity. Mortality is similar to the RYGB procedure, and the evidence suggests that up to 70% EWL can be maintained over long-term follow-up (up to 6 years post-surgery). The evidence supporting this conclusion includes multiple large case series.

Adjustable gastric banding (AGB)

AGB is a restrictive procedure which involves surgically placing a gastric band around the exterior of the stomach; the stomach is not entered. The procedure can be reversed by removing the band. Complications may include slippage of the external band or band erosion through the stomach wall (2-5% of surgeries). Furthermore, incorrect positioning of the band may result in vomiting, as well as ineffective weight loss. In June, 2001, the FDA cleared the Lap-Band[®] System (Allergan, Inc., Irvine, CA and sold to Apollo Endosurgery, Inc., Austin, TX, in 2013). On February 16, 2011, the FDA clearance was expanded to include individuals with a BMI of at least 40 kg/m² or a BMI of at least 30 kg/m² with one or more obesity related comorbid conditions who have failed more conservative measures.

In 2007, the FDA approved a second gastric band device, (REALIZE[™] Adjustable Gastric Band, Ethicon Endo-Surgery[®], Inc., Cincinnati, OH) to be used for 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 2016, Ethicon announced plans to discontinue marketing the REALIZE adjustable gastric band in the United States due to declining gastric band trends. The LAP-BAND system is the only FDA approved system for adjustable gastric banding in the United States.

A number of studies supported the clinical efficacy of adjustable gastric banding, although weight loss tended to be less robust when compared to other surgical procedures, such as Roux-en-Y (Anggrisani, 2007; Arterburn, 2014; Biertho, 2003; Bowne, 2006; Dolan, 2004; Jan, 2005; Morino, 2003). Initially, LAGB was a popular choice as the procedure is minimally invasive and reversible. While the short term results were promising, the long term failure and complications rates are substantial. Approximately 70% of individuals reported complications at 15 years follow-up with 61.7% requiring additional surgery to address the complication (Gangemi, 2018),

Sleeve gastrectomy

In 2010, Himpens published long-term (6 year) results of laparoscopic sleeve gastrectomy (LSG) for 53 consecutive persons considered to be “morbidly obese” who electively underwent LSG at a single institution in Belgium between November 2001 and October 2002. Full postoperative evaluation was possible for 41 of these subjects. Median age at the time of surgery was 44 years and median preoperative BMI was 39.0 kg/m² (range 31-57; standard deviation [SD] 5.4). Seven of the 41 trial participants admitted having preoperative conditions (5 were hypertensive, 1 had type II diabetes, and 1 suffered from symptoms of gastroesophageal reflux [GERD]). At 3 years postop, overall EWL was recorded as 72.8%. After the 6th year, weight regain was observed in 31 cases (75.6%), which resulted in a residual mean overall EWL of 57.3%. These results included 11 (of the 41 evaluated in follow-up) who underwent an additional malabsorptive procedure (duodenal switch) as a second stage procedure due to weight regain and 2 underwent a re-sleeve procedure between the 3rd and 6th postop years, due to weight regain and pouch dilation. Major complications (leakage, stenosis, bleeding and hernia) occurred in 12.2% of study subjects and symptoms associated with GERD were reported in 18% in the LSG stand-alone group and 21% in the overall group of surgical subjects. One diabetic subject reported resolution of symptoms and 2 of the 5 hypertensive subjects reported being normotensive at 6 years postop. Quality of life scores were reported as a mean of 5 BAROS score at 6 years. Despite the limitations of this small study, safety and efficacy results for the stand-alone LSG-treated group appear to be relatively equivalent to those obtained from other restrictive surgical techniques. These findings are consistent with results of other small studies of LSG as a stand-alone procedure, although symptoms associated with GERD seem to be a persistent complaint at follow-up of 1-5 years (Bohdjalian, 2010; Gandsas, 2010).

Malabsorptive procedures (other than the biliopancreatic bypass with duodenal switch)

Malabsorptive procedures include some of earliest forms of surgical treatment for severe obesity. Procedures such as jejunoileal bypass were associated with severe short and long term complications and are no longer recommended as a treatment of severe obesity (Morris, 2017).

The 2016 ASMBS position statement on SADS, also known as single-anastomosis loop duodenal switch (LDS), single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) or stomach intestinal pylorus sparing surgery (SIPS) notes that SADS:

should only be performed under a study protocol with third-party oversight (local or regional ethics committee, institutional review board, data monitoring and safety board, clinicaltrials.gov, or equivalent authority) to ensure continuous evaluation of patient safety and to review adverse events and outcomes.

The available evidence does not support that the safety, efficacy, and durability is comparable to the standard DS procedure.

Mini gastric bypass

Min gastric bypass has been proposed as a simple effective procedure which combines the benefits of Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy. A meta-analysis comparing mini gastric bypass (MGB) to RYGB included 10 cohort studies and 1 RCT (Wang, 2018). While the analysis indicated that the MGB had multiple advantageous indexes compared to RYGB, there were multiple limitations including small sample size and a short follow-up period. The authors concluded that the effectiveness and safety of MGB compared to RYGB remains unclear.

Natural orifice transluminal endoscopic surgery

A new minimally invasive surgical technique is done endoscopically and is referred to as endoluminal gastric restrictive surgery or “natural orifice” transluminal endoscopic surgery (NOTES). This technique utilizes flexible endoscopy with a specialized device, the EndoGastric StomaphyX™ device (EndoGastric Solutions™ Inc., Redmond, WA). The StomaphyX device received U.S. Food and Drug Administration (FDA) clearance through the 510(k) approval process on March 9, 2007. This endoluminal fastener and delivery system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the GI tract (FDA, 2007). Published evidence does not support that this surgical technique results in improved patient outcomes as compared to conventional surgical treatment options (Swanstrom, 2005; Tran, 2016).

Laparoscopic gastric plication

On October 6, 2011, the ASMBS issued a policy statement on laparoscopic gastric plication, also known as laparoscopic greater curvature plication (LGCP), which is a relatively new bariatric procedure being proposed as a surgical option for the treatment of obesity. Gastric plication involves mobilizing the greater curvature of the stomach similar to the dissection for a SG and infolding (or imbricating) the stomach to achieve gastric restriction utilizing specialized surgical tools and sutures manufactured by Ethicon Endo-Surgery, Inc. (Cincinnati, OH). According to the ASMBS statement “The rationale for this procedure addresses issues that may limit the acceptance of other bariatric procedures, specifically, gastric plication does not involve gastric resection, intestinal bypass or placement of a foreign body, and could potentially provide a lower risk alternative for patients and referring physicians. The current available literature regarding gastric plication procedures does not support that this procedure provides improved health outcomes, both long and short term over the standard techniques, such as laparoscopic sleeve gastrectomy (Grubnik, 2016; Tang, 2015; Ye, 2017).

Other procedures

Intragastric balloon devices (IGBs) are endoscopically implanted intragastric devices which are filled with saline after insertion and intended to reduce gastric capacity and stimulate the feeling of satiety. IGBs are intended for temporary use, approximately 6 months, as the risk of complications, such as balloon deflation and migration significantly increases after this time (Tate, 2018). There are currently three FDA approved devices: ReShape® Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA; ORBERA™ Intragastric Balloon System (Apollo Endosurgery, Inc., Austin, TX) and the Obalon Balloon System (Obalon® Therapeutics, Inc., San Diego, CA). Tate and Geliebter (2017) reviewed eight recent RCTs which compared percentage total body weight loss (%TBWL) between IGBs to control groups or bariatric surgery and pharmacotherapy. The authors noted that while IGBs did appear to provide statistically significant weight loss, IGB is not as efficacious as bariatric surgery. In June 2018, the FDA issued a warning regarding potential risk of possible death associated with the use of Orbera and ReShape.

In 2015, the FDA approved the MAESTRO® Rechargeable System (EnteroMedics, Inc., St. Paul, MN) for use in individuals with a BMI of 40 to 45 or with a BMI of 35 to 39.9 and one or more comorbidity. MAESTRO provides vagal blocking (VBLOC®) therapy by delivering intermittent, controllable, electrical blocking signals to the abdominal anterior and posterior nerve trunks of the vagus nerve. The FDA clearance was based on results of two randomized controlled trials, the first of which included 233 subjects with a BMI of 35 or greater. The weight loss and adverse events of 157 individuals who received the active Maestro device were compared to 76 subjects in the control group who received a Maestro electrical pulse generator that was not activated. The 12-month outcomes data found that the trial participants in the group with the activated device lost 8.5% more excess weight than the control group (with the inactivated device). The investigators noted that approximately half (52.5%) of the subjects in the activated device group lost at least 20% of their excess weight, while 38.3% of subjects with the activated device lost at least 25% of their excess weight. However, the study did not meet its original endpoint, which was for the group with the activated device to lose at least 10% more excess weight than the control group (Sarr, 2012). In

the second study, the ReCharge trial, all participants had devices implanted but no leads were placed in the sham group. Primary efficacy outcomes were not met in either of these trials (Ikramuddin, 2014).

Revision/Reoperation

According to the ASMBS, in 2016 a total of 216,000 bariatric surgeries were performed with 13.9% of these surgeries being classified as revisions. This is an increase from 2011 when the revision rate was reported as 6%. Some procedures, such as the adjustable gastric band, reported significant rates of revision at 30-60% (Kirshtein, 2016). In a retrospective review of 214 individuals who had subsequent revisional bariatric procedures following adjustable lap band removal, Kirshtein and associates (2016) noted that individuals who underwent band removal without conversion or rebanding gained weight, while those who underwent further bariatric surgery succeeded in further weight loss.

In a 2014 systematic review, Brethauer and colleagues reviewed the current evidence regarding reoperative bariatric surgery. 175 articles which covered a number of procedures, such as Roux-en-Y, adjustable gastric banding, sleeve gastrectomy, vertical banded gastroplasty and biliopancreatic diversion with or without duodenal switch, were included. The authors concluded:

The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.

Bariatric Surgery with BMI less than 35 kg/m²

On February 16, 2011, the FDA approved an expanded indication for the Lap-Band device to include individuals with a BMI at least 30 kg/m² with one or more obesity related comorbid conditions. This expansion was based on the results of a prospective, single-arm, nonrandomized, 5 year study sponsored by the manufacturer, Allergan, Inc. At the time of the FDA approval, the 1 year results showed device clinical efficacy with at least 80.5% of the participating individuals achieving at least a 30% EWL at 1 year (FDA, 2011). At 2 years, the 1 year results were maintained (Michaelson, 2013). There are several limitations associated with this study. The study included individuals with a BMI of up to 40 kg/m², only 41% had a BMI of 30-35 kg/m². Based upon the design of the study, there appears to be a significant potential for bias. Arterburn (2013) noted that as the prevalence of severe comorbidities in this population is less, the evidence currently does not support that the benefit of preventing comorbidities in this population outweighs the risk.

The Agency for Healthcare Research and Quality (AHRQ) conducted an evidence-based practice center systematic review protocol entitled: “Comparative Effectiveness of Bariatric Surgery and Non-Surgical Therapy in Adults with Metabolic Conditions and Body Mass Index of 30 to 34.9 kg/m²,” which examined the evidence regarding the comparative effectiveness of bariatric surgery versus conventional non-surgical therapies for treating adults with a BMI of 30 to 34.9 kg/m² and metabolic conditions, including diabetes or impaired glucose tolerance (IGT). The effectiveness of surgery versus nonsurgical interventions in these populations was also compared. This assessment attempted to determine if certain surgical procedures are more effective than others (LAGB, RYGB, SG or BPD/DS) and also investigated other individual factors (social support, counseling, pre-operative weight loss, compliance), in terms of how they are related to successful outcomes. This research also reviewed the evidence regarding adverse effects, complication rates and long-term benefits/harms of bariatric surgery for adults with a BMI of 30 to 34.9 kg/m² who have metabolic conditions and compared these findings to short-term outcomes (within 2 years from surgery). Twenty-four studies were included in this review which reported bariatric surgery results for the specific target populations. Two were trials comparing different procedures; three were trials of surgical versus nonsurgical interventions, and the rest were observational studies. Both weight and blood glucose improved significantly for the surgery subjects in the trials. In the

observational studies, the subjects who underwent surgery showed much greater weight loss at 1 year than what was reported in systematic reviews and randomized controlled trials (RCTs) on diet, exercise, medication, and other behavioral interventions. While both behavioral interventions and medications lowered HbA1c (glycosylated hemoglobin) levels significantly, the decreases reported for the surgical subjects were much greater. Improvements in blood glucose measures were reported as early as 1 month post-surgery. Improvements in hypertension, low-density lipoprotein (LDL) cholesterol, and triglycerides were also reported in some studies. Short-term rates of adverse events associated with bariatric surgery were relatively low. One death, a case of sepsis at 20 months in an LAGB subject, was reported. Short-term complications were minor and tended not to require major intervention. The investigators commented:

Due to the dearth of long-term studies of bariatric surgery in this particular target population, few data exist about long-term adverse effects, and we found no evidence regarding major clinical endpoints, such as all-cause mortality, cardiovascular mortality and morbidity, and peripheral arterial disease.

The American Association of Clinical Endocrinologists, the Obesity Society, and the American Society for Metabolic & Bariatric Surgery (AACE/TOS/ASMBS) practice guideline for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (Mechanick, 2013) includes lower level recommendations (Grade B, Best Evidence Level (BEL) 2; Grade C, BEL 3) for individuals with a BMI of 30-34.9kg/m² with diabetes or metabolic syndrome. The authors note that the current evidence does not support that surgery may be appropriate for individuals in this group.

Bariatric surgery for Metabolic Indications

Bariatric surgery has been investigated as a treatment for type 2 diabetes mellitus (T2DM). To date, studies reporting the results of bariatric surgery on T2DM have primarily included individuals with morbid obesity (that is, with a BMI greater than or equal to 40 or 35-39.9 kg/m² with a clinically significant obesity-related comorbidity). There have been very few studies that investigated the safety and efficacy of bariatric surgery, also referred to as metabolic surgery, in individuals with a BMI less than 35 kg/m². In 2012, Mingrone published results of a single-center, nonblinded, RCT of 60 subjects between the ages of 30 and 60 years with a BMI of 35 or more and a history of at least 5 years of diabetes. Study participants were randomly assigned to receive conventional medical therapy or bariatric surgery (either GB or BPD). The primary endpoint was the rate of diabetes remission at 2 years (defined as a fasting glucose level of < 100 mg per deciliter [5.6 mmol per liter] and a glycated hemoglobin level of < 6.5% in the absence of pharmacologic therapy). At 2 years, diabetes remission had occurred in no subjects in the medical-therapy group versus 75% in the GB group and 95% in the BPD group (p<0.001 for both comparisons). Age, sex, baseline BMI, duration of diabetes, and weight changes were not significant predictors of diabetes remission at 2 years or of improvement in glycemia at 1 and 3 months. At 2 years, the average baseline HbA1c level (8.65 ± 1.45%) had decreased in all groups, but subjects in the 2 surgical groups had the greatest degree of improvement (average HbA1c levels, 7.69 ± 0.57% in the medical-therapy group, 6.35 ± 1.42% in the GB group, and 4.95 ± 0.49% in the BPD group). The authors concluded that, in severely obese subjects with T2DM, bariatric surgery resulted in better glucose control than did medical therapy and that preoperative BMI and weight loss did not predict the improvement in hyperglycemia seen after surgery (Mingrone, 2012).

Another recent randomized, nonblinded, single-center study evaluated the efficacy of intensive medical therapy alone versus medical therapy plus RYGB or SG in 150 obese subjects with uncontrolled T2DM. The average pre-treatment HbA1c level was 9.2 ± 1.5%, and the primary endpoint was the proportion of subjects with an HbA1c level of 6.0% or less at 12 months post treatment. Results showed that of the 150 subjects, 93% completed 12 months of follow-up. The proportion of subjects meeting the primary endpoint at 12 months was 12% (5 of 41) in the medical therapy alone group versus 42% (21 of 50) in the RYGB group (p=0.002) and 37% (18 of 49) in the SG group (p=0.008). Glycemic control improved in all 3 groups, with a mean HbA1c level of 7.5 ± 1.8% in the medical-therapy group, 6.4 ± 0.9% in the RYGB group (p<0.001), and 6.6 ± 1.0% in the SG group (p=0.003). Weight loss was greater in the RYGB group and the SG group (−29.4 ± 9.0 kg and −25.1 ± 8.5 kg, respectively) than in the medical-therapy group (−5.4 ± 8.0 kg;

p<0.001) for both comparisons. It is noteworthy that during the study, use of anti-diabetic medications increased in the medical therapy group and decreased in both surgical groups. All subjects in the RYGB group who achieved the primary endpoint did so without medications, while 28% of those in the SG group who reached the primary endpoint required continued medication use. The authors concluded that in obese individuals with uncontrolled T2DM, 12 months of medical therapy plus bariatric surgery achieved glycemic control in significantly more subjects than in those treated with medical therapy alone (Schauer, 2012). However, both studies were small and limited by confounders, such as wide BMI ranges, short-term outcomes data and single center study design.

In 2018, the American Diabetes Association Standards of Medical Care in Diabetes added the following recommendation:

Metabolic surgery should be considered as an option for adults with type 2 diabetes and BMI 30.0–34.9 kg/m² (27.5–32.4 kg/m² in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin).

The supporting evidence for this recommendation is based upon cohort and case control studies (level B). The evidence demonstrates that bariatric surgery in diabetic individuals with a BMI of 35 or greater can result in greater glycemic control and a reduction of cardiovascular risk factors in obese patients with compared with various lifestyle/medical interventions. However, the current evidence does not support that the benefits of bariatric surgery outweigh the risk in those with a BMI less than 35 or that bariatric surgery provides definable lasting results in this population.

Bariatric Surgery in Adolescents and Children

Greater than one in five children in the U.S. are classified as obese. These rates continue to increase, with the rise of children with severe obesity experiencing the most significant rise (Skinner, 2018). The classification of obesity in children and adolescents varies from the adult classification system. Obesity categorization is typically based upon relative BMI or BMI percentile (Skinner, 2018). The use of bariatric surgery in children and adolescents has been limited (Shoar, 2017).

In a 2013 scientific statement on severe obesity in children and adolescents, the American Heart Association reviewed multiple comorbid conditions associated with severe obesity in youths, including metabolic disorders, hypertension, non-alcoholic fatty liver disease, musculoskeletal problems and obstructive sleep apnea syndrome, and noted that severely obese youths are much more likely to become severely obese adults with commensurate risks and adverse outcomes. Various medical treatment options were also described, along with results of the available studies. Regarding bariatric surgery, it was noted:

In light of the limited effectiveness of lifestyle modification and medical therapy, shown to date, for severe obesity, surgical procedures that have an evidence base that supports their efficacy and safety should be considered for patients who demonstrate medical necessity and psychosocial readiness... The most recent and authoritative practice recommendations (Pratt, 2009) emphasize the concept that a combination of both severe obesity and the existence of comorbidities should be present to medically justify an operation to treat obesity. There is good evidence that RYGB is reasonably safe and highly effective compared with lifestyle modification for the treatment of severe obesity. Relatively good safety and efficacy data for AGB (adjustable gastric banding) in adolescents have been reported, although a high rate of reoperation and sparse long-term data, along with a lack of FDA approval for the device, hamper recommendations for usage before adulthood. All adolescents undergoing bariatric surgery should be strongly encouraged to participate in prospective longitudinal outcomes studies to improve the evidence base to evaluate the risks and benefits of operations in this age group... Bariatric surgery is the most effective treatment for severe obesity in adolescents; however, surgery is appropriate and available for only some adolescents with severe obesity, and broadening availability will depend on the results of long-term outcome studies, currently in progress... Innovative approaches to fill the gap between

lifestyle/medication and surgery are urgently needed (Kelly, 2013).

The Endocrine Society clinical practice guideline on pediatric obesity (2017) reviewed the treatment of pediatric obesity, including bariatric surgery. Bariatric surgery is recommended only under limited circumstances in individuals in the later stages of development (Tanner pubertal development stages 4 or 5 and final or near final adult height) with a BMI of greater than 40 kg/m² and mild co-morbidities, or greater than 35 kg/m² and major co-morbidities. This recommendation is categorized as a weak recommendation based on low quality evidence. While the results of studies have been promising, there continues to be concerns regarding potential nutritional deficiencies and compliance in this population. Adolescents undergoing bariatric surgery will require life-long follow-up.

There is subset of adolescents with obesity in whom the risks from comorbidities and complications are sufficiently high that bariatric surgery may be indicated. Consequently, special consideration for such surgery may be given for an adolescent with severe morbid obesity presenting with unique circumstances (O’Brien, 2010; Pratt, 2009; Treadwell, 2008).

In eligible individuals under the age of 18 years, who are skeletally mature, it is the general consensus in the practice community that potential candidates for surgery be evaluated for the following:

- The individual's psychiatric profile and developmental stage is such that the candidate is able to understand, tolerate and comply with all phases of pre- and post-operative care and is committed to long-term post-operative follow-up requirements; and

An informed consent is conducted including documentation that the individual has received and can fully understand a thorough explanation of the risks, benefits, and uncertainties of the procedure being planned for.

Operator Dependence in the Safety and Efficacy of Bariatric Procedures

Evidence from a number of reports and case series exists for “operator dependence” in determining the risks and benefits of any bariatric procedure. It is important that the surgeon be extensively trained in the respective procedure and that the initial surgeries are supervised by an experienced bariatric surgeon during the early “learning curve.” It is also important that these surgeries be performed in facilities that are appropriately qualified to support peri-operative and post-op services by an appropriately trained, multi-disciplinary team to ensure maximal success.

Definitions

Adjustable Gastric Banding (AGB): A gastric restrictive procedure in which a gastric band which holds fluid is placed around the exterior of the stomach. Common complications may include slippage of the external band, band erosion, vomiting and ineffective weight loss.

Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure) BPB: A malabsorptive procedure which consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the small intestine by a long Roux-en-Y procedure. Potential complications in iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization.

Biliopancreatic Bypass with Duodenal Switch (BPD/DS): A variant of the biliopancreatic bypass in which a sleeve gastrectomy is performed instead of a distal gastrectomy.

Body mass index (BMI): The key index for relating body weight to height. The BMI is a person's weight in kilograms (kg) divided by their height in meters (m) squared. To convert pounds to kilograms, multiply pounds by 0.45; to convert inches to meters, multiply inches by 0.0254. (See the definition below for obesity for further information).

Excess body weight: This term refers to the difference between an individual’s actual (measured) and ideal body weight. Ideal body weight ranges are established based on height, body frame,

gender and age; an example is available from the National Heart Lung and Blood Institute [NHLBI] at: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm

Gastric balloon (Gastric bubble): This device is inserted into the stomach to reduce the stomach's capacity and produce early satiety. It was generally considered obsolete and was originally intended for temporary use as an adjunct to diet and behavior modification to assist with weight loss. Recently, new balloon systems have been cleared by the FDA (*see information in the above Background section*).

Gastric banding: This surgical procedure is intended to help a person lose weight. A band is placed around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrowed opening between the stomach pouch and the rest of the stomach controls how quickly food passes from the pouch to the lower part of the stomach. This system helps the person to eat less by limiting the amount of food that can be eaten at one time and increasing the time it takes for food to be digested.

Gastric bypass (RYGB): A restrictive and malabsorptive procedure reduces the stomach capacity and diverts partially digested food from the duodenum to the jejunum (section of the small intestine extending from the duodenum). Often associated with the dumping syndrome in which a large portion of partially digested food is delivered directly to part of the small intestine from the stomach and can cause nausea, weakness, sweating, faintness, abdominal pain and vomiting. This procedure requires that individuals take vitamin and mineral supplements due to decreased ability to absorb nutrients. Complications can include leakage and stomal stricture.

Gastroplasty: A surgical procedure that decreases the size of the stomach.

Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]): A gastric restrictive bariatric procedure, which is performed alone or in combination with adjustable gastric banding, where the stomach's volume is reduced by dissecting the greater omentum and short gastric vessels, and the greater curvature is invaginated using multiple rows of non-absorbable sutures performed over a bougie or endoscope to ensure a patent lumen.

Long Limb Gastric Bypass (i.e., greater than 150 cm): A malabsorptive procedure in which the stomach is bypassed, either by resection or stapling along the horizontal or vertical axis, and the jejunum functions as the alimentary limb. Potential complications are similar to other malabsorptive procedures.

Mini Gastric Bypass: A variant of the gastric bypass in which the stomach is divided, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y connection, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure to the stomach. Complications can include biliary reflux gastritis, in which bile flows back into the stomach and causes irritation.

Obesity: The state of being well above one's normal weight which is measured and determined by the Body Mass Index (BMI). Severe obesity is defined by the National Institutes of Health (NIH) as a BMI of 40 kg/m² or greater, or a BMI of 35 kg/m² or greater along with other medical complications. The NIH defines obesity as a BMI of greater than or equal to 30 kg/m² and considers a person overweight with a BMI of 25 to 29.9 kg/m².

Repair: Refers to a subsequent surgical procedure performed to correct an anatomic complication, and in this document is used to refer to a complication, resulting from a prior gastric bypass or gastric restrictive procedure.

Revision: Refers to a surgical procedure performed either to anatomically reverse a prior bypass/restrictive procedure or to anatomically convert the organs from a prior bypass/restrictive procedure to another procedure, (e.g., from a prior vertical banded gastroplasty to a conventional Roux-en-Y bypass procedure).

Sleep apnea: The temporary stoppage of breathing during sleep, often resulting in daytime

sleepiness.

Sleeve Gastrectomy (SG): Surgical alternative to gastrectomy which involves resection of the greater curvature of the stomach resulting in a sleeve or tube shaped stomach remnant. Can be performed alone with followed by a malabsorptive procedure.

Vertical Banded Gastroplasty (VBG): A gastric restrictive procedure in which the stomach is divided vertically, and a band is stapled around the top portion of the stomach to decrease its size. Common complications of this procedure include esophageal reflux, as well as either widening or blockage of the narrow portion of the stomach, which may require reoperation.

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Websites for Additional Information

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status Date Action

New	07/26/2018	review. Initial document development. Moved contents of SURG.00024 Bariatric Surgery and Other Treatments for Clinically Severe Obesity to clinical utilization management guideline document with the same title.
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